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19/04/2017
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 26 - ID : 381120

Released by s22 [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
45703		307402468	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22 [redacted]	19/04/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
19/05/2017	19/04/2017		15/05/2017
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

The patient alleges that the pump was over delivering insulin.

Clinical Event Information:

Medtronic received a report that a patient experienced seizures and passed out due to low blood glucose. The patient was hospitalised.

The patient alleges that the pump was over delivering insulin. No further information was provided to perform trouble shooting.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Unknown.

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Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: [redacted]

Reporter #:

Reporter Title: [redacted]

First Name: [redacted]

Surname: [redacted]

Position: Senior Regulatory Affairs Specialist

Company/Institution: Medtronic Australasia

Address 1: 5 Alma Road

Address 2:

Town/Suburb: North Ryde

State: NSW

Country: Australia

Postcode: 2122

Phone: [redacted]

Fax: 02

Mobile:

Email: [redacted]@medtronic.com

Last External Submission By: [redacted] - 19/05/2017 10:13

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

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Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: Medtronic Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711W

Serial #: NG1072107H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: 18000 Devonshire Street

Address 2:

Town/Suburb: Northridge

State/Province: NSW

Country: United States

Postcode: 91325

Phone:

Fax:

Email:

Manufacturer Informed:

Date Aware of Adverse Event:

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$22 @medtronic.com		Yes	$22
Contact Title:	Contact First Name:	Contact Surname:	
$22	$22	$22	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
29/05/2017	$22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	No	No	Serious Injury
Actual Effect:	Injured Party:		Found Prior To Use:	Risk Frequency:
No Injury	Patient		No	Frequently
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Likely	Not Investigated	No	
DIRE Meeting Notes:				

Sponsor Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:

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s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	s22 [redacted]
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section

Device Analysis Results:

The pump passed the functional test, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and the DAT Test at 0.08725 inches.

No delivery anomaly, bolus anomaly or basal anomaly noted during testing.

Unit had minor scratched display window, damaged (scratched) display window cover, scratched case, cracked case at battery tube side, pillowing keypad overlay and scratched keypad overlay.

Corrective/Preventative Actions:

The manufacturer will continue to monitor the rate of such incidents for trending purposes.

Details of Similar Events:

Australia:
2015: 7 similar incidents / 3567 install base
2016: 9 similar incidents / 8176 install base
2017 (to date): 2 similar incidents / 9389 install base

Worldwide:
2015: 15 similar incidents / 25048 install base
2016: 36 similar incidents / 49937 install base
2017 (to date): 9 similar incidents / 56060 install base

Additional Details (use for tables):



Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, Czech Republic, Denmark, Faroe Islands, Finland, Germany, Hungary, Netherlands, Slovakia, South Africa, Sweden, Switzerland, United Kingdom.

Additional Comments:

DIR closed on 29 May 2017.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table

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below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices							
Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details						
Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details							
Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Output Issue	Incorrect or Inadequate Test Result		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Returned device met specifications		

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Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time. However the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 108554

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
108554	DIR-REQ		Closed	s22	OPR Administration User	29/05/2017	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	29/05/2017 12:47:07	
Comment		

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

21/06/2017
SIGNED

DIR : 26 - ID : 389204

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
46667		CASE-2017-0031801	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	[redacted]	21/06/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
19/07/2017	21/06/2017		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
19/07/2017	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Customer alleges that the pump delivered an unprogrammed bolus, resulting in a hypoglycemic event.

Clinical Event Information:

Customer alleges that the pump delivered an unprogrammed bolus, resulting in a hypoglycemic event. Food and glucagon were administered to elevate blood glucose. Medtronic has requested that the pump be returned for analysis. Analysis results can only be provided if the pump is returned.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Unknown.

Patient History:

Patient Outcome/Consequences:

Unknown.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: Reporter #:

s22

Reporter Title: First Name: Surname:

s22 s22 s22

Position: Company/Institution:

Senior Regulatory Affairs Specialist Medtronic Australasia

Address 1: Address 2: Town/Suburb: State:

5 Alma Road Macquarie Park NSW

Country: Postcode: Phone: Fax:

Australia 2113 s22

Mobile: Email: Last External Submission By:

s22 @medtronic.com s22 - 19/07/2017 11:53

Initial Reporter Section

As Above?: *If No, fill out the following:* Initial Reporter Confidential:

Yes

Search Reporter By Surname: Initial Reporter #:

Title: First Name: Surname:

Position: Company/Institution:

Address 1: Address 2: Town/Suburb: State:

Postcode: Phone: Fax: Mobile:

Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G Insulin Pump

Initial Device Description: Minimed 640G Insulin Pump

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711H

Serial #: NG1198759H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Patient

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: 18000 Devonshire Street

Address 2:

Town/Suburb: Northridge

State/Province: CA

Country: United States

Postcode: 91325

Phone:

Fax:

Email: s22 [redacted] @medtronic.com

Manufacturer Informed: Yes

Date Aware of Adverse Event: s22 [redacted]

Contact Title:

Contact First Name:

Contact Surname:

s22 s22 s22

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
19/07/2017	s22	Yes	Yes	☑

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Temporary Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
Temporary Injury	Patient	No	Rarely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Unlikely	Not Investigated	No	

DIRE Meeting Notes:

Sponsor Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC

State:	Postcode:	Phone:	Fax:

NSW	1670	s22 [redacted]	s22 [redacted]

Email:

s22 [redacted]@medtronic.com

Investigation Information Section

Device Analysis Results:

The insulin pump passed the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and the DAT Test at 0.08730 inches.

The technician installed a water filled reservoir, primed pump, programmed with multiple boluses, and monitored for three (3) days. All boluses delivered properly and were listed in the bolus history screen. The insulin pump then was programmed with multiple basal profiles and monitored. All basal profiles delivered their indicated amounts and were verified in the daily and summary history screens. The units left on the insulin pump display matched properly the units left in the test reservoir. No delivery anomaly, bolus anomaly or basal anomaly was noted during testing.

Detailed insulin pump history file review and CareLink report review show that the bolus wizard was manually programmed at 9:02 am and 10:13 am on May 22, 2017 for the max allowed carbs (300 g) with a total calculated bolus of 42.8 units each. Verified the Max Bolus Delivery was set to 20 units. The pump did not allow a manual bolus delivery programmed to exceed the max amount (20 units) and when the bolus wizard is used to calculate the amount over the set max bolus amount (20 units), the insulin pump displays a warning screen telling the user the calculated bolus delivery exceeds the programmed max amount and automatically reduces the value to equal the set max amount. No unexpected bolus deliveries, deliveries that exceed the programmed max amount, or bolus wizard programming/delivery errors were noted during testing.

The insulin pump was received with scratched case, pillowing keypad overlay, and minor scratched LCD window.

Corrective/Preventative Actions:

As no root cause could be determined, there was no remedial / corrective / preventative action undertaken.

The manufacturer will continue to monitor the rate of such incidents for trending purposes.

Details of Similar Events:

Worldwide (including Australia)
2015: 0/25048 = 0%
2016: 0/49937 = 0%
2017 (to date): 10/59330 = 0.017%

Australia
2015: 0/3567 = 0%
2016: 0/8176 = 0%
2017 (to date): 2/11152 = 0.018%

Additional Details (use for tables):

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, Finland, Netherlands, Slovakia, United Kingdom

Additional Comments:

Report closed on 19 July 2017

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Infusion/Flow	Excessive Flow or Over-infusion	

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Returned device performed as intended		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 113732

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
113732	DIR-REQ		Closed	s22	OPR Administration User	19/07/2017	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	19/07/2017 13:27:31	
Comment		

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

04/08/2017
SIGNED

DIR : 26 - ID : 392948

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
47290		CASE-2017-00139306-1	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	[redacted]	04/08/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
14/09/2017	04/08/2017		05/09/2017
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
14/09/2017	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Medtronic has received a report that a customer has been hospitalized (intensive care) with High BG. The customer is claiming that the CGM sensor has a lower reading than the actual BG reading.

Clinical Event Information:

Medtronic has received a report that a customer has been hospitalized (intensive care) with High BG. The customer is claiming that the CGM sensor has a lower reading than the actual BG reading. Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Unknown.

Patient History:

Unknown.

Patient Outcome/Consequences:

Unknown.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: Reporter #:

s22

Reporter Title: First Name: Surname:

s22 s22 s22

Position: Company/Institution:

Senior Regulatory Affairs Specialist Medtronic Australasia Pty Ltd

Address 1: Address 2: Town/Suburb: State:

5 Alma Road Macquarie Park NSW

Country: Postcode: Phone: Fax:

Australia 2113 s22

Mobile: Email: Last External Submission By:

s22 @medtronic.com s22 - 14/09/2017 13:38

Initial Reporter Section

As Above?: *If No, fill out the following:* Initial Reporter Confidential:

Yes

Search Reporter By Surname: Initial Reporter #:

Title: First Name: Surname:

Position: Company/Institution:

Address 1: Address 2: Town/Suburb: State:

Postcode: Phone: Fax: Mobile:

Email:

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		95763	95763

Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class IIb	35983

GMDN / UMDN Text:	Brand Name:
Infusion pump, insulin, ambulatory	Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description:

Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device:	Software Version:
Reuse of Reusable	

Model #:	Serial #:	Batch #:	Lot #:
MMT-1712K	Unknown		

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Patient			

Access Contact Phone:	Access Contact Fax:

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	18000 Devonshire Street

Address 2:	Town/Suburb:	State/Province:	Country:
	Northridge	CA	United States

Postcode:	Phone:	Fax:
91329		

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
s22 [redacted] @medtronic.com	Yes	s22 [redacted]

Contact Title:	Contact First Name:	Contact Surname:

s22 s22 s22

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
14/09/2017	s22	Yes	Yes	☑

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Serious Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
Serious Injury	Patient	No	Unlikely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Unlikely	Not Investigated	No	

DIRE Meeting Notes:

Sponsor Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC

State:	Postcode:	Phone:	Fax:

NSW	1670	[redacted]	[redacted]

Email:

[redacted]@medtronic.com

Investigation Information Section

Device Analysis Results:

As the pump has not been returned for analysis, no Device Analysis Results are available.

Corrective/Preventative Actions:

Since no root cause has been determined no Remedial Action / Corrective Action / Preventative Action have been taken. The manufacturer will continue to monitor the rate of such incidents for trending purposes.

Details of Similar Events:

Worldwide (including Australia):
2015: 7 similar incidents / 25240 install base = 0.03%
2016: 62 / 55158 = 0.11%
2017 (to date): 34 / 72507 = 0.05%

Australia:
2015: 0 / 3567 = 0%
2016: 0 / 8176 = 0%
2017 (to date): 1 / 11747 = 0.01%

Additional Details (use for tables):



Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia, Austria, Belgium, Colombia, France, Germany, Israel, Italy, Poland, Singapore, Spain.

Additional Comments:

DIR closed 14/09/2017

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details						
Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details							
Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Output Issue	Incorrect or Inadequate Test Result		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	

Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

There is no further action required for this investigation; however, the TGA will continue to monitor the rate and pattern of occurrence and may reopen this case if appropriate.

Flow Details : DIR-REQ - Device Incident Request : 117488

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
117488	DIR-REQ		Closed	s22	OPR Administration User	14/09/2017	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	14/09/2017 15:52:18	
Comment		

The following data relates to similar incidents involving high blood glucose hospitalization, with a failed HP test.

Region	Year	# of Similar Events	Install Base
Worldwide (including Australia)	2015	0	11,851
	2016	0	39,124
	2017 (to date)	7	59,192
Australia	2015	0	1,946
	2016	0	5,913
	2017 (to date)	2	10,901

Document 5

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

14/09/2017
SIGNED

DIR : 26 - ID : 393896

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
47915	E17-44352	CASE-2017-00198933	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	[redacted]	14/09/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
09/11/2017	14/09/2017		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
10/11/2017	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient admitted to hospital for high blood glucose and ketones.

Clinical Event Information:

Medtronic received a complaint that a patient had been admitted to hospital for high blood glucose and ketones.

The high pressure test was performed on the device but the pump did not alarm as required. It is unclear if the test was performed correctly.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Unknown.

Document 5

Patient History:

Unknown.

Patient Outcome/Consequences:

Unknown.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: | Reporter #:

s22 |

Reporter Title: | First Name: | Surname:

s22 | s22 | s22

Position: | Company/Institution:

Senior Regulatory Affairs Specialist | Medtronic Australasia Pty Ltd

Address 1: | Address 2: | Town/Suburb: | State:

5 Alma Road | | North Ryde | NSW

Country: | Postcode: | Phone: | Fax:

Australia | 2113 | s22 |

Mobile: | Email: | Last External Submission By:

| s22 @medtronic.com | s22 - 09/11/2017 10:12

Initial Reporter Section

As Above?: | *If No, fill out the following:* | Initial Reporter Confidential:

Yes |

Search Reporter By Surname: | Initial Reporter #:

Title: | First Name: | Surname:

Position: | Company/Institution:

Address 1: | Address 2: | Town/Suburb: | State:

Postcode: | Phone: | Fax: | Mobile:

Document 5

Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711K

Serial #: NG1284638H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Reporter

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: 18000 Devonshire Street

Address 2:

Town/Suburb: Northridge

State/Province: CA

Country: United States

Postcode: 91329

Phone:

Fax:

Email:

Manufacturer Informed:

Date Aware of Adverse Event:

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$22 @medtronic.com		Yes	$22
Contact Title:	Contact First Name:	Contact Surname:	
$22	$22	$22	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
10/11/2017	$22	Yes	Yes	☑
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Serious Injury
Actual Effect:	Injured Party:		Found Prior To Use:	Risk Frequency:
Temporary Injury	Patient		No	Sometimes
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Unlikely	Not Investigated	No	
DIRE Meeting Notes:				

Sponsor Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:

Document 5

s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	s22 [redacted]
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section

Device Analysis Results:

Investigative action and analysis indicated that the insulin pump passed all functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and the Delivery Accuracy Test (DAT) testing at .08690 inches.

The Insulin Flow Blocked Alarm functioned properly during the Basic Occlusion, Occlusion, and Force Sensor Tests.

The insulin pump was received with a scratched case, pillowing keypad overlay, and minor scratched LCD window.

Corrective/Preventative Actions:

Investigation and analysis showed that the insulin pump functioned properly and no anomaly was noted. After testing it was concluded that the device operated within specifications.

Details of Similar Events:

The following data relates to similar incidents involving high blood glucose hospitalization, with a failed HP test.

Worldwide (including Australia):
2015: 0 similar incidents / 1,946 install base = 0%
2016: 1 / 5,913 = 0.017%
2017 (to date): 30 / 9,561 = 0.314%

Australia:
2015: 0 / 11,851 = 0%
2016: 0 / 39,147 = 0%
2017 (to date): 5 / 52,412 = 0.010%

Sponsor update (21/11/2017):
The previous details of similar events was incorrect. Please see the table to the right for correct information.

Additional Details (use for tables):

The following data relates to similar incidents involving high blood glucose hospitalization, with a failed HP test.

Region	Year	# of Similar Events	Install Base
Worldwide (including Australia)	2015	0	11,851
	2016	0	39,124
	2017 (to date)	7	59,192
Australia	2015	0	1,946
	2016	0	5,913
	2017 (to date)	2	10,901

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Sponsor provided update (21/11/2017): Netherlands

Additional Comments:

DIR closed 10/11/2017.

Amended final received 17/11/2017. Report updated 21/11/2017.

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Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Usability	Use of Device Issue	

Investigation Problem Causes

Document 5

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Returned device performed as intended		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

There is no further action required for this investigation; however, the TGA will continue to monitor the rate and pattern of occurrence and may reopen this case if appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Capture	37	Form Item	Sponsor Investigation / Additional Details (use for tables)

Flow Details : DIR-REQ - Device Incident Request : 119598

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
119598	DIR-REQ		Closed	s22	OPR Administration User	22/11/2017	Normal	0

Signature Details

Document 5

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	22/11/2017 16:46:56	
Comment		

Document 6

27/04/2018
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 26 - ID : 405749

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
51398		CASE-2018-00173587	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Death / Serious Injury	[redacted]	27/04/2018
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
16/07/2018	27/04/2018		05/06/2018
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
17/07/2018	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor			

Event Description for Website Publication:

Customer hospitalized due to high blood glucose with ketones, with blood glucose of 540 mg/dl at the time of the incident.

Clinical Event Information:

It was reported by the customer's parent that the customer got hospitalized due to high blood glucose with ketones on [redacted] with blood glucose of 540 mg/dl at the time of the incident. The customer was at 144 mg/dl at the time of the call.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Troubleshooting was not completed. The customer's doctor took them off the pump as they believed it was not treating the highs. The customer tried different infusion locations, settings changes, and infusion sets but nothing seemed to work. The insulin pump was returned for analysis.

Patient History:

Document 6

Patient Outcome/Consequences:

The customer was given manual injections to treat. The customer experienced symptoms such as nausea and vomiting. The customer was wearing the insulin pump during the incident.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: $22

Reporter #: $22 - Regulatory Affairs Officer - Medtronic

Reporter Title: $22

First Name: $22

Surname: $22

Position: Regulatory Affairs Officer

Company/Institution: Medtronic

Address 1: 97 Waterloo Road

Address 2:

Town/Suburb: North Ryde

State: New South Wales

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22 @medtronic.com

Last External Submission By: 106402_837 - 16/07/2018 17:53

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Document 6

Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711B

Serial #: NG1176937H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Patient

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: 18000 Devonshire Street

Address 2:

Town/Suburb: Northridge

State/Province: CA

Country: United States

Postcode: 91329

Phone:

Fax:

Email:

Manufacturer Informed: Yes

Date Aware of Adverse Event: s22 [redacted]

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Contact Title:	Contact First Name:	Contact Surname:
s22	s22	s22

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
17/07/2018	s22	Yes	Yes	☑

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Serious Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
Serious Injury	Patient	No	Sometimes

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Unlikely	Not Investigated	No	

DIRE Meeting Notes:

92 DIRs in 3 years
4 Recalls
1 Review

Sponsor Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

Document 6

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted]			

Investigation Information Section

Device Analysis Results:

Following our receipt of the returned device, the device passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and a Displacement Accuracy Test. The device functioned properly during testing. A minor scratched LCD window and a cracked retainer was noted during visual inspection.

Software version 2.9D, Not in manufacturing mode. Unit passed the DAT Test with 0.08715 inches.

Corrective/Preventative Actions:

Monitoring and trending.

Details of Similar Events:

Worldwide: 25 similar incidents/87,409 supplied = 0.029%.
Australia: 8 similar incidents/17,735 supplied - 0.045%.

Additional Details (use for tables):



Number of Similar Events:

8

Rate of Similar Events:

0.045% (re-usable)

Countries Similar Events Also Occurred:

Czech Republic, Denmark, Netherlands, Sweden, Switzerland, United Kingdom.

Additional Comments:

Medtronic is submitting this report to comply with the regulatory reporting requirements. This report is based upon information obtained by Medtronic, which the company may not have been able to fully investigate or verify prior to the date the report was required to be submitted. Medtronic has made reasonable efforts to obtain more complete information in the time allotted and has provided as much information as is available to the company as of the submission date of this reports. This report does not constitute an admission or a conclusion by the regulatory authority, Medtronic, or its employees that the device, Medtronic or its employees caused or contributed to the event described in the report. In particular, this report does not constitute an admission by anyone that the product described in the report has any "defects" or has "malfunctioned". Medtronic objects to the use of these words and others like it because of the lack of definition and the connotations implied by these terns. This statement should be included with any information or report disclosed to the public under applicable disclosure laws.
DIR closed 17/07/2018.

Document 6

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Infusion/Flow	No Flow	

Investigation Problem Causes

Document 6

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Returned device performed as intended		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 137952

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
137952	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	17/07/2018	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	17/07/2018 13:46:55	
Comment		

Document 6

Document 7

09/07/2018

SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 29 - ID : 410109

Released by Theta Technologies on 21/08/2018 17:03:32

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
52486		CASE-2018-00307700	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22 [redacted]	09/07/2018
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
14/09/2018	09/07/2018		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
17/09/2018	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Patient admitted to hospital for high blood glucose. Patient reported that the pump is not delivering insulin. Insulin pump failed the HP Test.

Clinical Event Information:

Medtronic has received a report of a customer admitted to hospital for high blood glucose. The customer is alleging that the pump is not delivering insulin.

Insulin pump failed the HP Test.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Describe any test (Lab, xray, etc.):	**Injured - Extent of Injury:**	**Other Consequence:**	**Other medical devices currently using/implanted:**
Additional Event Description:	**Medical Problem Device Used For:**	**Additional Patients Added:**	
		0	

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:	
s2 [redacted]	s22 [redacted] - Regulatory Affairs Officer - Medtronic	
Reporter Title:	**First Name:**	**Surname:**

Document 7

s2 | s22 | s22

Position: Post Market Vigillance Specialist

Company/Institution: Medtronic Australasia

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: s22

Fax:

Mobile:

Email: s22

Are you happy for the device company to contact you about the incident?: ☐

Last External Submission By: 106402_837 - 14/09/2018 12:13

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country: Australia

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711P

Serial #: NG1243903H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Reporter

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

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Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	18000 Devonshire Street

Address 2:	Town/Suburb:	State/Province:	Country:
	Northridge	CA	United States

Postcode:	Phone:	Fax:	Email:
91329			s22 @medtronic.com

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22	s2	s22

Contact Surname:

s22

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
18/07/2003	09/07/2018	Closed

Problems Observed:

Usability; Use of Device Issue;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	No root cause found	

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Document 7

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessed By:	Licence Status:	Status Reason:	Status Effective Date:
09/07/2018	s22	Active		18/07/2003
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Serious Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
No	Yes	No	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**
Yes	Sometimes	Serious	Major Risk	Team Review

Risk Assessment Notes:

Additional Risk Assesments Required: ☑

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Analysis Category:	**Date:**	**Assessed By:**	**Injured Party:**	**Potential Effect:**	**Actual Effect:**
Final	17/09/2018	s22	Patient	Serious Injury	Serious Injury
Update Device Details?:	**Found Prior To Use:**	**Sample Received:**	**Risk Frequency:**	**Risk Severity:**	**Risk Detectability:**
No	No	No	Sometimes	Serious	Unlikely
Copy Data From:	**Risk Rating:**				
Initial	Major Risk				
	Risk Assessment Notes:				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22			

Document 7

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Pump passed the functional tests, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08700 inches. The Insulin Flow Blocked Alarm functioning properly. Pump programmed with multiple bolus deliveries and all bolus delivered properly their indicated amounts and were properly recorded in the Daily History noted.

Corrective/Preventative Actions:

There are no Corrective Actions associated with this complaint.

Details of Similar Events:

Australia: 2015: 0 similar incidents / 4,397 units sold (0%) 2016: 0/5,199 (0%) 2017: 10/7,185 (0.139%) 2018 (to date): 17/5,295 (0.321%)
Worldwide: 2015: 0/49,575 (0%) 2016: 3/65,778(0.005%) 2017: 51/83,206 (0.061%) 2018 (to date): 36/78,191 (0.046%)

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:

Severity:

Rating:

Type Cause and Outcome:

Number of Similar Events:

Expected Rate:

Actual Rate:

Countries Similar Events Also Occurred:

Austria, Brazil, Finland, France, Germany, Hungary, Israel, Netherlands, South Africa, Switzerland, United Kingdom

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Medtronic, which the company may not have been able to fully investigate or verify prior to the date the report was required to be submitted. Medtronic has made reasonable efforts to obtain more complete information in the time allotted and has provided as much information as is
available to the company as of the submission date of this report. This report does not constitute an admission or a conclusion by the regulatory authority, Medtronic, or its employees that the device, Medtronic or its employees caused or contributed to the event described in the report. In
particular, this report does not constitute an admission by anyone that the product described in this report has any "defects" or has "malfunctioned". Medtronic objects to the use of these words and others like it because of the lack of definition and the connotations implied by these terms.
This statement should be included with any information or report disclosed to the public under applicable disclosure laws.

DIR Closed 17/09/18

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):

Brand Name:

Manufacturer Name:

Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Document 7

Rec No
1

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Details	Sample Details			Additional Details		
Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	Serial Number:	Model Number:
Sample #:						

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

Chronology

Chronology Details			
Heading:	Chronology Event (L1):	Email:	Expected:
Include?:	Chronology Event (L2):	Sent:	Received:
Notes:		Summary:	
TRIM Reference:	TRIM Container or Document?:	URL:	Comment:

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Usability	Use of Device Issue			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

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Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only		

Latest Investigation where this DIR is the Primary DIR:	Latest Investigation where this DIR is a Related DIR:	Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Other medical devices currently using/implanted:	Additional Event Description:
Medical Problem Device Used For:			

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

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Device Access - Details for where the device is, if not with the reporter.

Title: First Name: Last Name: Phone:

Fax: Email:

Incident Location Details

Occurred in Australia: Organisation: Address Line 1: Address Line 2:

Town/Suburb: State: Postcode:

Report Generation

Completion Letters

Flow Details : DIR-REQ - Device Incident Request : 144060

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
144060	DIR-REQ		Closed	s22	OPR Administration User	17/09/2018	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	17/09/2018 08:45:09	
Comment		

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25/01/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 418540

Released by §22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
55547	E19-579552	CASE-2019-00044409	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	§22	25/01/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
13/06/2019	25/01/2019	18/06/2019	05/06/2019
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
16/04/2020	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Sponsor has been informed that a customer of an insulin pump was found deceased in bed.

Clinical Event Information:

Medtronic has been informed that a customer of an insulin pump was found deceased in bed. The cause of death is unknown at this stage.

The pump will be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:
Unknown.	Unknown.
Patient Outcome/Consequences:	**Additional Event Description:**
Unknown.	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to death?:	Other medical devices currently using/implanted:
	Death	No	
Medical Problem Device Used For:	**Additional Patients Added:**		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:	Preferred Contact Method:
§2		
Reporter Title:	**First Name:**	**Surname:**
§2	§22	§22

Position:	Company/Institution:
PMV Manager	Medtronic Australasia
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

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2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	Email:	Are you happy for the device company to contact you about the incident?:	Last External Submission By:
	s22	☐	s22 _837 - 13/06/2019 09:43

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident: ☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1711W	NG1263558H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Place of Implantation:	Reported Device Location:	Access Contact Title:	Access Contact First Name:
Access Contact Surname:	Access Contact Phone:	Access Contact Fax:	Access Contact Email:

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	18000
Address 2:	Town/Suburb:	State/Province:	Country:
	Northridge	CA	United States
Postcode:	Phone:	Fax:	Email:

91329			s22 @medtronic.com Document 8
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22	s2	s22
Contact Surname:			
s22			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:		
18/07/2003	25/01/2019	Closed		
Problems Observed:				
Insufficient Information; ;				

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)
Report Priority:				
Routine				

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:	
18/06/2019	Death	Investigation (within DIR) is recommended	
Team Meeting Notes:			
Attempt to get coroner's report either from Sponsor or get patient details from the Sponsor			

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:	
Meeting Notes:			

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
25/01/2019	s22	Active		18/07/2003
Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Patient	Death	Death	No	No
Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
No	Yes	No	No	No
Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:

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Yes		Life threatening		Team Review

Risk Assessment Notes:

DIR not expedited at initial triage stage due to lack of information as to why patient died. Discussed DIR initial triage with 4 other investigators in a group discussion and conclusion was to not expedite at this stage.

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details: Statistics Checklist Section

Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	05/06/2019	$22	Active	Active	18/07/2003
Copy Data From:	**Injured Party:**	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Initial	**Patient**	**Death**	**Death**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Unknown**	**Life threatening**		No
	Risk Assessment Notes:				
	Follow up report				

Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	14/06/2019	$22	Active	Active	18/07/2003
Copy Data From:	**Injured Party:**	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Previous	**Patient**	**Death**	**Death**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Rarely**	**Life threatening**	**Major Risk**	Yes
	Risk Assessment Notes:				
	Patient death.113 DIRs in 3 years; no similar event found for this product. Should this be sent to DPRC?				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:

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s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump has not been returned for analysis. We are unable to determine if the insulin pump failed to meet specifications.

5 requests were made to return the device for analysis. On the 5th request, s22 confirmed that the device would not be returned and that she would be in touch if she wished for further investigation to be performed.

Corrective/Preventative Actions:

All complaints are monitored for trend and signals. Quality Review decides on formal investigations based on trending including signal detection of complaint data.

Details of Similar Events:

Australia:
2016: 1 similar incident / 5199 units sold = 0.02%
2017: 0 / 7185 = 0%
2018: 0 / 8128 = 0%
2019 (to date): 1 / 333 = 0.30%

Worldwide:
2016: 2 similar incident / 65,779 units sold = 0.00%
2017: 5 / 83,207 = 0.01%
2018: 8 / 124,526 = 0.01%
2019 (to date): 4 / 47,653 = 0.01%

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Brazil, Colombia, Denmark, France, Ireland, Japan, Netherlands, Slovenia, Switzerland, United Kingdom

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		19/06/2019	17/07/2019	28/06/2019		
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		16/04/2020				D20-524395

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Insufficient Information			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The TGA has reviewed the coroner's report in relation to this incident and no further investigation will occur at this time.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details	Additional Details

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	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 160285

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Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
160285	DIR-REQ		Closed	s22	OPR Administration User	16/04/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	16/04/2020 10:21:21	
Comment		

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07/03/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 419560

Released by $22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
56185		CASE-2019-00149488	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	$22	07/03/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
25/06/2019	07/03/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
28/06/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Medtronic has received a report of a patient who was hospitalized for low blood glucose.

Clinical Event Information:

Medtronic has received a report of a patient who was hospitalized for low blood glucose.

Trouble shooting was performed but did not resolve the issue. Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:
Hospitalization treatment: IVR with Sugar	
Patient Outcome/Consequences:	**Additional Event Description:**

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$2	$22	$22	
Position:		**Company/Institution:**	
PMV Manager		Medtronic Australasia	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

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2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	Email:	Are you happy for the device company to contact you about the incident?:	Last External Submission By:
	s22	☐	s22 _837 - 25/06/2019 16:43

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident: ☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1711K	NG1111632H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Place of Implantation:	Reported Device Location:	Access Contact Title:	Access Contact First Name:
Access Contact Surname:	Access Contact Phone:	Access Contact Fax:	Access Contact Email:

Additional Devices Added:

2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	18000 Devonshire Street
Address 2:	Town/Suburb:	State/Province:	Country:
	Northridge	CA	United States
Postcode:	Phone:	Fax:	Email:

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91329			$22 @medtronic.com
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22
Contact Surname:			
$22			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:		
18/07/2003	07/03/2019	Closed		
Problems Observed:				
Patient Device Interaction Problem; Patient-Device Incompatibility;				

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Root cause not found	Team B (IIb, Is & Im)
Report Priority:				
Not Investigated				

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:	
Team Meeting Notes:			

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:	
Meeting Notes:			

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
07/03/2019	$22	Active		18/07/2003
Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Patient	Serious Injury	Serious Injury	No	No
Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
No	Yes	No	No	No
Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:

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Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	28/06/2019	s22	Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Serious Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Sometimes**	**Serious**	**Major Risk**	Yes
	Risk Assessment Notes:				
	113 DIRs in 3 years, but no similar event found in the past 1 year. root cause not established, rate considered low.				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test.

A scratched case, pillowing keypad overlay, cracked select button keypad overlay, keypad overlay texture damage, and a minor scratched LCD window was noted during visual inspection. These are considered cosmetic damages, which do not impact the functional performance of the pump.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

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Review of the Carelink report downloaded from the returned pump, indicated that the customer changed infusion sets every 4 days. The last infusion set change prior to $22 occurred at $22 . The customer was not using sensors and did not record BG values in the pump.
From $22 all boluses were programmed and delivered using the bolus wizard function based on carb entries (no BG values were entered). On $22 total daily insulin delivered was 70.83 U; 64.33U basal and 6.5 U bolus. On February 27, the total daily insulin delivery was 61.43, 57.33U basal and 4.1 U bolus; the insulin pump was suspended by the user for 2 hours. On $22 the total daily insulin delivery was 70U, 64.40U basal and 5.60 U bolus. On $22 , the total daily insulin delivered was 58.9; 58.9U basal, 0U bolus; the pump was suspended by the user at 21:35 PM.

Based on the analysis of the returned pump and review of the Carelink report, we confirm that the pump delivered insulin as programmed.

Details of Similar Events:

Australia
2016: 0 similar incidents / 5199 units sold = 0%
2017: 1 / 7185 = 0.01%
2018: 0 / 8128 = 0%
2019 (to date): 1 / 2333 units sold = 0.04%

Worldwide:
2016: 0 similar incidents / 65779 units sold = 0%
2017: 13 / 83207 = 0.02%
2018: 9 / 124526 = 0.01%
2019 (to date): 8 / 47653 = 0.02%

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Belgium, Colombia, Denmark, Finland, France, Germany, Netherlands, Spain, Sweden, United Kingdom.

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed. 28/6/2019

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Patient Device Interaction Problem	Patient-Device Incompatibility		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

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Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-943					
Device ARTG No:	**Manufacturer Name:**	**Sponsor/Supplier:**	**GMDN / UMDN Text:**	**Trade/Brand Name:**	**Serial #:**
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-332A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:

Document 9

1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:
					Who sent the device to the TGA?:			Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 163357

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Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
163357	DIR-REQ		Closed	s22	OPR Administration User	28/06/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	28/06/2019 16:23:19	
Comment		

Document 10

12/03/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 420693

Released by [redacted] on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
56276		CASE-2019-00128823	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	[redacted]	12/03/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
09/08/2019	12/03/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
09/08/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient hospitalized for high BG and DKA.

Clinical Event Information:

Medtronic has become aware of a customer who was hospitalized for high BG and DKA.

No troubleshooting was performed.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
[redacted]		[redacted]	

Patient Focused Corrective Action Taken:	Patient History:
Admitted to ICU for IV infusion of insulin.	Unknown
Patient Outcome/Consequences:	**Additional Event Description:**
Unknown	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
[redacted]			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institution:**	
PMV Manager		Medtronic Australasia	

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Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		North Ryde	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	s22	
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**	**Last External Submission By:**
	s22	☐	110403_837 - 09/08/2019 12:18

Initial Reporter Section

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:
Yes		
Search Reporter By Surname:	**Initial Reporter #:**	**Preferred Contact Method:**

Title:	First Name:	Surname:
Position:	**Company/Institution:**	

Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1763396H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**	**Access Contact First Name:**
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**	**Access Contact Email:**

Additional Devices Added:

2

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	18000 Devonshire Street
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
	Northridge	CA	United States

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Postcode:	Phone:	Fax:	Email:
02048			s22 @medtronic.com
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22	s2	s22
Contact Surname:			
s22			

Supplier Information Section

Supplier Name:	Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
18/07/2003	12/03/2019	Closed

Problems Observed:
Appropriate Term/Code Not Available; ;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Root cause not found	Team B (IIb, Is & Im)

Report Priority:
Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
13/03/2019	s22	Active		18/07/2003
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Temporary Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**

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No	Yes	No	No	No
Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:
Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	09/08/2019	s22	Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Temporary Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Rarely**	**Serious**	**Minor Risk**	Yes
	Risk Assessment Notes:				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		

Email:

s22 s22 @medtronic.com; s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, pillowing keypad overlay, and minor scratched LCD window. Analysis testing identified the insulin pump met specifications.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Document 10

Details of Similar Events:	Additional Details (use for tables):
Australia 2016: 2 similar incidents / 5199 units sold = 0.04% 2017: 0 / 7185 = 0% 2018: 1 / 8128 = 0.01% 2019 (to date): 2 / 3014 = 0.07% Worldwide: 2016: 32 similar incidents / 65778 units sold = 0.05% 2017: 27 / 83206 = 0.03% 2018: 33 / 124525 = 0.03% 2019 (to date): 34 / 70727 = 0.05%	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hungry, Iceland, Israel, Korea, Mexico, Netherlands, Poland, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom.

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR Closed on 09/08/2019

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			Patient factors	

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

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Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-332A					

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
Unknown					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 164681

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
164681	DIR-REQ		Closed	s22	OPR Administration User	09/08/2019	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	09/08/2019 14:59:18	
Comment		

Document 11

26/04/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 423987

Released by s22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
57139		CASE-2019-00211410	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	26/04/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
23/07/2019	26/04/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
24/07/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

A customer was admitted to hospital with low BG. Customer claims they have had multiple low BG events within the month.

Clinical Event Information:

Medtronic received a report that a customer was admitted to hospital with low BG. Customer claims they have had multiple low BG events within the month.

Customer refused to troubleshoot.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
Female			

Patient Focused Corrective Action Taken:	Patient History:
Customer was given gluco gel. Medtronic has replaced the insulin pump.	Unknown.
Patient Outcome/Consequences:	**Additional Event Description:**
Discharged from hospital with a new pump.	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s2			
Reporter Title:	**First Name:**	**Surname:**	
s2	s22	s22	
Position:		**Company/Institution:**	
PMV Manager		Medtronic Australasia	

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Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	s22	
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**	**Last External Submission By:**
	s22	☐	110403_837 - 23/07/2019 15:22

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		NA	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Minimed 640G Insulin Pump	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1457831H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**	**Access Contact First Name:**
	With Reporter		
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**	**Access Contact Email:**

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	2 Alma Road
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
	Macquarie Park	NSW	Australia

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Postcode:	Phone:	Fax:	Email:
2113	s22		s22

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22	s2	s22

Contact Surname:

s22

Supplier Information Section

Supplier Name:		Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
18/07/2003	26/04/2019	Closed

Problems Observed:

Infusion or Flow Problem; Improper Flow or Infusion;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Root cause not found	Team B (IIb, Is & Im)

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
26/04/2019	s22	Active		18/07/2003

Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Patient	Serious Injury	Temporary Injury	No	No

Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:

Document 11

No	Yes	No	No	No
Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:
Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	24/07/2019		Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Temporary Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Sometimes**	**Serious**	**Major Risk**	Yes
	Risk Assessment Notes:				
	- Rate of 0.02% given by supplier. - 113 DIRs in the last 3 years. - 1 PMR was closed in 2015. - 6 recalls for this ARTG; hard to determine if related as they cannot determine cause ofBG. - Action: No further action (trend data), due to patient factors				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:

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The pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. The following physical damages observed did not impact the functionality of the pump; a scratched case, pillowing keypad overlay, cracked select button keypad overlay, keypad overlay texture damage, and a minor scratched LCD window.

Analysis testing identified the insulin pump met specifications.

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

Australia
2016: 3 similar incidents / 5199 units sold = 0.06%
2017: 3 / 7185 = 0.04%
2018: 0 / 8128 = 0%
2019 (to date): 2 / 2624 = 0.08%
Worldwide:
2016: 16 similar incidents / 65778 units sold = 0.02%
2017: 41 / 83206 = 0.05%
2018: 47 / 124525 = 0.04%
2019 (to date): 36 / 61694 = 0.06%

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Austria, Belgium, Brazil, Colombia, Denmark, Finland, France, Germany, Israel, Italy, Japan, Netherlands, Norway, Slovakia, Spain, Sweden, Switzerland, Turkey, and United Kingdom.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐	Final report due	TGA Regulatory Action	Regulatory Information Request (s41)		26/04/2019	05/08/2019	24/07/2019		

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Infusion or Flow Problem	Improper Flow or Infusion		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

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Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
			s22	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 169927

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
169927	DIR-REQ		Closed	s22	OPR Administration User	24/07/2019	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22	
Signed At	24/07/2019 16:03:22	
Comment		

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03/05/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 424134

Released by [redacted] on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
57230		CASE-2019-00293767-1 + CASE-2019-00293741	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	[redacted]	03/05/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
23/07/2019	03/05/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
24/07/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Hospitalization due to DKA.

Clinical Event Information:

Hospitalization due to DKA. Pump will be returned for analysis

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
Male			

Patient Focused Corrective Action Taken:	Patient History:
IV fluids and Insulin administered during hospitalization.	Diabetes.
Patient Outcome/Consequences:	**Additional Event Description:**
Unknown.	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
[redacted]			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institution:**	
Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW

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Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**	**Last External Submission By:**
	s22	☐	110403_837 - 23/07/2019 15:43

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		NA	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Medtronic MiniMed 640G - Infusion pump, insulin, ambulatory	Medtronic MiniMed 640G - Infusion pump, insulin, ambulatory	Single Use	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1365655H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**	**Access Contact First Name:**
	With Patient		
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**	**Access Contact Email:**

Additional Devices Added:

1

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	18000 Devonshire Street
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
	Northridge	CA	United States
Postcode:	**Phone:**	**Fax:**	**Email:**
91329-1219			

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Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22

Contact Surname:

$22

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
18/07/2003	03/05/2019	Closed

Problems Observed:

Appropriate Term/Code Not Available; ;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
03/05/2019	$22	Active		18/07/2003
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Serious Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
No	Yes	No	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**

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Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:	No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	24/07/2019		Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Serious Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Sometimes**	**Serious**	**Major Risk**	Yes
	Risk Assessment Notes:				
	- Rate of 0.02% given by supplier. - 113 DIRs in the last 3 years; 6 DIRs with patient exhibiting DKA in last 5 years. - 1 PMR was closed in 2015. - 6 recalls for this ARTG; hard to determine if related as they cannot determine cause of DKA. - Action: No further action (trend data), due to patient factors				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted] s22 [redacted] @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
Since the insulin pump has not returned for analysis testing, we are not able to confirm the complaint or determine a root cause.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	Additional Details (use for tables):

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Australia
2016: 0 similar incidents / 5199 units sold = 0%
2017: 0 / 7185 = 0%
2018: 0 / 8128 =0%
2019 (to date): 1 / 2624 = 0.04%

Worldwide:
2016: 0 similar incidents / 65778 units sold = 0%
2017: 3 / 83206 = 0%
2018: 6 / 124525 = 0%
2019 (to date): 10 / 61694 = 0.02%

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Austria, Colombia, Finland, France, Germany, Netherlands, Norway, South Africa, Spain, United Kingdom

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Regulatory Information Request (s41)		03/05/2019	12/08/2019	24/07/2019		Final report due

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			Patient factors

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details		
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

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Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
			s22	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	UNKNOWN
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-332A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

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Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 170500

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
170500	DIR-REQ		Closed	s22	OPR Administration User	24/07/2019	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	24/07/2019 15:54:07

Comment		

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Document 13

06/05/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 424183

Released by [redacted] on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
57271		CASE-2019-00296497-1 & 00296496 & 00296500	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	[redacted]	06/05/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
22/07/2019	06/05/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
24/07/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Customer presented to emergency department with low BG (1.2mmol).

Clinical Event Information:

Customer presented to emergency department with low BG (1.2mmol). Customer states that they had been using insulin pump system within 48 hours of reported event.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
Female			

Patient Focused Corrective Action Taken:	Patient History:
Glucagon shot and food.	unknown
Patient Outcome/Consequences:	**Additional Event Description:**
Alive, no further injury or complications reported	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
[redacted]			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institution:**	
Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW

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Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**	**Last External Submission By:**
	s22	☐	110403_837 - 22/07/2019 15:19

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Medtronic MiniMed 670G - Infusion pump, insulin, ambulatory	Medtronic MiniMed 670G - Infusion pump, insulin, ambulatory	Single Use	V4.11 MM
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
PUMP-1782K	NG1796886H		HG33DFM
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**	**Access Contact First Name:**
	With Patient		
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**	**Access Contact Email:**

Additional Devices Added:

2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	18000 Devonshire Street
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
	Northridge	CA	United States
Postcode:	**Phone:**	**Fax:**	**Email:**
91329-1219			

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Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22

Contact Surname:

$22

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
11/08/2018	06/05/2019	Closed

Problems Observed:

Patient Device Interaction Problem; ;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
06/05/2019	$22	Active		11/08/2018
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Serious Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
No	Yes	No	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**

Document 13

Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:	No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	24/07/2019	s22	Active	Active	11/08/2018
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Serious Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Sometimes**	**Serious**	**Major Risk**	Yes
	Risk Assessment Notes:				
	- 3 DIRs this year; first incidence of low BG - Isolated issue and device not returned for investigation. - Action: No further investigation, device not returned.				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
Since the insulin pump has not returned for analysis testing, we are not able to confirm the complaint or determine a root cause.	All complaints are monitored for trend and signals. Quality Review decides on formal investigations based on trending including signal detection of complaint data.
Details of Similar Events:	Additional Details (use for tables):

Document 13

2016: Australia - 0 similar incidents / 0 units sold = 0% Worldwide: 0 similar incidents / 0 units sold = 0%
2017: Australia - 0 similar incidents / 0 units sold = 0% Worldwide: 69 similar incidents / 72,692 units sold = 0.1%
2018: Australia - 0 similar incidents / 404 units sold = 0% Worldwide: 311 similar incidents / 113,864 units sold = 0.27%
2019 (to date): Australia - 1 similar incidents / 2,618 units sold = 0% Worldwide: 184 similar incidents / 71,661units sold = 0.25%

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Canada, United States.

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		06/05/2019	12/08/2019	23/07/2019		

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Patient Device Interaction Problem			

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

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Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
			s22	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
313741	Medtronic Minimed	Medtronic Australasia Pty Ltd	Subcutaneous glucose sensor	Guardian Sensor (3) - Subcutaneous glucose sensor	L078

Model Number:	Batch #:	Lot #:	Expiry Date:
MMT-7020C1			

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	HG3656A

Model Number:	Batch #:	Lot #:	Expiry Date:
MMT-332A			

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

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Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 170605

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
170605	DIR-REQ		Closed	s22	OPR Administration User	24/07/2019	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	24/07/2019 13:37:50

Comment		

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15/05/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 424403

Released by [redacted] on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
57426		CASE-2019-00310970 & CASE-2019-00310973	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	[redacted]	15/05/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
22/07/2019	15/05/2019		21/05/2019
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
24/07/2019	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Hospitalization for treatment of DKA. Symptoms include nausea, vomiting and abdominal pain.

Clinical Event Information:

Hospitalization for treatment of DKA. Symptoms include nausea, vomiting and abdominal pain. Positive results in Ketones, BGL 25.4.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
Female	Unknown	Unknown	

Patient Focused Corrective Action Taken:	Patient History:
Insulin, potassium and saline infusions.	Diabetes
Patient Outcome/Consequences:	**Additional Event Description:**
Pump will be replaced	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
[redacted]			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institution:**	
Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW

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Country:	Postcode:	Phone:	Fax:
Australia	2113	$22	
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**	**Last External Submission By:**
	$22	☐	110403_837 - 22/07/2019 14:42

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		$22	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
$22		$22	NSW
Postcode:	**Country:**	**Phone:**	**Fax:**
$22			
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Medtronic Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	Medtronic Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	Single Use	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1640277H		HG2QG7N
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**	**Access Contact First Name:**
	With Patient		
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**	**Access Contact Email:**

Additional Devices Added:

1

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	1800 Devonshire Street
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
	Northridge	CA	United States
Postcode:	**Phone:**	**Fax:**	**Email:**
91325	$22		

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Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22

Contact Surname:

$22

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:
18/07/2003	15/05/2019	Closed

Problems Observed:

Appropriate Term/Code Not Available; ;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
15/05/2019	$22	Active		18/07/2003
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Serious Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
No	Yes	No	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**

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Yes		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment: No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	23/07/2019	s22	Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Serious Injury**	**Serious Injury**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Sometimes**	**Serious**	**Major Risk**	Yes
	Risk Assessment Notes:				
	- Rate of 0.02% given by supplier. - 113 DIRs in the last 3 years; 6 DIRs with patient exhibiting DKA in last 5 years. - 1 PMR was closed in 2015. - 6 recalls for this ARTG; hard to determine if related as they cannot determine cause of DKA. - Action: No further action (trend data), due to patient factors				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			
s22 com; s22 @medtronic.com; s22 @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
Since the insulin pump has not returned for analysis testing, we are not able to confirm the complaint or determine a root cause.	All complaints are monitored for trend and signals. Quality Review decides on formal investigations based on trending including signal detection of complaint data.
Details of Similar Events:	Additional Details (use for tables):

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2016: Australia - 2 similar incidents / 5,199 units sold = 0% Worldwide: 32 similar incidents / 65,778 units sold = 0%
2017: Australia - 0 similar incidents / 7,185 units sold = 0% Worldwide: 27 similar incidents / 83,206 units sold = 0%
2018: Australia - 1 similar incidents / 8,128 units sold = 0% Worldwide: 32 similar incidents / 124,525 units sold = 0%
2019 (to date): Australia - 2 similar incidents / 2,624 units sold = 0% Worldwide: 30 similar incidents / 61,694 units sold = 0%

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Australia, Austria, Belgium, Brazil, Colombia, Czech Republic, Finland, France, Germany, Hungary, Iceland, Israel, Korea, Mexico, Netherlands, Poland, Slovakia, Slovenia, Spain, Sweden, Switzerland, and United Kingdom.

Completed Actions:	Planned Actions and Proposed Timelines:
	TBA

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		16/05/2019	26/08/2019	22/07/2019		

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			Diabetic ketone acidosis

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, for Trending Purposes Only		

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Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
			s22	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	HG2NUAN

Model Number:	Batch #:	Lot #:	Expiry Date:
MMT-332A			

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

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Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 171291

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
171291	DIR-REQ		Closed	s22	OPR Administration User	24/07/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	24/07/2019 13:52:08	
Comment		

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05/12/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 38 - ID : 466787

Released by [redacted] on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
60932	E20-45930	CASE-2019-00840457 / 8 /9	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	[redacted]	05/12/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
03/03/2020	05/12/2019	10/03/2020	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
23/06/2020	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Hypoglycaemic episode.

Clinical Event Information:

Medtronic was notified of a customer hospitalized for low blood glucose. The customer was using the auto feature on their 670G pump (continuous glucose monitoring).
No troubleshooting was performed as the customer refused.
Medtronic has requested that the pump be returned for analysis.

As of today 03/03/2020- more detailed description of the event:

Customer called and reported that they were hospitalized due to low blood glucose on [redacted] with blood glucose of 20 to 32 mg/dl at the time of the incident.
The customer's blood glucose was 144 mg/dl at the time of the call. The customer was given glucose and intravenous fluids to treat.
The customer did not mention any symptoms. The customer was wearing the insulin pump during the incident. The Auto Mode on the insulin
pump was active and automatically adjusting insulin delivery during the event. The customer reported pump physical damage.
The customer suspected the pump was over delivering. Troubleshooting was not completed as the customer declined.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Investigations and Diagnostic Tests -> Hypoglycemia -> ;
Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

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The customer was treated with glucose and IV fluids.

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Preferred Contact Method:

$2

Reporter Title:

First Name:

Surname:

$2

$22

$22

Position:

Company/Institution:

PMV Manager

Medtronic Australasia Pty Ltd

Address 1:

Address 2:

Town/Suburb:

State:

2 Alma Road

Macquarie Park

NSW

Country:

Postcode:

Phone:

Fax:

Australia

2113

$22

Mobile:

Email:

Last External Submission By:

$22

$22 _837 - 03/03/2020 12:53

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

Search Device ARTG:

Device ARTG #:

Therapeutic Licence Type:

No

95763

95763

Medical Device

Product Licence Category:

Device Class:

GMDN / UMDN Code:

GMDN / UMDN Text:

Included

Class IIb

35983

Infusion pump, insulin, ambulatory

Brand Name:

Initial Device Description:

Usage of Device:

Software Version:

Minimed 670G pump - Infusion pump, insulin, ambulatory

Minimed 670G pump - Infusion pump, insulin, ambulatory

Reuse of Reusable

Model #:

Serial #:

Batch #:

Lot #:

MMT-1782K

NG1784493H

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Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22	s2	s22
Contact Surname:			
s22			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
10/03/2020	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:
sending to meeting due to lv1 - no issue found. 1 similar DIR in 6mths; no recall no pmr

Outcomes from Team Meeting:
Request further explanation of the rates in Australia. Are their rates for low blood glucose? Or hospitalisation? Over delivering?

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

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Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
10/12/2019	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	Yes - some potential factors (up to 3)			Yes	
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
	Compatibility of device - patient characteristics, Use of device - operator/user error	Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	04/03/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 1 Investigation (to complete screening)	**Level 1 Investigation (to complete screening)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			Yes - some potential factors (up to 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**1 incidents**		Compatibility of device - patient characteristics, Use of device - operator/user error	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No		

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3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:	
3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
			Yes

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test. The test P-cap locks properly in the reservoir compartment. The following physical damages were noted but did not impact the insulin pump's performance: a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	Additional Details (use for tables):
Australia: 2017: 0 similar incidents / 0 units sold 2018: 0 / 404 2019: 0 / 5,006 2020 (to date): 0 / 372 Worldwide: 2017: 13 similar incidents/ 73,157 sold worldwide 2018: 72/ 113,938 2019: 70 / 159,734 2020: (to date): 18 / 13,339	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:	
Canada, Sweden, United Kingdom, United States.	
Completed Actions:	Planned Actions and Proposed Timelines:
Additional Comments:	
DIR closed 23/6/2020	

Reason for Level 1 Investigation

Details of Reasons	

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Reason for Level 1 Investigation	
Rate information is required	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Questionnaire to confirm the rates.

Potential Risks

Delays in response by product manufacturers: ☐

Delays in response by incident reporters: ☐

Delays in analysis within the TGA: ☐

Delays in reporting by other sources (e.g. clinical registries): ☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Case Closure

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		06/12/2019	17/03/2020	04/03/2020		
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		18/03/2020	15/04/2020	16/04/2020		

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			low blood glucose	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	

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Investigations and Diagnostic Tests	Hypoglycemia		
Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The manufacturer stated that they have conducted an analysis on the returned device. Review of their findings confirmed the insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test. The test P-cap locks properly in the reservoir compartment. The device was also found to have a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads. The manufacturer has confirmed that the physical damage noted in the analysis would not impact the device's performance. (what did you find or are you just going with what the manufacturer has stated is the issue)The sponsor has stated one similar event has been reported. This is consistent with a search of the TGA database. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

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This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-332A					
Device ARTG No:	**Manufacturer Name:**	**Sponsor/Supplier:**	**GMDN / UMDN Text:**	**Trade/Brand Name:**	**Serial #:**
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-945					

Related DIR Information - Click **New** to begin entering information.

Rec No
1

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Injured - Extent of Injury:	**Was device directly linked to death?:**	**Was device directly linked to permanent disabiltiy?:**	**Consequence:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Device Information

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Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 60932 - Questionnaire Letter - response	416	Form	

Flow Details : DIR-REQ - Device Incident Request : 229101

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
229101	DIR-REQ		Closed	s22	OPR Administration User	23/06/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	24/08/2020 14:54:34	
Comment		

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12/12/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 37 - ID : 468994

Released by Theta Technologies on 11/03/2020 10:28:02

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
61081		CASE-2019-00874126/ 123/ 125	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	12/12/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
03/03/2020	12/12/2019	17/03/2020	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
17/03/2020	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Customer hospitalized for high blood glucose.

Clinical Event Information:

Medtronic was notified of a customer hospitalized for high blood glucose.
Medtronic has requested that the pump be returned for analysis.

As of today 03/03/2020 more detailed description of the event:

Information received by Medtronic indicated the user was hospitalized due to hyperglycemia on s22 with a blood glucose value of 20 mmol/l at the time of the incident. The user reported the pump alarmed insulin flow blocked. The user was given intravenous fluids and insulin injections to treat. The user did not mention any symptoms.
Troubleshooting was not completed because the user declined as he was still in the hospital.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Insufficient Information -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

$2

Reporter #:

Preferred Contact Method:

Reporter Title:

$2

First Name:

$22

Surname:

$2

Position:

PMV Specialist

Company/Institution:

Medtronic Australasia

Address 1:

2 Alma Road

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

$22

Fax:

Mobile:

Email:

$22

Last External Submission By:

$22 _837 - 03/03/2020 15:16

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

No

Search Device ARTG:

95763

Device ARTG #:

95763

Therapeutic Licence Type:

Medical Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

35983

GMDN / UMDN Text:

Infusion pump, insulin, ambulatory

Brand Name:

Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description:

Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device:

Reuse of Reusable

Software Version:

Model #:

MMT-1711K

Serial #:

NG1262530H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

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Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Not enough information has been provided	

Notes for Team meeting:

ARTG 95763 is already being investigated by s22. Should this report be added to the investigation?

Outcomes from Team Meeting:

Known complication. Closed NFA

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

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Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
12/12/2019	0 - Insufficient information to determine level of severity			s22 [redacted]	
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 3 Investigation (for multiple DIRs/a DII)	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		Waiting on final report		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	7 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		Yes
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	12/03/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 3 Investigation (for multiple DIRs/a DII)	**Level 3 Investigation (for multiple DIRs/a DII)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Sent to Team meeting as ARTG 95763 is already being investigated for a similar event.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**6 incidents**			Expedite	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		Yes - some potential sensitivities (up to 3)	Sent to Team meeting as ARTG 95763 is already being investigated for a similar event.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown		I did none of the above incidents	**Yes**	

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Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and the Displacement Accuracy Test. The Insulin Flow Blocked Alarm functioned properly during the Basic Occlusion Test, Occlusion Test and Force Sensor Test. No unexpected Insulin Flow Blocked Alarm/No Delivery Alarm noted during testing. The insulin pump uploaded properly using Carelink. The following physical damages were noted but did not impact the insulin pump's performance: a minor scratched display window, scratched case, stained serial number label, scratched keypad overlay, pillowing keypad overlay and cracked keypad overlay at the Select Button.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

Australia:
2017: 0 similar incidents / 7,185 units sold
2018: 0 / 8,128
2019: 0 / 4,953
2020 (to date): 0/ 411

Worldwide:
2017: 4 similar incidents/ 83,206 sold worldwide
2018: 1/ 124,525
2019: 6 / 111,395
2020: (to date): 0 / 13,371

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Colombia, Germany, Netherlands, Slovakia, United Kingdom.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 17/3/20

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		12/12/2019	23/03/2020	04/03/2020		

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List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Insufficient Information				

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Metabolism and Nutrition	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
Unable to remove investigation outcomes = trending purposes. Please fix when closing this report.	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

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Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	

Model Number:	Batch #:	Lot #:	Expiry Date:
MMT-332A			

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	

Model Number:	Batch #:	Lot #:	Expiry Date:
MMT-862			

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

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Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 229633

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
229633	DIR-REQ		Closed	s22	OPR Administration User	17/03/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	17/03/2020 16:42:47	
Comment		

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E20-72530
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 61609 - ARTG # 95763 - Infusion pump, insulin, ambulatory

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on (02) 6289 4642 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

09/07/2020

DIR 61609 - ARTG # 95763 - Infusion pump, insulin, ambulatory

Reporter Reference #: CASE-2020-00020427

Date of Adverse Event:
s22

Date of Initial Report:
16/01/2020

ARTG #:
95763

Brand Name:
Minimed 640G pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1711KL

Serial #:
NG1437260H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22

Phone:

Fax:

Email: s22 @medtronic.com

Reporter:
s22
PMV Manager
Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park NSW 2113
Email: s22 @medtronic.com

Confidential: N/A

Phone: s22
Fax:

Clinical Event Information:
Medtronic received notification that a customer had a low blood glucose event. The customer is alleging that the pump overdelivered insulin.

Trouble shooting was performed. Programming confirmed to be inaccurate.

Medtronic has requested that the pump be returned for analysis.

Patient Outcome/Consequences:
Patient has disconnected from the pump and has reverted to back-up plan.

Device Analysis Results:
The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. No over-delivery anomaly was noted during testing. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, and scratched display window. Analysis testing identified the insulin pump met specifications.

Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:
Similar events* in Australia in the past 3 years: 1
Similar events* worldwide (Australia excluded) in the past 3 years: 92
*Similar event data is generated using FDA Annex A code
Sales in Australia in the past 3 years: 21568
This correlates to a complaint rate of 0.0046%
Sales worldwide (Australia excluded) in the past 3 years: 354,569
This correlates to a complaint rate of 0.0259%
Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Austria, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Saudi Arabia, Spain, Sweden, United Kingdom.

Type of Problem (Level 1)	Type of Problem (Level 2)
Infusion or Flow Problem	Excess Flow or Over-Infusion

Cause of Problem (Level 1)	Cause of Problem (Level 2)
No Device Problem Found	

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:
The sponsor has provided the rates for overdelivery and hypoglycaemia. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:

***** End of DIR 61609 *****

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16/01/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 38 - ID : 479790

Released by s22 on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
61609	E20-72530	CASE-2020-00020427	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	16/01/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
08/05/2020	16/01/2020		07/05/2020
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/07/2020	Carer		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Pump overdelivered insulin.

Clinical Event Information:

Medtronic received notification that a customer had a low blood glucose event. The customer is alleging that the pump overdelivered insulin.

Trouble shooting was performed. Programming confirmed to be inaccurate.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Excess Flow or Over-Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Metabolism and Nutrition -> Hypoglycemia -> ;
Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Unexpected Medical Intervention -> Medication Required ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Carer administered glucose tables.

Patient History:

Patient Outcome/Consequences:

Patient has disconnected from the pump and has reverted to back-up plan.

Additional Event Description:

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $2

First Name: $22

Surname: $22

Position: PMV Manager

Company/Institution: Medtronic Australasia Pty Ltd

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: $22 _837 - 08/05/2020 09:56

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G pump - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G pump - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711KL

Serial #: NG1437260H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

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		With Patient	
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22
Contact Surname:			
$22			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Increase in rate or rates not complete	Investigation (within DIR) is recommended

Notes for Team meeting:

3 DIR's in last 6 motyhs sponsor notes 1 in last 3yrs. Recalls for other issues. PMR for usablilty in 2015. Do we want to clarify the rates?

Outcomes from Team Meeting:

Ask for correct rates.

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

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Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
17/01/2020	0 - Insufficient information to determine level of severity			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		awaiting final report		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	Yes - some potential factors (up to 3)			Yes	3 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
	Use of device - operator/user error, Management of device - performance over time	Routine	Routine		No
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details: Statistics Checklist Section

Update Device Details?: Yes

Copy Data From: Initial

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
11/05/2020	**4 - An illness/injury resolved without treatment by a health professional (or by self-management)**		Yes		
Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 1 Investigation (to complete screening)	**Level 1 Investigation (to complete screening)**
Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
Patient	**0. No recalls for similar incidents in Australia**	1			
Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
No		92	Yes - some potential factors (up to 3)		
Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
Yes	**3 incidents**		Use of device - operator/user error, Management of device - performance over time	Routine	**Routine**
	3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
	No		No		
	3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
	Unknown	21568			

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	3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
	Unknown	354569	I did none of the above incidents	**Yes**

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. No over-delivery anomaly was noted during testing. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, and scratched display window. Analysis testing identified the insulin pump met specifications.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

Similar events* in Australia in the past 3 years: 1
Similar events* worldwide (Australia excluded) in the past 3 years: 92
*Similar event data is generated using FDA Annex A code
Sales in Australia in the past 3 years: 21568
This correlates to a complaint rate of 0.0046%
Sales worldwide (Australia excluded) in the past 3 years: 354,569
This correlates to a complaint rate of 0.0259%

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Austria, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Saudi Arabia, Spain, Sweden, United Kingdom.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Rate information is required	

Focus of Level 2 Investigation

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Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		03/06/2020	03/06/2020

Evidence

Investigation Questions (Level 1 and Level 2):

Clarification on rates

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☐	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		17/01/2020	28/04/2020		Not received	
☐		Sponsor Routine Correspondence	Sponsor Request for a Final Report Letter - s41JA		04/05/2020	18/05/2020	08/05/2020		
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		20/05/2020	17/06/2020	04/06/2020		
☐		Sponsor Routine Correspondence	Email to Sponsor		22/06/2020		29/06/2020	D20-958026	D20-912943
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		09/07/2020				D20-1016872

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Excess Flow or Over-Infusion			

Clinical signs symptoms and conditions

Details	

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Level 1	Level 2	Level 3	
Others	Insufficient Information		
Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Unexpected Medical Intervention	Medication Required		

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The sponsor has provided the rates for overdelivery and hypoglycaemia. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

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Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	HG3PUM6
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-326A					

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	5286744
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT- 941					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

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Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:

Town/Suburb:	State:	Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		RE DIR 61609 - Request For Information (RFI) L...	66	Form	
FILE		DIR 61609_Sponsor_Completion_Letter	282	Form	

Flow Details : DIR-REQ - Device Incident Request : 242626

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
242626	DIR-REQ		Closed	s22	OPR Administration User	09/07/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/07/2020 14:08:57	
Comment		

From: s22 [redacted] @medtronic.com>
Sent: Monday, 25 November 2019 2:27 PM
To: s22 [redacted]
Subject: Medical Device Safety Alert - MiniMed 600 Series Insulin Pump (Pump Retainer Ring)

22 Nov 2019

MEDICAL DEVICE SAFETY ALERT

MiniMed™ 600 series insulin pump
Pump Retainer Ring
TGA Reference: RC-2019-RN-01694-1
MiniMed™ 640G: MMT-1711, MMT-1712 MiniMed™ 670G: MMT-1782

You are receiving this letter because our records indicate you may be using a MiniMed™ 600 series insulin pump. Because your safety is our top priority, we are making you aware of a potential safety risk.

Issue Description:

The MiniMed™ 600 series insulin pump is designed with a pump retainer ring to lock the reservoir in the insulin pump. There have been reported incidents of a loose reservoir that can no longer be locked into the pump. The reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock. The retainer ring can be broken, for example as a result of dropping or bumping your pump on a hard surface.

If the reservoir is not properly locked into the pump, it could lead to over or under delivery of insulin, which could then result in hypoglycaemia or hyperglycaemia.

- For example, if the pump retainer ring is broken or becomes detached from the pump, and the user inserts the reservoir back into the pump while the infusion set is still connected to the body, it could result in a rapid infusion of insulin, which could cause hypoglycaemia. The under delivery of insulin could occur if the reservoir is not properly locked in place by the retainer ring, creating a space between the pump and the reservoir, and prevent the pump from pushing the expected insulin into the body, which could cause hyperglycaemia.

This issue may affect users on the MiniMed™ 600 series insulin pump. The pump model number can be found directly on the bottom or on the back of your device.

Insulin Pump	Model Number

MiniMed™ 640G pump	MMT-1711, MMT-1712
MiniMed™ 670G pump	MMT-1782

ACTIONS REQUIRED:

1. Examine the retainer ring on your pump.



Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump



2. If the reservoir does not lock into the pump or the retainer ring is loose, damaged or missing, **discontinue using the insulin pump** and revert to a back-up plan of manual insulin injections per your doctor's recommendations**. DO NOT insert the reservoir back into your pump while connected because you could mistakenly give yourself a large insulin bolus**, and contact our Medtronic 24-Hour Technical Support line at 1800 777 808.

3. If your reservoir properly locks in place by the retainer ring, continue to use your pump. Remember to always follow the Instructions for Use on how to correctly insert the reservoir.

PRECAUTIONS RECOMMENDED FOR ALL PATIENTS

1. If by accident you drop or bump your pump, check your pump and retainer ring for damage.
2. Routinely examine your pump retainer ring and check that your reservoir locks in place at every set change.

Additional Information:

Medtronic is issuing this notice in consultation with the Therapeutic Goods Administration.

Contact Details:
We apologise for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you continue to experience issues or have questions, please contact our Global Help Line on 1800-777-808.

Sincerely,

s22 [redacted] Quality and Regulatory Affairs

Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 |
Australia s22 [redacted]

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Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

01/03/2020
UNSIGNED

DIR : 36 - ID : 490835

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Released by Theta Technologies on 13/02/2020 10:09:06 Print

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
62330			Final

ARTG:

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Triage		s22	01/03/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
01/03/2020	01/03/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	

Event Description for Website Publication:

Device is A Medtronic Insulin Pump 640G.

There is a known problem with the retainer ring that hold the insulin cartridge in place: (TGA Reference: RC-2019-RN-01694-1 MiniMed™ 640G: MMT-1711, MMT-1712 MiniMed™ 670G: MMT-1782). This known issue may lead to an over or underdose of insulin resulting in possible high or low blood suger with one reported death overseas. The device has been recalled in the USA by the FDA. Medtronic have advided Australians to stop using the device if the retainer ring is loose and to contact Medtronic for a repair.

My pump's retainer ring is loose. I have been in contact with Medtronic. The issue is that Medtronic will only address the issue if the pump is within its 4 year warranty period. My pump is 4.5 years old but I am still using it as I am waiting for the release of new insulin pumps.

My view is that the pump is dangerous in its current state and Medtronic should replace or repair the pump (with the same model is acceptable).

I would like to see the TGA force Medtronic to address the issue regardless of the age of the pump if the pump is still in use.

Clinical Event Information:

Device is A Medtronic Insulin Pump 640G.

There is a known problem with the retainer ring that hold the insulin cartridge in place: (TGA Reference: RC-2019-RN-01694-1 MiniMed™ 640G: MMT-1711, MMT-1712 MiniMed™ 670G: MMT-1782). This known issue may lead to an over or underdose of insulin resulting in possible high or low blood suger with one reported death overseas. The device has been recalled in the USA by the FDA. Medtronic have advided Australians to stop using the device if the retainer ring is loose and to contact Medtronic for a repair.

My pump's retainer ring is loose. I have been in contact with Medtronic. The issue is that Medtronic will only address the issue if the pump is within its 4 year warranty period. My pump is 4.5 years old but I am still using it as I am waiting for the release of new insulin pumps.

My view is that the pump is dangerous in its current state and Medtronic should replace or repair the pump (with the same model is acceptable).

I would like to see the TGA force Medtronic to address the issue regardless of the age of the pump if the pump is still in use.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Health Impact

Recorded Health Impacts:

Patient Information

Sex:	Weight:	Age:
Male	s2	s

Patient Focused Corrective Action Taken:	Patient History:
	Diabetes Type 1.
Patient Outcome/Consequences:	**Additional Event Description:**

Possible death from overdose of insulin. Possible hign or low blood sugar as a result of incorrect insulin dose.

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: No Injury

Other medical devices currently using/implanted:

Medical Problem Device Used For:

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Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: s2

Reporter #:

Preferred Contact Method: Email

Reporter Title: s

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country: Australia

Postcode:

Phone: s22

Fax:

Mobile:

Email: s22 @gmail.com

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG:

Device ARTG #:

Therapeutic Licence Type:

Product Licence Category:

Device Class:

GMDN / UMDN Code:

GMDN / UMDN Text:

Brand Name: Medtronic - 640G Insulin Pump

Initial Device Description: Insuline Pump

Usage of Device:

Software Version:

Model #: 640G

Serial #:

Batch #:

Lot #:

Purchase Date: 03/08/2015

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure: 01/08/2016

Place of Implantation:

Reported Device Location: With Reporter

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Access Contact Email:

Licence Status:

Status Effective Date:

Additional Devices Added: 0

Manufacturer Information Section

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Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic		

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:
Medtronic	2 Alma Road	

Town/Suburb:	State:	Country:	Postcode:
Macquarie Park	NSW	Australia	2113

Phone:	Fax:	Email:	Website:
s22		s22 @medtronic.com	

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Yes	28/02/2020	s	s22

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:
s22	s22		s22 @medtronic.com

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
	No			Unassigned	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
01/03/2020					
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only			
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No				
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:

Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
		Yes

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Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
Attention To:	Address 1:	Address 2:	Town/Suburb:
State:	Postcode:	Phone:	Fax:
Email:			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables): 	CAPA# Reference:

Risk Assessment

Frequency:	Severity:
Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3

Health Impact

Details

Level 1	Level 2	Level 3	
			Document 20

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
Investigator's Notes:		**Summary Findings:**		**Recall Number:**

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No
1

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

Who sent the device to the TGA?:	Why does the TGA have the sample?:
	Document 20

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Injured - Extent of Injury:	**Was device directly linked to death?:**	**Was device directly linked to permanent disabiltiy?:**	**Consequence:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:
Fax:	**Email:**		

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes		s22 [redacted]	
Town/Suburb:	**State:**	**Postcode:**	
s22 [redacted]	NSW	s22 [redacted]	

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Medical Device Safety Alert - MiniMed 600 Seri...	244	Form Item	Report Information Section / Brand Name

Flow Details : DIR-REQ - Device Incident Request : 255268

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
255268	DIR-REQ		Triage	theta	IRIS Coordinator	01/03/2020	Normal	0

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Signature Details		
Role	IRIS Investigator	
User		
Signed At		
Comment		

Document 21

01/03/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 36 - ID : 490835

Released by Theta Technologies on 13/02/2020 10:09:06

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
62330	E20-37937		Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	01/03/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
01/03/2020	01/03/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
05/03/2020			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		Trend data only	

Event Description for Website Publication:

The pump's retainer ring on the device is loose.

Clinical Event Information:

Device is A Medtronic Insulin Pump 640G.

There is a known problem with the retainer ring that hold the insulin cartridge in place: (TGA Reference: RC-2019-RN-01694-1 MiniMed™ 640G: MMT-1711, MMT-1712 MiniMed™ 670G: MMT-1782). This known issue may lead to an over or underdose of insulin resulting in possible high or low blood suger with one reported death overseas. The device has been recalled in the USA by the FDA. Medtronic have advided Australians to stop using the device if the retainer ring is loose and to contact Medtronic for a repair.

My pump's retainer ring is loose. I have been in contact with Medtronic. The issue is that Medtronic will only address the issue if the pump is within its 4 year warranty period. My pump is 4.5 years old but I am still using it as I am waiting for the release of new insulin pumps.

My view is that the pump is dangerous in its current state and Medtronic should replace or repair the pump (with the same model is acceptable).

I would like to see the TGA force Medtronic to address the issue regardless of the age of the pump if the pump is still in use.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Material Integrity Problem -> Material Separation ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Insufficient Information -> ->

Patient Information

Sex:	Weight:	Age:
Male	s2	s

Patient Focused Corrective Action Taken:

Patient History:

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Diabetes Type 1.

Patient Outcome/Consequences:

Possible death from overdose of insulin. Possible hign or low blood sugar as a result of incorrect insulin dose.

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

No Injury

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

$2

Reporter #:

Preferred Contact Method:

Email

Reporter Title:

$

First Name:

$22

Surname:

$22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Australia

Postcode:

Phone:

$22

Fax:

Mobile:

Email:

$22 @gmail.com

Last External Submission By:

Initial Reporter Section

As Above?:

Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

No

Search Device ARTG:

95763

Device ARTG #:

95763

Therapeutic Licence Type:

Medical Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

35983

GMDN / UMDN Text:

Infusion pump, insulin, ambulatory

Brand Name:

Medtronic - 640G Insulin Pump - Infusion pump, insulin, ambulatory

Initial Device Description:

Medtronic - 640G Insulin Pump - Infusion pump, insulin, ambulatory

Usage of Device:

Software Version:

Model #:

640G

Serial #:

Batch #:

Lot #:

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Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
03/08/2015			
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
01/08/2016		With Reporter	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic		2 Alma Road	
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Macquarie Park	NSW	Australia	2113
Phone:	**Fax:**	**Email:**	**Website:**
$22		$22 @medtronic.com	
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	28/02/2020	$	$22
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
$22	$22		$22 @medtronic.com

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

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Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 04/03/2020	Severity: 2 - No harm - but incident could have resulted in illness/injury (near miss)	Incidents in the last 12 months:	Manufacturer analysis: No	Assessor: s22	Manufacturer documentation: Yes - manufacturer HAS documented issues or complications of this type
Incidents in last 24 months:	Manufacturer action: Unable to take action (device was not returned for analysis)	ESTIMATED LEVEL OF INVESTIGATION: Screening only	FINAL LEVEL OF INVESTIGATION: Screening only	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: User report; Closed known complication. TGA ref: RC-2019-RN-01694-1 Recall.		Found Prior To Use: No	Is AE covered by current recall: Unknown
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model: No
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL: TGA ref: RC-2019-RN-01694-1 Recall.			3 or more events - health district: No
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation: No
Products supplied Worldwide:	Consultations during risk assessment: I undertook an internet search (e.g., Google)	Final Risk Assessment: Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC

State:	Postcode:	Phone:	Fax:
NSW	1670	s22	

Email: s22

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Details of Similar Events:

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:

Rating:

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

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Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		05/03/2020				
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		05/03/2020				

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Material Integrity Problem	Material Separation		ring loose

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Others	Insufficient Information	

Health Impact

Details

Level 1	Level 2	Level 3
Insufficient Information		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
Mechanical Problem Identified	Stress Problem Identified		

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Known Inherent Risk of Device		recall released

Investigation Outcomes

Outcome Details

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Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:

Summary Findings:

The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to):

- the commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc.
- the individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Should you require further information or clinical assistance related to the use of this medical device and your individual health circumstances, please contact your treating medical professional, hospital or health care service.

Assistance and information regarding product refunds, returns or product compensation should be addressed with the Australian Competition and Consumer Commission (ACCC) via https://www.accc.gov.au/consumers/complaints-problems or 1300 302 502.

If you would like to lodge a complaint regarding the clinical practice of an Australian healthcare professional you should contact the Australian Health Practitioner Regulation Agency (AHPRA) via https://www.ahpra.gov.au/notifications/make-a-complaint.aspx, or the Health Care Complaints Commission within your State or Territory. More information on the respective State and Territory health complaint organisations can be accessed via https://www.ahpra.gov.au/notifications/further-information/health-complaints-organisations.aspx.

Recall Number: RC-2019-RN-01694-1

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

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Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

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Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1: s22

Address Line 2:

Town/Suburb: s22

State: NSW

Postcode: s22

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Medical Device Safety Alert - MiniMed 600 Seri...	244	Form Item	Report Information Section / Brand Name
FILE		DIR 62330 - Original User Report	322	Form	

Flow Details : DIR-REQ - Device Incident Request : 255268

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
255268	DIR-REQ		Closed	s22	OPR Administration User	05/03/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	05/03/2020 11:17:21	
Comment		

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02/06/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 38 - ID : 498127

Released by s22 on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
63629		CASE-2020-00381049	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	02/06/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
22/06/2020	02/06/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
23/06/2020			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Pump is not sending proper amount of insulin and patient was hospitalised due to High Blood Glucose (BG)/Under Delivery.

Clinical Event Information:

Customer called to state pump is not sending proper amount of insulin and she is hospitalised due to High Blood Glucose (BG)/Under Delivery. Customer reported that they did not feel okay to troubleshoot. Suggested calling HCP and following the guidelines outlined in the IFU, or seek medical attention and call back to troubleshoot.
Patient's BG at time of incident: 32.7 mmol/l.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Insufficient Flow or Under Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

General Disorders -> ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:
Female		

Patient Focused Corrective Action Taken:

Customer is being treated by just the bolus from the pump sending it manually and monitoring it, the hospital hasn't given her any other insulin. Customer stated she has gastritis also being treated now in the hospital. Advised customer to discontinue use of pump and revert to back up plan. Advised customer that pump will be replaced.

Patient History:

Patient Outcome/Consequences:

Customer stated she's feeling okay at time of call.

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:

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	Temporary Injury		
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	First Name:	Surname:	
$2	$22	$22	
Position:		Company/Institution:	
PMV Manager		Medtronic Australasia Pty Ltd.	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	$22	
Mobile:	Email:	Last External Submission By:	
	$22	$22 837 - 22/06/2020 19:29	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
		$22	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Minimed 640G - Infusion pump, insulin, ambulatory	Minimed 640G - Infusion pump, insulin, ambulatory		
Model #:	Serial #:	Batch #:	Lot #:
MMT-1711K	NG1217370H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D

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Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
04/06/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
		Level 1 Investigation (to complete screening)		Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
				No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	No			Yes	0 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
		Routine			
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	No				
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	23/06/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		No		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Device not returned.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	No		No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**0 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
				I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

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Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The product has not been returned for analysis testing. We are unable to determine if the product failed to meet specifications.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	Additional Details (use for tables):
Similar events in Australia in the past 3 years (ie 1 Jan 2017 until today): 5 Similar events worldwide (Australia excluded) in the past 3 years: 74 Sales in Australia in the past 3 years: 21777. This correlates to a complaint rate of 0.023% Sales worldwide (Australia excluded) in the past 3 years: 358,187 This correlates to a complaint rate of 0.021%	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:
Austria, Belgium, Colombia, Denmark, Finland, France, Germany, Ireland, Israel, Mexico, Netherlands, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:
DIR closed 23 June 2020.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Insufficient Flow or Under Infusion			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
General Disorders			

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

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Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 266338

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
266338	DIR-REQ		Closed	s22	OPR Administration User	23/06/2020	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	23/06/2020 14:58:39	
Comment		

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19/06/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 40 - ID : 498891

Released by s22 on 01/10/2020 16:07:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
63917		CASE-2020-00418038/39/11	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	19/06/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
02/10/2020	19/06/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
08/10/2020			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient required multiple hospitalisation due to DKA.

Clinical Event Information:

Customer called in to report issue on her pump
Inquired what led up to the complaint. Customer responded that she tried to prime her pump and usually insulin will exit at 7 but now it only exited at 14u. She was hospitalised twice over the weekend and had DKA.
Patient's BG at time of incident: 30 mmol/l. Vomiting
Auto Mode feature was not active and automatically adjusting insulin at time of High BG event

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
2			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Insufficient Flow or Under Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Blood and Lymphatic System -> ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:
Female		

Patient Focused Corrective Action Taken:

Customer injected herself to correct high BG. Customer agreed to proceed with troubleshooting. A replacement will be processed .
Advised customer to revert to back up plan as per HCP instructions and monitor BG

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:

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	Temporary Injury		
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	First Name:	Surname:	
$	$22	$2	
Position:		Company/Institution:	
Associate PMV Specialist		Medtronic Australasia Pty Ltd.	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road, Macquarie Park, NSW, 2113	2 Alma Road, Macquarie Park, NSW, 2113	Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	$22	
Mobile:	Email:	Last External Submission By:	
	$22	113429_837 - 02/10/2020 15:37	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
		$22	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1782K	NG2013833H		HG3P5Y4
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Root cause not found	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D

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Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
19/06/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
		Screening only	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
				No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	No			Yes	1 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
		Routine	Routine		
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	Yes - some potential sensitivities (up to 3)				
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
	Device used in high risk populations				
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	08/10/2020	**0 - Insufficient information to determine level of severity**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 1 Investigation (to complete screening)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Device returned and tested. All passed. Please note that the displacement measurement is in Inches not mm which suggest the device could have been tested overseas.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:	Physical damages were noted. Device reviewed 19-2-2015. PMR -	
	No	Unknown		No	Two similar events in qlik but nil in sponsor's similar's event. (my similar events is based on BG high)	
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**2 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		No		Yes - some potential sensitivities (up to 3)	Device returned and tested. All passed. Please note that the displacement measurement is in Inches not mm which suggest the device could have been tested overseas.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:	Physical damages were noted. Device reviewed 19-2-2015. PMR -	
		No		Device used in high risk populations	Two similar events in qlik but nil in sponsor's similar's event. (my similar events is based on BG high)	

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	3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
	No		I undertook an internet search (e.g., Google)	**Yes**

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump passed the functional test, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and the DAT Test at 0.08700 inches. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case and pillowing keypad overlay. A test P-Cap and reservoir were able to lock in place correctly in the reservoir compartment.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

Similar events in Australia in the past 3 years: 0
Similar events worldwide (Australia excluded) in the past 3 years: 456450
Sales in Australia in the past 3 years: 8778
This correlates to a complaint rate of 0.0001%
Sales worldwide (Australia excluded) in the past 3 years: 456450
This correlates to a complaint rate of 0.003%

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Canada, Germany, Spain, Switzerland, United States.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Report Closed 8-10-2020.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus

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Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Insufficient Flow or Under Infusion			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Blood and Lymphatic System			

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
No Problem Detected			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
Device returned and tested. All passed. Please note that the displacement measurement is in Inches not mm which suggest the device could have been tested overseas. Physical damages were noted. Device reviewed 19-2-2015. PMR -	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

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Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

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Flow Details : DIR-REQ - Device Incident Request : 267707

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
267707	DIR-REQ		Closed	s22	OPR Administration User	08/10/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	08/10/2020 11:40:54	
Comment		

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06/07/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 40 - ID : 500788

Released by §22 on 01/10/2020 16:07:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
64204		CASE-2020-00468168/70/71	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	§22	06/07/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
02/10/2020	06/07/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
12/10/2020			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

User was hospitalized due to high blood glucose in spite of delivery of multiple boluses.

Clinical Event Information:

Customer called to inform that her son was hospitalised due to High Blood Glucose
Customer states that they keep sending boluses and BG still won't come down. Patient's BG at time of incident: 28 mmol/l.
Time and date of hospitalization: §22
Length of hospitalization: §22
BG value when admitted to hospital: 28.
Customer won't push through in troubleshooting and states their son is not using the pump since he got hospitalised and just wants the pump to be replaced as advised by HCP.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:
Male		

Patient Focused Corrective Action Taken:

Patient treated with IV injections and insulin pens in hospital
Assisted patient over the phone and advised that the pump will be replaced.

Patient History:

Patient Outcome/Consequences:

Patient currently not reporting any symptoms related to their High BG.

Additional Event Description:

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Temporary Injury

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $

First Name: $22

Surname: $2

Position: Associate PMV Specialist

Company/Institution: Medtronic Australasia Pty Ltd.

Address 1: 2 Alma Road, Macquarie Park, NSW, 2113

Address 2: 2 Alma Road, Macquarie Park, NSW, 2113

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: 113429_837 - 02/10/2020 15:43

Initial Reporter Section

As Above?: No

If No, fill out the following:

Initial Reporter Confidential: Yes

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution: $22

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory

Initial Device Description: 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711K

Serial #: NG1833761H

Batch #:

Lot #: HG36AQF

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

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Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Access Contact Email:

Licence Status: A

Status Effective Date: 18/07/2003

Additional Devices Added: 2

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1:

Address 2:

Town/Suburb:

State/Province:

Country:

Postcode:

Phone:

Fax:

Email:

Manufacturer Informed: Yes

Date Aware of Adverse Event: s22

Contact Title:

Contact First Name:

Contact Surname:

Supplier Information Section

Supplier Name:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Email:

Website:

Supplier Informed:

Date of Supplier Contact:

Contact Title:

Contact First Name:

Contact Surname:

Contact Phone:

Contact Fax:

Contact Email:

Report Status

For website publication: Yes

Ready for Publication: Yes

Investigated: No

Investigation Reason: Known complication

Team Assignment: Team B (IIb, Is & Im)

Team Priority: Not Investigated

Team Review

Reviewed by Team:

Reason Sent To Meeting:

Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:

DPRC Reason Sent To Meeting:

Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

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Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
06/07/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 3 Investigation (for multiple DIRs/a DII)		Patient	1. Recalls for similar incidents in Australia have occurred within the past 12 months
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		Recall RC-2019-RN-01694-1 related to missing or damaged retaining ring not locking the reservoir and potentially resulting in hyperglycaemia or hypoglycaemia.		No	Unknown
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	6 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Expedite			Yes
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	12/10/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Yes - manufacturer HAS documented issues or complications of this type**		No	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**1. Recalls for similar incidents in Australia have occurred within the past 12 months**			Known Complication, Monitoring for trends.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	Unknown		No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**6 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		Yes - some potential sensitivities (up to 3)		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

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		Unknown		I did none of the above incidents	**Yes**

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08700 inches. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case and pillowing keypad overlay.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	**Additional Details (use for tables):**
Similar events in Australia in the past 3 years: 3 Similar events worldwide (Australia excluded) in the past 3 years: 382696 Sales in Australia in the past 3 years: 22542 This correlates to a complaint rate of 0.0001% Sales worldwide (Australia excluded) in the past 3 years: 382696 This correlates to a complaint rate of 0.0003%	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Australia, Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, France, Germany, Hungary, Iceland, Israel, Japan, Korea, Mexico, Netherlands, Poland, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, United Kingdom.

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR Closed - 12 October 2020.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem				

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

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Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details		
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details		
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, for Trending Purposes Only		

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-864					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	HG452DJ
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-326A					

Related DIR Information - Click **New** to begin entering information.	
Rec No	

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1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

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Town/Suburb: State: Postcode:

Flow Details : DIR-REQ - Device Incident Request : 270187

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
270187	DIR-REQ		Closed	s22	OPR Administration User	12/10/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	12/10/2020 10:31:41	
Comment		

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02/10/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 41 - ID : 508180

Released by s22 on 19/11/2020 14:40:19

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
65754		CASE-2020-00705728	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	02/10/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
29/01/2021	02/10/2020	09/02/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
10/02/2021			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

Death due to diabetic ketoacidosis. Blood glucose was 306 mg/dL as the last reading in the pump.

Clinical Event Information:

It was reported via phone call that the customer passed away at home. The cause of death was diabetic ketoacidosis. The caller stated that the customer had some major illnesses that may have led to the customer's passing. The customer's blood glucose was 306 mg/dL as the last reading in the pump. The customer was wearing the insulin pump at the time of death. The caller was unsure if the customer was using sensors. The caller agreed to return the insulin pump for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Insufficient Information -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Death -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Death

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to death?:	Other medical devices currently using/implanted:
	Death	No	

Medical Problem Device Used For:

Additional Patients Added:

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0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$	$22	$2	
Position:		**Company/Institution:**	
Associate PMV Specialist		Medtronic Australasia Pty Ltd.	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road, Macquarie Park, NSW, 2113	2 Alma Road, Macquarie Park, NSW, 2113	Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22	113429_837 - 29/01/2021 12:00	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Yes			
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Pump MMT-1782K 670G V4.11 MM	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782K	NG2034564H		HG3QSNP
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
		With Supplier	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
09/02/2021	Death	No further action

Notes for Team meeting:

Device not returned. Sending to the meeting due to death occurring and very little information. Spoken to s22 and she suggest to send to team meeting for review. No PMR, 3 similar events (DKA) and no recall.

Outcomes from Team Meeting:

closed as patient's condition was bad and device was not returned.

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:

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02/10/2020	9 - Death			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 2 Investigation (for a single DIR)		Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	1 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Expedite			
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	02/02/2021	**9 - Death**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Final: Device not returned. Sent to the meeting due to death occurring and very little information. Spoken to Keryn and she suggest to send to team meeting for review.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**3 incidents**			Expedite	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		Yes - some potential sensitivities (up to 3)	Final: Device not returned. Sent to the meeting due to death occurring and very little information. Spoken to Keryn and she suggest to send to team meeting for review.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device used in high risk populations, Device used in high acuity clinical environments		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown			**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

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Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump has not been returned for analysis testing. We are unable to determine if the insulin pump failed to meet specifications.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

In Australia:
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5006 units (0%) sold in CY2019;
1 similar events from 4094 units (0.02443%) sold in CY2020 (Includes this event).

Worldwide:
4 similar events from 113938 units (0.00351%) sold in CY2018;
11 similar events from 159734 units (0.00689%) sold in CY2019;
7 similar events from 145562 units (0.00481%) sold in CY2020.

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Canada, United States

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 10/02/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source

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Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Insufficient Information			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Death			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details	Additional Details

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	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 280731

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Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
280731	DIR-REQ		Closed	s22	OPR Administration User	10/02/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	10/02/2021 16:57:47	
Comment		

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18/10/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 510548

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
65977			Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	18/10/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
29/01/2021	18/10/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
25/05/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Diabetic ketoacidosis.

Clinical Event Information:

It was reported that the patient was hospitalized due to diabetic ketoacidosis. The customer’s blood glucose level was 16.1 mmol/l at time of incident . It was unknown that auto mode feature was active or not at the time of event. The insulin pump will not be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Customer treated with manual injection.			
Patient Outcome/Consequences:		**Additional Event Description:**	
Describe any test (Lab, xray, etc.):	**Injured - Extent of Injury:**	**Consequence:**	**Other medical devices currently using/implanted:**
	Temporary Injury		
Medical Problem Device Used For:	**Additional Patients Added:**		

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0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$	$22	$2	
Position:		**Company/Institution:**	
Associate PMV Specialist		Medtronic Australasia Pty Ltd.	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road, Macquarie Park, NSW, 2113	2 Alma Road, Macquarie Park, NSW, 2113	Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22	113429_837 - 29/01/2021 12:17	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Yes			
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782K	NG2221222H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
		With Reporter	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Information required has not been made available nor will be	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
18/10/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			$22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

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				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	1 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	25/05/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		No		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Known complication	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			Yes - some potential factors (up to 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**5 incidents**		Compatibility of device - patient characteristics, Use of device - according to IFUs, Use of device - operator/user error	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		Yes - some potential sensitivities (up to 3)		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device is difficult to substitute, Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown			**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:

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NSW	1670	s22 [redacted]	

Email:

s22 [redacted] s22 [redacted] @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump has not been returned for analysis testing. We are unable to determine if the insulin pump failed to meet specifications.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

In Australia
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5006 units (0%) sold in CY2019;
3 similar events from 4094 units (0.07328%) sold in CY2020;

WorldWide
304 similar events from 113938 units (0.26681%) sold in CY2018;
660 similar events from 159734 units (0.41319%) sold in CY2019;
594 similar events from 145562 units (0.40807%) sold in CY2020;

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:	Type Cause and Outcome:	Number of Similar Events:

Rating:			

Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Canada, Germany, Spain, Switzerland, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Report closed 25 May 2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source

Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			hyperglycemia	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Results Pending Completion of Investigation				

Investigation Conclusion

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Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time. The TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 283563

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
283563	DIR-REQ		Closed	s22	OPR Administration User	25/05/2021	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	25/05/2021 13:41:22	
Comment		

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20/10/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 41 - ID : 510588

Released by s22 on 19/11/2020 14:40:19

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
66014		CASE-2020-00749591/92/93	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	20/10/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
29/01/2021	20/10/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
08/02/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

A customer called to report that he was hospitalised due to high Blood glucose and vomiting.

Clinical Event Information:

A customer called to report that he was hospitalised due to high Blood glucose and vomiting.
Patient's BG at time of incident was 27 mmol/L.
Customer states that he was instructed by his doctor to have the pump replaced because the boluses he delivered were not showing on his pump data

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Communication or Transmission Problem -> Failure to Transmit Record ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Insufficient Information -> ->

Patient Information

Sex:	Weight:	Age:
Male		

Patient Focused Corrective Action Taken:	Patient History:
Patient was treated with IV insulin drip and injections at hospital. Pump will be replaced.	
Patient Outcome/Consequences:	**Additional Event Description:**
Customer did not report any further symptoms related to their high BGs	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:
	Temporary Injury		

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Medical Problem Device Used For:

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$2

Reporter #:

Preferred Contact Method:

Reporter Title:
$

First Name:
$22

Surname:
$2

Position:
Associate PMV Specialist

Company/Institution:
Medtronic Australasia Pty Ltd.

Address 1:
2 Alma Road, Macquarie Park, NSW, 2113

Address 2:
2 Alma Road, Macquarie Park, NSW, 2113

Town/Suburb:
Macquarie Park

State:
NSW

Country:
Australia

Postcode:
2113

Phone:
$22

Fax:

Mobile:

Email:
$22

Last External Submission By:
113429_837 - 29/01/2021 12:19

Initial Reporter Section

As Above?:
No

If No, fill out the following:

Initial Reporter Confidential:
Yes

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:
Northwest Regional Hospital

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:
☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
95763

Device ARTG #:
95763

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

Brand Name:
PUMP MMT-1711KL 640G V4.10 BK SF MM - Infusion pump, insulin, ambulatory

Initial Device Description:
PUMP MMT-1711KL 640G V4.10 BK SF MM - Infusion pump, insulin, ambulatory

Usage of Device:
Reuse of Reusable

Software Version:

Model #:
MMT-1711KL

Serial #:
NG2260754H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:

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20/10/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			Nagarajesh Gorlamandala	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	1 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I undertook an internet search (e.g., Google)	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	08/02/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		No		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			1 similar DIR was found. No recall action happened. Device was not returned.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			Yes - some potential factors (up to 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	No	**1 incidents**		Production of device - design fault, Production of device - manufacture/batch, Use of device - according to IFUs	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
					Yes	

Sponsor/Manufacturer Information Section

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Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22 ; s22 @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump has not been returned for analysis testing. We are unable to determine if the insulin pump failed to meet specifications.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	**Additional Details (use for tables):**
In Australia 1 similar events from 8128 units (0.0123%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 4 similar events from 3151 units (0.12694%) sold in CY2020; WorldWide 35 similar events from 124526 units (0.02811%) sold in CY2018; 69 similar events from 111396 units (0.06194%) sold in CY2019; 34 similar events from 89414 units (0.03803%) sold in CY2020;	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:
Australia, Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, France, Germany, Hungary, Iceland, Israel, Japan, Korea, Mexico, Netherlands, Norway, Poland, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, United Kingdom.

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:
DIR closed 08/02/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

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Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Communication or Transmission Problem	Failure to Transmit Record			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Insufficient Information			

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected

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No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-332A					
Device ARTG No:	**Manufacturer Name:**	**Sponsor/Supplier:**	**GMDN / UMDN Text:**	**Trade/Brand Name:**	**Serial #:**
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-864					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

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Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Document 27

Flow Details : DIR-REQ - Device Incident Request : 283747

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
283747	DIR-REQ		Closed	s22	OPR Administration User	08/02/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	08/02/2021 14:51:25	
Comment		

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27/11/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 42 - ID : 512392

Released by s22 on 15/02/2021 17:33:07

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
66790		CASE-2020-00841875-1	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	27/11/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
24/02/2021	27/11/2020	02/03/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
03/03/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

A patient was hospitalized due to DKA, High BG and Presence of Ketones.

Clinical Event Information:

According to a report from a patient, she was hospitalized due to DKA, High BG and Presence of Ketones and was advised by her HCP to discontinue using the pump. Customer drove herself to the hospital and was admitted to the ER as a result of high BGs.
Time and date of hospitalization: arrived at s22 .
Length of hospitalization: less than 24 hrs
BG value when admitted to hospital: 21 mmol/L.
She added that she is not doing well with insulin injection/pens either since her latest BG is at 23 mmol/L
Patient's BG Value at time of call: 23 mmol/L, patient is not reporting any symptoms related to their High BGs
Customer has been using insulin pump system within 48 hours of reported High BG event.
Customer is not using CGM
Infusion set was last changed prior to event on s22 .
Customer declined to perform a CareLink upload. Patient stated that it's her doctor that does the upload.
Patient was Advised that site related issues, such as bent cannulas tend to be contributing factors in HBGs. Patient stated she had no issues with cannula she took out yesterday.
Customer declined to check their settings. Customer declined to test pump.

Based on customer report, customer does not allege pump was under delivering.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Investigations and Diagnostic Tests -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> -> ;
Unexpected Medical Intervention -> Medication Required ->

Patient Information

Sex:	Weight:	Age:

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Female

$

Patient Focused Corrective Action Taken:

Patient was treated in hospital with IV insulin drip, additional fluids, BG monitoring, and some tests: gases, lungs and blood works .Patient was given long acting insulin so she won't have to use the pump in the meantime.

A replacement pump was processed.

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

$2

Reporter #:

Preferred Contact Method:

Reporter Title:

$

First Name:

$22

Surname:

$2

Position:

Associate Post Market Vigilance Specialist

Company/Institution:

Medtronic Australasia Pty Ltd

Address 1:

2 Alma Road

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

$22

Fax:

Mobile:

Email:

$22

Last External Submission By:

113429_837 - 24/02/2021 12:23

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

$22

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

No

Search Device ARTG:

95763

Device ARTG #:

95763

Therapeutic Licence Type:

Medical Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

35983

GMDN / UMDN Text:

Infusion pump, insulin, ambulatory

Brand Name:

Initial Device Description:

Usage of Device:

Software Version:

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640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1711K	NG1400663H		HG293BQ
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22 [redacted]		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Increase in reports	No further action

Notes for Team meeting:

2 other DIR's No PMR or Recalls. Do we want to follow up on the rates. Should we review the IFU to see if there is anything about the site or add to other DIR or close?

Outcomes from Team Meeting:

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DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
02/12/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 3 Investigation (for multiple DIRs/a DII)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		initial: Known Complication - unable to determine recall similar until final.		No	Unknown
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	3 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		Yes
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No	initial: Known Complication - unable to determine recall similar until final.			No
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					No
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	26/02/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 3 Investigation (for multiple DIRs/a DII)	**Level 3 Investigation (for multiple DIRs/a DII)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	Unknown		No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**3 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	

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Yes		Yes - some potential sensitivities (up to 3)	
3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:	
No		Device used in high risk populations	
3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
No		I did none of the above incidents	**Yes**

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		

Email:

s22 [redacted] @medtronic.com; s22 [redacted]

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The pump passed the functional tests, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08730 inches.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

In Australia
2 similar events from 8128 units (0.02461%) sold in CY2018;
10 similar events from 4953 units (0.2019%) sold in CY2019;
5 similar events from 3151 units (0.15868%) sold in CY2020;
0 similar events from 254 units (0%) sold in CY2021;

WorldWide
68 similar events from 124526 units (0.05461%) sold in CY2018;
97 similar events from 111396 units (0.08708%) sold in CY2019;
55 similar events from 89414 units (0.06151%) sold in CY2020;
0 similar events from 3711 units (0%) sold in CY2021;

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Austria, Belgium, Colombia, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Netherlands, Norway, Poland, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, United Kingdom

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

DIR Closed 3/3/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

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Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			High Blood Glucose	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Investigations and Diagnostic Tests	Hyperglycemia	Diabetic Ketoacidosis	

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Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			
Unexpected Medical Intervention	Medication Required		

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Known Inherent Risk of Device			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	
Investigator's Notes:		**Summary Findings:**		**Recall Number:**
		No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.		

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

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Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

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Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 287285

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
287285	DIR-REQ		Closed	s22	OPR Administration User	03/03/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	03/03/2021 13:20:26	
Comment		

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04/12/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 42 - ID : 512525

Released by s22 on 15/02/2021 17:33:07

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
66917		CASE-2020-00868354	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	04/12/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
24/02/2021	04/12/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
03/03/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

A customer was hospitalized due to series of DKA.

Clinical Event Information:

According to a report from a customer, she was hospitalized due to series of DKA. She was advised by the Diabetes Educator that there's an issue with the site. The infusion type was changed. Customer stated that she can't see blue shield on the home screen and just resumes basal.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Use of Device Problem -> Device Handling Problem ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

Additional Patients Added:

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0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$	$22	$2	
Position:		**Company/Institution:**	
Associate Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22	113429_837 - 24/02/2021 12:18	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Minimed 670G - Infusion pump, insulin, ambulatory	Minimed 670G - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782K	NG2089444H		HG3X7CY
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
		With Patient	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	[redacted]		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Increase in reports	No further action

Notes for Team meeting:

2 other DIR's No PMR or Recalls. Do we want to follow up on the rates. Should we review the IFU to see if there is anything about the site or add to other DIR or close?

Outcomes from Team Meeting:

Known complication

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:

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04/12/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)		Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	2 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine			
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	26/02/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	**Level 1 Investigation (to complete screening)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**2 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Unknown		Yes - some potential sensitivities (up to 3)		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:

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837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump has not been returned for analysis testing. We are unable to determine if the insulin pump failed to meet specifications.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	Additional Details (use for tables):

In Australia
0 similar events from 475 units (0%) sold in CY2018;
1 similar event from 5006 units (0.01998%) sold in CY2019;
4 similar events from 4094 units (0.0977%) sold in CY2020;
0 similar events from 204 units (0%) sold in CY2021;

WorldWide
887 similar events from 113938 units (0.77849%) sold in CY2018;
1835 similar events from 159734 units (1.14878%) sold in CY2019;
1660 similar events from 145563 units (1.1404%) sold in CY2020;
46 similar events from 4896 units (0.93954%) sold in CY2021;

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Belgium, Canada, Colombia, Germany, Italy, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 3/3/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Use of Device Problem	Device Handling Problem		

Clinical signs symptoms and conditions

Details		
Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis

Health Impact

Details		
Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

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Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available			Device not returned	

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Known Inherent Risk of Device			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
https://www.medtronic-diabetes.com.au/sites/default/files/minimed_670g_getting_started_guide_-_cgm.pdf	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:

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Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:

Lot Number:	Batch Number:	Model Number:	Version Number:

Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 287776

Request Details

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ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
287776	DIR-REQ		Closed	s22	OPR Administration User	03/03/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	03/03/2021 13:17:27	
Comment		

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01/01/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 514046

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
67426	E21-284733	CASE-2020-00922453/56/57	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	01/01/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
09/04/2021	01/01/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
17/06/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

Patient was admitted to the hospital due to DKA.

Clinical Event Information:

According to a customer, patient was admitted to the hospital due to DKA.
Customer alleges that the pump was not delivering properly, they checked the settings and everything was accurate according to Diabetes Educator.
Patient's Blood Glucose was unknown because it was too high and did not register on the meter.
Patient experienced positive results in ketones test, Nausea, Vomiting, Abdominal pain, Difficulty breathing and DKA

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Hepatic and Biliary System -> ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:
Pump was replaced	
Patient Outcome/Consequences:	**Additional Event Description:**

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:

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	Temporary Injury		
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	First Name:	Surname:	
$	$22	$2	
Position:		Company/Institution:	
Associate Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	$22	
Mobile:	Email:	Last External Submission By:	
	$22	113429_837 - 09/04/2021 09:58	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Minimed 670G - Infusion pump, insulin, ambulatory	Minimed 670G - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1782K	NG2285129H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
		With Supplier	

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	1

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
20/04/2021	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:
6 similar DIR in 6 mths; no relevant recalls or PMR. sending to meeting because the similar events data appears to be wrong for Australia.

Outcomes from Team Meeting:
Clarification for similar events required- Level 1 Investigation

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
07/01/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			Jim Andrews	
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:

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		Screening only		Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine			
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	12/04/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		No	Level 3 Investigation (for multiple DIRs/a DII)	**Level 1 Investigation (to complete screening)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Cause not found. similar event information provided by the sponsor appears to be wrong.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**6 incidents**			Expedite	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		No	Cause not found.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown				
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC

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State:	Postcode:	Phone:	Fax:
NSW	1670	s22	

Email:

s22 medtronic.com; s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The pump passed the functional tests, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08720 inches.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

In Australia
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5006 units (0%) sold in CY2019;
0 similar events from 4094 units (0%) sold in CY2020;
0 similar events from 369 units (0%) sold in CY2021;

WorldWide
14 similar events from 113938 units (0.01229%) sold in CY2018;
71 similar events from 159734 units (0.04445%) sold in CY2019;
64 similar events from 145532 units (0.04398%) sold in CY2020;
11 similar events from 10097 units (0.10894%) sold in CY2021;

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Canada, Netherlands, Spain, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 17/6/21

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Sensitivities - requests for information	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		25/05/2021	Document 30

Evidence

Investigation Questions (Level 1 and Level 2):

The rates of similar events provided in the final report is not consistent with the IRIS database. Please confirm the similar events of "hyperglycaemia, DKA" in Australia.

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		22/04/2021	21/05/2021	18/05/2021		
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA		18/05/2021	04/06/2021	03/06/2021	D21-2703080	D21-2653576 Rates as they are not consistent with IRIS.
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		17/06/2021				Letter D21-2738196 Email D21-2738307

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Infusion or Flow Problem			

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Hepatic and Biliary System		

Health Impact

Details

Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

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Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
D21-2100442 - minimed_670g_getting_started_guide_-_auto_mode D20-3190506 MiniMed 670g_ifu System user Guide	Review of the information provided by the sponsor confirmed that the pump passed all tests conducted on the returned device. Review of the instructions for use noted that Diabetic Ketoacidosis is included in the list of 'Risks related to insulin administration and pump use'. The TGA clarified the similar event rates provided by the sponsor and confirmed they are consistent with a search of the IRIS database.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-332A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details	Additional Details

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	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

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Type	Open	Name	Size	Attached Within	Attached To
FILE		Medtronic Response - DIR 67426 - Request For I...	202	Form	

Flow Details : DIR-REQ - Device Incident Request : 290508

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
290508	DIR-REQ		Closed	s22	OPR Administration User	17/06/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	17/06/2021 09:46:32	
Comment		

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18/06/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 524353

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
70620		CASE-2021-00407314-1/00407316-1/00407315	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	18/06/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
22/09/2021	18/06/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
24/09/2021	Patient		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient hospitalised due to hyperglycaemia and DKA.

Clinical Event Information:

Initial Notes: Patient called in asking how can she have her old 640g pump fixed Inquired what led up to the complaint.
Customer response: Patient has an old 640G pump that she would like to use again Patient's pump is now Tandem and she doesn't want to use it anymore and would like to switch to 640G again.
Patient had an instance where her Blood Glucose went very high and was hospitalized while using the pump Bumped/Dropped/Cosmetic Damage T/S per DOP114-980. Adv to D/C from the pump.
Is customer calling back after being instructed to call for troubleshooting upon receiving tubing clamp: No.
Customer states the pump has neither been bumped nor dropped.
Customer states the infusion set does not show signs of damage. Customer states the reservoir does not show signs of damage.
Customer states the pump does show signs of physical damage.
1. Type of damage is: Crack.
2. Damage occurred: Unsure.
3. Location of the damage is: Battery Compartment.
Did customer report out-of-box damage: No.
Is the physical damage to the pump's Retainer Ring: No.
Did damage occur while using a silicone case: No Expl we encourage the use of the new silicone case which can provide a cushion against bumps during your daily activities and is an extra barrier against lotions, sunscreen, insect repellent, or household cleaners.
Was damage to pump caused by the customer and/or by normal wear and tear: No.
Advised to discontinue use of the pump and revert to backup plan per HCP's instructions.
Explained OOW RPL policy. Reviewed Pump Care Best Practices with the customer. Customer's outcome pertaining to the complaint: run Troubleshooting but pump has a crack advised that we will create a product observation report advised to discontinue using the pump since crack may affect the delivery of the insulin.

Past event hospitalisation details:
Customer was admitted into hospital as a result of high BGs.
Was hospitalised overnight.
BG value when admitted to hospital: 42.0 mmol/L
Time and date of hospitalization:s22 .
Any significant events leading to hospitalization: Severe Hyperglycemia.
Reason of hospitalization: DKA.
Document the hospitalization treatment: IV Drip.

Based on customer report proceeding in T/S per customer alleging possible pump Under Delivery. Advised leaks in the tubing and/or Air Bubbles can limit the amount of insulin received during a bolus. Question - Does customer wish to check for the presence of leaks or air bubbles in the tubing reservoir? Response: Past event.
Advised that site related issues, such as bent cannulas tend to be contributing factors in HBGs. Adv High BGs may occur if the insulin is expired or cloudy. Question - Does the customer wish to check for possible site/insulin issues? Response: Past Event.
Advised inaccurate pump settings may result in HBGs. Adv if any recent changes have been made to programming, or they have concerns that settings may be inaccurate we can review them.
Question - Does the customer wish to check their settings? Response: Past event.
Advised the pump is designed to trigger an alarm if it detects a blockage preventing the flow of insulin. Advised if they have concerns their pump may not have detected an occlusion we can test this alarm using a tubing clamp. If they do not have the necessary equipment to test this alarm we can send it to them. Customer declined to test pump. Advised to change entire set, reservoir and insulin and treat per HCP's instructions. Advised to call back for assistance.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

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Infusion or Flow Problem -> Insufficient Flow or Under Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex: | Weight: | Age:

Patient Focused Corrective Action Taken:

Patient was hospitalised over night and treated with IV Drip

Patient History:

Patient Outcome/Consequences:

Patient was hospitalised over night and treated with IV Drip

Additional Event Description:

Describe any test (Lab, xray, etc.): | Injured - Extent of Injury: | Other medical devices currently using/implanted: | Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname: $22 | Reporter #: | Preferred Contact Method:

Reporter Title: $ | First Name: $22 | Surname: $22

Position: Associate PMV Specialist | Company/Institution: Medtronic Australasia Pty Ltd.

Address 1: 2 Alma Road, Macquarie Park, NSW, 2113 | Address 2: | Town/Suburb: Macquarie Park | State: NSW

Country: Australia | Postcode: 2113 | Phone: $22 | Fax:

Mobile: | Email: $22 @medtronic.com | Last External Submission By: 114395_837 - 22/09/2021 14:15

Initial Reporter Section

As Above?: | *If No, fill out the following:* | Initial Reporter Confidential:

Search Reporter By Surname: | Initial Reporter #: | Preferred Contact Method:

Title: | First Name: | Surname:

Position: | Company/Institution:

Address 1: | Address 2: | Town/Suburb: | State:

Postcode: | Country: | Phone: | Fax:

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Mobile:	Email:	Allow the device company to contact you about the incident:
		☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
MiniMed® 640G - Infusion pump, insulin, ambulatory	MiniMed® 640G - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1681142H		HG2UAWV
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22 [redacted]		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:

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Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
22/06/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	2 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	24/09/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Known issue	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:

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Yes	**9 incidents**			Expedite	**Routine**
	3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
	Yes		No	Known issue	
	3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
	Unknown				
	3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
	Unknown		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
$22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	$22 [redacted]	
Email:			
$22 [redacted] @medtronic.com; $22 [redacted] @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	**Additional Details (use for tables):**
Australia: 0 similar events from 8128 units (0%) sold in CY2018; 1 similar events from 4953 units (0.02019%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 1 similar events from 1097 units (0.09116%) sold in CY2021 (Includes this event). Worldwide: 13 similar events from 235920 units (0.00551%) sold in CY2018; 26 similar events from 111396 units (0.02334%) sold in CY2019; 44 similar events from 89414 units (0.04921%) sold in CY2020; 19 similar events from 36561 units (0.05197%) sold in CY2021.	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:	
Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, Finland, Germany, Hungary, Ireland, Israel, Italy, Netherlands, Norway, Poland, Saudi Arabia, Slovakia, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States	
Completed Actions:	**Planned Actions and Proposed Timelines:**
Additional Comments:	
DIR closed 24-09-2021.	

Reason for Level 1 Investigation

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Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Insufficient Flow or Under Infusion			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	

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Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available			Device not returned.	

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established		Device not returned.	

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only		Device not returned.	

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	
Investigator's Notes:		Summary Findings:		Recall Number:
		No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.		

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

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Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

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Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Town/Suburb:	**State:**	**Postcode:**	

Flow Details : DIR-REQ - Device Incident Request : 309553

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
309553	DIR-REQ		Closed	s22	OPR Administration User	24/09/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	24/09/2021 06:55:07	
Comment		

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15/07/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 525906

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71155		CASE-2021-00480102/03/04	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	15/07/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
07/10/2021	15/07/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor			

Event Description for Website Publication:

A patient reported ketones and high Blood Glucose.

Clinical Event Information:

A patient called reporting that they were hospitalised for one day due to ketones and high Blood Glucose.
Patient's Blood glucose level was 19mmol/L at time of admission
Patient stated they were using a Sure-T which was not changed when he was admitted to hospital. Patient was informed by Medtronic Global Help Line that the Sure-T can only be used for 2 days. Patient stated they were told it is okay to use for 3 days and that they sometimes use it for 4 days. Patient ran pump self-test and it passed

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> Incorrect, Inadequate or Imprecise Result or Readings ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Hepatic and Biliary System -> ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
		s	

Patient Focused Corrective Action Taken:

Patient was treated with IV and insulin.

Patient History:

Patient Outcome/Consequences:

No further adverse events were reported.

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:

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	Temporary Injury		
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	First Name:	Surname:	
$	$22	$2	
Position:		Company/Institution:	
Post Market Vigilance Specialist		Medtronic Australisa Pty Ltd	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	$22	
Mobile:	Email:	Last External Submission By:	
	$22	113429_837 - 07/10/2021 16:36	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Minimed 670G - Infusion pump, insulin, ambulatory	Minimed 670G - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1782K	NG2305953H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
		With Patient	

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	1

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information		Risk Assessment - Section A		Risk Assessment - Section B		Risk Assessment - Section C		Risk Assessment - Section D	
Date:		**Severity:**		**Incidents in the last 12 months:**		**Manufacturer analysis:**		**Assessor:**	**Manufacturer documentation:**
15/07/2021		5 - An illness/injury was resolved or prevented with treatment by a health professional						Patrick Hislop	
Incidents in last 24 months:		**Manufacturer action:**		**ESTIMATED LEVEL OF INVESTIGATION:**		**FINAL LEVEL OF INVESTIGATION:**		**Injured Party:**	**Device Recalls:**
				Screening only		Screening only		Patient	0. No recalls for similar incidents in

Australia Document 32

Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	No			Yes	2 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
		Routine	Routine		
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	No				
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	08/10/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		No		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Yes - manufacturer HAS documented issues or complications of this type**		Unable to take action (device was not returned for analysis)	Screening only	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**2 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
				I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**

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NSW	1670		

Email:

s22 @medtronic.com;s22 medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5006 units (0%) sold in CY2019;
3 similar events from 4094 units (0.07328%) sold in CY2020;
0 similar events from 1356 units (0%) sold in CY2021;

WorldWide
289 similar events from 112873 units (0.25604%) sold in CY2018;
640 similar events from 159733 units (0.40067%) sold in CY2019;
628 similar events from 145150 units (0.43266%) sold in CY2020;
341 similar events from 44937 units (0.75884%) sold in CY2021;

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Canada, Colombia, Germany, Spain, Switzerland, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 08/10/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source

Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Output Problem	Incorrect, Inadequate or Imprecise Result or Readings			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Hepatic and Biliary System			

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

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Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	There is no further action required for this investigation; however, the TGA will continue to monitor the rate and pattern of occurrence and may reopen this case if appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	5342436
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-864A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 312278

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
312278	DIR-REQ		Closed	s22	OPR Administration User	08/10/2021	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	08/10/2021 12:38:36	
Comment		

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 525907

15/07/2021
SIGNED

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71156		CASE-2021-00483605/07/08	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	15/07/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
07/10/2021	15/07/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
11/10/2021			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient was admitted to emergency due to high ketones and elevated Blood Glucose levels.

Clinical Event Information:

A patient's mother called reporting that her son was hospitalised due to 6.9 ketones. Patient was admitted to emergency overnight with a Blood Glucose level of 33mmol/L.
The reporter stated that the infusion set was changed twice the day prior and that they have hospital papers stating the pump malfunctioned. The reporter as advised by the Diabetes Educator that the pump needed replacement.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> Incorrect, Inadequate or Imprecise Result or Readings -> Incorrect Measurement

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> ;
Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:
Male		s

Patient Focused Corrective Action Taken:	Patient History:
Patient reverted to using injections and a replacement pump was organised.	
Patient Outcome/Consequences:	**Additional Event Description:**

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:
	Temporary Injury		

Medical Problem Device Used For:

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$2

Reporter #:

Preferred Contact Method:

Reporter Title:
$

First Name:
$22

Surname:
$2

Position:
Post Market Vigilance Specialist

Company/Institution:
Medtronic Australisa Pty Ltd

Address 1:
2 Alma Road

Address 2:

Town/Suburb:
Macquarie Park

State:
NSW

Country:
Australia

Postcode:
2113

Phone:
$22

Fax:

Mobile:

Email:
$22

Last External Submission By:
113429_837 - 07/10/2021 16:30

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:
☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
95763

Device ARTG #:
95763

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

Brand Name:
Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Initial Device Description:
Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Usage of Device:

Software Version:

Model #:
MMT-1711K

Serial #:
NG2155967H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
15/07/2021	4 - An illness/injury resolved without treatment by a health professional (or by self-management)			$22	
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	5 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	11/10/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Final: Device not returned. Root cause not established. known Complicaiton.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	No		Yes - some potential factors (up to 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**5 incidents**		Compatibility of device - patient characteristics	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				Yes - some potential sensitivities (up to 3)	Final: Device not returned. Root cause not established.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
				Device used in high risk populations, Device used in high acuity clinical environments		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
				I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:

NSW	1670		

Email:

s22 @medtronic.com;s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
1 similar events from 8128 units (0.0123%) sold in CY2018;
2 similar events from 4953 units (0.04038%) sold in CY2019;
0 similar events from 3151 units (0%) sold in CY2020;
3 similar events from 1097 units (0.27347%) sold in CY2021;

WorldWide
20 similar events from 124526 units (0.01606%) sold in CY2018;
43 similar events from 111396 units (0.0386%) sold in CY2019;
40 similar events from 89414 units (0.04474%) sold in CY2020;
24 similar events from 36561 units (0.06564%) sold in CY2021;

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Belgium, Colombia, Czech Republic, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Mexico, Netherlands, Norway, Poland, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Report Closed 11/10/2021.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Output Problem	Incorrect, Inadequate or Imprecise Result or Readings	Incorrect Measurement	

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis
Endocrine, Metabolism and Nutrition	Hyperglycemia	

Health Impact

Details

Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			device not returned

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-332A					
Device ARTG No:	**Manufacturer Name:**	**Sponsor/Supplier:**	**GMDN / UMDN Text:**	**Trade/Brand Name:**	**Serial #:**
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	5341363
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		
MMT-943A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:

Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:

Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 312280

Request Details

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ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
312280	DIR-REQ		Closed	s22	OPR Administration User	11/10/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	11/10/2021 11:51:25	
Comment		

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03/08/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 527240

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71487		CASE-2021-00525805-1	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	03/08/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
23/11/2021	03/08/2021	07/12/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/12/2021			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

Patient was found deceased

Clinical Event Information:

Patient was found deceased on the floor in her bedroom, next to her bed. Her sons had been trying to contact her on the 16th and had been unable to reach her, so attended her property to find her deceased. They noted her insulin pump was beeping and had the following message: "Insulin flow blocked 11:08 AM Check BG. Consider injection and testing ketones. Estimated O U insulin in reservoir. Change reservoir and infusion set."
Cause of death is currently unknown.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Death -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

T1DM, mental health issues, breast cancer, fibromyalgia, arthritis, and was deaf. She had surgeries on her feet which caused her to be immobile for the last 2 years. Family have stated that patient did not manage her illnesses/medical requirements properly and was not on top of her regular medications and ate poorly.

Patient Outcome/Consequences:

Death

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to death?:	Other medical devices currently using/implanted:

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	Death	No	
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			
Reporter Title:	First Name:	Surname:	
s	s22	s22	
Position:		Company/Institution:	
PMV Specialist		Medtronic Australasia Pty Ltd.	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road, Macquarie Park, NSW, 2113		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	Email:	Last External Submission By:	
	s22 @medtronic.com	114395_837 - 23/11/2021 12:51	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
MiniMed™ 670G Infusion pump, insulin, ambulatory	MiniMed™ 670G Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	Serial #:	Batch #:	Lot #:
MMT-1782KL	NG2375366H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
07/12/2021	Death	No further action

Notes for Team meeting:

0 DIRs, 0 PMRs, 0 Recalls. Sent to the meeting as the patient passed away and the sponsor has provided the similar events based on No Delivery/Occlusion Alarm rather than the clinical event. Just want to seek input from the meeting whether we should ask for the rate based on the clinical event?

Outcomes from Team Meeting:

PMR done on this issue - rate low - close

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
06/08/2021	9 - Death			s22	
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
		Screening only	Screening only	Patient	
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**

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				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	01/12/2021	**9 - Death**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 2 Investigation (for a single DIR)	**Level 1 Investigation (to complete screening)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Sent to meeting - see notes above	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**0 incidents**			Expedite	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				Yes - some potential sensitivities (up to 3)	Sent to meeting - see notes above	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
				Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
				I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted] s22 [redacted] @medtronic.com			

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Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending for this type of event.

Details of Similar Events:

Australia:
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5005 units (0%) sold in CY2019;
0 similar events from 4093 units (0%) sold in CY2020;
0 similar events from 1356 units (0%) sold in CY2021 (Includes this event).

Worldwide:
298 similar events from 112872 units (0.26402%) sold in CY2018;
609 similar events from 159732 units (0.38126%) sold in CY2019;
763 similar events from 145149 units (0.52567%) sold in CY2020;
441 similar events from 44936 units (0.9814%) sold in CY2021.

Similar incident rates were determined using RFR code (No Delivery/Occlusion Alarm During Therapy - AA21) for the platform family type of product reported per subject event.

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Canada, Colombia, Finland, Germany, Italy, Luxembourg, Netherlands, Norway, Spain, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			Death

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Others	Insufficient Information	

Health Impact

Details

Level 1	Level 2	Level 3
Death		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

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Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Form Details.htm DIR 71487	446	Form	

Flow Details : DIR-REQ - Device Incident Request : 314382

Request Details

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ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
314382	DIR-REQ		Closed	s22	OPR Administration User	09/12/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/12/2021 09:23:13	
Comment		

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20/08/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 527647

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71889		CASE-2021-00573172-1	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	20/08/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
11/01/2022	20/08/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
14/01/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Customer admitted to hospital due to hyperglycemia with vomiting, nausea and positive results in ketones. Customer alleged the insulin pump was possibly under delivering insulin.

Clinical Event Information:

It was reported that customer was admitted to the hospital due to hyperglycemia on unknown date. Customer blood glucose level was 15 mmol/l at the time of incident. Customer current blood glucose level was 7.8 mmol/L. Customer stated that they had a symptoms like vomiting, nausea and positive results in ketones. Customer treated high blood glucose with insulin pen. Customer had been using insulin pump system within 48 hours current of reported high blood glucose event. Customer stated that the auto mode feature was active at the time of high blood glucose event. The user alleged the insulin pump was possibly under delivering insulin. Customer was assisted with troubleshooting for high blood glucose. The device will not be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:
Patient Outcome/Consequences:	**Additional Event Description:**

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

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Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$2	$22	$2	
Position:		**Company/Institution:**	
Post Market Vigilance Specialist		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22 @medtronic.com	113291_837 - 11/01/2022 17:06	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
MiniMed™ 670G Insulin pump - Infusion pump, insulin, ambulatory	MiniMed™ 670G Insulin pump - Infusion pump, insulin, ambulatory		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782K	NG1901199H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
20/08/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 3 Investigation (for multiple DIRs/a DII)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

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				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	4 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		Yes
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	14/01/2022	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Device not returned	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**4 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		No	Device not returned	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown				
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	
Email:			

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s22 @medtronic.com; s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.
Details of Similar Events:	Additional Details (use for tables):
In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5005 units (0%) sold in CY2019; 2 similar events from 4093 units (0.48863%) sold in CY2020; 0 similar events from 3207 units (0%) sold in CY2021; WorldWide 344 similar events from 112872 units (0.30477%) sold in CY2018; 578 similar events from 159732 units (0.36185%) sold in CY2019; 810 similar events from 145149 units (0.55804%) sold in CY2020; 752 similar events from 44936 units (1.67349%) sold in CY2021;	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Canada, Colombia, Denmark, Finland, Germany, Italy, Netherlands, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIr closed 14/1/22

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

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Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			hyperglycaemia, DKA

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hyperglycemia	

Health Impact

Details

Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested

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Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

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Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 315562

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
315562	DIR-REQ		Closed	s22	OPR Administration User	14/01/2022	Normal	0

Signature Details

Role	IRIS Investigator

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User	s22 [redacted]	
Signed At	14/01/2022 13:45:39	
Comment		

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07/10/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 529639

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
72869		CASE-2021-00696014 /15/19	Final

ARTG: 95763 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	07/10/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
27/01/2022	07/10/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
01/02/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Customer had chronic seizure and went to DKA.

Clinical Event Information:

Customer was calling in regards to her pump. She said that on Saturday she had chronic seizure and went to DKA.
Her BG was at 3.7 mmol/L. They had stabilized her in the hospital then yesterday had high BG at 22 mmol/L.
Educator noticed that there is a big crack on the side along battery cartridge.
Customer spent 4 days at the hospital.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> Incorrect, Inadequate or Imprecise Result or Readings -> Erratic Results

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
Female			

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

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Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $2

First Name: $22

Surname: $2

Position: Post Market Vigilance Specialist

Company/Institution: Medtronic Australasia Pty Ltd

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: 113291_837 - 27/01/2022 16:32

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory

Initial Device Description: 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711KL

Serial #:

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information		Risk Assessment - Section A		Risk Assessment - Section B		Risk Assessment - Section C		Risk Assessment - Section D	
Date:		Severity:		Incidents in the last 12 months:		Manufacturer analysis:		Assessor:	Manufacturer documentation:
07/10/2021		5 - An illness/injury was resolved or prevented with treatment by a health professional						s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:		Manufacturer action:		ESTIMATED LEVEL OF INVESTIGATION:		FINAL LEVEL OF INVESTIGATION:		Injured Party:	Device Recalls:
				Level 1 Investigation (to complete		Screening only		Patient	0. No recalls for similar incidents in

		screening)			Australia Document 36
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	2 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	01/02/2022	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Closed: Device not returned	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**5 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		No		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown				
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:

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NSW	1670	§22	

Email:

§22 @medtronic.com; §22 @medtronic.com; §22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The insulin pump was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

Australia:
2 similar events from 8128 units (0.02461%) sold in CY2018;
3 similar events from 4953 units (0.06057%) sold in CY2019;
5 similar events from 3151 units (0.15868%) sold in CY2020;
5 similar events from 1273 units (0.39277%) sold in CY2021 (Includes this event).

Worldwide:
246 similar events from 122660 units (0.20055%) sold in CY2018;
261 similar events from 110335 units (0.23655%) sold in CY2019;
178 similar events from 88292 units (0.2016%) sold in CY2020;
135 similar events from 49614 units (0.2721%) sold in CY2021.

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, Ecuador, Finland, France, Germany, Hungary, Iceland, Israel, Italy, Japan, Korea, Mexico, Netherlands, Poland, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, United States, United Kingdom

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Closed: 01/02/2022.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Output Problem	Incorrect, Inadequate or Imprecise Result or Readings	Erratic Results	

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hypoglycemia	

Health Impact

Details

Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			Device not returned

Investigation Conclusion

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Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

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Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

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Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 320562

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
320562	DIR-REQ		Closed	s22	OPR Administration User	01/02/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	01/02/2022 17:08:02	
Comment		

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23/05/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 543031

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
79178		CASE-2022-00305422	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	23/05/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
10/08/2022	23/05/2022		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
11/08/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Customer reported pump not delivering properly leading to hospitalisation due to diabetic ketoacidosis.

Clinical Event Information:

Customer mentioned that his BG is not going down and he was hospitalised and it seems like pump is not delivering properly.

Hospitalization details:
1) Nature of treatment. Findings: Admitted.
2) Time and date of hospitalization: s22
3) Length of hospitalization: Overnight.
4) BG value when admitted to hospital: 20.0 mmol/L.
4A) SG value when admitted to hospital: not using sensor.
8) Any significant events leading to hospitalization: Hyperglycemia.
9) Symptoms customer reported at the time of hospitalization event: headache, vomitting.
10) Did customer test for ketones: Yes.
10A) Results of ketones test: 4.7.
11) Reason of hospitalization: DKA.
12) Document the hospitalization treatment: IV Insulin Drip.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Insufficient Flow or Under Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:

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Patient Focused Corrective Action Taken:
Customer was hospitalised and treated with IV insulin Drip.

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$22

Reporter #:

Preferred Contact Method:

Reporter Title:
$

First Name:
$22

Surname:
$22

Position:
PMV Specialist

Company/Institution:
Medtronic Australasia Pty Ltd

Address 1:
2 Alma Road

Address 2:

Town/Suburb:
Macquarie Park

State:
NSW

Country:
Australia

Postcode:
2113

Phone:
$22

Fax:

Mobile:

Email:
$22 @medtronic.com

Last External Submission By:
114395_837 - 10/08/2022 16:03

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
95763

Device ARTG #:
95763

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

Brand Name:
PUMP MMT-1711KL 640G V4.10 MM - Infusion pump, insulin, ambulatory

Initial Device Description:
PUMP MMT-1711KL 640G V4.10 MM - Infusion pump, insulin, ambulatory

Usage of Device:
Reuse of Reusable

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

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MMT-1711KL	NG2255096H		HG4AQZQ
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**

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Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
11/08/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	[redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
	Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
		Device not returned		No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	No			Yes	2 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
		Routine	Routine		Yes
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	No				Unknown
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
					Unknown
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
		Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

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Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
5 similar events from 5271 units (0.09486%) sold in CY2019;
2 similar events from 3239 units (0.06175%) sold in CY2020;
10 similar events from 3453 units (0.2896%) sold in CY2021;
2 similar events from 297 units (0.6734%) sold in CY2022;

WorldWide
50 similar events from 124490 units (0.04016%) sold in CY2019;
26 similar events from 91005 units (0.02857%) sold in CY2020;
55 similar events from 76107 units (0.07227%) sold in CY2021;
16 similar events from 38746 units (0.04129%) sold in CY2022;

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

AUSTRIA, BELGIUM, BRAZIL, COLOMBIA, CZECH REPUBLIC, DENMARK, FRANCE, GERMANY, HUNGARY, ICELAND, IRELAND, ISRAEL, ITALY, JAPAN, NETHERLANDS, NORWAY, POLAND, SAUDI ARABIA, SLOVAKIA, SLOVENIA, SOUTH AFRICA, SPAIN, SWITZERLAND, TURKEY, UNITED KINGDOM

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Closed 11/08/2022

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

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Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Insufficient Flow or Under Infusion			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	

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No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	
Investigator's Notes:		**Summary Findings:**		**Recall Number:**
		No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.		

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

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					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 342625

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
342625	DIR-REQ		Closed	s22	OPR Administration User	11/08/2022	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	11/08/2022 15:43:06	
Comment		

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24/12/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 535462

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
74674		CASE-2021-00884725	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	24/12/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
07/04/2022	24/12/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
12/04/2022			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Reported DKA and was admitted to hospital as a result of insulin pump failure.

Clinical Event Information:

Medtronic received information that a patient had gone into DKA and was admitted to hospital as a result of insulin pump failure. The patient requested a replacement pump noting that they experience much greater Blood Glucose control while using insulin Pump Therapy.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> -> ;
Output Problem -> No Device Output ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
		s	

Patient Focused Corrective Action Taken:

A replacement pump was organised for the patient.

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

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Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$	$22	$2	
Position:		**Company/Institution:**	
Post Market Vigilance Specialist		Medtronic Australisa Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22	113429_837 - 07/04/2022 11:44	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Minimed 640G Minimed 640G Infusion pump, insulin - Infusion pump, insulin, ambulatory	Minimed 640G Minimed 640G Infusion pump, insulin - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1711K	NG1392494H		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
05/01/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional			Shawn Hazel	
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

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				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	12/04/2022	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		No		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Yes - manufacturer HAS documented issues or complications of this type**		Unable to take action (device was not returned for analysis)	Screening only	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**2 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
				I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]		Level 10	Pitt Street
State:	Postcode:	Phone:	Fax:
NSW	2000	s22 [redacted]	

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Email:

s22 [redacted]

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
3 similar events from 5270 units (0.05693%) sold in CY2019;
5 similar events from 3239 units (0.15437%) sold in CY2020;
6 similar events from 3453 units (0.17376%) sold in CY2021;
1 similar events from 172 units (0.5814%) sold in CY2022;

WorldWide
261 similar events from 124661 units (0.20937%) sold in CY2019;
179 similar events from 91155 units (0.19637%) sold in CY2020;
190 similar events from 76249 units (0.24918%) sold in CY2021;
35 similar events from 14471 units (0.24186%) sold in CY2022;

Similar incidents include this event (DIR 74674)

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Belgium, Brazil, Colombia, Czech Republic, Denmark, Ecuador, Finland, France, Germany, Hungary, Iceland, Israel, Italy, Japan, Korea, Mexico, Netherland, Norway, Poland, Saudi Arabia, Slovakia, Slovenia, South Africa, Sweden, Spain, Switzerland, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR Closed 12/04/2022

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			Diabetic Keto Acidosis	
Output Problem	No Device Output			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

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Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 329714

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
329714	DIR-REQ		Closed	s22	OPR Administration User	12/04/2022	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	12/04/2022 08:41:20	
Comment		

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11/03/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 538790

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
76971	E22-597809	CASE-2022-00116776	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	11/03/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
08/07/2022	11/03/2022		19/07/2022
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
27/02/2024			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Hospitalised due to Diabetic Ketoacidosis

Clinical Event Information:

Patient called in regarding cracked/damaged on the pump.

Additional notes were made that the customer was hospitalised.
Nature of treatment. Findings: Admitted to Hospital.
Time and date of hospitalization: s22 .
Length of hospitalization: not yet discharged.
BG value when admitted to hospital:
SG value when admitted to hospital:
Any significant events leading to hospitalization: DKA.
Symptoms customer reported at the time of hospitalization event: All of the above.
Did customer test for ketones: Yes.
Results of ketones test: 6.6.
Reason of hospitalization: Admitted was provide with manual injection and IV insulin drip.
Document the hospitalization treatment: NA

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:

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Patient Focused Corrective Action Taken:
Admitted was provide with manual injection and IV insulin drip.

Patient History:

Patient Outcome/Consequences:
Admitted to Hospital.

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$22

Reporter #:

Preferred Contact Method:

Reporter Title:
$

First Name:
$22

Surname:
$22

Position:
PMV Specialist

Company/Institution:
Medtronic Australasia Pty Ltd.

Address 1:
2 Alma Road, Macquarie Park, NSW, 2113

Address 2:

Town/Suburb:
Macquarie Park

State:
NSW

Country:
Australia

Postcode:
2113

Phone:
$22

Fax:

Mobile:

Email:
$22 @medtronic.com

Last External Submission By:
114395_837 - 08/07/2022 15:50

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:
☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
308140

Device ARTG #:
308140

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

Brand Name:
PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory

Initial Device Description:
PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory

Usage of Device:
Reuse of Reusable

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

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MMT-1782K	NG2345541H		HG4J5ZR
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**

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Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
12/08/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	[redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
	Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
		Device not returned		No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	No			Yes	More than 10 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
		Expedite	Routine		Unknown
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	No	Device not returned			Unknown
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
					Unknown
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

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Attention To:	Address 1:	Address 2:	Town/Suburb:
$22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	$22	

Email:

$22 ; $22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
No corrective action. Monitoring and trending this type of event.	The device was not returned to Medtronic for analysis.

Details of Similar Events:

In Australia
0 similar events from 5512 units (0%) sold in CY2019;
5 similar events from 4233 units (0.11812%) sold in CY2020;
6 similar events from 3533 units (0.16983%) sold in CY2021;
15 similar events from 1044 units (1.43678%) sold in CY2022;

WorldWide
1966 similar events from 155151 units (1.26715%) sold in CY2019;
1957 similar events from 146661 units (1.33437%) sold in CY2020;
1511 similar events from 77617 units (1.94674%) sold in CY2021;
404 similar events from 25270 units (1.59873%) sold in CY2022;

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

UNITED STATES, ITALY, CANADA, SWITZERLAND, SPAIN, SWEDEN, UNITED KINGDOM, SLOVENIA, AUSTRIA, NETHERLANDS, GERMANY, BELGIUM, FINLAND, NORWAY, DENMARK, SOUTH AFRICA, SAUDI ARABIA, MEXICO, COLOMBIA

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 12/08/22

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

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Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Information Requested/Pushback		19/07/2022	26/07/2022		28/07/2022 - Response not received - s41JA sent as an RFI	19/07/2022 - Pushback sent for Clinical Event Information Clarification.
☐		Sponsor Routine Correspondence	Sponsor Request for Information Reminder Letter - s41JA		28/07/2022	15/08/2022	10/08/2022	10/08/2022 - D22-5778602	28/07/2022 - D22-5738410

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			Hospitalised DKA

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis	

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

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Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details		
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details		
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, for Trending Purposes Only		

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:

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Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:

Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To

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FILE		TGA Action Requested for DIR 76971 SECOFFICIAL	44	Form
FILE		RE_ DIR 76971 - __URGENT ACTION REQUIRED__ - ...	192	Form

Flow Details : DIR-REQ - Device Incident Request : 335745

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
335745	DIR-REQ		Closed	s22	OPR Administration User	08/03/2024	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	08/03/2024 15:30:30	
Comment		

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27/06/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 543836

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
79969		CASE-2022-00404841-1	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	27/06/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
27/09/2022	27/06/2022		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
27/09/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

The customer was hospitalized due to high blood glucose and diabetic ketoacidosis.

Clinical Event Information:

The customer reported via phone call that they were hospitalized due to high blood glucose on s22 with high blood glucose of 26.4 mmol/l and diabetic ketoacidosis. The customer's current blood glucose is 10-20 mmol/l. The customer did experienced the symptoms such as felt sick. The customer was treated by intravenous drip. Troubleshooting was done for high blood glucose and under delivery. Customer states the drive support cap appears normal. The customer was wearing the insulin pump during the hospitalization. The customer report did not allege under delivery on insulin pump. No further complications were reported. The customer will discontinue to use the device.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

In November 2019 Medtronic issued a Field Safety Corrective Action (FA896) to inform health care professional and patients who may be using a MiniMed™ 600 series insulin pump that the reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock into the pump. The retainer ring can be broken, for example as a result of dropping or bumping the pump on a hard surface. If the reservoir is not properly locked into the pump, it could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia. Patients received actions and precautions in order to mitigate the risks associated with this issue.

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

$2

Reporter #:

Preferred Contact Method:

Reporter Title:

$2

First Name:

$22

Surname:

$2

Position:

Post Market Vigilance Specialist

Company/Institution:

Medtronic Australasia Pty Ltd

Address 1:

2 Alma Road

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

$22

Fax:

Mobile:

Email:

$22

Last External Submission By:

113291_837 - 27/09/2022 13:51

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

No

Search Device ARTG:

308140

Device ARTG #:

308140

Therapeutic Licence Type:

Medical Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

35983

GMDN / UMDN Text:

Infusion pump, insulin, ambulatory

Brand Name:

Medtronic MINIMED - Infusion pump, insulin, ambulatory

Initial Device Description:

Medtronic MINIMED - Infusion pump, insulin, ambulatory

Usage of Device:

Reuse of Reusable

Software Version:

Model #:

MMT-1782K

Serial #:

NG1901097H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

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Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Rate considered low at this stage	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
27/09/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	s22	Unknown - updated information from the manufacturer is required

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Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	Yes	Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		low rates		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	4 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		Unknown
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:

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NSW	1670		

Email:

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The customer was hospitalized for alleged DKA/High BG's and retuned for alleged cosmetic damage at the reservoir compartment/reservoir does not sit in properly on s22 .

Using a test battery cap. The pump passed the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test and Force Sensor Test. Unable to perform the Displacement Test, Occlusion Test and DAT due to missing retainer.
The pump was received with a missing retainer, missing reservoir tube O-ring, and broken reservoir tube lip.
The following were noted during visual inspection: minor scratched display window, scratched case, pillowing keypad overlay and stained keypad overlay.
The test P-Cap and reservoir will not lock in place in the reservoir compartment due to missing retainer.
The battery cap was received broken. The battery cap contact was broken off from the battery cap.
History download was successful using THUS and Carelink upload was successful.

The pump passed the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test and Force Sensor Test. Unable to perform the Displacement Test, Occlusion Test and DAT due to missing retainer. Unable to confirm alleged DKA/High BG's.
Cosmetic damage was confirmed at reservoir compartment (missing retainer, missing reservoir tube O-ring, and broken reservoir tube lip).
The test P-Cap and reservoir will not lock in place in the reservoir compartment was confirmed.

Details of Similar Events:

In Australia
0 similar events from 5512 units (0%) sold in CY2019;
2 similar events from 4233 units (0.04725%) sold in CY2020;
4 similar events from 3533 units (0.11322%) sold in CY2021;
8 similar events from 1044 units (0.76628%) sold in CY2022;

WorldWide
924 similar events from 155151 units (0.59555%) sold in CY2019;
965 similar events from 146661 units (0.65798%) sold in CY2020;
734 similar events from 77617 units (0.94567%) sold in CY2021;
189 similar events from 25270 units (0.74792%) sold in CY2022;

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:		Severity:	
Rating:			

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

UNITED STATES, CANADA, SWITZERLAND, SPAIN, SLOVENIA, NETHERLANDS, GERMANY, UNITED KINGDOM, SOUTH AFRICA, BELGIUM, COLOMBIA, FINLAND

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 27/09/2022

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

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Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			Hyperglycaemia, DKA

Clinical signs symptoms and conditions

Details		
Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis

Health Impact

Details		
Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected

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Material and/or Chemical Problem Identified				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

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					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 344544

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
344544	DIR-REQ		Closed	s22	OPR Administration User	27/09/2022	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	27/09/2022 16:04:04	
Comment		

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12/07/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 46 - ID : 544251

Released by s22 on 28/09/2022 14:44:45

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
80377		CASE-2018-00000981	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	12/07/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
03/11/2022	12/07/2022		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/11/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Patient had been experiencing low blood glucose levels and was hospitalized due to diabetic coma and severe brain injury.

Clinical Event Information:

Medtronic received information that a patient was hospitalized and was in the hospital due to diabetic coma and severe brain injury. The patient had been experiencing low blood glucose levels before she was found unconscious 16 hours later. She also had multiple suspensions and resumes of basal in her pump history. It was later confirmed that the patient was hospitalized on s22 and passed away on s22

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Adverse Event Without Identified Device or Use Problem -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Death -> ->

Patient Information

Sex:	Weight:	Age:
Female		

Patient Focused Corrective Action Taken:	Patient History:
Patient Outcome/Consequences:	**Additional Event Description:**

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to death?:	Other medical devices currently using/implanted:
	Death	No	
Medical Problem Device Used For:	**Additional Patients Added:**		

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0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $

First Name: $22

Surname: $2

Position: Post Market Vigilance Specialist

Company/Institution: Medtronic Australisa Pty Ltd

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: 113429_837 - 03/11/2022 10:12

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: MiniMed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: MiniMed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Single Use

Software Version:

Model #: MMT-1711K

Serial #: NG1212222H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Rate considered low at this stage	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
12/07/2022	9 - Death		Yes	s22	Yes - manufacturer HAS documented issues or complications of this type
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	Not required (device was performing within specified parameters)	Screening only	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	

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Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			

Investigation Information Section - Submitted by Sponsor/Manufacturer

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Device Analysis Results:

The unit did not have a battery installed when received.
Unit passed the functional test, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and the DAT Test at 0.08730 inches.
Unit uploaded properly using Carelink.
The Formatted History File lists multiple suspend activity. The latest suspend activity was on 03/31/2017 for LowPredictedSuspend, SuspendPredictThreshold, ThresholdSuspendInput, TSuspendMXST, SuspendedByAlarm, and LowTresholdSuspend.
The Long Trace History File lists some data on 3/31/2017, and on 8/6/2017 to 12/7/2017 for button presses activity.
The suspended and resume options functions properly when using the Suspend Delivery feature.
No anomaly noted when using the Suspend Delivery feature.
Unit had scratched case, pillowing keypad overlay and cracked retainer.
The test P-Cap and reservoir does lock in place in the reservoir compartment.
Data Analysis:
From 10/04/2017 to 10/10/2017 DailyTotalOfAllInsulinDelivered = 0
09/03/2020
The case bottom was milled off to perform a visual inspection.
During the visual inspection, no moisture damage or loose components noted on the electronic assembly. No damage noted on the motor assembly.

Corrective/Preventative Actions:

No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
0 similar events from 5271 units (0%) sold in CY2019;
0 similar events from 3239 units (0%) sold in CY2020;
0 similar events from 3453 units (0%) sold in CY2021;
1 similar events from 297 units (0.3367%) sold in CY2022*

Worldwide
27 similar events from 124490 units (0.02169%) sold in CY2019;
37 similar events from 91005 units (0.04066%) sold in CY2020;
11 similar events from 76107 units (0.01445%) sold in CY2021;
14 similar events from 38746 units (0.03613%) sold in CY2022.

*The one event referenced is this event, DIR 80377

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Canada, France, Germany, Ireland, Switzerland, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed on 09 Nov 2022

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Adverse Event Without Identified Device or Use Problem				

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Death			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details	Additional Details

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	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 345474

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Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
345474	DIR-REQ		Closed	s22	OPR Administration User	09/11/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/11/2022 11:42:52	
Comment		

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Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

31/08/2017
SIGNED

DIR : 26 - ID : 393514

Released by s22 [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
47698		CASE-2017-00175832	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22 [redacted]	31/08/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
17/10/2017	31/08/2017		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
17/10/2017	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Low blood glucose and seizures. Self-test could not be completed due to a pump error.

Clinical Event Information:

Medtronic has been informed that a customer was hospitalized with low Blood Glucose and experienced seizures. Troubleshooting was performed on the pump but the self-test could not be completed due to a Pump Error.
Medtronic has requested that the pump be returned for analysis

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Unknown.

Patient History:

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Unknown.

Patient Outcome/Consequences:

Unknown.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: Reporter #:

s22

Reporter Title: First Name: Surname:

s22 s22 s22

Position: Company/Institution:

Senior Regulatory Affairs Specialist Medtronic Australasia Pty Ltd

Address 1: Address 2: Town/Suburb: State:

5 Alma Road North Ryde NSW

Country: Postcode: Phone: Fax:

Australia 2113 s22

Mobile: Email: Last External Submission By:

s22 @medtronic.com s22 _837 - 16/10/2017 17:19

Initial Reporter Section

As Above?: *If No, fill out the following:* Initial Reporter Confidential:

Yes

Search Reporter By Surname: Initial Reporter #:

Title: First Name: Surname:

Position: Company/Institution:

Address 1: Address 2: Town/Suburb: State:

Postcode: Phone: Fax: Mobile:

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Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711

Serial #: NG1001131H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Patient

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: 18000 Devonshire Street

Address 2:

Town/Suburb: Northridge

State/Province: CA

Country: United States

Postcode: 91329

Phone:

Fax:

Email: s22 [redacted] @medtronic.com

Manufacturer Informed: Yes

Date Aware of Adverse Event: 24/08/2017

Contact Title:

Contact First Name:

Contact Surname:

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s22	s22	s22

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
17/10/2017	s22	Yes	Yes	☐
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Temporary Injury
Actual Effect:	Injured Party:		Found Prior To Use:	Risk Frequency:
Temporary Injury	Not Applicable		No	Sometimes
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Unlikely	Not Investigated	No	
DIRE Meeting Notes:				

Sponsor Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:

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NSW	1670	$22 [redacted]	$22 [redacted]

Email:

$22 [redacted]@medtronic.com

Investigation Information Section

Device Analysis Results:

As the insulin pump has not been received for analysis, no device analysis results are available.

Corrective/Preventative Actions:

The manufacturer will continue to monitor the rate of such incidents for trending purposes.

Details of Similar Events:

The following similar event data relates to cases of 'low blood glucose hospitalization' and 'pump error'.

Worldwide (including Australia)
2015: 14 similar incidents / 25,048 install base = 0.06%
2016: 37 / 49,937 = 0.07%
2017 (to date): 22 / 64,583 = 0.03%

Australia
2015: 6 / 3,567 = 0.17%
2016: 9 / 8,176 = 0.11%
2017 (to date): 2 / 12,281 = 0.02%

Additional Details (use for tables):



Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

o Argentina, Australia, Austria, Bahamas, Bahrain, Barbados, Belarus, Bermuda, Bosnia-Herzegovina, Brazil, Bulgaria, Canada, Chile, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Rep., Ecuador, Egypt, El Salvador, Estonia, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Iraq, Ireland, Israel, Italy, Jordan, Kazakhstan, Kuwait, Latvia, Lebanon, Libya, Lithuania, Macedonia, Mexico, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Panama, Paraguay, Peru, Poland, Portugal, Qatar, Romania, Russian Fed., Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Trinidad, Tobago, Turkey, Ukraine, United Kingdom, Uruguay, USA, United Arab Emirates, Venezuela.

Additional Comments:

DIR Closed on 17/10/2017

Device Lookup

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This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Usability	Use of Device Issue		

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	

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Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 118798

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
118798	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	17/10/2017	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	17/10/2017 11:01:31	
Comment		

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22/03/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 541195

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
77388	E22-598511	CASE-2022-00167455/00167454/00167453	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		$22	22/03/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
14/07/2022	22/03/2022	26/07/2022	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
27/09/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Unable to pair glucometer with continuous glucose monitor.
Also discovered infusion cannula kinked at 2 points.

Clinical Event Information:

Patient calling in to get assistance with his pump. He said that he is in the hospital and needs to get pump started, however, the glucometer and cgm is not connecting. He mentioned his hospitalization was because they discovered bent cannula , pump is okay and wanted to just get the pump paired to his glucometer and xmtr.
Hospitalization details:
Nature of treatment. Findings: hospital admission.
Time and date of hospitalization: $22
Length of hospitalization: ongoing 2 days.
BG value when admitted to hospital: >33 mmol/L.
SG value when admitted to hospital: not using sensor at that time.
Any significant events leading to hospitalization: n/a.
Symptoms customer reported at the time of hospitalization event: weak/tired, vomitting, muscle aches, DKA.
Did customer test for ketones: Yes.
Results of ketones test: n/a.
Reason of hospitalization: DKA.
Document the hospitalization treatment: IV drip, hospital admission.
Additional Notes: Hospitalization: -brought to $22 on $22 . -cannula kinked at 2 points/area (looked like a mountain) -site was on the abdomen -BG reading was above 33 mmol/L -current BG is 19 mmol/L- correction via IV drip in the hospital -was not using sensor at that time -does not have ref for inf set and res, but said he is using the Mio set. -does not want to further t/s for pump

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Communication or Transmission Problem -> Wireless Communication Problem -> ;
Material Integrity Problem -> Material Deformation -> Material Twisted / Bent

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

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Patient Information

Sex:

Weight:

Age:

Patient Focused Corrective Action Taken:
IV drip, hospital admission.

Patient History:

Patient Outcome/Consequences:
Hospitalised and treated for DKA

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$22

Reporter #:

Preferred Contact Method:

Reporter Title:
$

First Name:
$22

Surname:
$22

Position:
PMV Specialist

Company/Institution:
Medtronic Australasia Pty Ltd.

Address 1:
2 Alma Road, Macquarie Park, NSW, 2113

Address 2:

Town/Suburb:
Macquarie Park

State:
NSW

Country:
Australia

Postcode:
2113

Phone:
$22

Fax:

Mobile:

Email:
$22 @medtronic.com

Last External Submission By:
114395_837 - 14/07/2022 16:47

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:
☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
308140

Device ARTG #:
308140

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

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Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
MMT-1782KL 670G MM RPL - Infusion pump, insulin, ambulatory	MMT-1782KL 670G MM RPL - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782KL	NG2404876H		HG4PRRA
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	$22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
26/07/2022	Not enough information has been provided	

Notes for Team meeting:

Clinical event states bent cannula + pump/monitor connection problem. ARTG # provided is for pump not for cannula. Rates provided appears to be for cannula not for pump connection problems. Seek clarification from sponsor regarding rates and ARTG #.

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Outcomes from Team Meeting:

Go back to sponsor and request clarification on why the ARTG is for the pump and why the rates are for the canula.

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
20/07/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	$22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		To clarify ARTG # and rates		No	No
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I undertook an internet search (e.g., Google)	Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

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Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	
Email:			
s22 ; s22 @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.
Details of Similar Events:	**Additional Details (use for tables):**
In Australia 0 similar events from 5512 units (0%) sold in CY2019; 5 similar events from 4233 units (0.11812%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 15 similar events from 1044 units (1.43678%) sold in CY2022; WorldWide 1966 similar events from 155151 units (1.26715%) sold in CY2019; 1957 similar events from 146661 units (1.33437%) sold in CY2020; 1511 similar events from 77617 units (1.94674%) sold in CY2021; 404 similar events from 25270 units (1.59873%) sold in CY2022;	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

UNITED STATES, ITALY, CANADA, SWITZERLAND, SPAIN, SWEDEN, UNITED KINGDOM, SLOVENIA, AUSTRIA, NETHERLANDS, GERMANY, BELGIUM, FINLAND, NORWAY, DENMARK, SOUTH AFRICA, SAUDI ARABIA, MEXICO, COLOMBIA

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

DIR Closed 27/09/2022

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus

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Essential Principles	If 'Other' Selected
Others (Note relevant EP and describe as a 'may' statement)	Reporting obligations

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		31/08/2022	

Evidence

Investigation Questions (Level 1 and Level 2):

Clarify ARTG for cannula and infusion pump
Clarify rates for cannula and infusion pump issue

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☐	☑	☑

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		03/08/2022	31/08/2022	30/08/2022	31/08/2022 - D22-5844516	03/08/2022 - D22-5757076.

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Communication or Transmission Problem	Wireless Communication Problem		
Material Integrity Problem	Material Deformation	Material Twisted / Bent	

Clinical signs symptoms and conditions

Details		
Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hyperglycemia	Diabetic Ketoacidosis

Health Impact

Details

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Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
		s22 [redacted]	No	

Investigator's Notes:	Summary Findings:	Recall Number:
	The ARTG was provided for the pump as the event description referred to an issue regarding pairing the glucometer with continuous glucose monitor. The ARTG for the infusion set was confirmed as 119216. The ARTG for the pump is 308140. A review of the similar events for the infusion set (119216) found no significant trend . The event of the alleged bent cannula could not be confirmed as the material number of the infusion set was unknown. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

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Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

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Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		RE_ DIR 77388 - Request For Information Letter...	227	Form	

Flow Details : DIR-REQ - Device Incident Request : 338430

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
338430	DIR-REQ		Closed	s22	OPR Administration User	27/09/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	27/09/2022 13:50:27	
Comment		

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08/02/2022
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 536805

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
75998	E22-576163	CASE-2022-00079616	Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22 [redacted]	08/02/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
20/05/2022	08/02/2022	31/05/2022	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
10/08/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

Patient was admitted in emergency room due to high blood glucose.

Clinical Event Information:

It was reported that the customer was admitted in emergency room on s22 [redacted] due to high blood glucose. Customer blood glucose was 23.3 mmol/L. Customer was treated with insulin drip for high blood glucose. Customer stated symptoms related to high blood glucose that were pain in the stomach, sweating, shakiness and nausea. Customer's result of ketone test was 4.5. The insulin pump was off when customer woke up and the belt clip rails were damaged. It was unknown whether the customer was using auto mode feature or not at the time of event. The insulin pump will not be returned for the analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Gastrointestinal System -> Nausea -> ;
General Disorders -> Pain -> Abdominal Pain;
Investigations and Diagnostic Tests -> Hyperglycemia -> Diabetic Ketoacidosis

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Patient Outcome/Consequences:		**Additional Event Description:**	
Describe any test (Lab, xray, etc.):	**Injured - Extent of Injury:**	**Other medical devices currently using/implanted:**	**Medical Problem Device Used For:**

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Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $2

First Name: $22

Surname: $2

Position: Post Market Vigilance Specialist

Company/Institution: Medtronic Australasia Pty Ltd

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: 113291_837 - 20/05/2022 15:37

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 308140

Device ARTG #: 308140

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory

Initial Device Description: PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1782K

Serial #: NG2117824H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
31/05/2022	Increase in rate or rates not complete	Investigation (within DIR) is recommended

Notes for Team meeting:
More than 10 DIR's for Hyperglycaemia. The sponsors S/E rate is 0. Do you want to go back to the sponsor and ask them to review this S/E rates as it looks like they have not put rates in for Hyperglycaemia.

Outcomes from Team Meeting:
Lvl 1 investigation to clarify similar event rates and whether they are being reported correctly.

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
23/05/2022	5 - An illness/injury was resolved or prevented with treatment by a health professional		Yes	s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**

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	Unable to take action (device was not returned for analysis)	Level 3 Investigation (for multiple DIRs/a DII)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		Device not returned. Rates are in question.		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	More than 10 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Expedite	Routine		Unknown
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No	Device not returned. Rates are in question.			Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	

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Email:

s22 ; s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The device was not returned to Medtronic for analysis.	No corrective action. Monitoring and trending this type of event.
Details of Similar Events:	Additional Details (use for tables):
In Australia 0 similar events from 5513 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 0 similar events from 3533 units (0%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 1413 similar events from 155151 units (0.91073%) sold in CY2019; 1280 similar events from 146661 units (0.87276%) sold in CY2020; 1425 similar events from 77617 units (1.83594%) sold in CY2021; 217 similar events from 8406 units (2.58149%) sold in CY2022;	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	Number of Similar Events:
Rating:			
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Canada, Denmark, Finland, France, Germany, Italy, Luxembourg, Netherlands, Norway, Singapore, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Rate information is required	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

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Evidence

Investigation Questions (Level 1 and Level 2):

Rate information not provided correctly. Obtaining correct rates, and educating sponsor.

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☐	☑	☑

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		03/06/2022	04/07/2022	08/06/2022	09/06/2022 - D22-5566474	TRIM #: D22-5548772
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		10/08/2022				D22-5776706

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Appropriate Term/Code Not Available			High Blood glucose

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Investigations and Diagnostic Tests	Hyperglycemia	Diabetic Ketoacidosis
General Disorders	Pain	Abdominal Pain
Gastrointestinal System	Nausea	

Health Impact

Details

Level 1	Level 2	Level 3
Hospitalization or Prolonged Hospitalization		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected

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No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

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	Who sent the device to the TGA?:	Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		RE_ DIR 75998 - Request For Information Letter	246	Form	

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Flow Details : DIR-REQ - Device Incident Request : 332544

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
332544	DIR-REQ		Closed	s22	OPR Administration User	10/08/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	10/08/2022 11:48:27	
Comment		

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25/03/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 517608

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
68922	E21-259926		Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	25/03/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
25/03/2021	25/03/2021	30/03/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
24/06/2021	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Nurse		For Team Meeting	

Event Description for Website Publication:

Recurrent hypoglycaemia as the insulin pump began to self-deliver insulin boluses multiple times over a four day period uninitiated by the patient or carer.

Clinical Event Information:

The insulin pump began to self-deliver insulin boluses multiple times over a four day period uninitiated by the patient or carer. This resulted in severe and recurrent hypoglycaemia requiring multiple interventions to raise the blood glucose level. The incidents are clearly evident in the insulin pump report.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
32	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Improper Flow or Infusion -> Inaccurate Delivery

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Insufficient Information -> ->

Patient Information

Sex:	Weight:	Age:
s22	s22	s22

Patient Focused Corrective Action Taken:

Patient History:

Type 1 diabetes

Patient Outcome/Consequences:

The s22 patient suffered from severe and recurrent hypoglycaemia following these errant boluses of rapid-acting insulin which required significant intervention on the part of the parent through ongoing administration of fast-acting carbohydrate to reverse the hypoglycaemia. Upon learning of the insulin pump fault, our team advised the mother to disconnect the insulin pump and instead administer insulin through injection until the insulin pump can be replaced.

Additional Event Description:

The Medtronic 670G insulin pump the patient was using began to erroneously deliver insulin boluses multiple times on successive occasions over a four day period resulting in severe and recurrent hypoglycaemia before the problem was identified by the parent who contacted both Medtronic and us - the paediatric diabetes care team at the s22 - to advise of the fault/error with the pump. Upon viewing the insulin pump history report, this showed there were 32 separate occasions where the insulin pump has self-delivered the maximum carbohydrate dose of 300g resulting in multiple insulin doses being delivered. The actual amount of insulin that the patient received was significantly lower than the pump tried to administer due to the safety

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feature called 'Maximum Bolus' which was set at 5 units, however this was still up to 300% more than what the patient usually receives in a typical day.

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Near Miss

Other/Near Miss:

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: s22

Reporter #:

Preferred Contact Method: Email

Reporter Title:

First Name: s22

Surname: s22

Position: Clinical Nurse Specialist Credentialled Diabetes Educator (Paediatrics)

Company/Institution: s22

Address 1: s22

Address 2:

Town/Suburb: s22

State: TAS

Country: Australia

Postcode: s22

Phone:

Fax:

Mobile:

Email: s22

Last External Submission By:

Initial Reporter Section

As Above?: No

If No, fill out the following:

Initial Reporter Confidential: Yes

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1: s22

Address 2:

Town/Suburb: s22

State: TAS

Postcode: s22

Country: Australia

Phone:

Fax:

Mobile: s22

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 308140

Device ARTG #: 308140

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic 670G insulin pump - Infusion pump, insulin, ambulatory

Initial Device Description: Medtronic 670G insulin pump - Infusion pump, insulin, ambulatory

Usage of Device:

Software Version:

Model #: 670G

Serial #: NG2320984H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

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12/09/2020			
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
		With Patient	
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic		5 Alma Road	
Town/Suburb:	State:	Country:	Postcode:
Macquarie Park	NSW	Australia	2113
Phone:	Fax:	Email:	Website:
1800777808			
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Yes	24/03/2021		s22
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:
s22	s22		s22 @medtronic.com

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
30/03/2021	User report	Investigation (within DIR) is recommended

Notes for Team meeting:

One more DIR with similar issue and this DIR reports 32 incidents. The report states that insulin pump report confirmed the unintended bolus delivery. No Recalls for this issue. Need to investigate

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:

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25/03/2021	4 - An illness/injury resolved without treatment by a health professional (or by self-management)		No	s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	No	Level 3 Investigation (for multiple DIRs/a DII)	Level 2 Investigation (for a single DIR)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		Only one more incident in IRIS database besides this report.		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	More than 10 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Expedite	Routine		Yes
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No	Only one more incident in IRIS database besides this report.			Yes
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Yes
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I discussed issues with one of the team leaders	Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		Details of Similar Events:	
Additional Details (use for tables):		CAPA# Reference:	
		Risk Assessment	
		Frequency:	Severity:
		Rating:	
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			
Completed Actions:		Planned Actions and Proposed Timelines:	
Additional Comments:			
DIR closed 24/6/21			

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Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP2-Design/construction may not conform with principles	

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		05/04/2021	26/04/2021

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers: ☐

Delays in response by incident reporters: ☐

Delays in analysis within the TGA: ☐

Delays in reporting by other sources (e.g. clinical registries): ☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Case Closure

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		01/04/2021				
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		01/04/2021	03/05/2021	26/04/2021		
☐		Reporter Routine Correspondence	Reporter Notification & Request for Information Letter		28/04/2021	12/05/2021	29/04/2021		
☐		Reporter Routine Correspondence	Email to Reporter		21/05/2021			D21-2663782 notification that the device has been sent to the manufacturer for analysis	D21-2663225 re where the devcie curretnly is and sending a aredacted report for analysis by the manufacturer
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA		24/05/2021	23/06/2021	24/06/2021	D21-2738018	Email D21-2668770 Letter D21-2668529 update on on the manufacturers analysis and rates

☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		24/06/2021				D21-2773510 Document 45 email D21-2773643
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		24/06/2021				D21-2773517 Email D21-2773667

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Improper Flow or Infusion	Inaccurate Delivery		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Insufficient Information			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to User			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
		s22 [redacted]	No	
Investigator's Notes:		**Summary Findings:**		**Recall Number:**
https://www.medtronic-diabetes.com.au/sites/default/files/m988666a021doc_2_final_web_670g_ifu.pdf		Review of the outcome manufacturer's analysis of the returned insulin pump, confirmed that the insulin pump passed functional test including the Self-Test, Sleep Current Measurement,		

Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and a Displacement Accuracy Test. No over delivery anomaly or under delivery anomaly was noted.
The manufacture's review of the insulin pump's, CareLink, and pump memory from s22 [redacted] confirmed that the boluses programmed and delivered by the insulin pump were initiated by the user. The insulin pump was working as intended and met specifications. No bolus anomaly noted.
The sponsor provided the rates of similar events and a review of the TGA database has confirmed that the rates are consistent with those received by the TGA for this issue.

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Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

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Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1: s22 [redacted]

Address Line 2:

Town/Suburb: s22 [redacted]

State: TAS

Postcode: s22 [redacted]

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		s22 [redacted] 25-03-2021	1508	Form Item	Report Information Section / Brand Name
FILE		s22 [redacted] 25-03-2021 (2)	2018	Form Item	Report Information Section / Brand Name
FILE		DIR 68922 - Original User Report	436	Form	
FILE		report #68922	108	Form	
FILE		RE DIR 68922 - Questionnaire Letter - respons...	606	Form	
FILE		TGA Reporter Complete Letter DIR 68922	139	Form	
FILE		TGA Sponsor User Complete Letter DIR 68922	123	Form	

Flow Details : DIR-REQ - Device Incident Request : 298366

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
298366	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	24/06/2021	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	24/06/2021 13:54:14	
Comment		

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17/02/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 515844

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
68198	E21-241948		Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	17/02/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
17/02/2021	17/02/2021	02/03/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
28/06/2021			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Carer		For Team Meeting	

Event Description for Website Publication:

Alerts not provided by the CGM when levels go out of range.

Clinical Event Information:

We switched to the Medtronic Guardian Continuous Glucose Monitor (CGM) today (to get the best from this new insulin pump).
My son is unable to manage his blood glucose levels himself. As such, we rely on being able to get the alerts provided by the CGM when our son's levels go out of range.
However, we have been unable to get these notifications and Medtronic have advised us that this has been an issue for more than 24 hours and they have no timeline or estimate for when the issue will be resolved.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Protective Measures Problem -> Device Alarm System -> Defective Alarm

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> No Clinical Signs, Symptoms or Conditions ->

Health Impact

Recorded Health Impacts:

No Health Consequences or Impact -> ->

Patient Information

Sex:	Weight:	Age:
Male	s	s22

Patient Focused Corrective Action Taken:	Patient History:
	Autism, Type 1 Diabetes
Patient Outcome/Consequences:	**Additional Event Description:**
Without these alerts, my son is at risk of suffering a fatal hypoglycemic event.	Have contacted Medtronic, but they have not resolved the issue and have no timeline or estimate of when they will be able to resolve it.

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other/Near Miss:	Consequence:

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	Near Miss		
Other medical devices currently using/implanted:	Medical Problem Device Used For:	Additional Patients Added:	
		0	

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			Email
Reporter Title:	First Name:	Surname:	
s	s22	s22	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Country:	Postcode:	Phone:	Fax:
Australia		s22	
Mobile:	Email:	Last External Submission By:	
	s22		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Yes			
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Guardian CGM Infusion pump, insulin, ambulatory	Guardian CGM Infusion pump, insulin, ambulatory		2.1.1 [1148]
Model #:	Serial #:	Batch #:	Lot #:
Carelink Connect			
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
17/02/2021			
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
17/02/2021		Insitu	

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic - by way of NDSS			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
		Australia	
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	17/02/2021		s22
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
	s22		

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
02/03/2021	User report	Investigation (within DIR) is recommended

Notes for Team meeting:

0 similar incidents in the past 6 months, no recalls and no PMR, This clinical event could result in serious injury to the end user. do you want to review rates and IFU, Are there any adequate troubleshooting steps present in IFU to address the reported incident.

Outcomes from Team Meeting:

Level 2 investigation, send questionnaire- for rates and also confirm the action the sponsor may be taking to mitigate the risk of this issue.

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
17/02/2021	0 - Insufficient information to determine level of severity			s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**

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		Level 1 Investigation (to complete screening)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		Details of Similar Events:	
Additional Details (use for tables):		CAPA# Reference:	
		Risk Assessment	
		Frequency:	Severity:
		Rating:	
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			
Completed Actions:		Planned Actions and Proposed Timelines:	
Additional Comments:			

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

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Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP1-Use may compromise patient health and safety	

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		04/03/2021	03/05/2021

Evidence

Investigation Questions (Level 1 and Level 2):

In addition to questionnaire, please provide what actions they have taken to fix the issue and whether the customers were informed through recalls?

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☑	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:
	Case Closure

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		04/03/2021				
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		05/03/2021	04/05/2021	03/05/2021	Sponsor has asked more info from reporter _____ 26/03/2021 - Sponsor has been provided with the image sent by reporter (see attached) _____ 30/03/2021 - Extension request granted, originally due 02/04/2021, now due 20/04/2021 _____ 31/03/2021 - Sponsor requested serial number to identify patient, this request was declined D21-2475793 _____ 20/04/2021 - Extension request	

								granted, originally due 02/04/2021, then 20/04/2021, now due 04/05/2021 s22 [redacted]	Document 46	
☐		Reporter Routine Correspondence	Email to Reporter		17/03/2021	02/04/2021	26/03/2021	26/03/2021 - no response rec'd, follow-up reminder email sent. ——— 26/03/2021 - See attached		
☐		Reporter Routine Correspondence	Email to Reporter		26/05/2021		28/06/2021	Response not received from the reporter	D21-2675755 D21-2719944	
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		28/06/2021				D21-2780505	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		28/06/2021				D21-2780526	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Protective Measures Problem	Device Alarm System	Defective Alarm		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Others	No Clinical Signs, Symptoms or Conditions		

Health Impact

Details			
Level 1	Level 2	Level 3	
No Health Consequences or Impact			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

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Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	The device was not returned to the sponsor for further manufacturer's analysis. No further investigation will occur at this time; however, the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

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Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 68198 - Original User Report	432	Form	
FILE		Re FOLLOW-UP DIR 68198 - sponsor request SECOF...	2828	Form	
FILE		DIR 68198 - Image	44	Form	
FILE		DIR 68198_Sponsor_Completion_Letter	458	Form	
FILE		DIR 68198_Reporter_Completion_Letter	453	Form	

Flow Details : DIR-REQ - Device Incident Request : 294562

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
294562	DIR-REQ		Closed	s22	OPR Administration User	28/06/2021	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	28/06/2021 09:05:54	
Comment		

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12/02/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 42 - ID : 515761

Released by [redacted] on 15/02/2021 17:33:07

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
68118	E21-238369		Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		[redacted]	12/02/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
12/02/2021	12/02/2021	23/02/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/06/2021			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient	patient	For Team Meeting	

Event Description for Website Publication:

Device pump showing 7.9, finger prick showing 23.2mmol.

Clinical Event Information:

Medtronic closed loop 670G with CGM.
Could feel my blood sugar rising, pump showing 7.9 finger prick showing 23.2mmol.
Tried several times to recalibrate pump by entering blood sugar and selecting yes to calibrate, repeated 6x over 5 hours early hours of the morning. Woke up vomiting, unable to hold down water blood sugar 26, called ambulance, was monitored closely in [Redacted] ICU, diagnosed DKA. 2 weeks off auto mode increasing constant insulin 60% my insulin to carb ratio changed back, not quite as low. I stopped using the pump and CGM.
I have since returned to 2x daily Levemir, 4x Novarapid and configured my own I:C

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> Incorrect, Inadequate or Imprecise Result or Readings -> Incorrect Measurement

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:
Male	[redacted]	[redacted]

Patient Focused Corrective Action Taken:

Patient History:

Metformin xr 1000
Candesartan 16mg
Perindopril 8mg
Carbimazole 5mg X2, X1 morning X1 night
Rosuastatin 10mg
Mirtazapine 15mg

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Patient Outcome/Consequences:

Hba1c increased from 7.8 - 8.9.
I unit to 15g is now 1 unit to 8g of carbohydrates.
My blood sugars are more stable + more predictable especially with the return of insulin sensitivity.
1 incidence of 3.9mmol which was dosed, predicted, and timed, all signs of hypoglycaemia, immediately treated.
Second ever Thyroid storm due to graves occurred 3 weeks following. Treated with Carbimazole, immediate TSH lowering, now .04

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Unknown

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: $22

Reporter #:

Preferred Contact Method: Email

Reporter Title: $

First Name: $22

Surname: $22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country: Australia

Postcode:

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 308140

Device ARTG #: 308140

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic 670G & Guardian CGM - Infusion pump, insulin, ambulatory

Initial Device Description: Medtronic 670G & Guardian CGM - Infusion pump, insulin, ambulatory

Usage of Device:

Software Version:

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Model #:	Serial #:	Batch #:	Lot #:
670G	NG1905070H ref MMT-782K, CGM: GT7703424M		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
05/10/2020			
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
12/10/2020		With Patient	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
	NSW	Australia	
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
No			
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
23/02/2021	User report	Investigation (within DIR) is recommended

Notes for Team meeting:

User report, Patient requiring ambulance, was monitored closely in ICU, diagnosed DKA. four similar events, no recall, no pmr. Spoken to [redacted] Submit to Team meeting for further discussion. Device being investigated by another person.

Outcomes from Team Meeting:

Check to see if the sponsor report exists, investigation required

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DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 16/02/2021	Severity: 5 - An illness/injury was resolved or prevented with treatment by a health professional	Incidents in the last 12 months:	Manufacturer analysis: Yes	Assessor: s22 [redacted]	Manufacturer documentation: Yes - manufacturer HAS documented issues or complications of this type
Incidents in last 24 months:	Manufacturer action: Unable to take action (device was not returned for analysis)	ESTIMATED LEVEL OF INVESTIGATION: Screening only	FINAL LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: Final: User, Known Complication.		Found Prior To Use: No	Is AE covered by current recall: No
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 4 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model: No
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL: Final: USer, Known Complication.			3 or more events - health district: No
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation: No
Products supplied Worldwide:	Consultations during risk assessment: I discussed issues with one of my peers	Final Risk Assessment: Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		

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	3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			
s22 @medtronic.com; s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:	
Additional Details (use for tables):	**CAPA# Reference:**	
	Risk Assessment	
	Frequency:	**Severity:**
	Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:	
Completed Actions:	**Planned Actions and Proposed Timelines:**
Additional Comments:	

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP2-Design/construction may not conform with principles	
EP13-Information may not have been provided	

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		26/03/2021	

Evidence

Investigation Questions (Level 1 and Level 2):

Does the sponsor know about this clinical event?

Potential Risks

Delays in response by product manufacturers: ☐

Delays in response by incident reporters: ☐

Delays in analysis within the TGA: ☐

Delays in reporting by other sources (e.g. clinical registries): ☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		01/03/2021	29/03/2021	29/03/2021		Dear s22 Please see the attached Questionnaire Letter for action. Please note the due date for a response is 29 March 2021. Kind regards,
☐		Reporter Routine Correspondence	Reporter Notification Letter		01/03/2021				
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA	s22 @health.gov.au	15/04/2021	03/05/2021	03/05/2021	D21-2600890	D21-2535476
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		09/06/2021				Letter D21-2718392 Email D21-2718401
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		09/06/2021				D21-2718732

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Output Problem	Incorrect, Inadequate or Imprecise Result or Readings	Incorrect Measurement		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	

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Endocrine, Metabolism and Nutrition	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
		s22	No	

Investigator's Notes:	Summary Findings:	Recall Number:
	The sponsor has noted that the device has not been returned for analysis, hence no root cause is able to be established for this event. A Review of the instructions for use noted that Diabetic Ketoacidosis is included in the list of 'Risks related to insulin administration and pump use'. The IFU also states 'The Guardian Sensor (3) is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor'. The TGA clarified the similar event rates provided by the sponsor and confirmed they are consistent with a search of the IRIS database. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

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This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Chemist/Pharmacy

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

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Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes			

Town/Suburb:	State:	Postcode:
s22	NSW	s22

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 68118 - Original User report	800	Form	
FILE		Medtronic Response DIR 68118 - Questionnaire L...	691	Form	
FILE		DEVICE INCIDENT REPORT DIR 68118 Reporter Com...	142	Form	
FILE		DEVICE INCIDENT REPORT DIR 68118 Sponsor Compl...	124	Form	

Flow Details : DIR-REQ - Device Incident Request : 294101

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
294101	DIR-REQ		Closed	s22	OPR Administration User	09/06/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/06/2021 15:48:49	
Comment		

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18/11/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 41 - ID : 512196

Released by [redacted] on 19/11/2020 14:40:19

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
66605	E20-398429		Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		[redacted]	18/11/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
18/11/2020	18/11/2020	24/11/2020	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
27/08/2021	Patient		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Specialist		For Team Meeting	

Event Description for Website Publication:

Noted the pump+sensor system, interferes with the ECG being performed.

Clinical Event Information:

Patient (person to contact) has type 1 diabetes and works as a psychiatry nurse. They are using the Medtronic 670G insulin pump and Guardian 3 continuous glucose monitoring system. They have noted on two occasions whereby the pump+sensor system, inteferes with the ECG being performed on the patient they are caring for. She showed me an ECG tracing of a patient with interrupted tracing through telehealth.

They also reports inteference to/by patient's duress alarms but I did not manage to clarify this based on time constraints of the consultation.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
2	Initial Reporter	[redacted]	[redacted]
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**
[redacted]	[redacted]		[redacted]

Recorded Problems Observed

Recorded Problems Observed:

Electrical /Electronic Property Problem -> Electromagnetic Compatibility Problem -> Radiofrequency Interference (RFI)

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> ->

Health Impact

Recorded Health Impacts:

No Health Consequences or Impact -> ->

Patient Information

Sex:	Weight:	Age:
Unknown		

Patient Focused Corrective Action Taken:

Patient History:

Medical information of patient's patient unknown to me.

Patient Outcome/Consequences:

The concern is interference with other medical devices of patients.

Additional Event Description:

I have contacted the patient to clarify the exact date of the events and to get a copy of the ECG printout but she has not gotten back to me.

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:

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ECG tracing of patient's patient with patient.	No Injury		

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			Email
Reporter Title:	First Name:	Surname:	
$	$2	$22	
Position:		Company/Institution:	
Endocrinologist		$22	
Address 1:	Address 2:	Town/Suburb:	State:
$22		$22	WA
Country:	Postcode:	Phone:	Fax:
Australia	$22		
Mobile:	Email:	Last External Submission By:	
	$22		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Yes			
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
Title:	First Name:	Surname:	
$2	$22	$22	
Position:		Company/Institution:	
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Country:	Phone:	Fax:
Mobile:	Email:	Allow the device company to contact you about the incident:	
$22	$22	☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	95763	95763	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Guardian 3 and Medtronic 670G, Continous glucose monitoring system (sensor+transmitter) plus insulin pump	Guardian 3 and Medtronic 670G, Continous glucose monitoring system (sensor+transmitter) plus insulin pump)	Single Use	
Model #:	Serial #:	Batch #:	Lot #:
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
	Self	With Patient	

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Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	1

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
		Australia	
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	12/11/2020	$2	$22
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
$22	$22		$22 @medtronic.com

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
24/11/2020	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:

No other DIRs/recalls. Unusual event, ? if IFU states anything about electrical interference with this device. Note: I changed the ARTG to be for the electrical component (pump) not the sensor, couldnt find ARTG for the system.

Outcomes from Team Meeting:

lv 2 investigation - Questionnaire; check IFU, see if there're relevant warnings (reminder to check the evidence page)

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

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Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 19/11/2020	Severity: 2 - No harm - but incident could have resulted in illness/injury (near miss)	Incidents in the last 12 months:	Manufacturer analysis:	Assessor: s22 [redacted]	Manufacturer documentation: Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	FINAL LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: No other DIRs/recalls. Unusual event, ? if IFU states anything about electrical interference with this device. Changed the ARTG to be for the electrical component (pump)		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment: Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To: s22 [redacted]	Address 1: PO Box 945	Address 2:	Town/Suburb: NORTH RYDE BC
State: NSW	Postcode: 1670	Phone:	Fax:
Email: s22 [redacted] @medtronic.com; s22 [redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		Details of Similar Events:	
Additional Details (use for tables):		CAPA# Reference:	
		Risk Assessment	
		Frequency:	Severity:
		Rating:	
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			
Completed Actions:		Planned Actions and Proposed Timelines:	
Additional Comments:			

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DIR Closed 27/08/2021

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP13-Information may not have been provided	

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		04/01/2021	27/01/2021

Evidence

Investigation Questions (Level 1 and Level 2):

1. What is the correct ARTG number for the device?
2. Does the IFU contain the information specified in 13.4(3)(3)?
3. IS the sponsor aware of this problem?
4. What is the rate of this issue in Australia (%)?
5. What is the rate of this issue WW(%)?

Potential Risks

Delays in response by product manufacturers: ☐

Delays in response by incident reporters: ☐

Delays in analysis within the TGA: ☐

Delays in reporting by other sources (e.g. clinical registries): ☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation: Case Closure

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		02/12/2020	27/01/2021	27/01/2021	Extension request granted, Original date due 06/01/2021 Response D21-2115465	
☐		Reporter Routine Correspondence	Reporter Notification & Request for Information Letter		08/01/2021	29/01/2021		More time given for patient to provide the response. 15/01/21	s22 [redacted] requested for TGA to obtain any information from the patient. letter forwarded to the patient
☐		Sponsor Routine Correspondence	Email to Sponsor		19/01/2021				Sponsor emailed to enquire if reporter has provided requested

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								information, advised this has not yet been received.	
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA	s22 @health.gov.au	08/02/2021	10/03/2021	01/03/2021	D21-2320876	what is meant by 'environmental' and how many of these events is consistent with the description of this DIR	
☐		Referral Routine Correspondence		s22 @health.gov.au	05/03/2021	21/04/2021			D21-2352658 request for engineering review	
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA	s22 @health.gov.au	03/05/2021	23/06/2021	30/07/2021	Email from sponsor D21-2696987 request extension Extension granted D21-2702927 Test reports D21-2904472	letter D21-2596702 Email D21-2598662	
☐		Referral Routine Correspondence			14/07/2021	30/08/2021	23/08/2021	D21-2916236	Engineering request rd 2vD21-2845888	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		27/08/2021				D21-3029138 Email D21-3029441	
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		27/08/2021				D21-3029476 D21-3029053 letter	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Electrical /Electronic Property Problem	Electromagnetic Compatibility Problem	Radiofrequency Interference (RFI)		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition			

Health Impact

Details			
Level 1	Level 2	Level 3	
No Health Consequences or Impact			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available			Device not returned	

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

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Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
		s22	No	

Investigator's Notes:	Summary Findings:	Recall Number:
Sponsor confirms no similar events in Australia https://www.medtronic-diabetes.com.au/sites/default/files/m988666a021doc_2_final_web_670g_ifu.pdf notes possible interference pg 311. 1.Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones, Wi-Fi, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications. 2.Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.	The TGA conducted engineering reviews on the information provided by the sponsor. These reviews confirmed no detectable evidence of electromagnetic interference was identified in the testing reports provided. Review of the instructions for use (IFU) confirmed they meet the Australian regulatory requirements. The sponsor confirmed that they have not received any reports of similar events. This consistent with a search of the IRIS database. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
313741	Medtronic Minimed	Medtronic Australasia Pty Ltd	Subcutaneous glucose sensor	Guardian Sensor (3) - Subcutaneous glucose sensor	
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

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		Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Supplier

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 66605 - Original User report	178	Form	
FILE		DIR 66605 Questionnaire - Medtronic Response	660	Form	

FILE		Reporter Complete Letter DIR 66605	140	Form	Document 48
FILE		Sponsor User Complete Letter DIR 66605	123	Form	

Flow Details : DIR-REQ - Device Incident Request : 286535

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
286535	DIR-REQ		Closed	s22	OPR Administration User	27/08/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	27/08/2021 13:52:39	
Comment		

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02/10/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 43 - ID : 508182

Released by s22 on 04/03/2021 17:04:25

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
65755	E21-229071	CASE-2020-00699801/03/04/05	Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	02/10/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
29/01/2021	02/10/2020	09/02/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
15/04/2021			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For Team Meeting	

Event Description for Website Publication:

Hyperglycaemia

Clinical Event Information:

It was reported that the customer was rushed to hospital as she had collapsed with blood glucose level of 2.2 mg/dL. Customer stated that she was treated but it was too late. It was unknown whether the auto mode feature was on or not. Insulin delivery was not suspended due to sensor glucose versus blood glucose difference. The insulin pump will be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Hospitalization or Prolonged Hospitalization -> ->

Patient Information

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Patient Outcome/Consequences:		**Additional Event Description:**	
Describe any test (Lab, xray, etc.):	**Injured - Extent of Injury:**	**Consequence:**	**Other medical devices currently using/implanted:**
	Temporary Injury		
Medical Problem Device Used For:	**Additional Patients Added:**		

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0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			
Reporter Title:	**First Name:**	**Surname:**	
$	$22	$2	
Position:		**Company/Institution:**	
Associate PMV Specialist		Medtronic Australasia Pty Ltd.	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road, Macquarie Park, NSW, 2113	2 Alma Road, Macquarie Park, NSW, 2113	Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	$22	
Mobile:	**Email:**	**Last External Submission By:**	
	$22	113429_837 - 29/01/2021 12:13	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
Yes			
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Country:**	**Phone:**	**Fax:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**	
		☐	

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	Reuse of Reusable	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
MMT-1782K	NG2035187H		HG3VB5X
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
		With Supplier	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

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Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	11/08/2018	3

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	

Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	Email:

Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	s22		

Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Country:	Postcode:

Phone:	Fax:	Email:	Website:

Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:

Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	CAPA initiated , however no details given	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:

4 other event in past 6 months of hyperglycaemia, no recall or PMR relevant to issue. The investigation states 'pump received with a high Sleep Current Measurement and Active Current Measurement due to corroded battery tube.' There was no information provided about if this is a known issue, or what action was taken to resolve the issue. Should this pump be kept dry and is it in the IFU?.Does this need to be looked at further?

Outcomes from Team Meeting:

Full CAPA analysis is required, how does the alarm set up, level 2 investigation required

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
02/10/2020	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)		Patient	1. Recalls for similar incidents in Australia have occurred within the past

					12 months Document 49
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		RC-2019-RN-01694-1- relating to loose reservoir due to broken or missing retainer ring- may result in hypoglycaemia/hyperglycaemia		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	3 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine			No
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	04/02/2021	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 3 Investigation (for multiple DIRs/a DII)	**Level 1 Investigation (to complete screening)**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**1. Recalls for similar incidents in Australia have occurred within the past 12 months**			Analysis for incident is incomplete Referred to team meeting	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No			Yes - multiple potential factors (more than 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**4 incidents**		Compatibility of device - patient characteristics, Use of device - interaction with other equipment, Use of device - operator/user error, Management of device - performance over time	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
		Yes		Yes - some potential sensitivities (up to 3)		
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		Unknown		Device used in high risk populations		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
		Unknown			**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:

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837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
$22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	$22	
Email:			
$22 ; $22 @medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Corrective/Preventative Actions:
The pump passed the self test, rewind test, prime/seating test, basic occlusion test, occlusion test, force sensor test, displacement test and DAT at 0.08730 inches. However, pump received with a high Sleep Current Measurement and Active Current Measurement due to corroded battery tube. The test Guardian Link with the Glucose Sensor Simulator and the test BG meter communicates properly to the pump. Pump programmed with multiple SG value and all registered properly in the Summary History noted.	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:	Additional Details (use for tables):
In Australia 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953 units (0%) sold in CY2019; 1 similar events from 411 units (0.24331%) sold in CY2020; WorldWide 31 similar events from 124525 units (0.02489%) sold in CY2018; 43 similar events from 111395 units (0.0386%) sold in CY2019; 31 similar events from 13371 units (0.23185%) sold in CY2020;	
CAPA# Reference:	

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

United States

Completed Actions:	Planned Actions and Proposed Timelines:
Additional Comments:	

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP13-Information may not have been provided	

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		17/03/2021	

Evidence

Investigation Questions (Level 1 and Level 2):

1. Please provide the detailed CAPA analysis in our report.
2. Please explain if it is required to set up an alarm.

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:
	Case Closure

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		17/02/2021	17/03/2021	16/03/2021		
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		15/04/2021				Trim D21-2535495

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available				

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Hospitalization or Prolonged Hospitalization			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
		s22 [redacted]	No	

Investigator's Notes:	Summary Findings:	Recall Number:
	The sponsor was asked to explain if it is required to set up an alarm and they have confirmed that the alert cannot be silenced and is always enabled, whether the pump is in Auto Mode or Manual Mode. Additional alarms can be set to alert on or before a low SG value which can be set manually and suspend insulin delivery due to a suspend on low or suspend before low event. This information was evaluated and verified from the Minimed 670G system User Guide. Therefore, no further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
313741	Medtronic Minimed	Medtronic Australasia Pty Ltd	Subcutaneous glucose sensor	Guardian Sensor (3) - Subcutaneous glucose sensor	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-7020C5					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		

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MMT-326A					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	Unknown
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-386A					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

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Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:

Town/Suburb:	State:	Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Medtronic Response - DIR 65755 - Questionnaire...	560	Form	
FILE		DIR 65755_Sponsor_Complete_Letter	464	Form	

Flow Details : DIR-REQ - Device Incident Request : 280733

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
280733	DIR-REQ		Closed	s22	OPR Administration User	15/04/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	15/04/2021 10:49:06	
Comment		

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25/08/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 38 - ID : 505852

Released by s22 on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
65028	E20-334193		Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	25/08/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
25/08/2020	25/08/2020	01/09/2020	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
30/09/2020			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

The maximum bolus will not allow beyond 25u of insulin.

Clinical Event Information:

I have recently upgraded to a Medtronic 670g insulin pump from a Medtronic Paradigm pump.

There is a fault in the product where the maximum bolus will not allow beyond 25u of insulin. This arbitrarily determined number does not take into consideration the following:
1) Insulin to carbohydrate ratio at time of dose
2) Insulin sensitivity ratios at time of dose
3) BSL at time of dose
4) Amount of carbohydrate being consumed

Please inform Medtronic that whilst a "Maximum bolus" function is useful, placing a "cap" on the number of units does not allow for correct diabetes management.

Recently, Friday night, is a prime example of not being able to dose correctly for the amount of carbohydrate consumed: https://drive.google.com/file/d/1MYyknZhZaAjNQMJzbF1kdtNz1Ka24I4P/view?usp=sharing

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
2	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> No Device Output ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Endocrine, Metabolism and Nutrition -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

No Health Consequences or Impact -> ->

Patient Information

Sex:	Weight:	Age:
Male	s	s

Patient Focused Corrective Action Taken:

Patient History:

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Type 1 Diabetes.

Patient Outcome/Consequences:

Additional Event Description:

Administration in the way of health management.

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Near Miss

Other/Near Miss:

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: S

Reporter #:

Preferred Contact Method: Email

Reporter Title: S

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country: Australia

Postcode:

Phone: s22

Fax:

Mobile:

Email: s22

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 308140

Device ARTG #: 308140

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic 670g insulin pump - Infusion pump, insulin, ambulatory

Initial Device Description: Medtronic 670g insulin pump - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version: 4.11J

Model #: 670g MMT-1782

Serial #: NG2294248H

Batch #:

Lot #:

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Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
13/08/2020			
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
13/08/2020		With Patient	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
		Australia	
Phone:	**Fax:**	**Email:**	**Website:**
1800 777 808			
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes			
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
01/09/2020	Event is a serious one needing further consideration	Investigation (within DIR) is recommended

Notes for Team meeting:
4 incidents in the past 6 months, No recalls related to this issue, User's query in the CEI needs further response from the sponsor/Manufacturer.

Outcomes from Team Meeting:
Obtain comment from sponsor - investigate

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

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Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 25/08/2020	Severity: 2 - No harm - but incident could have resulted in illness/injury (near miss)	Incidents in the last 12 months:	Manufacturer analysis:	Assessor: s22 [redacted]	Manufacturer documentation: Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	FINAL LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 4 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model: No
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district: Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation: Unknown
Products supplied Worldwide:	Consultations during risk assessment: I undertook an internet search (e.g., Google)	Final Risk Assessment: Yes			

Sponsor/Manufacturer Information Section

Search Sponsors: 837	Name: Medtronic Australasia Pty Ltd		Client #: 837
Attention To: s22 [redacted]	Address 1: PO Box 945	Address 2:	Town/Suburb: NORTH RYDE BC
State: NSW	Postcode: 1670	Phone: s22 [redacted]	Fax:
Email: s22 [redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		Details of Similar Events:	
Additional Details (use for tables):		CAPA# Reference:	
		Risk Assessment	
		Frequency:	Severity:
		Rating:	
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			

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Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Rate information is required	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		30/09/2020	18/09/2020

Evidence

Investigation Questions (Level 1 and Level 2):

Please comment on why the Medtronic 670g insulin pump will not allow the maximum bolus of insulin to go beyond 25u?

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☐	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:
Case Closure	

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		02/09/2020				
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		02/09/2020	30/09/2020	24/09/2020	D20-3435778	
☐		Sponsor Routine Correspondence	Email to Sponsor		28/09/2020			D20-3452431 confirmed to be 308140	D20-3450754 - Request to confirm correct ARTG

☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		30/09/2020				D20-3470124 Document 50	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		30/09/2020				D20-3470200	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Output Problem	No Device Output			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Endocrine, Metabolism and Nutrition	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
No Health Consequences or Impact			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
No Problem Detected			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
IFU D20-3190506	The manufacturer has confirmed that the Maximum bolus is a safety measure that limits the amount of insulin that can be delivered in a single bolus to 25 units of insulin. They also stated that the device was	

	designed to follow conservative settings to better prevent Hypoglycemia incidents. A review of the Instructions for use (IFU) has noted Bolus settings are mentioned (pg 80 Max bolus), which states; 'Bolus settings provides a safety measure by limiting the total amount of bolus insulin you can program for a single bolus delivery and Max Bolus limits the amount of insulin that can be delivered in a single bolus. Your pump prevents single bolus insulin deliveries that exceed the max bolus you set. You can set your max bolus from 0 to 25 units. Set your max bolus as prescribed by your healthcare professional'. The manufacture has noted only a few complaints in relation to this safety feature, also noting none of the complaints received involved a clinical event that required medical intervention for the user. This is consistent with a search of the IRIS database. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	Document 50

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	

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Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Hospital

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1: s22 [redacted]

Address Line 2:

Town/Suburb: s22 [redacted]

State: ACT

Postcode: s22 [redacted]

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 65028 - Original User Report	592	Form	
FILE		RE DIR 65028 - Questionnaire Letter - received	546	Form	
FILE		DVMS_Reporter_Complete_Letter DIR 65028	123	Form	

Flow Details : DIR-REQ - Device Incident Request : 276975

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
276975	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	30/09/2020	Normal	0

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Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	23/11/2020 15:12:56	
Comment		

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22/04/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 41 - ID : 495444

Released by s22 on 19/11/2020 14:40:19

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
63123	E20-66383		Final

ARTG: 308140

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed			20/04/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
20/04/2020	22/04/2020	28/04/2020	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
05/02/2021			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For Team Meeting	

Event Description for Website Publication:

There is one fault in the programming that has caused me to have a number of Hypos over the last three months, and a many instances where the pump delivered insulin when the BGL was close to the safe minimum.

Clinical Event Information:

I am a type 1 diabetic and am using a Medtronic 670G pump and the Guardian 3 Sensors to control the insulin delivery. The system has improved my HbA1c considerably over the previous methods, however there is one fault in the programming that has caused me to have a number of Hypos over the last three months, and a many instances where the pump delivered insulin when the BGL was close to the safe minimum. Attached is a report for the some of days involved. I have circled when the insulin has been injected.

I have had a number of representations to Medtronic and they defend the system, and they have no answer to how this can be fixed. The people I spoke to did not think they could get any action of getting the pump reprogrammed, so I am writing to you to get the problem fixed ot the product recalled.

The pump is set to suspend on a low of 5 mmo however this does not work correctly and it still injects insulin. This risk is increased because of the inaccuracy of the sensor. Sometimes it is out by 2 or 3 mmo. This morning it showed 6.8 and it was in fact 3.9 and I was having a hypo. This is extreme. I would say that 90% of the time it is spot on and maybe once a week it is out by about 2 mmo. If the pump didn't deliver below 5mmo this wouldn't matter. There is "Suspend on Low" feature which is set to on but it doesn't work. Medtronic thought that this doesn't work in auto mode???

Fortunately I have been waking up when my BGL gets too low but I am aware that some people just go into a diabetic coma. This is a significant safety risk and could easily cause a fatality.

01/05/2020 - Additional information received from reporter by email:

Dear Sirs,

I wrote an email on 20th April (copy below) regarding a potentially life threatening fault with the Medtronic 670G Insulin pump and sensor combination.

Since that time I have had instances of insulin being delivered when the BGL was below 5.0 and twice inducing a hypo. The worst of these when I did a finger prick check my BGL was 2.3 mmol which is the lowest I have ever recorded and in the dangerous category. The sensor was out of calibration by 1.5 mmol high even though it had been calibrated at midnight.

I have been passing this on the Medtronic and yesterday they did a test of the transmitter and discovered it was faulty and are replacing it.

This highlights that the system has a programming error as the pump should go into a safe mode, especially if it detects a fault, not provide extra insulin. it should FAILSAFE.

Perhaps you can give them a nudge to get this fixed ASAP.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Output Problem -> Incorrect, Inadequate or Imprecise Result or Readings -> Incorrect Measurement;
Output Problem -> Unexpected Therapeutic Results ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

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Endocrine, Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Change in Therapeutic Response -> ->

Patient Information

Sex:

Weight:

Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Preferred Contact Method:

Reporter Title:

First Name:

Surname:

$ $22 $22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Mobile:

Email:

Last External Submission By:

$22

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

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Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	308140	308140	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	35983	Infusion pump, insulin, ambulatory
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory	Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory		
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
670G			
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:
Medtronic Minimed	40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:	Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

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Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
28/04/2020	User report	Investigation (within DIR) is recommended

Notes for Team meeting:

No DIR's for this event. No PMR No Recall The reporter mentions 2 isues- the sensor is not providing accurate results and the device is providing insulin when "Suspend on Low" feature is set. ? do we get the reporter to submit another DIR for the Sensor and also get info form the sponsor why the "Suspend on Low" feature may have failed?

Outcomes from Team Meeting:

Confirm the ARTG number for The device. Seek information from the sponsor as to why are not able to rectify this issue. And why the 'suspend on Low' capability does work on Auto mode.

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
22/04/2020	4 - An illness/injury resolved without treatment by a health professional (or by self-management)		No	s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	Unable to take action (device was not returned for analysis)	Level 1 Investigation (to complete screening)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	Yes - some potential sensitivities (up to 3)				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
	Device used in high risk populations				
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		

Email:

s22

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:

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Additional Details (use for tables):	CAPA# Reference:
	Risk Assessment
	Frequency: / Severity:
	Rating:

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Sensitivities - requests for information	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected
EP13-Information may not have been provided	

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		28/05/2020	01/05/2020

Evidence

Investigation Questions (Level 1 and Level 2):

Questionaire
IFU

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☑	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

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Next Steps for Level 1 Investigation:

For Level 2 Investigation

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		01/05/2020				
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		01/05/2020	29/05/2020	29/05/2020		
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA	s22 @health.gov	30/06/2020	30/07/2020	21/07/2020		D20-957255
☐		Referral Routine Correspondence	Referred to Clinical	s22 @health.gov.au	24/09/2020	05/11/2020		D20-3545400	
☐		Sponsor Routine Correspondence	Email to Sponsor		28/09/2020				D20-3450754 - Request to confirm correct ARTG
☐		Sponsor Routine Correspondence	Sponsor Request for Information Letter - s41JA	s22 @health.gov.au	22/10/2020	30/11/2020	30/11/2020	request for extension D20-3778811 Response D20-3845818	D20-3596376 Extension D20-3778879
☐		Referral Routine Correspondence	Referred to Clinical	s22 @health.gov.au	18/12/2020	29/01/2021	13/01/2021	D21-2067574	D20-3958854

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Output Problem	Incorrect, Inadequate or Imprecise Result or Readings	Incorrect Measurement	
Output Problem	Unexpected Therapeutic Results		

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Endocrine, Metabolism and Nutrition	Hypoglycemia	

Health Impact

Details

Level 1	Level 2	Level 3
Change in Therapeutic Response		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			Device not returned

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Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:

Rd 1 The Medical Devices Clinical Section- does not satisfy EP 1, 2, 3, 6, 13 and 14
Rd 2 justification provided to demonstrate compliance with EP1,2,3,6,13 and 14

Summary Findings:

Review of the information provided by the user, the sponsor and the manufacturer was conducted by the TGA which included evaluation by the Medical Devices Clinical Section. The MINIMEDTM 670G System User Guide and the Minimed 670g getting started guide – auto mode' (current Instructions for Use (IFU)) were reviewed and demonstrated ongoing compliance with regulatory requirements.
The MINIMEDTM 670G System User Guide informs the user that the suspend on low is not active when the Smartguard Auto mode is active. It states,"When SmartGuard Auto Mode is active, the SmartGuard suspend features are unavailable and automatically turned off. If you are using Suspend before low or Suspend on low, they are automatically turned off when Auto Mode becomes active. If your pump exits Auto Mode, the SmartGuard suspend features are not active until you turn them on after you exit Auto Mode. The IFU also provides a reminder to the user to manually turn the SmartGuard suspend features on. It states "If you want to use the SmartGuard suspend features, you must manually turn them on after you exit Auto Mode."

Review of the 'Minimed 670g getting started guide – auto mode' (IFU) provides information about the Auto Mode algorithm that will transition the pump to Safe Basal (as a safe mode) . It states, "There are times in Auto Mode when basal insulin is being delivered according to your recent insulin needs, but is not being adjusted based on an SG reading. This is called Safe Basal". The circumstances the 'Safe Basal' is activated are (pg 21):
1. An SG reading is not available because your transmitter and pump are not communicating, or the sensor calibration has expired.
2. Your sensor might be reading lower than your actual glucose values.
3. Your BG value is different from your SG value by 35% or more.
4. After you change your sensor, during the sensor warm up.
5. Auto Mode has been at your personal minimum Auto Mode basal delivery rate for 2 1/2 hours.
6. Auto Mode has been at your personal maximum Auto Mode basal delivery rate for 4 hours.

The sponsor noted when the pump enters Safe Basal, the pump will issue an alert if an action is required by the user, and the Auto Mode shield appears with a white outline. The IFU also states the duration of the time the device will stay in Safe Basal is "The maximum time your pump will stay in Safe Basal is 90 minutes.". It also states, "At other times, when the pump is in Safe Basal and there is an action you can take to help resolve the issue, you will receive an alert that indicates the action to take. Examples of these actions are entering a calibration, entering a new BG, or responding to a Lost Sensor alert."
The manufacturer has confirmed no other reported similar events in Australia and this is consistent with a search of the TGA database. The TGA encourages patients with diabetes to consult regularly with their treating doctor with regards to tailoring their insulin pump device to their specific circumstances.

No further investigation will occur at this time however the TGA will continue to monitor the rate and pattern of occurrence and may re open the file as appropriate.

Recall Number:

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

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This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		**Patient History:**	
Injured - Extent of Injury:	**Was device directly linked to death?:**	**Was device directly linked to permanent disabiltiy?:**	**Consequence:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

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Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:

Town/Suburb:	State:	Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 63123 - Original User Report	109	Form	
FILE		Additinal information from reporter - Medtroni...	146	Form	
FILE		DIR 63123 - Additional information from Reporter	296	Form	
FILE		DIR 63123 - Questionnaire Letter - Response	503	Form	
FILE		TGA Augt 20 ltr	23	Form	
FILE		s22 2-09-2020 to TGA	16	Form	
FILE		scan Medtronic Report 020920200001	573	Form	
FILE		TGA Reporter_Complete_Letter_DIR 63123	126	Form	
FILE		Sponsor_Complete_Letter_DIR 63123	170	Form	

Flow Details : DIR-REQ - Device Incident Request : 261793

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
261793	DIR-REQ		Closed	s22	OPR Administration User	05/02/2021	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	05/02/2021 11:48:42

Comment		

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16/01/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 38 - ID : 479790

Released by s22 on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
61609	E20-72530	CASE-2020-00020427	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	16/01/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
08/05/2020	16/01/2020		07/05/2020
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/07/2020	Carer		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

Pump overdelivered insulin.

Clinical Event Information:

Medtronic received notification that a customer had a low blood glucose event. The customer is alleging that the pump overdelivered insulin.

Trouble shooting was performed. Programming confirmed to be inaccurate.

Medtronic has requested that the pump be returned for analysis.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Excess Flow or Over-Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Metabolism and Nutrition -> Hypoglycemia -> ;
Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Unexpected Medical Intervention -> Medication Required ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:	Patient History:
Carer administered glucose tables.	
Patient Outcome/Consequences:	**Additional Event Description:**
Patient has disconnected from the pump and has reverted to back-up plan.	

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:

Other medical devices currently using/implanted:

Medical Problem Device Used For: Document 52

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

$2

Reporter #:

Preferred Contact Method:

Reporter Title:

$2

First Name:

$22

Surname:

$22

Position:

PMV Manager

Company/Institution:

Medtronic Australasia Pty Ltd

Address 1:

2 Alma Road

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

$22

Fax:

Mobile:

Email:

$22

Last External Submission By:

$22 _837 - 08/05/2020 09:56

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:

No

Search Device ARTG:

95763

Device ARTG #:

95763

Therapeutic Licence Type:

Medical Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

35983

GMDN / UMDN Text:

Infusion pump, insulin, ambulatory

Brand Name:

Minimed 640G pump - Infusion pump, insulin, ambulatory

Initial Device Description:

Minimed 640G pump - Infusion pump, insulin, ambulatory

Usage of Device:

Reuse of Reusable

Software Version:

Model #:

MMT-1711KL

Serial #:

NG1437260H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

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		With Patient	
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	2

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	$22	$2	$22
Contact Surname:			
$22			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Increase in rate or rates not complete	Investigation (within DIR) is recommended

Notes for Team meeting:

3 DIR's in last 6 motyhs sponsor notes 1 in last 3yrs. Recalls for other issues. PMR for usablilty in 2015. Do we want to clarify the rates?

Outcomes from Team Meeting:

Ask for correct rates.

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

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Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
17/01/2020	0 - Insufficient information to determine level of severity			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
		awaiting final report		No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	Yes - some potential factors (up to 3)			Yes	3 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
	Use of device - operator/user error, Management of device - performance over time	Routine	Routine		No
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				Unknown
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
					Unknown
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details: Statistics Checklist Section

Update Device Details?: Yes

Copy Data From: Initial

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
11/05/2020	**4 - An illness/injury resolved without treatment by a health professional (or by self-management)**		Yes		
Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
s22 [redacted]	**Unknown - updated information from the manufacturer is required**		Not required (device was performing within specified parameters)	Level 1 Investigation (to complete screening)	**Level 1 Investigation (to complete screening)**
Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
Patient	**0. No recalls for similar incidents in Australia**	1			
Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
No		92	Yes - some potential factors (up to 3)		
Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
Yes	**3 incidents**		Use of device - operator/user error, Management of device - performance over time	Routine	**Routine**
	3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
	No		No		
	3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
	Unknown	21568			

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3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
Unknown	354569	I did none of the above incidents	**Yes**

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670		
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. No over-delivery anomaly was noted during testing. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, and scratched display window. Analysis testing identified the insulin pump met specifications.

Corrective/Preventative Actions:

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:

Similar events* in Australia in the past 3 years: 1
Similar events* worldwide (Australia excluded) in the past 3 years: 92
*Similar event data is generated using FDA Annex A code
Sales in Australia in the past 3 years: 21568
This correlates to a complaint rate of 0.0046%
Sales worldwide (Australia excluded) in the past 3 years: 354,569
This correlates to a complaint rate of 0.0259%

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Austria, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Saudi Arabia, Spain, Sweden, United Kingdom.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Rate information is required	

Focus of Level 2 Investigation

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Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		03/06/2020	03/06/2020

Evidence

Investigation Questions (Level 1 and Level 2):

Clarification on rates

Potential Risks

Delays in response by product manufacturers:	Delays in response by incident reporters:	Delays in analysis within the TGA:	Delays in reporting by other sources (e.g. clinical registries):
☐	☐	☐	☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:	Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		TGA Regulatory Action	Final Report Due		17/01/2020	28/04/2020		Not received	
☐		Sponsor Routine Correspondence	Sponsor Request for a Final Report Letter - s41JA		04/05/2020	18/05/2020	08/05/2020		
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		20/05/2020	17/06/2020	04/06/2020		
☐		Sponsor Routine Correspondence	Email to Sponsor		22/06/2020		29/06/2020	D20-958026	D20-912943
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		09/07/2020				D20-1016872

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Excess Flow or Over-Infusion			

Clinical signs symptoms and conditions

Details	

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Level 1	Level 2	Level 3	
Others	Insufficient Information		
Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Unexpected Medical Intervention	Medication Required		

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The sponsor has provided the rates for overdelivery and hypoglycaemia. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

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Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
169959	Medtronic Minimed	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	HG3PUM6
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT-326A					

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
119216	Unomedical A/S	Medtronic Australasia Pty Ltd	Infusion administration set, insulin pump	Infusion administration set, insulin pump	5286744
Model Number:	Batch #:	Lot #:	Expiry Date:		
MMT- 941					

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Document 52

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:

Town/Suburb:	State:	Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		RE DIR 61609 - Request For Information (RFI) L...	66	Form	
FILE		DIR 61609_Sponsor_Completion_Letter	282	Form	

Flow Details : DIR-REQ - Device Incident Request : 242626

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
242626	DIR-REQ		Closed	s22	OPR Administration User	09/07/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	09/07/2020 14:08:57	
Comment		

Document 53

13/01/2020
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 37 - ID : 479684

Released by Theta Technologies on 11/03/2020 10:28:02

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
61530	E20-25098		Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	13/01/2020
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
13/01/2020	13/01/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
16/10/2020			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

Unexpected delivery of insulin

Clinical Event Information:

The Medtronic 640g Insulin Pump delivered additional insulin, to almost 10 units, in the space of 50 minutes and started a temporary basal of 200% for 3 hours.
This caused an insulin overdose in my 5 year old son, which was only just treated at home due to being detected so early.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Infusion or Flow Problem -> Excess Flow or Over-Infusion ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Metabolism and Nutrition -> Hypoglycemia ->

Health Impact

Recorded Health Impacts:

Minor Injury/ Illness / Impairment -> ->

Patient Information

Sex:	Weight:	Age:
Male	s	s22

Patient Focused Corrective Action Taken:

Patient History:

None

Patient Outcome/Consequences:

Insulin overdose, led to low blood sugars (2-3.5) from 11:15am through to 8pm that night.
Hospital was called, however due to diagnosis time and ability t o keep him drinking\eating sugars we did not go to hospital.
s22 diabetes team will have a record of the call

Injections were done over next 36 hours, replacement pump arrived on Friday morning.
Pump was running newer firmware (4.11 vs 2.9D on faulty pump) sow as connected and has been closely monitored since.

Additional Event Description:

Pump shows 4 logs related to the event:
10:15am AWST - Temp basal started 200% for 3 hours
*10:15am AWST - Modification Bolus delivered 3.9units
11:03am AWST - Carb Bolus of 38g (2u) + modification bolus*\ of 1.9u for total of 3.9u delivered
*11:11am AWST - Modification Bolus delivered 3.9units

Document 53

*No CGM is connected nor was any BG or carbs entered during these deliveries

Type-1 Babysitter [redacted] called Medtronic after smelling insulin like sweat, then they disconnected the pump and insulin projected out of the connection to the cannula, like i was pressurized.
The pump was disconnected at 11:15am
[redacted] also has Type 1 diabetes and treated [redacted] until my Wife and I arrived home
[redacted] heart rate was about 120 and was very dozy during the first 3 hours

Once we spoke to PCH Diabetes department they advised as it was over the first 2 hours and he was conscious and able to eat we were best to continue to self manage at home

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Near Miss

Other/Near Miss:

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: [redacted]

Reporter #:

Preferred Contact Method: Email

Reporter Title: [redacted]

First Name: [redacted]

Surname: [redacted]

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country: Australia

Postcode:

Phone: [redacted]

Fax:

Mobile:

Email: [redacted]

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name:

Initial Device Description:

Usage of Device:

Software Version:

Document 53

Medtronic 640G Insulin Pump - Infusion pump, insulin, ambulatory	Medtronic 640G Insulin Pump - Infusion pump, insulin, ambulatory	Reuse of Reusable	2.9D
Model #:	Serial #:	Batch #:	Lot #:
MMT-1711	NG1437260H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
12/12/2018		s22	s22
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
	Right thigh	With Patient	
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:
Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Originally supplied ~s22 in hospital following diagnosis on 21st March this was a replacement unit following an urgent recall TGA Reference: RC-2018-RN-01321-1			
Town/Suburb:	State:	Country:	Postcode:
		Australia	
Phone:	Fax:	Email:	Website:
s22			
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Yes	08/01/2020		
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:

USER REPORT : I am unsure what this means: 'Pump was running newer firmware (4.11 vs 2.9D on faulty pump)' Found in Report info - patient info - patient outcomes section. Was the pump already faulty or does this mean something else? 2 similar events in the past 6 months.

Outcomes from Team Meeting:

Document 53

Send standard questionnaire for manufacturer's analysis.

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 16/01/2020	Severity: 4 - An illness/injury resolved without treatment by a health professional (or by self-management)	Incidents in the last 12 months:	Manufacturer analysis: No	Assessor: s22 [redacted]	Manufacturer documentation: Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	FINAL LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: Device not returned. Only 2 similar events in the past 6 months. Previous PMR 2015. Send to team meeting.		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 2 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment: Yes			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	

Document 53

3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:	
3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	CAPA# Reference:
	Risk Assessment
	Frequency: / Severity:
	Rating:

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		14/02/2020				
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		14/02/2020	13/03/2020	13/03/2020		
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		15/06/2020				D20-875349
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		15/06/2020				D20-875401

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List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Infusion or Flow Problem	Excess Flow or Over-Infusion			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Metabolism and Nutrition	Hypoglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Minor Injury/ Illness / Impairment			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause cannot be Traced to Device			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The manufacturer confirmed they have conducted a pump trace download and specification analysis on returned device. Review of the outcomes of the manufacturer's analysis of the device and trace download, confirmed the device passed all analysis testing and was found to meet functional specifications. The manufacturer noted there was no over delivery anomaly, no under delivery anomaly, no prime/fill anomaly, no unexpected bolus delivery anomaly, bolus anomaly, basal anomaly or (TDD) total daily dose anomaly during their testing. In addition, in the test P-Cap and reservoir did lock in place in the reservoir compartment. The manufacturers noted the following from the trace download; the Temp Basal on 1/8/2020 was programmed at the user end; the device programmed was programmed at the user end and delivered the 3.9 unit bolus on 01/08/2020 10:15:51; on 01/08/2020 11:03:40 and on 01/08/2020 11:11:37 (per button presses). From the pump memory, the manufacturer noted; the sensor was not used on Jan 8, 2020; the temporary basal of 200% of basal rate and the three 3.9U boluses were programmed at	

	the user end. It was also noted the boluses were often given without BG input. The manufacturer has confirmed 17 Similar events since 2015. This is consistent with a search of the TGA database. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	Document 53

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Document 53

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1: s22

Address Line 2:

Town/Suburb: s22

State: WA

Postcode: s22

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		IMG_3223	855	Form Item	Report Information Section / Brand Name
FILE		IMG_3224	801	Form Item	Report Information Section / Brand Name
FILE		IMG_3225	733	Form Item	Report Information Section / Brand Name
FILE		IMG_3226	909	Form Item	Report Information Section / Brand Name
FILE		IMG_3227	1043	Form Item	Report Information Section / Brand Name
FILE		IMG_3228	718	Form Item	Report Information Section / Brand Name
FILE		IMG_3229	860	Form Item	Report Information Section / Brand Name
FILE		IMG_3230	686	Form Item	Report Information Section / Brand Name
FILE		IMG_3231	683	Form Item	Report Information Section / Brand Name
FILE		IMG_3232	816	Form Item	Report Information Section / Brand Name
FILE		IMG_3233	707	Form Item	Report Information Section / Brand Name
FILE		IMG_3234	775	Form Item	Report Information Section / Brand Name
FILE		IMG_3235	746	Form Item	Report Information Section / Brand Name
FILE		IMG_3236	770	Form Item	Report Information Section / Brand Name

Document 53

FILE		DIR 61530 - Original User Report	325	Form
FILE		DIR 61530 - Questionnaire received	667	Form
FILE		TGA DIR 61530 -DVMS_Reporter_Complete_Letter~2...	124	Form
FILE		DIR 61530- DVMS_Sponsor_Complete_Letter~2020-06-15	124	Form

Flow Details : DIR-REQ - Device Incident Request : 242319

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
242319	DIR-REQ		Closed	s22	OPR Administration User	15/06/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	16/10/2020 17:38:31	
Comment		

Document 54

27/10/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 33 - ID : 452648

Released by Theta Technologies on 01/11/2019 15:13:08

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
60132	E19-668856		Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22 [redacted]	27/10/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
27/10/2019	27/10/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
15/06/2020			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Carer		For IRIS Meeting	

Event Description for Website Publication:

My Daughters Medtronic 640g Insulin Pump, had a major failure, with extremely loud alarms, and had 10 errors.

Clinical Event Information:

My Daughters Medtronic 640g Insulin Pump, had a major failure, with extremely loud alarms, and had 10 errors
4
3
68
49
49
23
68
49
49
23

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Electrical /Electronic Property Problem -> Failure to Conduct ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Metabolism and Nutrition -> ->

Health Impact

Recorded Health Impacts:

No Health Consequences or Impact -> ->

Patient Information

Sex:	Weight:	Age:
Female	s [redacted]	s22 [redacted]

Patient Focused Corrective Action Taken:

Patient History:

Document 54

Patient Outcome/Consequences:
The pump was replaced a few days later by medtronic

Additional Event Description:
We have had other pumps fail, but never this many alarms go off

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury:
No Injury

Other medical devices currently using/implanted:

Medical Problem Device Used For:
Other (not listed above)

Other Medical Problem:
Diabetes Type 1

Additional Patients Added:
0

Submitting Reporter Section

Search Reporter By Surname:
$2

Reporter #:

Preferred Contact Method:
Email

Reporter Title:
$2

First Name:
$22

Surname:
$22

Position:

Company/Institution:

Address 1:
$22

Address 2:

Town/Suburb:
$22

State:
QLD

Country:
Australia

Postcode:
$22

Phone:
$22

Fax:

Mobile:

Email:
$22

Last External Submission By:

Initial Reporter Section

As Above?:
Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company
to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
308140

Device ARTG #:
308140

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class IIb

GMDN / UMDN Code:
35983

GMDN / UMDN Text:
Infusion pump, insulin, ambulatory

Brand Name:
Medtronic Australia, 640G INSULIN PUMP - Infusion pump, insulin, ambulatory

Initial Device Description:
640G INSULIN PUMP

Usage of Device:

Software Version:

Model #:
640G`

Serial #:
NG1684477H

Batch #:
MMT-1711K

Lot #:

Document 54

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
		With Manufacturer	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	11/08/2018	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
			Australia
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic Australia			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	27/09/2019		CALL
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
CENTRE			

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
04/11/2019	Not enough information has been provided	Investigation (within DIR) is recommended

Notes for Team meeting:
4 for this ARTG. 2 other DIRs for alarms/malfunctions. DIR 55626 under investigation. Should we ask sponsor for a comment on this one?

Outcomes from Team Meeting:
Questionnaire

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Document 54

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 27/10/2019	Severity: 2 - No harm - but incident could have resulted in illness/injury (near miss)	Incidents in the last 12 months:	Manufacturer analysis: Yes	Assessor: $22	Manufacturer documentation: Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	Manufacturer action: Not required (device was performing within specified parameters)	ESTIMATED LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	FINAL LEVEL OF INVESTIGATION: Level 1 Investigation (to complete screening)	Injured Party: Patient	Device Recalls: 0. No recalls for similar incidents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: Yes	Similar events (past 6 months): 1 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities: No	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment: Yes			

Sponsor/Manufacturer Information Section

Search Sponsors: 837	Name: Medtronic Australasia Pty Ltd		Client #: 837
Attention To: $22	Address 1: PO Box 945	Address 2:	Town/Suburb: NORTH RYDE BC
State: NSW	Postcode: 1670	Phone:	Fax:
Email: $22			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		Details of Similar Events:	
Additional Details (use for tables):		CAPA# Reference:	
		Risk Assessment	
		Frequency:	Severity:
		Rating:	
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			

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Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		04/11/2019				
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		04/11/2019	16/12/2019	13/12/2019	D19-6558494	Extension granted until the 16 december 2019 at sponsor request
☐		Reporter Routine Correspondence	Email to Reporter		04/11/2019				D19-6295254
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		04/11/2019	02/12/2019	13/12/2019	Request for extension D19-6400025 Extension granted D19-6400013 Data received D19-6558494	D19-6295281

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Electrical /Electronic Property Problem	Failure to Conduct		

Clinical signs symptoms and conditions

Details

Level 1	Level 2	Level 3
Metabolism and Nutrition		

Health Impact

Details

Level 1	Level 2	Level 3
No Health Consequences or Impact		

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Device Problem Found			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested

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Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The manufacturer has stated they have conducted an analysis of the returned device. This analysis consisted of testing in accordance with functional specifications and review of the pump history. Review of the outcome of the manufactures analysis confirmed the device was found to meet functional specifications, confirmation the user did receive pump errors 3, 4, 23, 49 and 68. The pump history review also confirmed that the user did clear and rewind the device successfully. The manufacturer has confirmed no reported similar events for the model in this event (model MMT-17-11 K). This is consistent with a search of the TGA database. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**		

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	

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Who sent the device to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 60132 - Original report	376	Form	
FILE		RE DIR 60132 - Questionnaire Letter - response	304	Form	
FILE		DIR 60132~DVMS_Sponsor_Complete_Letter~2020-06-15	122	Form	

FILE		TGA-DIR 60132 _DVMS_Reporter_Complete_Letter~2...	121	Form	Document 54

Flow Details : DIR-REQ - Device Incident Request : 210226

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
210226	DIR-REQ		Closed	s22	OPR Administration User	15/06/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	15/06/2020 12:18:54	
Comment		

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03/02/2019
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 418684

Released by $22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
55626	E19-520388		Final

ARTG: 308140 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		$22	03/02/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
03/02/2019	03/02/2019	12/02/2019	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
20/12/2019			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

Injury to ankle sustained during a hypoglycaemic episode resulting from a device malfunction. Pump has been replaced 5 times in last 5 months due to malfunction.

Clinical Event Information:

I am type 1 diabetic and use the Medtronic 670G insulin pump. The insulin pump is a wonderful device which assists me with my management of type 1 diabetes. Unfortunately, I have experienced numerous malfunctions. I normally update my pump every four years and this is organised through my private health insurance. The last update occurred in June/July 2018. Since this time I have had to to get 5 replacement pumps because the pump has malfunctioned 5 times. This effectively means I am getting a new pump every month. This is disrupting the management of my diabetes and placing me under significant stress. On the $22, due this incident, I have suffered a serious hypoglycaemic attack to the point where I feel down the stairs and injured my ankle.

It seems that the insulin pump is not fit for purpose and there are serious consequences for me as a result of these malfunctions. I need access to an insulin pump and I must have confidence that the pump is working wel$

*Additional information received 18/03/2019:

I have had a number of malfunctions and these malfunctions keep on reoccurring. This is completely unacceptable and is affecting the management of my diabetes.

To summarise the malfunctions include:

1. In late July 2018, I upgraded to a 640G Medtronic pump. This is part of normal process, I upgrade every 4 years.
2. In late August 2018, I was required to replace the pump because the entire back cracked. It had not been dropped or anything. I followed process and the pump was replaced through Medtronic.
3. Around early October 2018 while I was asleep the pump starting beeping and there was a message stating that there was a 'critical error' and the pump could not perform. Again I notified Medtronic technical team. However, this was a critical event for me because I was required to rely on insulin injection therapy and this has a great impact on my diabetes management.
4. Towards mid- October 2018, I was required to replace the pump again because the entire back was cracked. This was similar to the event that occurred back in August 2018. However, I was extremely frustrated that I was required to replace my pump again within 2 weeks.
5. In February 2019, I was required to replace the pump again because I got another critical pump error message. The pump was not functioning. I was required to rely on insulin injection pump therapy and suffered a serious hypoglycemic attack where I fell down the stairs and injured my ankle pretty badly.
6. Now mid March 2019 and I need to replace my pump again because the entire back has cracked. This is not ok. I'm using it appropriately and place it in a sock to protect it from sweat etc. I've always slept with and had my insulin pump with me at all time. It is really concerning that this is happening. It is affecting the management of my type 1 diabetes and this is extremely critical.

Medtronic have been responsive and provided me with a spare. However, they are unable to diagnose the issue and this is concerning. I am unable to live without an insulin pump. It is valuable to me and in the management of my diabetes.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:
Female	$	$22

Patient Focused Corrective Action Taken:	Patient History:
	Type 1 diabetic
Patient Outcome/Consequences:	**Additional Event Description:**

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Serious Injury

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For: Other (not listed above)

Other Medical Problem: Type 1 diabetes

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: s22

Reporter #:

Preferred Contact Method: Email

Reporter Title: s2

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country: Australia

Postcode:

Phone: s22

Fax:

Mobile:

Email: s22

Are you happy for the device company to contact you about the incident?: ☑

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 308140

Device ARTG #: 308140

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic Insulin pump 670G -Infusion pump, insulin, ambulatory

Initial Device Description: Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: 670G

Serial #: NG1658151H

Batch #: MMT-1782K

Lot #:

Purchase Date: 30/10/2018

Expiry Date: 31/10/2022

Date of Implant: s22

Date of Explant:

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Place of Implantation: s22 [redacted]
Reported Device Location: With Patient
Access Contact Title:
Access Contact First Name:
Access Contact Surname:
Access Contact Phone:
Access Contact Fax:
Access Contact Email:
Additional Devices Added: 0

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed
Manufacturer Client Id: 40022
Address 1: 2 Alma Road
Address 2:
Town/Suburb: Macquarie Park
State/Province: NSW
Country: Australia
Postcode: 2113
Phone: s22 [redacted]
Fax:
Email: s22 [redacted]@medtronic.com
Manufacturer Informed:
Date Aware of Adverse Event:
Contact Title:
Contact First Name:
Contact Surname:

Supplier Information Section

Supplier Name: Medtronic
Address 1:
Address 2:
Town/Suburb:
State:
Country:
Postcode:
Phone:
Fax:
Email:
Website:
Supplier Informed: Yes
Date of Supplier Contact: 03/02/2019
Contact Title: s2 [redacted]
Contact First Name: s22 [redacted]
Contact Surname: s22 [redacted]
Contact Phone: s22 [redacted]
Contact Fax:
Contact Email: s22 [redacted]@medtronic.com

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date: 11/08/2018
Date of Initial TGA Action: 03/02/2019
Report Status: Closed
Problems Observed: Insufficient Information; ;

Report Status

For website publication: Yes
Ready for Publication: Yes
Investigated: Yes
Investigation Reason: More information is required
Team Assignment: Team B (IIb, Is & Im)
Report Priority: Routine

Team Review

Reviewed by Team: 12/02/2019
Reason Sent To Meeting: Not enough information has been provided
Outcome from team meeting: Investigation (within DIR) is recommended
Team Meeting Notes: ask reporter what malfuntions have occurred and obtain information from sponsor

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DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
03/02/2019	s22	Active		11/08/2018
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	Temporary Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
No	Yes	No	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**
Yes	Unknown	Serious	Minor Risk	Team Review

Risk Assessment Notes:

2 DIR's in 3 years. No recalls, do we want to try and contact reporter and ask what "malfunctions" she is having?

Final Risk Assessment:

Yes

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details | Statistics Checklist Section

Update Device Details?:	Date:	Assessor:	Assessed By (Historical):	Licence Status:	Status Reason:
Copy Data From:	**Status Effective Date:**	**Injured Party:**	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**
	Sample Received:	**Sterile:**	**Invasive Device:**	**Single Use:**	**Human Origin:**
	Genetically Modified:	**Reusable:**	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**
	Final Risk Assessment:				
	Risk Assessment Notes:				

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Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	

Email:

s22 [redacted]; s22 [redacted]@medtronic.com; s22 [redacted]@medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:

Rating:

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		12/02/2019	20/03/2019		*As at 13/03/2019 no response received. s22 [redacted] is now sending a s41JA reminder letter, see below.	
☐		Reporter Routine Correspondence	Reporter Notification & Request for Information Letter		12/02/2019	20/03/2019	17/03/2019	Originally due 12/03/2019. *As at 13/03/2019 the reporter had not responded. s22 [redacted] is sending a follow up email. The due date is now 20/03/2019.	
☐		Sponsor Routine Correspondence	Questionnaire Reminder - s41JA		13/03/2019	29/03/2019	27/03/2019		
☐		Sponsor Routine Correspondence	Email to Sponsor		10/04/2019		29/04/2019	D19-5433995	D19-5372394
☐		Sponsor Routine Correspondence	Email to Sponsor		28/05/2019		14/06/2019	D19-5641325	D19-5556030
☐		Sponsor Routine Correspondence	Email to Sponsor		17/06/2019		01/07/2019	D19-5972466	D19-5641325
☐		Sponsor Routine Correspondence	Email to Sponsor		29/08/2019		05/09/2019	D19-5556033	D19-6020967

☐		Sponsor Routine Correspondence	Email to Sponsor		24/10/2019		25/10/2019	D19-6386218 full response received	D19-6232890 Document 55 $22 asked for the full response after few delays and extensions	
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		20/12/2019				D19-6583765	
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		20/12/2019				D19-6583895	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Insufficient Information				

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Mechanical Problem Identified	Leakage/Seal			

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to Component Failure			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The manufacturers analysis confirmed that the device had moisture damage, and multiple cracks, scratches on a number of components of the device. The manufacturer stated that no anomalies in the manufacturing process have been identified to be potentially related to the reported incident. The manufacturer advised that improvements in the design of the belt clip and the case cover has been done to improve the durability and robustness of the casing for this device. The TGA has reviewed the Instructions for Use (IFU) for this device, and has concluded that the IFU contains sufficient information on the precautions need to be taken for the users to minimise the chance of moisture damage. The sponsor stated that there has been no other similar event of this nature reported in Australia as of 12/2/2019. A search in the IRIS database confirmed that there has been no other similar event of this nature reported in Australia as of 20/12/2019. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

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Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

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Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?: 5

Date of Recent Report: 08/10/2018

Event Reported To: Manufacturer

Reporter Reference Number: No reference numbers provided. However, I have email confirmation and can make this available to the TGA.

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Medtronic Response DIR 55626 Questionnaire SE...	552	Form	
FILE		Re DIR 55626 - Reporter Request for Informatio...	89	Form	
FILE		RE Medtronic Response 2 DIR 55626 Questionnair...	353	Form	

Flow Details : DIR-REQ - Device Incident Request : 160620

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
160620	DIR-REQ		Closed	s22	OPR Administration User	20/12/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	20/12/2019 15:04:58	
Comment		

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]

File Reference: E21-229071
Sent by email

Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com; s22 [redacted]@medtronic.com

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 65755 - ARTG # 308140 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 17/03/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

(02) 6289 4642 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

17/02/2021

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 17/02/2021

DIR: 65755 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement				
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:			**YES**	**NO**
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	20,677 in CY2017-2020		
	Worldwide:	332,497 in CY2017-2020		
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A		
	Worldwide:	N/A		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?				X

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many:

If **YES**, please give details:

31 similar events from 124525 units (0.02489%) sold in CY2018;
43 similar events from 111395 units (0.0386%) sold in CY2019;
31 similar events from 13371 units (0.23185%) sold in CY2020

9) Please provide details of any action you have taken, or intend to take, regarding this problem

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The pump passed the self test, rewind test, prime/seating test, basic occlusion test, occlusion test, force sensor test, displacement test and DAT at 0.08730 inches. However, pump received with a high Sleep Current Measurement and Active Current Measurement due to corroded battery tube. The test Guardian Link with the Glucose Sensor Simulator and the test BG meter communicates properly to the pump. Pump programmed with multiple SG value and all registered properly in the Summary History noted.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

1. Please provide the detailed CAPA analysis in our report.

This product (MMT-1782) currently does not have a CAPA initiated for the reported issue (Sensor Glucose versus blood glucose value difference) or the malfunction identified during failure analysis testing (Unexpected battery power loss due to a corroded battery tube). All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

2. Please explain if it is required to set up an alarm.

A low Sensor Glucose (SG) under 50 mg/dl or 2.77 mmol/l alert will trigger if the sensor glucose falls below these thresholds, this alert is factory set and cannot be changed or turned off. This alert cannot be silenced and is always enabled, whether the pump is in Auto Mode or Manual Mode.

Additional alarms can be set to alert on or before a low SG value which can be set manually and suspend insulin delivery due to a suspend on low or suspend before low event.

After review of the pump's history on Sep 23, 2020 the customer's pump suspended before low and alerted before low, and alerted on low, including a severe low SG alert. The pump operated as designed by suspending and notifying the customer of approaching low SG values and low SG values.

This information can be found in the Minimed 670G System User Guide located here:
https://www.medtronic-diabetes.com.au/support/guides-and-manuals/minimed-670g/

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]

Signature s22 [redacted]

Position Product Reporting Specialist

Phone s22 [redacted]

Fax

Email s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

DIR 65755 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:
CASE-2020-00699801/03/04/05

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
29/01/2021

ARTG #:
308140

Brand Name:
Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1782K

Serial #:
NG2035187H

Software Version:

Batch #:

Lot #:
HG3VB5X

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]@medtronic.com;
s22 [redacted]@medtronic.com

Fax:

Reporter:
s22 [redacted]
Associate PMV Specialist
Medtronic Australasia Pty Ltd.
2 Alma Road, Macquarie Park, NSW, 2113
2 Alma Road, Macquarie Park, NSW, 2113
Macquarie Park NSW 2113

Confidential: N/A

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted]@medtronic.com

Clinical Event Information:
It was reported that the customer was rushed to hospital as she had collapsed with blood glucose level of 2.2 mg/dL. Customer stated that she was treated but it was too late. It was unknown whether the auto mode feature was on or not. Insulin delivery was not suspended due to sensor glucose versus blood glucose difference. The insulin pump will be returned for analysis.

Patient Outcome/Consequences:

Additional Event Description:

Device Analysis Results:
The pump passed the self test, rewind test, prime/seating test, basic occlusion test, occlusion test, force sensor test, displacement test and DAT at 0.08730 inches. However, pump received with a high Sleep Current Measurement and Active Current Measurement due to corroded battery tube. The test Guardian Link with the Glucose Sensor Simulator and the test BG meter communicates properly to the pump. Pump programmed with multiple SG value and all registered properly in the Summary History noted.

Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:
In Australia
0 similar events from 8128 units (0%) sold in CY2018;
0 similar events from 4953 units (0%) sold in CY2019;
1 similar events from 411 units (0.24331%) sold in CY2020;

WorldWide
31 similar events from 124525 units (0.02489%) sold in CY2018;
43 similar events from 111395 units (0.0386%) sold in CY2019;
31 similar events from 13371 units (0.23185%) sold in CY2020;

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
United States

TGA
RB Reference: 61609
SVN: 310732899

640G Over-delivery anomaly

Medtronic

Thank you for your inquiry. The responses to your questions are presented below.

TGA asks:

TGA DIR: 61609	CASE-2020-00020427	Event Date: s22 [redacted]		
ARTG: 95763	**GMDN: 35983**	**CFN: 95763**	**Product Description:** Minimed 640G pump	**Serial Number: NG1437260H**
Year	**Similar Incidents Australia**	**Number sold AUS**	**Similar Incidents Worldwide**	**Number sold Worldwide**
2017	2	7,185	23	83,260
2018	0	8,128	24	124,525
2019	2	4,953	73	111,395
2020 (to date)	1	1,302	19	35,389

Manufacturer's Investigation	
Manufacturer's analysis results:	The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. No over-delivery anomaly was noted during testing. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, and scratched display window. Analysis testing identified the insulin pump met specifications.
Countries where similar events occurred	Austria, Belgium, Colombia, Czech Republic, Denmark, Finland, France, Germany, Guatemala, Hungary, Ireland, Italy, Netherlands, Norway, Saudi Arabia, Spain, Sweden, Switzerland, United Kingdom.
Event Description	Information received by Medtronic indicated the user alleged the insulin pump over-delivered insulin. Blood glucose reading at the time of the event was 3.1 mmol/l. The user did not mention any symptoms. The user treated with glucose tablets. The user was neither in ER, nor admitted into hospital, nor was EMS dispatched as a result of low BG.
Corrective Action	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E17-14471
Sent by email

Attention: s22 [redacted]

DEVICE INCIDENT REPORT DIR 46531 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 20/07/2017.

Please send responses via email to IRIS@tga.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8886 or email: IRIS@tga.gov.au.

Yours sincerely

Signed electronically by

s22 [redacted]

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

22/06/2017

Sent by email

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 22/06/2017

DIR: 46531 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number	**ARTG:** 95763	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export		
3) How many of this model have been supplied	In Australia:	59,330
	Worldwide:	11,152
4) How many of this batch (if applicable) have been supplied:	In Australia:	
	Worldwide:	
5) Are you aware of this problem, as reported?	X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X
7) Have you had any other reports of similar* problems with this product in Australia?	X	

If **YES**, how many: 8

If **YES**, please give details:

From March 2015 to July 2017, there have been eight (8) customer complaints of being unable to upload/download. None of these eight complaints reported a clinical event associated with the upload/download anomaly.

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 58 [ ]

If **YES**, how many: 41

If **YES**, please give details:

Worldwide (including Australia)
2015: 6/25048 = 0.024%,
2016:17/49937 = 0.034%,
2017 (to date): 18/59330 = 0.030%

Australia
2015: 2/3567 = 0.056%,
2016: 4/8176 = 0.049%,
2017 (to date): 2/11512 = 0.017%

Countries Where These Similar Adverse Events Occurred: Australia, Denmark, Netherlands, Norway, Sweden United Kingdom.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

The manufacturer will continue to monitor the rate of such incidents for trending purposes.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The insulin pump has not been received for analysis yet.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if ticked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [X] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

Reporter Reference #:

1) Do we require dedicated software to upload the Insulin Pump data? If yes, Does the software come along with the device?

Date of Adverse Event:
[redacted]

Date of Final Report:
13/06/2017

The de[redacted] are made available to customers is web-based, on CareLink Personal. The customers are provided with the link device, Contour Next Link 2.4 meter, which is used to upload the pump data into their CareLink Personal account.

ARTG #:
95763

Brand Name:
Medtronic MiniMed 640G Insulin Infusion Pump

Device Class:
Class IIb

Model #:
MiniMed

Serial #:
NG1001395H

2) Please provide Instructions For Use (IFU). – See attached.

Software Version:

Batch #:
N/K

Lot #:
N/K

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

Manufacturer:
Medtronic Australasia Pty Ltd [837]

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family
3. What material has been used to insulate, both internally an[redacted]pplicable to leads only)

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name:
[redacted]

Phone: [redacted]

Email [redacted]@medtronic.com

Fax: 02 8904 8643

Informat[redacted]

14)

Name [redacted]

Phone [redacted]

Sig[redacted]

Reporter: [redacted]

Fax

Confidential: No

02 9888 1283

Phone: 0425834355

Position

Spr Regulatory Affairs Specialist

Email:

[redacted]@medtronic.com

This q[redacted] appended documents should be returned to the TGA within **20 working days.**

Email:

Elect[redacted] information is preferred.

Please [redacted]ormation to email address: **IRIS@tga.gov.au**

Other Devices Involved:

N/K

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Patient Outcome/Consequences:

My diabetes educator is unable to view the data on my pump so is having problems doing the necessary adjustments. I am concerned that the pump may not be working properly which has been further Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

al devised from a recent issue reported to the TGA - reference number RC-2017-RN-00661-1. As the pump costs in excess of $9000.00 and my health fund only provides a rebate every 4 years, I can not afford to purchase another unit.

Medtronic have not offered to replace the pump.

If you are sending a device/s to the TGA please follow the instructions via link:
https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user#send

Device Analysis Results:

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Clinical Event Information:
Patient is unable to upload the data from their insulin pump to provide this information to their diabetes educator so adjustments can be made to their insulin dosages. Medtronics were aware there was a problem but did not inform patients. Patient has made numerous calls to Medtronics and they are unable to provide them with a time frame for this problem to be fixed. Patient asked that they could provide them with a written assurance that the pump is working correctly and that the upload problem doesn't affect the way the pump operates. They said they could not do this.

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14/11/2018
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 414677

Released by $22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
54413	E18-389414	No	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		$22	14/11/2018
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
14/11/2018	14/11/2018		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
19/12/2018			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Carer		For IRIS Meeting	

Event Description for Website Publication:

My daughter is a type 1 diabetic and using a Medtronic 640g pump. Today I received notification from a friend about a product recall of the pump. And after going through the instructions discovered that the pump is in fact faulty and has to be replaced. Medtronic have not even sent a email about this recall.

Clinical Event Information:

My daughter is a type 1 diabetic and using a Medtronic 640g pump. Today I received notification from a friend about a product recall of the pump. And after going through the instructions discovered that the pump is in fact faulty and has to be replaced.

We are very distressed that Medtronic have not even sent a email (which they have our email address) about this recall. I thought these companies had to contact patients about these recalls.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:	
Female	$	$22	

Patient Focused Corrective Action Taken:

Patient History:

None.

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:
	No Injury		Other (not listed above)
Other Medical Problem:	**Additional Patients Added:**		
Type 1 Diabetes	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
$2			Email
Reporter Title:	**First Name:**	**Surname:**	
$2	$22	$22	
Position:		**Company/Institution:**	

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Address 1: | Address 2: | Town/Suburb: | State:

Country: Australia | Postcode: | Phone: s22 | Fax:

Mobile: | Email: s22 | Are you happy for the device company to contact you about the incident?: ☐ | Last External Submission By:

Initial Reporter Section

As Above?: Yes | *If No, fill out the following:* | Initial Reporter Confidential:

Search Reporter By Surname: | Initial Reporter #: | Preferred Contact Method:

Title: | First Name: | Surname:

Position: | Company/Institution:

Address 1: | Address 2: | Town/Suburb: | State:

Postcode: | Country: | Phone: | Fax:

Mobile: | Email: | Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No | Search Device ARTG: 95763 | Device ARTG #: 95763 | Therapeutic Licence Type: Medical Device

Product Licence Category: Included | Device Class: Class IIb | GMDN / UMDN Code: 35983 | GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic 640g Insulin Pump - Infusion pump, insulin, ambulatory | Initial Device Description: Medtronic 640g Insulin Pump - Infusion pump, insulin, ambulatory | Usage of Device: | Software Version:

Model #: | Serial #: | Batch #: | Lot #:

Purchase Date: | Expiry Date: | Date of Implant: | Date of Explant:

Place of Implantation: | Reported Device Location: With Patient | Access Contact Title: | Access Contact First Name:

Access Contact Surname: | Access Contact Phone: | Access Contact Fax: | Access Contact Email:

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed | Manufacturer Client Id: 40022 | Address 1:

Address 2: | Town/Suburb: | State/Province: | Country: Australia

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Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Medtronic Australia			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	13/11/2018	Call centre	
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
	their 1800 no		

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:		
18/07/2003	14/11/2018	Closed		
Problems Observed:				
Insufficient Information; ;				

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	Yes	More information is required	Team B (IIb, Is & Im)
Report Priority:				
Routine				

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
20/11/2018	User report	Investigation (within DIR) is recommended
Team Meeting Notes:		
Contact Recalls for standard wordings to close this DIR.		

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:
Meeting Notes:		

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
14/11/2018	s22 [redacted]	Active		18/07/2003
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Temporary Injury	Not Known	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**

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No	Yes	No	No	No
Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:
Yes				Team Review

Risk Assessment Notes:

Shall we follow up for the

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section				
Update Device Details?:	Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
Yes	19/12/2018	$22 [redacted]	Active	Active	18/07/2003
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Initial	**Patient**	**Temporary Injury**	**Not Known**	No	**No**
	Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:
	No	**Yes**	**No**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	Yes	**Unlikely**	**Minor**	**Non-significant Risk**	Yes
	Risk Assessment Notes:				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
$22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			
$22 [redacted]@medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	CAPA# Reference:

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Risk Assessment

Frequency:	Severity:
Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		19/12/2018				D18-11352266
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		19/12/2018				D18-11352369

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Insufficient Information				

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

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Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	This report was referred to the Recalls Section from Devices Vigilance and Monitoring Section. A TGA Departmental Officer from Recalls has stated they attempted to contact the reporter on multiple occasions, however no responses were received. Without information about the recall mentioned in the report, we are unable to determine which recall action the reporter is concerned about. Published recall actions can be found on the TGA website at http://www.tga.gov.au/recall-actions-database. The published recalls are stored in a database called the "System for Australian Recall Actions (SARA)" which provides consumers, health care professionals, sponsors, wholesalers, hospitals and retailers with access to information about recall actions occurring in Australia for therapeutic goods. The Database holds information on recall actions that have been undertaken in Australia since 1 July 2012. The Database is searchable for therapeutic good recall action notifications that include recalls, product defect corrections and hazard alerts (implanted medical devices and biologicals) and product defect alerts. No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Manufacturer

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:
1	25/07/2017	Manufacturer	I don't have one. The pump was replaced

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes			

Town/Suburb:	State:	Postcode:

Flow Details : DIR-REQ - Device Incident Request : 153557

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
153557	DIR-REQ		Closed	s22	OPR Administration User	19/12/2018	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	19/12/2018 12:50:53	
Comment		

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Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

05/04/2018
SIGNED

DIR : 26 - ID : 405058

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
50984	E18-276423		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed			05/04/2018
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
05/04/2018	05/04/2018	10/04/2018	26/06/2018
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
26/06/2018			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

Degraded battery performance with crack over battery compartment, from edge of clip retainer.

Clinical Event Information:

I am on my third Minime 640G replacement insulin pump, with the same crack over battery compartment, from edge of clip retainer. This degrades the IPX rating, and allows moisture into the battery compartment and pump, causing degraded battery performance.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
3	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
Male	[redacted]	[redacted]

Patient Focused Corrective Action Taken:

Patient History:

Insulin dependent type 1 diabetic, on a pu, four over 7 years.

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Patient Outcome/Consequences:

Battery usage drops from over 2 weeks on a AA lithium cell, to 4 days on the same battery.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: $22

Reporter #:

Reporter Title: $2

First Name: $22

Surname: $22

Position: $22

Company/Institution: $22

Address 1: $22

Address 2:

Town/Suburb: $22

State: NSW

Country:

Postcode: 2153

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:

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Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		95763	95763
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class IIb	35983
GMDN / UMDN Text:		Brand Name:	
Infusion pump, insulin, ambulatory		Minimed 640G - Insulin pump with CGM capability	

Initial Device Description:

Insulin pump with CGM capability

Usage of Device:	Software Version:		
Reuse of Reusable			
Model #:	Serial #:	Batch #:	Lot #:
640G	NG1302944H		
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
17/06/2017			
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Patient	$2	$22	$22
Access Contact Phone:	Access Contact Fax:		
$22			

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	2 Alma Road
Address 2:	Town/Suburb:	State/Province:	Country:
Macquarie Park NSW 2113			United States
Postcode:	Phone:	Fax:	
	$22	$22	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
Contact Title:	Contact First Name:	Contact Surname:	

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Supplier Information Section

Supplier Name:	Address 1:	Address 2:
See above		

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:
		Yes

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
05/04/2018			

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
05/04/2018	s22 [redacted]	Yes	Yes	☐

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Temporary Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
Temporary Injury	Patient	Yes	Unlikely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Likely	Routine	Yes	10/04/2018

DIRE Meeting Notes:

MDOSI Score: 18(orange)7,7,4. 87 DIRs for the last 3 yrs for this ARTG number. 3 recalls none for this issue in the last 3 years.
Query design or materials issue, what are the current rates. Was it part of the recall in 2013. - investigate
Issue not related to any recalls. The 640G user guide provides information regarding manhandling including "If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump to ensure there are no cracks before exposing your pump to water".

Sponsor Information Section

Search Sponsors:	Name:	Client #:
837	Medtronic Australasia Pty Ltd	837

Attention To:	Address 1:	Address 2:	Town/Suburb:

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s22	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22	
Email:			
s22			

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:	Additional Details (use for tables):
Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

DIR closed on 26 June 2018.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

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Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
s22 [redacted]						

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Reporter notification letter		13/04/2018				
Questionnaire		13/04/2018	16/05/2018			Originally due 11/05/2018, extension granted. *Response not received by extension date.
Questionnaire reminder under 41JA		17/05/2018	23/05/2018			
Email to sponsor		24/05/2018	05/06/2018			*Response not received. s22 [redacted] phoned s22 [redacted] 24/05/2018 stating that they need to provide the information that they currently have and to let us know when they will received the rest from the manufacturer. Part 1 response received - 29/05/2018. Part 2 still to come - putting due date as 05/06/2018.

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Email to sponsor	s22 [redacted]@health.gov.au	18/06/2018	20/06/2018			Requested rates and for questionnaire to be completed in full	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Material	Crack		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Returned device performed as intended		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

A review of this device was conducted by the manufacturer and the complaint regarding the reduced battery life could not be confirmed. The unit passed the functional test, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind test, Prime-Seating Test, basic Occlusion Test, Force Sensor Test, Displacement Test and the DAT Test. The power management tool was within the specified range and all battery alert alarms were functional.

The returned device had a minor scratched display window, a cracked case at the battery side and a cracked case at the corner of the belt clip rail, scratched keypad overlay, keypad overlay texture damage, pillowing keypad overlay, cracked keypad overlay at the Select Button, a cracked retainer and a scratched case.

In response to this the 640G user guide provides the following information:

"• At the time of manufacture and when the reservoir and tubing are properly inserted, your pump is waterproof. It is protected against the effects of being underwater to a depth of up to 3.6 meters (12 feet) for up to 24 hours. If the pump is dropped, hit against a hard object, or otherwise damaged, the waterproof characteristics of the outer casing of the pump may be compromised. If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump

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to ensure there are no cracks before exposing your pump to water. If you believe that water has entered your pump or you observe any other possible pump malfunction, check your blood glucose, and treat high blood glucose as necessary, using an alternative source of insulin. Contact your local representative for further assistance. Always contact your healthcare professional if you experience excessively high or low blood glucose levels or if you have any questions about your care'.

- Caution: If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump to ensure there are no cracks before exposing your pump to water.

Based on the manufacturer's investigation this incident could not be confirmed. The current rate for similar events in Australia is low. No further investigation will occur at this time. However, the TGA will continue to monitor the rate and pattern of occurrences and may reopen the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Blank 3	1076	Form Item	Report Information Section / Brand Name
FILE		DIR 50984 - Original User Report	198	Form	
FILE		DIR 50984 - Part 1 questionnaire response	142	Form	
FILE		DVM Reporter Complete Letter - DIR 50984 - 640...	105	Form	
FILE		DVM Sponsor Completion Letter - DIR 50984 - AR...	107	Form	

Flow Details : DIR-REQ - Device Incident Request : 136560

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
136560	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	26/06/2018	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	

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Signed At	03/10/2018 15:27:03	
Comment		

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Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

27/09/2017
SIGNED

DIR : 26 - ID : 394190

Released by s22 [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
48092	E17-34624		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed			22/09/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
22/09/2017	27/09/2017	03/10/2017	20/11/2017
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
27/02/2018			Yes
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

Patient on third 640G pump. The first two failed in the first 15 months of use.

Clinical Event Information:

First I am currently on my third 640G pump. The first two failed in the first 15 months of use. They become flaky and then stopped working.

Not suitable for a type 1 diabetic that depends on it. They tell you they will send a new pump within 2 working days, but that doesn't take into account an extra 2 days for the weekend and at least another 1 or 2 days despatch time.

Also their Canulas have been faulty the whole 15 months until now. I have only tried 1 new one so far and it appears good. Time will tell. They could not supply an exact replacement owing to a stock shortage. I got the same story with the 64OG replacement pump when the last one failed.

The last box of reservoirs I opened reference MMT 332A LOT HG1G8EW was completely faulty. The plunger came out the bottom on the reservoir when drawing insulin out of the bottle. The insulin went everywhere. Same again with another out of the same batch.

The replacement box reference MM 332A LOT HG1WMDF is marginally better but only just.

There appears to be a quality issue covering the whole range of products which is diabolical for the patient.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

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Patient Information

Sex: Male

Weight:

Age:

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Reporter Title:

First Name: s22

Surname: s22

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Mobile: s22

Email: s22

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: MiniMed Insulin Reservoirs

Initial Device Description: MiniMed Insulin Reservoirs

Usage of Device: Reuse of Reusable

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1:

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Address 2:	Town/Suburb:	State/Province:	Country:

Postcode:	Phone:	Fax:	

Email:	Manufacturer Informed:	Date Aware of Adverse Event:

Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
27/09/2017	s22 [redacted]	Yes	Yes	☐

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	Yes	No	Serious Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
Temporary Injury	Patient	No	Unlikely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Likely	Routine	Yes	03/10/2017

DIRE Meeting Notes:

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MDOSI score: 21(Orange) 7,9,5

Investigate - ask sponsor about reservoirs and cannulas re: the issues in the report regarding these products, ask about similar events for them.
Note: there was a recent recall on the giving sets.

Sponsor Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	(02) 8904-8643
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Additional Details (use for tables):



Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

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DIR closed on 01/03/2018.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Reporter notification letter		27/09/2017				*Also mentioned that if he had any extra info, he can email to the IRIS email address.
Questionnaire		06/10/2017	20/11/2017	20/11/2017	D17-958418	Due COB 03/11/2017. Extension to 10/11/2017 granted. 2nd extension granted to 20/11/2017.
Question for reporter		13/10/2017	27/10/2017	13/10/2017		Dear s22 [redacted]

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						Thank you for submitting an adverse event report to the Therapeutic Goods Administration (TGA). We are in the process of investigating this incident. I am contacting you to ask if you have any objections to the TGA providing your name to the sponsor of the reported device? If you do have any objections we will keep your identity confidential and anonymous. I look forward to your response. Kind regards, IRIS	
email to reporter	s22 [redacted]	21/11/2017				Arrange collection of affected devices between Medtronic & reporter - requested permission to give Medtronic his details	
Email to Sponsor	s22 [redacted]	21/11/2017	02/12/2017			Requested following information: 1. Did Medtronic try to obtain the alleged faulty pumps and reservoirs described in the DIR and if so, what actions were taken to obtain them? 2. I have requested permission from the user to arrange collection between Medtronic and the customer to enable the investigation to be conducted. How shall we proceed to obtain the devices under this review? 3. In your submission for ARTG 169959, please submit actual numbers for both model and batch number supplied in Australia. "For local team to respond" is not an acceptable answer. 4. Please provide details of the 3 complaints received	

						within Australia for other reports with similar problems (question 7) to include the following: a. Details of each similar event, reported separately and including type of complaint received, whether the complaint was validated and the outcome of each of the 3 complaints. b. Year for each of the 3 complaints c. DIR number associated with each of the 3 complaints listed in question7. If no DIR, please provide rationale as to why these similar problems were not reported to the TGA.	

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List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Electrical/Electronic	Device Inoperable		
Mechanical	Leak		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:	

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Investigation Summary:

The device was not returned upon request so no investigation could be carried out. No further investigation will occur at this time. However, the TGA will continue to monitor the rate and pattern of occurrences and may reopen the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Email correspondence with attachments from s22	3537	Form	
FILE		RE Reporting issues with MiniMed Reservoir TGA...	3636	Form	
FILE		RESPONSE DIR 48092 SECNo Protective Marking	1140	Form	
FILE		DVM closing letter - DIR 48092 - ARTG 95763	100	Form	
FILE		DVM Sponsor Complete Letter - DIR 48092 - ARTG...	105	Form	

Flow Details : DIR-REQ - Device Incident Request : 120160

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
120160	DIR-REQ		Closed	s22	OPR Administration User	01/03/2018	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	01/03/2018 15:19:36	
Comment		

Document 62

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

03/04/2017
SIGNED

DIR : 26 - ID : 379480

Released by [redacted] on 17/11/2016 14:13:04

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
45502	E17-8670		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed		[redacted]	03/04/2017
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
03/04/2017	03/04/2017	11/04/2017	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
06/07/2017			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Patient		For IRIS Meeting	

Event Description for Website Publication:

Insulin pump warned low battery approximately. A day later it alarmed warning battery critically now and to replace immediately. Replaced battery but insulin pump didn't recognise new battery. Tried 4 different batteries including a new sealed package. Contacted sponsor's helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu.

Clinical Event Information:

Insulin pump warned low battery approximately. A day later it alarmed warning battery critically now and to replace immediately. Replaced battery but insulin pump didn't recognise new battery. Tried 4 different batteries including a new sealed package. Contacted sponsor's helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu. Call taker advised replacement pump required and would need to be coordinated with ** office. Replacement device not received for >72 hours following report.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:
Female	[redacted]	[redacted]

Patient Focused Corrective Action Taken:

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Patient History:

Type 1 diabetes since 1996. Insulin pump therapy since approx 2002.

Patient Outcome/Consequences:

Pump didnt recognise new batteries. Internal battery died and did not recognise new batteries.
Tried 4 different batteries including a new sealed package. Contacted medtronic helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu. Call taker advised replacement pump required and would need to be coordinated with ** office. Replacement device not received for >72 hours following report.
Pump stopped and unable to deliver insulin. User reverted to multiple injections as pump unable to deliver insulin at all.
Have identified others with same/similar issues on forums in Australia. Have previously reported to Sponsor rep that there is a short length of time between battery low warning and critical battery warning.

May be relevant to TGA warning released Feb 17th 2017: https://www.tga.gov.au/node/735389

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: $22

Reporter #:

Reporter Title: $22

First Name: $22

Surname: $22

Position:

Company/Institution:

Address 1: $22

Address 2:

Town/Suburb: $22

State: SA

Country:

Postcode: $22

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By:

Initial Reporter Section

As Above?: Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:

Device Information Section

Product Exempt: No

If No, fill out ARTG No:

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Medtronic 640g Insulin Pump

Initial Device Description: Insulin Pump

Usage of Device: Reuse of Reusable

Software Version: unknown

Model #: 640g

Serial #: NG1111286H

Batch #: unknown

Lot #: unknown

Purchase Date: 01/01/2016

Expiry Date:

Date of Implant:

Date of Explant:

Reported Device Location: With Patient

Access Contact Title: $22

Access Contact First Name: $22

Access Contact Surname: $22

Access Contact Phone: $22

Access Contact Fax:

Manufacturer Information Section

Manufacturer Name: Medtronic Minimed

Manufacturer Client Id: 40022

Address 1: MEDTRONIC AUSTRALASIA PTY LTD

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Address 2:	Town/Suburb:	State/Province:	Country:
5 Alma Road,	Macquarie Park	<>	Australia

Postcode:	Phone:	Fax:	
2113	1800 777 808		

Email:	Manufacturer Informed:	Date Aware of Adverse Event:
s22 [redacted]		

Contact Title:	Contact First Name:	Contact Surname:

Supplier Information Section

Supplier Name:	Address 1:	Address 2:
as above		

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:
		Yes

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
29/03/2017			unknown

Contact Phone:	Contact Fax:
1800 777 808	

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
04/04/2017	s22 [redacted]	Yes	Yes	

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	No	No	Yes	Temporary Injury

Actual Effect:	Injured Party:	Found Prior To Use:	Risk Frequency:
No Injury	Patient	Yes	Unlikely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Likely	Routine	Yes	11/04/2017

DIRE Meeting Notes:

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MDOSI Score; 19(orange)7,8,4
investigate

Sponsor Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	(02) 9888 1283
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:	Additional Details (use for tables):	
		
Number of Similar Events:	**Rate of Similar Events:**	

Countries Similar Events Also Occurred:

Additional Comments:

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Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

Related DIR Information - Click **New** to begin entering information.

Samples Record - Click **[N]** to begin entering information.

Sample Details

Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details

Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Reporter notification letter		12/04/2017				
Questionnaire letter	iris@health.gov.au	12/04/2017	16/05/2017	20/04/2017		
further information requested	s22 [redacted] @health.gov.au	26/04/2017	10/05/2017			
further information requested		19/05/2017	02/06/2017	30/05/2017		
Further Information Requested	s22 [redacted] @health.gov.au	01/06/2017	16/06/2017	14/06/2017		E17-8670

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Further Information Requested	s22 [redacted] @health.gov.au	14/06/2017	27/06/2017	03/07/2017		D17-488734	
RC Letter		06/07/2017				D17-567760	
SC letter		06/07/2017				D17-567735	

List of Problem Type Codes - Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Electrical/Electronic	Power Source Issue		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Electrical	Electrical component		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Manufacturing process improvements		
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

The sponsor received the device and a thorough analysis revealed that internal battery connector was the root cause of the low battery alarm. Rest of the functions of the device were working properly after fixing connector issue.

In order to prevent this issue in future the manufacturer has changed the battery connector material and implemented in products manufactured since January 2017. The sponsor has stated if troubleshooting does not resolve the issue that the user has called about, the user will be offered an insulin pump replacement. The sponsor trend shows there is a decrease in the Incidents with low battery alarm.

No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

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Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 45502 - original web report	121	Form	
FILE		FW DIR 45502 - questionnaire letter - response	289	Form	
FILE		307408460 - DIR 45502 - Updated 15.5.17	488	Form	
FILE		DIR 45502_Sponsor_Complete_Letter	249	Form	
FILE		DIR 45502_Reporter_Complete_Letter	244	Form	

Flow Details : DIR-REQ - Device Incident Request : 107894

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
107894	DIR-REQ		Closed	s22 [redacted]	OPR Administration User	06/07/2017	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	06/07/2017 11:26:34	
Comment		

Medtronic

Medtronic Australasia Pty Ltd
ABN 47 001 162 661
2 Alma Road
Macquarie Park, NSW 2113
Australia
www.medtronic.com.au

tel 02 9857 9000
fax 02 9878 5100

8 June 2022,

Subject: DIR 75998, CASE-2022-00079616

To Whom it May Concern:

Thank you for your request dated June 3, 2022, with respect to above referenced report number. Please find answers to your questions below.

TGA Request:

Q1: In your final report, you stated that there have been no similar events in any of the units sold since 2019. However, according to the IRIS database there have been 16 reported incidents of high blood glucose. Please explain this discrepancy.

R1: s22 [redacted] the user was hospitalized due to hyperglycemia. Blood glucose value at the time of the event was 23.3 mmol/l. The user also reported high ketones. The user experienced pain in the stomach, sweating, shakiness, and nausea as symptoms of hyperglycemia. The user was treated with intravenous fluid, meslapan, potassium and nova rapid. Before the hospitalization, the user woke up and noticed the pump was off. After inserting a new battery, the user input a correction bolus which the user stated did not register to the pump. The user was feeling ill and after a set change, bolus and ketones check the user's mother took the user to the hospital. The user also mentioned the belt clip rails were damaged. The insulin pump is expected to return for analysis.

The similar incidents for this case were calculated based on other reportable cases involving the 670G insulin pump which were reported for unexpected battery power loss from 2019-2022.

*Similar events will be calculated based on the clinical event for future submissions.

Q2: Please provide the rate of similar events for high blood glucose for Australia and Worldwide. Please provide this data by the incident date by year (not by the units sold each year)

R2: Please see below for similar events involving the 670G insulin pump which were considered reportable due to hyperglycemia during 2019-2022 for Australia and Worldwide.

Year	Region	Similar Events
2019	Australia	1
	Worldwide (not including Australia)	10,133
2020	Australia	4
	Worldwide (not including Australia)	8,646
2021	Australia	7
	Worldwide (not including Australia)	5,803
2022 (till May)	Australia	16
	Worldwide (not including Australia)	1,725

Sincerely,

Medtronic Diabetes

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]

File Reference: E21-259926
Sent by email

Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 68922 - ARTG # 308140 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 29/04/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

(02) 6289 4642 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

01/04/2021

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 01/04/2021

DIR: 68922 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	9,943		
	Worldwide:	429,331		
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A		
	Worldwide:	N/A		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?			X	

If **YES**, how many: Please see below.

If **YES**, please give details:

There has been one report of a complaint received in Australia involving Hypoglycemia with the same problem code - (Critical Pump error (Open Book Image)).

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many: Please see below.

If **YES**, please give details:

There have been a total of 178 reports of complaints received worldwide involving Hypoglycemia with the same problem code - (Critical Pump error (Open Book Image)).

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: N/A

The Minimed 670G insulin infusion pump was not returned for analysis.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

1. Please send out a questionnaire and ask the sponsor:

• Have you submitted a DIR for this event, if so, please provide the DIR number, if not please provide the rationale for not doing so.

DIR 68922

Please go back to the reporter with the following:

• It is noted that you have viewed the insulin pump history report. If this report is still available, please provide this report to the TGA for review.

Since the Minimed 670G insulin infusion pump was not returned for analysis, the pump history report is not available.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
Position	Product Reporting Specialist	Email	s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

DIR 68922 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
25/03/2021

ARTG #:
308140

Brand Name:
Medtronic 670G insulin pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
670G

Serial #:
NG2320984H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
The insulin pump began to self-deliver insulin boluses multiple times over a four day period uninitiated by the patient or carer. This resulted in severe and recurrent hypoglycaemia requiring multiple interventions to raise the blood glucose level. The incidents are clearly evident in the insulin pump report.

Patient Outcome/Consequences:
The s22 [redacted] year old patient suffered from severe and recurrent hypoglycaemia following these errant boluses of rapid-acting insulin which required significant intervention on the part of the parent through ongoing administration of fast-acting carbohydrate to reverse the hypoglycaemia. Upon learning of the insulin pump fault, our team advised the mother to disconnect the insulin pump and instead administer insulin through injection until the insulin pump can be replaced.

Additional Event Description:
The Medtronic 670G insulin pump the patient was using began to erroneously deliver insulin boluses multiple times on successive occasions over a four day period resulting in severe and recurrent hypoglycaemia before the problem was identified by the parent who contacted both Medtronic and us - the paediatric diabetes care team at the s22 [redacted] to advise of the fault/error with the pump. Upon viewing the insulin pump history report, this showed there were 32 separate occasions where the insulin pump has self-delivered the maximum carbohydrate dose of 300g resulting in multiple insulin doses being delivered. The actual amount of insulin that the patient received was significantly lower than the pump tried to administer due to the safety feature called 'Maximum Bolus' which was set at 5 units, however this was still up to 300% more than what the patient usually receives in a typical day.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

TGA
RB Reference: 68922
SVN: 312511516

Medtronic

670G Hypoglycemia Events

Thank you for your inquiry. The responses to your questions are presented below.

TGA asks:

I have made a decision under subsection 41JA(1) of the Therapeutic Goods Act 1989 (the Act) to require you to provide information/documents about Infusion pump, insulin, ambulatory. I am the delegate of the Secretary of the Department of Health for the purposes of section 41JA of the Act. The information is required for the purposes of the investigation of the above incident report.

You are requested to provide the information/documents listed below including details of any action you have taken in relation to this matter:

1. In your response dated 26 April 2021, it states 'There has been one report of a complaint received in Australia involving Hypoglycemia with the same problem code - (Critical Pump error (Open Book Image)).

   Please provide the rates for all similar events of hypoglycemia regardless of the problem codes.

   As requested, the following table shows similar incidents and rates regarding hypoglycemia regardless of the problem code for the 670G insulin pump.

Year	Region	Reportable Complaints	670G Install Base	Reportable Complaints Rates
2018	Australia	0	198	0.0000%
	Worldwide	5,021	160,148	3.1352%
2019	Australia	3	3,692	0.0813%
	Worldwide	5,186	259,696	1.9970%
2020	Australia	1	8,021	0.0125%
	Worldwide	4,527	323,017	1.4015%
2021	Australia	0	8,686	0.0000%
	Worldwide	969	303,515	0.2293%

2. The reporter has informed the TGA that the device has been returned to the manufacturer for analysis. Please provide details of the manufacturer's investigation to date, including expected Manufacturer's investigation completion date.

   Following our receipt of the returned insulin pump, the test P-Cap and reservoir locked in place in the reservoir compartment. The insulin pump passed functional test including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and a Displacement Accuracy Test. No over delivery anomaly or under delivery anomaly noted. The insulin pump was monitored for 11 days. No Critical Pump Error (Open Book Image), unexpected pump restart, or pump error alarm were noted. The insulin pump was programmed with multiple test boluses and monitored. All boluses delivered properly and were recorded in the daily history screen. No bolus anomaly noted. The insulin pump properly uploaded using CareLink.

   A minor scratched display window, scratched display window cover, scratched case, and a pillowing keypad overlay was noted, however, these are considered cosmetic damage and did not impact functional performance.

   A Review of the insulin pump's analysis, CareLink, and pump memory from March 20, 2021 to March 24, 2021 was performed. Data downloaded from the pump confirms that the boluses programmed and delivered by the insulin pump were initiated by the user. The information reasonably suggests that the insulin pump was working as intended and met specifications.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]

File Reference: E21-241948
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 68198 - ARTG # 308140 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 02/04/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

(02) 6289 4642 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

05/03/2021

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 05/03/2021

DIR: 68198 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	176,400		
	Worldwide:	6,369,334		
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A		
	Worldwide:	N/A		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?				X

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many: Please see below.

If **YES**, please give details:

There have been a total of thirty-six (36) reports of complaints received worldwide with the same problem code (Cannot Find Sensor Signal).

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: N/A

The Guardian 3 MMT-7020C5 sensor was not returned for analysis.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

Please confirm what actions have you taken to fix the issue?

Also, please confirm if a recall action was taken through TGA to inform the customers about the issue?

Based on the limited information we have about the customer or the complaint regarding absence of sensor notifications, we are unable to address the questions regarding a fix of the issue or if it is applicable to any field corrective action.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
Position	Product Reporting Specialist	Email	s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

DIR 68198 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
17/02/2021

ARTG #:
308140

Brand Name:
Guardian CGM Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
Carelink Connect

Serial #:

Software Version:
2.1.1 [1148]

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
We switched to the Medtronic Guardian Continuous Glucose Monitor (CGM) today (to get the best from this new insulin pump).
My son is unable to manage his blood glucose levels himself. As such, we rely on being able to get the alerts provided by the CGM when our son's levels go out of range.
However, we have been unable to get these notifications and Medtronic have advised us that this has been an issue for more than 24 hours and they have no timeline or estimate for when the issue will be resolved.

Patient Outcome/Consequences:
Without these alerts, my son is at risk of suffering a fatal hypoglycemic event.

Additional Event Description:
Have contacted Medtronic, but they have not resolved the issue and have no timeline or estimate of when they will be able to resolve it.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]

File Reference: E21-238369
Sent by email

Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com; s22 [redacted]

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 68118 - ARTG # 308140 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 29/03/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

(02) 6289 4642 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

01/03/2021

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 01/03/2021

DIR: 68118 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:		**YES**	**NO**
a) To the Australian Market		X	
b) For Export		X	
3) How many of this model have been supplied	In Australia:	9,943	
	Worldwide:	429,331	
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A	
	Worldwide:	N/A	
5) Are you aware of this problem, as reported?		X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X	
7) Have you had any other reports of similar* problems with this product in Australia?		X	

If **YES**, how many: Please see below.

If **YES**, please give details:

There has been one report of a complaint received in Australia involving hospitalization or emergency medical services due to diabetic ketoacidosis with the same problem code - (Harm reported, with no Allegation of Device Deficiency).

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many: Please see below.

If **YES**, please give details:

There have been a total of 1,641 reports of complaints received worldwide involving hospitalization or emergency medical services due to diabetic ketoacidosis with the same problem code - (Harm reported, with no Allegation of Device Deficiency).

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: N/A

The Minimed 670G insulin infusion pump was not returned for analysis.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]

Signature s22 [redacted]

Position Product Reporting Specialist

Phone 1-818-576-4744

Fax

Email s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

DIR 68118 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22

Date of Final Report:
12/02/2021

ARTG #:
308140

Brand Name:
Medtronic 670G & Guardian CGM - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
670G

Serial #:
NG1905070H ref MMT-782K,

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22

Phone:

Email: s22 @medtronic.com;
s22 @medtronic.com

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
Medtronic closed loop 670G with CGM.
Could feel my blood sugar rising, pump showing 7.9 finger prick showing 23.2mmol.
Tried several times to recalibrate pump by entering blood sugar and selecting yes to calibrate, repeated 6x over 5 hours early hours of the morning. Woke up vomiting, unable to hold down water blood sugar 26, called ambulance, was monitored closely in [Redacted] ICU, diagnosed DKA. 2 weeks off auto mode increasing constant insulin 60% my insulin to carb ratio changed back, not quite as low. I stopped using the pump and CGM.
I have since returned to 2x daily Levemir, 4x Novarapid and configured my own I:C

Patient Outcome/Consequences:
Hba1c increased from 7.8 - 8.9.
I unit to 15g is now 1 unit to 8g of carbohydrates.
My blood sugars are more stable + more predictable especially with the return of insulin sensitivity.
1 incidence of 3.9mmol which was dosed, predicted, and timed, all signs of hypoglycaemia, immediately treated.
Second ever Thyroid storm due to graves occurred 3 weeks following. Treated with Carbimazole, immediate TSH lowering, now .04

Additional Event Description:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

From: [redacted]
To: [redacted]
Subject: Medtronic Response - s41JA Requirement for Information for DIR letter- DIR 68118
Date: Monday, 3 May 2021 5:27:31 PM
Attachments: image001.gif

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear [redacted]

Thank you for your query relating to DIR 68118. Please see below for all similar incidents for the 670G involving diabetic ketoacidosis.

Year	Similar Incidents (Australia)	Similar Incidents (Worldwide, excluding AU)
2018	0	466
2019	0	1,212
2020	5	1,166
2021 (to date)	0	234

Below are all DIRs relating to these incidents:

- 63917
- 65754
- 65977
- 66917
- 67426

Best Regards,

[redacted]
Associate Post Market Vigilance Specialist | Quality and Regulatory Affairs

---

From: [redacted]@health.gov.au>
Sent: Thursday, 15 April 2021 10:45 AM
To: [redacted]@medtronic.com>
Subject: [EXTERNAL] s41JA Requirement for Information for DIR letter- DIR 68118 [SEC=OFFICIAL]

Dear [redacted]

Please find attached a Request for Information Letter for your action. **A response is due 3 May 2021.**

Please send your response to : IRIS@health.gov.au

Kind regards,

s22 [redacted]
Departmental Officer
Devices Post Market monitoring Section
Medical Devices Surveillance Branch

Phone: s22 [redacted]
Email: s22 [redacted] @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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Medtronic
Medtronic Australasia Pty Ltd
ABN 47 001 162 661
2 Alma Road
Macquarie Park, NSW 2113
Australia
www.medtronic.com.au
Tel: 02 9857 9000
Fax: 02 9878 5100

18th May 2021

s22 [redacted]

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health
136 Narrabundah Lane
Symonston ACT 2609

Re: DIR 67426 - Request For Information Letter

Dear s22 [redacted]

Please see below for similar incident data based on the clinical event description, i.e. hospitalization due to DKA.

Year	Similar Incidents (Australia)	Sales (Australia)	Incident Rate
2018	0	474	0%
2019	0	5,006	0%
2020	4	4,094	0.0977%
2021 (to date)	0	369	0%

Year	Similar Incidents (Worldwide excluding AU)	Sales (Worldwide excluding AU)	Incident Rate
2018	399	113,938	0.3502%
2019	968	159,734	0.6060%
2020	907	145,532	0.6232%
2021 (to date)	172	10,097	1.7035%

Best Regards,

s22 [redacted]
s22 [redacted]

Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
s22 [redacted] s22 [redacted]
s22 [redacted] @medtronic.com

Medtronic
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Australia
www.medtronic.com.au
Tel: 02 9857 9000
Fax: 02 9878 5100

03 June 2021

s22 [redacted]
Departmental Officer
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration
Department of Health

Re: TGA s41JA Requirement for Information for DIR letter 67426

Dear s22 [redacted]

Thank you for your inquiry dates 18th May 2021. Please see below for Medtronic's response to your question.

> "In your response dated 18 May 2021, it states the similar event code used was "hospitalization due to DKA". The similar event rates in 2020 were noted to be four and similar events to date for 2021was zero. The TGA has received only 2 reports of diabetic ketoacidosis in 2020 and 4 reports of diabetic ketoacidosis in the last 6 months. The information provided in your response is not consistent with the IRIS database. Please provide the overall rates for all similar events of diabetic ketoacidosis regardless of extra codes (i.e. hospitalization)."

Our similar incidents calculation is based on reportable complaints where the customer mentioned having Diabetic Ketoacidosis that required hospitalization documented on the 670G insulin pump specifically. The 4 reports of diabetic ketoacidosis in the last 6 months may have been related to other pump models (640G,770G) or other devices such as infusion sets or sensors.

The following table shows the four complaints (including the complaint related to this inquiry) that were identified per this search scope.

Notified Date	DIR Number	Harm	Treatment
12-Jun-2020	63917	Diabetic Ketoacidosis	Hospitalization
08-Oct-2020	65977	Diabetic Ketoacidosis	Hospitalization
28-Nov-2020	66917	Diabetic Ketoacidosis	Hospitalization
22-Dec-2020	67426	Diabetic Ketoacidosis	Hospitalization

Medtronic

The similar incidents calculation based on reportable complaints where the customer mentioned having Diabetic Ketoacidosis documented on the 670G insulin pump (excluding extra codes i.e. hospitalization) included one additional case involving a death.

The following table shows the incident rates calculated based on our 670G insulin pump install base.

Year	Reportable Complaints	Incident Rates
2018	0	0.0000%
2019	0	0.0000%
2020	5	0.0623%
2021	0	0.0000%

Best Regards,

s22 [redacted]
s22 [redacted]

Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
s22 [redacted] s22 [redacted]
s22 [redacted] @medtronic.com

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]

File Reference: E20-398429

Sent by email

Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com; s22 [redacted]@medtronic.com

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 66605 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 06/01/2021.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

(02) 6289 4642 or email: IRIS@health.gov.au.

Yours sincerely
Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

02/12/2020

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME –
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 02/12/2020

DIR: 66605 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			
11) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 95763**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:		**YES**	**NO**
a) To the Australian Market		X	
b) For Export		X	
3) How many of this model have been supplied **Jan 2017-Dec 2020**	In Australia:	9,736	
	Worldwide:	492,425	
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A	
	Worldwide:	N/A	
5) Are you aware of this problem, as reported?		X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X	
7) Have you had any other reports of similar* problems with this product in Australia?			X

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Yes [ ] No

If **YES**, how many: Please see below.

If **YES**, please give details:

There have been a total of Eighty-two (82) reports of complaints received worldwide with the same problem code - Environment (Surgery, Equipment, Etc.) Seven (7) of the complaints involved a clinical event requiring medical intervention. Of these, 4 involved Hyperglycemia and 3 involved Hypoglycemia and loss of consciousness.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: N/A

The Minimed 670G insulin infusion pump was not returned for analysis.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [X] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

The instructions for use can be found on the following web address:
https://www.medtronic-diabetes.com.au/support/guides-and-manuals/minimed-670g/

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
Position	Product Reporting Specialist	Email	s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

DIR 66605 - ARTG # 95763 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
18/11/2020

ARTG #:
95763

Brand Name:
Guardian 3 and Medtronic 670G, Continous glucose monitoring system (sensor+transmitter) plus insulin pump

Device Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone:

Email: s22 [redacted]@medtronic.com;
s22 [redacted]@medtronic.com

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
Patient (person to contact) has type 1 diabetes and works as a psychiatry nurse. They are using the Medtronic 670G insulin pump and Guardian 3 continuous glucose monitoring system. They have noted on two occasions whereby the pump+sensor system, inteferes with the ECG being performed on the patient they are caring for. She showed me an ECG tracing of a patient with interrupted tracing through telehealth.

They also reports inteference to/by patient's duress alarms but I did not manage to clarify this based on time constraints of the consultation.

Patient Outcome/Consequences:
The concern is interference with other medical devices of patients.

Additional Event Description:
I have contacted the patient to clarify the exact date of the events and to get a copy of the ECG printout but she has not gotten back to me.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E20-66383
Sent by email

Australian Government
Department of Health
Therapeutic Goods Administration

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 63123 - ARTG # 308240 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 29/05/2020.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

01/05/2020

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 01/05/2020

DIR: 63123 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	7,194		
	Worldwide:	403,645		
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A		
	Worldwide:	N/A		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?				X

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many: Sixty-Eight (68)

If **YES**, please give details:

Medtronic has received sixty-eight other complaints of MiniMed 670G insulin infusion pump users who received the same combination of possible over delivery anomaly complaints where the user was not hospitalized and did not require emergency medical services, also no harm was reported to the user in these cases. These complaints range from March 2018 to April 2020 and involved a MiniMed 670G pump from the following countries: Canada, the Netherlands, Norway, Spain, United States.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: N/A

The Minimed 670G insulin infusion pump was not returned for analysis.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

The reporter has mentioned the pump continues to deliver insulin when their BGL was close to the safe minimum. Can this be rectified by reprogramming the device ? If not, why?

The safety of using Auto Mode, Suspend before low, and Suspend on low in people who have no pump experience is not known. Auto Mode, Suspend before low, and Suspend on low should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, or insulin sensitivity factors. Always discuss with your healthcare professional before using Auto Mode, Suspend before low, or Suspend on low.

- Please provide clarification why the 'Suspend on Low' function doesn't work in auto mode?

When Auto Mode is active, then the Low Management features are unavailable and automatically turned off. If you are using Suspend before low or Suspend on low, they are automatically turned off when Auto Mode becomes active. If your pump exits Auto Mode, the Low Management features are not active until you turn them on after you exit Auto Mode. If you want to use these features, you must manually turn them on after you exit Auto Mode.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]

Signature s22 [redacted]

Position Product Reporting Specialist

Phone s22 [redacted]

Fax

Email s22 [redacted]@medtronic.c

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

DIR 63123 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
20/04/2020

ARTG #:
308140

Brand Name:
Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
670G

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone:

Email: s22 [redacted]@medtronic.com

Fax:

Reporter:
s22 [redacted]

Confidential: No

Phone:
Fax:

Email:
s22 [redacted]

Clinical Event Information:
I am a type 1 diabetic and am using a Medtronic 670G pump and the Guardian 3 Sensors to control the insulin delivery. The system has improved my HbA1c considerably over the previous methods, however there is one fault in the programming that has caused me to have a number of Hypos over the last three months, and a many instances where the pump delivered insulin when the BGL was close to the safe minimum. Attached is a report for the some of days involved. I have circled when the insulin has been injected.

I have had a number of representations to Medtronic and they defend the system, and they have no answer to how this can be fixed. The people I spoke to did not think they could get any action of getting the pump reprogrammed, so I am writing to you to get the problem fixed ot the product recalled.

The pump is set to suspend on a low of 5 mmo however this does not work correctly and it still injects insulin. This risk is increased because of the inaccuracy of the sensor. Sometimes it is out by 2 or 3 mmo. This morning it showed 6.8 and it was in fact 3.9 and I was having a hypo. This is extreme. I would say that 90% of the time it is spot on and maybe once a week it is out by about 2 mmo. If the pump didn't deliver below 5mmo this wouldn't matter. There is "Suspend on Low" feature which is set to on but it doesn't work. Medtronic thought that this doesn't work in auto mode???

Fortunately I have been waking up when my BGL gets too low but I am aware that some people just go into a diabetic coma. This is a significant safety risk and could easily cause a fatality

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E20-25098
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 61530 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 13/03/2020.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

14/02/2020

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 14/02/2020

DIR: 61530 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**95763**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	29,441		
	Worldwide:	449,301		
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A		
	Worldwide:	N/A		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?			X	

If **YES**, how many: 17

If **YES**, please give details:

Since 2015, there have been 17 other similar complaints received from Australia where there was an allegation of a Possible Over Delivery Anomaly that was associated with a hypoglycemia event that was self-remedied by the pump user (i.e. did not require medical intervention).

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 73 [ ]

If **YES**, how many: 153 (excluding Australia)

If **YES**, please give details:

Since 2015, there have been 153 other similar complaints received worldwide - excluding Australia - where there was an allegation of a Possible Over Delivery Anomaly that was associated with a hypoglycemia event that was self-remedied by the pump user (i.e. did not require medical intervention).

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9) Please provide details of any action you have taken, or intend to take, regarding this problem

There are thresholds (upper control limits) for complaint rates for this issue. All complaints are monitored for trends and signals. Complaint rates are trended and monitored monthly against the upper control limits. The upper control limits may be reevaluated, and if necessary recalculated, if they are impacted by a change or improvement (such as a process change, design change, or other significant change). In the past two years, the complaint rate for allegations of Possible Over Delivery Anomaly has not exceeded the control limits.

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10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The customer was using MMT-1711KL for treatment purposes. The diagnosis was hypoglycemia. The customer was wearing the pump at the time of incident. Per caller, pump got automatically set at a temporary target of 200% at 10:15 AM and also gave a 3.9 bolus on it's own, which is the max bolus set up on the pump. Then, per caller, at 11:03 AM, when they input 48g of carbohydrates, it gave 2 units of insulin but it topped it up with 1.9 units of insulin so it seems like the pump was delivering the max bolus amount. Then, per caller, at 11:11AM, it did another 3.9 units without any input. Per Returned Product Analysis, the device passed all analysis testing and was found to meet functional specifications. No over delivery anomaly or under delivery anomaly was noted. During the Occlusion Test, they inserted a test P-Cap and a water filled reservoir into the reservoir compartment. The unit recognized the water filled reservoir in the reservoir compartment. They programmed and delivered a 2.0 unit fill cannula and the water exited the infusion set during the 2.0 unit fill cannula delivery. No prime/fill anomaly was noted. The test reservoir volume matched the units left on the pump status screen. The Pump Trace Download confirmed that the customer manually programmed the Temp Basal on 1/8/2020. The customer also manually programmed and delivered the 3.9 unit bolus on 01/08/2020 10:15:51, on 01/08/2020 11:03:40 and on 01/08/2020 11:11:37 (per button presses). Unit was also monitored with a basal profile for 3 days. No unexpected bolus delivery anomaly, bolus anomaly, basal anomaly or (TDD) total daily dose anomaly were noted during testing. The test P-Cap and reservoir did lock in place in the reservoir compartment. Per pump memory, sensor was not used on Jan 8, 2020. Customer programmed the temporary basal of 200% of basal rate. Customer also programmed the three 3.9U boluses. Boluses were often given without BG input. Information in the file reasonably suggests that the relationship between the device and the incident was unlikely.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required: Document 73

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
		Email	s22 [redacted]@medtronic.com
Position	Business Process Program Management Specialist		

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #:

Date of Adverse Event:
s22

Date of Final Report:
13/01/2020

ARTG #:
95763

Brand Name:
Medtronic 640G Insulin Pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1711

Serial #:
NG1437260H

Software Version:
2.9D

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22

Phone: s22

Email: s22 @medtronic.com

Fax:

Reporter:

Confidential: Yes

Phone:
Fax:

Email:

Date of Implant:
s22

Date of Explant:
s22

Clinical Event Information:
The Medtronic 640g Insulin Pump delivered additional insulin, to almost 10 units, in the space of 50 minutes and started a temporary basal of 200% for 3 hours.
This caused an insulin overdose in my s2 year old son, which was only just treated at home due to being detected so early.

Patient Outcome/Consequences:
Insulin overdose, led to low blood sugars (2-3.5) from 11:15am through to 8pm that night.
Hospital was called, however due to diagnosis time and ability t o keep him drinking\eating sugars we did not go to hospital.
s22 diabetes team will have a record of the call

Injections were done over next 36 hours, replacement pump arrived on Friday morning.
Pump was running newer firmware (4.11 vs 2.9D on faulty pump) sow as connected and has been closely monitored since.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E20-45930
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 60932 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 15/04/2020.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

18/03/2020

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 18/03/2020

DIR: 60932 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG:** 95763
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:		**YES** / **NO**
a) To the Australian Market		X /
b) For Export		/
3) How many of this model have been supplied 1 Jan 2017 - 31 March 2020	In Australia:	5,782
	Worldwide:	360.168
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A – Product is serialised
	Worldwide:	N/A – Product is serialised
5) Are you aware of this problem, as reported?		X /
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X /
7) Have you had any other reports of similar* problems with this product in Australia?		/ X
If **YES**, how many:		
If **YES**, please give details:		

The following data is based on a search for allegations over Possible Over Delivery Anomaly.

Australia:
2017: 0 similar incidents / 0 units sold
2018: 0 / 404
2019: 0 / 5,006
2020 (to date): 0 / 372

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 74 [ ]

If **YES**, how many:

If **YES**, please give details:

The following data is based on a search for allegations over Possible Over Delivery Anomaly.

Worldwide:
2017: 13 similar incidents/ 73,157 sold worldwide
2018: 72/ 113,938
2019: 70 / 159,734
2020: (to date): 18 / 13,339

9) Please provide details of any action you have taken, or intend to take, regarding this problem

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test.
The test P-cap locks properly in the reservoir compartment.
The following physical damages were noted but did not impact the insulin pump's performance: a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

Please explain the rates supplied in more detail.
Are they for low blood glucose, hospitalisation, over-delivery or all together?"

The Similar Incident data provided is based on a search for allegations over 'Possible Over Delivery Anomaly.' The hypoglycemia and hospitalisation were not factored into the calculations.

This customer complaint reported physical damage to the pump, an allegation of over delivery of insulin, and hospitalisation due to hypoglycemia. Similar incident data below is provided on the basis of other complaints containing this combination of codes.

When all four keywords are included in the search - 'Possible Over Delivery Anomaly', 'Physical/Cosmetic Damage', 'hypoglycemia' and 'hospitalisation', the similar incident data is as follows:

Australia:

2017: 0 / 0 units

2018: 0 / 404

2019: 1* / 5,006

2020 (to date): 0 / 372

Worldwide**:

2017: 0 / 73,157 units

2018: 3 / 113,938

2019: 3 / 159,734

2020 (to date): 2 / 13,339

*The only incident matching this criteria is the complaint associated with this report.

**All worldwide complaints occurred in the United States. Worldwide data is inclusive of Australia.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]

Signature s22 [redacted]

Position BP Program Management Spec

Phone s22 [redacted]

Fax

Email s22 [redacted]@medtronic.com

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #: CASE-2019-00840457 / 8 /9

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
03/03/2020

ARTG #:
95763

Brand Name:
Minimed 670G pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1782K

Serial #:
NG1784493H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted] @medtronic.com

Fax:

Reporter:
s22 [redacted]
PMV Manager
Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park NSW 2113

Confidential: N/A

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted] @medtronic.com

Clinical Event Information:
Medtronic was notified of a customer hospitalized for low blood glucose. The customer was using the auto feature on their 670G pump (continuous glucose monitoring).
No troubleshooting was performed as the customer refused.
Medtronic has requested that the pump be returned for analysis.

As of today 03/03/2020- more detailed description of the event:

Customer called and reported that they were hospitalized due to low blood glucose on s22 [redacted] with blood glucose of 20 to 32 mg/dl at the time of the incident.
The customer's blood glucose was 144 mg/dl at the time of the call. The customer was given glucose and intravenous fluids to treat.
The customer did not mention any symptoms. The customer was wearing the insulin pump during the incident. The Auto Mode on the insulin
pump was active and automatically adjusting insulin delivery during the event. The customer reported pump physical damage.
The customer suspected the pump was over delivering. Troubleshooting was not completed as the customer declined.

Patient Outcome/Consequences:

Device Analysis Results:
The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test,
Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test.
The test P-cap locks properly in the reservoir compartment.
The following physical damages were noted but did not impact the insulin pump's performance: a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads.

Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:
Australia:
2017: 0 similar incidents / 0 units sold
2018: 0 / 404
2019: 0 / 5,006
2020 (to date): 0 / 372

Worldwide:
2017: 13 similar incidents/ 73,157 sold worldwide
2018: 72/ 113,938
2019: 70 / 159,734
2020: (to date): 18 / 13,339

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Canada, Sweden, United Kingdom, United States.

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E19-668856
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 60132 - ARTG # 308140 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 02/12/2019.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days,** when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

[redacted]

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

[redacted]
04/11/2019

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 04/11/2019

DIR: 60132 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number	**ARTG: 308140**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export	X	
3) How many of this model have been supplied	In Australia:	28,323
	Worldwide:	421,670
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A
	Worldwide:	N/A
5) Are you aware of this problem, as reported?	X	
6) If deemed ne[redacted] sample of the mentioned device available for review and/or testing?	X	
7) Have you had any other reports of similar* problems with this product in Australia?		

If **YES**, how many:

If **YES**, please give details:

[redacted]

[redacted]

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

[redacted]

[redacted]

8) Is the manufacturer aware of reports of similar problems with this product? [X] [ ]

If **YES**, how many: One (1)

If **YES**, please give details:

Medtronic has received one other complaint of a MiniMed 640G insulin infusion pump user who received this same combination of Pump Error Alarms (Pump Error 3; Pump Error 4; Pump Error 23; Pump Error 49; Pump Error 68). The complaint was received on 12 December 2018 and involved a MiniMed 640G (model number MMT-1712K) pump user in Japan. Returned product analysis was performed on the pump associated with that complaint and could not confirm the occurrence of any of the Pump Error alarms during testing. The product was found to meet functional specifications. The user did not report experiencing an adverse or clinical event of any kind.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

Based on the information in the complaint file, no action has been deemed to be necessary at this time.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: 12 December 2019

Returned product analysis was completed on the insulin pump associated with this event on 6 December 2019. The returned product was found to meet functional specifications. A review of the pump history file confirmed that the user did receive the following Pump Error Alarms (Pump Error 3; Pump Error 4; Pump Error 23; Pump Error 49; Pump Error 68). As the complaint notes state, the pump user was able to clear the Pump Error Alarms and successfully rewind the pump. The user did not report experiencing an adverse or clinical event as a result of receiving the Pump Error Alarms. The user's insulin pump was replaced.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

[redacted]

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	s22 [redacted]
		Email	s22 [redacted]@medtronic.com
Position	Program Analyst		

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

[redacted]

[redacted]

DIR 60132 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
27/10/2019

ARTG #:
308140

Brand Name:
Medtronic Australia, 640G INSULIN PUMP - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
640G`

Serial #:
NG1684477H

Software Version:

Batch #:
MMT-1711K

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone:

Email: s22 [redacted]@medtronic.com

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
My Daughters Medtronic 640g Insulin Pump, had a major failure, with extremely loud alarms, and had 10 errors
4
3
68
49
49
23
68
49
49
23

Patient Outcome/Consequences:
The pump was replaced a few days later by medtronic

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

[redacted]
Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

[redacted]

[redacted]

[redacted]

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: [redacted]@medtronic.com; [redacted]@medtronic.com

File Reference: E19-520388
Sent by email

Dear [redacted]

DEVICE INCIDENT REPORT DIR 55626 - ARTG # 144577 - Invasive interstitial-fluid glucose monitoring system

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 12/03/2019.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

12/02/2019

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 12/02/2019

DIR: 55626 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export		X
3) How many of this model have been supplied	In Australia:	953
	Worldwide:	TBA
4) How many of this batch (if applicable) have been supplied:	In Australia:	NA - serialised
	Worldwide:	NA - serialised
5) Are you aware of this problem, as reported?	X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?	X	
7) Have you had any other reports of similar* problems with this product in Australia?		X

If **YES**, how many: 0

If **YES**, please give details:

There have been no previous similar events for this device for the 670G Medtronic Minimed pump

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? ☐ ☐ Document 76

If **YES**, how many: TBA

If **YES**, please give details:

TBA

9) Please provide details of any action you have taken, or intend to take, regarding this problem

TBA

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The device is expected to be returned for analysis but has not yet been received for investigation (currently in transit). Expected investigation completion date will be able to be determined upon receipt of the device.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- ☐ Service History, and Safety and Performance Test Results
- ☐ Configuration Information and Documentation
- ☐ HHE (Health Hazard Evaluation)

12) Additional Information required: Document 76

This reporter has mentioned she has had 5 pump replacements- please provide information as to the cause of these five individual problems.

Please see the attached response.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22	Phone	s22
Signature	s22	Fax	
Position	Post Market Vigilance Specialist	Email	s22 @medtronic.com

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
03/02/2019

ARTG #:
144577

Brand Name:
Medtronic Insulin pump 670G -Invasive interstitial-fluid glucose monitoring system

Device Class:
Class IIb

Model #:
670G

Serial #:
NG1658151H

Software Version:

Batch #:
MMT-1782K

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: Sarah Timms

Phone:

Email: s22 [redacted] @medtronic.com;
s22 [redacted] @medtronic.com

Fax:

Reporter:
s22 [redacted]

Confidential: No

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted]

Date of Implant:
31/10/2018

Date of Explant:

Clinical Event Information:
I am type 1 diabetic and use the Medtronic 670G insulin pump. The insulin pump is a wonderful device which assists me with my management of type 1 diabetes. Unfortunately, I have experienced numerous malfunctions. I normally update my pump every four years and this is organised through my private health insurance. The last update occurred in June/July 2018. Since this time I have had to to get 5 replacement pumps because the pump has malfunctioned 5 times. This effectively means I am getting a new pump every month. This is disrupting the management of my diabetes and placing me under significant stress. On the s22 [redacted], due this incident, I have suffered a serious hypoglycaemic attack to the point where I feel down the stairs and injured my ankle.

It seems that the insulin pump is not fit for purpose and there are serious consequences for me as a result of these malfunctions. I need access to an insulin pump and I must have confidence that the pump is working well.

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: [redacted]@medtronic.com; [redacted]@medtronic.com

File Reference: E19-520388
Sent by email

Dear [redacted]

DEVICE INCIDENT REPORT DIR 55626 - ARTG # 144577 - Invasive interstitial-fluid glucose monitoring system

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 12/03/2019.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

12/02/2019

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 12/02/2019

DIR: 55626 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 308140**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:		**YES**	**NO**
a) To the Australian Market		X	
b) For Export			X
3) How many of this model have been supplied	In Australia:	953	
	Worldwide:	205,685	
4) How many of this batch (if applicable) have been supplied:	In Australia:	NA - serialised	
	Worldwide:	NA - serialised	
5) Are you aware of this problem, as reported?		X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X	
7) Have you had any other reports of similar* problems with this product in Australia?			X

If **YES**, how many: 0

If **YES**, please give details:

There have been no previous similar events for this device for the 670G Medtronic Minimed pump in Australia – Note: This device is new to the Australian Market

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 77 [ ]

If **YES**, how many: See table below

If **YES**, please give details:

Year	Pump Error 35, Hyperglycemia	Pump Error 35, Hypoglycemia	Pump Error 35, Medical Intervention
2016	0	0	0
2017	19	2	0
2018	239	67	0
2019 (Including February 28, 2019)	33	9	12

9) Please provide details of any action you have taken, or intend to take, regarding this problem

There are thresholds (upper control limits) for complaint rates for this issue. All complaints are monitored for trends and signals. Complaint rates are trended and monitored monthly against the upper control limits. The upper control limits are dynamically adjusted based on the prior two years of complaint rates. At this time, no signals are detected but should one be detected, an investigation will occur to determine if corrective action is required.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: TBA

A review of the manufacturing records for this device (Serial Number NG1658151H) was completed on March 14, 2019. The product met specifications for release at the time of distribution. The manufacturing records contain no data that requires further investigation. To date, our investigation is still pending as returned goods analysis has still not received the product back from the customer to perform functional testing.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required: Document 77

This reporter has mentioned she has had 5 pump replacements- please provide information as to the cause of these five individual problems.

Please see the attached response.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]

Signature s22 [redacted]

Position Post Market Vigilance Specialist

Phone s22 [redacted]

Fax

Email s22 [redacted]@medtronic.com

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

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PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

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Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
03/02/2019

ARTG #:
144577

Brand Name:
Medtronic Insulin pump 670G -Invasive interstitial-fluid glucose monitoring system

Device Class:
Class IIb

Model #:
670G

Serial #:
NG1658151H

Software Version:

Batch #:
MMT-1782K

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone:

Email: s22 [redacted] @medtronic.com;
s22 [redacted] @medtronic.com

Fax:

Reporter:
s22 [redacted]

Confidential: No

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted]

Date of Implant:
31/10/2018

Date of Explant:

Clinical Event Information:
I am type 1 diabetic and use the Medtronic 670G insulin pump. The insulin pump is a wonderful device which assists me with my management of type 1 diabetes. Unfortunately, I have experienced numerous malfunctions. I normally update my pump every four years and this is organised through my private health insurance. The last update occurred in June/July 2018. Since this time I have had to to get 5 replacement pumps because the pump has malfunctioned 5 times. This effectively means I am getting a new pump every month. This is disrupting the management of my diabetes and placing me under significant stress. On the s22 [redacted], due this incident, I have suffered a serious hypoglycaemic attack to the point where I feel down the stairs and injured my ankle.

It seems that the insulin pump is not fit for purpose and there are serious consequences for me as a result of these malfunctions. I need access to an insulin pump and I must have confidence that the pump is working well.

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

Document 78

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 21/06/2018

DIR: 50984 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 95763**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export			X	
3) How many of this model have been supplied	In Australia:	18,062		
	Worldwide:	111,035		
4) How many of this batch (if applicable) have been supplied:	In Australia:	Not applicable – this is a serialized product		
	Worldwide:	Not applicable – 1 – this is a serialized product		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?				X

If **YES**, how many: Not applicable -see below details

If **YES**, please give details:

The reported issue regarding reduced degraded battery life could not be confirmed through returned product analysis. Product analysis included electrical testing, as well as review of the pump trace download (pump memory).
The returned pump was found to be damaged, but the damage did not affect functional performance.

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? ☐ Document 78 ☒ X

If **YES**, how many: Not applicable, see below details

If **YES**, please give details:

The reported issue regarding reduced degraded battery life could not be confirmed through returned product analysis. Product analysis included electrical testing, as well as review of the pump trace download (pump memory).
The returned pump was found to be damaged, but the damage did not affect functional performance.

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9) Please provide details of any action you have taken, or intend to take, regarding this problem

Not applicable - The reported issue regarding reduced degraded battery life could not be confirmed through returned product analysis. Product analysis included electrical testing, as well as review of the pump trace download (pump memory). The returned pump was found to be damaged, but the damage did not affect functional

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: 10/05/2018

Following our receipt of the returned device, the device passed functional testing including the Self-Test, Sleep Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and a Displacement Accuracy Test. The power management tool confirmed the Unloaded Voltage and Loaded Voltage was within specification range. No Power Error 25, Low Battery alert, Power Loss alarm, Replace Battery alert or Replace Battery Now alarm was noted during testing. No unexpected Power Loss alarm, Replace Battery alert, Replace Battery Now alarm was noted in the trace download. A minor scratched display window, cracked case on the battery tube side, cracked case on the corner of the belt clip rail, scratched keypad overlay, keypad overlay texture damage, pillowing keypad overlay, cracked keypad overlay on the Select Button, cracked retainer, and a scratched case was noted during visual inspection.

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11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- ☐ Service History, and Safety and Performance Test Results
- ☐ Configuration Information and Documentation
- ☐ HHE (Health Hazard Evaluation)

12) Additional Information required:

1) Was this issue capture in the 2013 recall?

s22 . As this is a different model (640G) it is not affected by this recall.

2) Please provide the batch or lot number.

Serial Number: NG1302944H

3) Please provide current rates for this issue of alleged blockage and subsequent non-delivery of insulin.

Response: There is no reference in the clinical even information to an alleged blockage or subsequent non-delivery of insulin

4) Please provide rationale as to how this blockage may have occurred.

Response: There is no reference in the clinical even information to an alleged blockage or subsequent non-delivery of insulin

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22	Phone	s22
Signature	s22	Fax	
		Email	s22 @medtronic.com
Position	Post Market Vigilance Specialist		

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

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Woden ACT 2606

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DIR 50984 - ARTG # 95763 - Infusion pump, insulin, ambulatory

Document 78

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
05/04/2018

ARTG #:
95763

Brand Name:
Minimed 640G - Insulin pump with CGM capability

Device Class:
Class IIb

Model #:
640G

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: (02) 9857-9000

Email: s22 [redacted] @medtronic.com

Fax:

Reporter:
s22 [redacted]

Confidential: No

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted]

Clinical Event Information:
I am on my third Minime 640G replacement insulin pump, with the same crack over battery compartment, from edge of clip retainer. This degrades the IPX rating, and allows moisture into the battery compartment and pump, causing degraded battery performance.

Patient Outcome/Consequences:
Battery usage drops from over 2 weeks on a AA lithium cell, to 4 days on the same battery.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E17-34624
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 48092 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 03/11/2017.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8695 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

s22 [redacted]

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

06/10/2017

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 06/10/2017

DIR: 48092 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 95763 – 640G Pump**
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export	X	
3) How many of this model have been supplied	In Australia:	18,760
	Worldwide:	110,167
4) How many of this batch (if applicable) have been supplied:	In Australia:	
	Worldwide:	
5) Are you aware of this problem, as reported?	X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?	X	
7) Have you had any other reports of similar* problems with this product in Australia?	X	

If **YES**, how many: 110 Total

If **YES**, please give details:

The above total includes three years of similar problems (all causes) reported in Australia from 2015 to current.

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 79 [ ]

If **YES**, how many: 617 Total

If **YES**, please give details:

The above total includes three years of similar problems (all causes) reported worldwide from 2015 to current.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

No corrective or remedial action is possible at this time. If, at a later date, the product returns, this investigation will be re-opened.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

Currently, it is unknown whether or not the device may have caused or contributed to the event as no product has been returned. No conclusion can be drawn at this time.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required: Document 79

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
		Email	s22 [redacted]@medtronic.com
Position	Post Market Vigilance Specialist		

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

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Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

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Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
22/09/2017

ARTG #:
95763

Brand Name:
MiniMed Insulin Reservoirs

Device Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]@medtronic.com

Fax: s22 [redacted]

Reporter:

Confidential: Yes

Clinical Event Information:
First I am currently on my third 640G pump. The first two failed in the first 15 months of use. They become flaky and then stopped working.

Not suitable for a type 1 diabetic that depends on it. They tell you they will send a new pump within 2 working days, but that doesn't take into account an extra 2 days for the weekend and at least another 1 or 2 days despatch time.

Also their Canulas have been faulty the whole 15 months until now. I have only tried 1 new one so far and it appears good. Time will tell. They could not supply an exact replacement owing to a stock shortage. I got the same story with the 64OG replacement pump when the last one failed.

The last box of reservoirs I opened reference MMT 332A LOT HG1G8EW was completely faulty. The plunger came out the bottom on the reservoir when drawing insulin out of the bottle. The insulin went everywhere. Same again with another out of the same batch.

The replacement box reference MM 332A LOT HG1WMDF is marginally better but only just.

There appears to be a quality issue covering the whole range of products which is diabolical for the patient.

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: [redacted]@medtronic.com

File Reference: E17-34624
Sent by email

Dear [redacted]

DEVICE INCIDENT REPORT DIR 48092 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 03/11/2017.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8695 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

[redacted]

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

06/10/2017

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 06/10/2017

DIR: 48092 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 95763 – 640G Pump**
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export	X	
3) How many of this model have been supplied	In Australia:	18,760
	Worldwide:	110,167
4) How many of this batch (if applicable) have been supplied:	In Australia:	
	Worldwide:	
5) Are you aware of this problem, as reported?	X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?	X	
7) Have you had any other reports of similar* problems with this product in Australia?	X	

If **YES**, how many: 110 Total

If **YES**, please give details:

The above total includes three years of similar problems (all causes) reported in Australia from 2015 to current.

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 30 [ ]

If **YES**, how many: 617 Total

If **YES**, please give details:

The above total includes three years of similar problems (all causes) reported worldwide from 2015 to current.

9) Please provide details of any action you have taken, or intend to take, regarding this problem

No corrective or remedial action is possible at this time. If, at a later date, the product returns, this investigation will be re-opened.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

Currently, it is unknown whether or not the device may have caused or contributed to the event as no product has been returned. No conclusion can be drawn at this time.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required: Document 80

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
		Email	s22 [redacted]@medtronic.com
Position	Post Market Vigilance Specialist		

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
22/09/2017

ARTG #:
95763

Brand Name:
MiniMed Insulin Reservoirs

Device Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]@medtronic.com

Fax: s22 [redacted]

Reporter:

Confidential: Yes

Clinical Event Information:
First I am currently on my third 640G pump. The first two failed in the first 15 months of use. They become flaky and then stopped working.

Not suitable for a type 1 diabetic that depends on it. They tell you they will send a new pump within 2 working days, but that doesn't take into account an extra 2 days for the weekend and at least another 1 or 2 days despatch time.

Also their Canulas have been faulty the whole 15 months until now. I have only tried 1 new one so far and it appears good. Time will tell. They could not supply an exact replacement owing to a stock shortage. I got the same story with the 64OG replacement pump when the last one failed.

The last box of reservoirs I opened reference MMT 332A LOT HG1G8EW was completely faulty. The plunger came out the bottom on the reservoir when drawing insulin out of the bottle. The insulin went everywhere. Same again with another out of the same batch.

The replacement box reference MM 332A LOT HG1WMDF is marginally better but only just.

There appears to be a quality issue covering the whole range of products which is diabolical for the patient.

Patient Outcome/Consequences:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E17-8670
Sent by email

Attention: s22 [redacted]

DEVICE INCIDENT REPORT DIR 45502 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 16/05/2017.

Please send responses via email to IRIS@tga.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8695 or email: IRIS@tga.gov.au.

Yours sincerely

Signed electronically by

s22 [redacted]

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

12/04/2017

Sent by email

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 12/04/2017

DIR: 45502 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 95763**
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	X	
b) For Export	X	
3) How many of this model have been supplied	In Australia:	**9389**
	Worldwide:	**56,003**
4) How many of this batch (if applicable) have been supplied:	In Australia:	**N/A**
	Worldwide:	**N/A**
5) Are you aware of this problem, as reported?	X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X
7) Have you had any other reports of similar* problems with this product in Australia?		X

If **YES**, how many:

If **YES**, please give details:

Please note: As no clinical event description was provided, there is no 'similar event' information available.

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? ☐ ☒ Document 81

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

The manufacturer will continue to monitor the rate of such incidents for trending purposes.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The insulin pump has not yet been received for analysis. Once returned, the results of the analysis will be provided to the TGA.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if ticked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- ☐ Service History, and Safety and Performance Test Results
- ☐ Configuration Information and Documentation
- ☐ HHE (Health Hazard Evaluation)

12) Additional Information required:

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14) Name s22 [redacted]

Phone s22 [redacted]

Signature s22 [redacted]

Fax s22 [redacted]

Position **Senior Regulatory Affairs Specialist**

Email s22 [redacted] **@medtronic.com**

This questionnaire and any appended documents should be returned to the TGA within **20 working days.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@tga.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:
https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user#send

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #:

Date of Adverse Event:
s22

Date of Final Report:
03/04/2017

ARTG #:
95763

Brand Name:
Medtronic 640g Insulin Pump

Device Class:
Class IIb

Model #:
640g

Serial #:
NG1111286H

Software Version:
unknown

Batch #:
unknown

Lot #:
unknown

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Email: s22 @medtronic.com

Contact Name:
s22

Phone: s22

Fax: s22

Reporter:
s22

s22

Email:
s22

Confidential: No

Phone: s22
Fax:

Patient Outcome/Consequences:
Pump didnt recognise new batteries. Internal battery died and did not recognise new batteries.
Tried 4 different batteries including a new sealed package. Contacted medtronic helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu. Call taker advised replacement pump required and would need to be coordinated with ** office. Replacement device not received for >72 hours following report.
Pump stopped and unable to deliver insulin. User reverted to multiple injections as pump unable to deliver insulin at all.
Have identified others with same/similar issues on forums in Australia. Have previously reported to Sponsor rep that there is a short length of time between battery low warning and critical battery warning.

May be relevant to TGA warning released Feb 17th 2017: https://www.tga.gov.au/node/735389

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Countries Similar Events Also Occurred:

Clinical Event Information:
Insulin pump warned low battery approximately. A day later it alarmed warning battery critically now and to replace immediately. Replaced battery but insulin pump didn't recognise new battery. Tried 4 different batteries including a new sealed package. Contacted sponsor's helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu. Call taker advised replacement pump required and would need to be coordinated with ** office. Replacement device not received for >72 hours following report.

TGA ref.# DIR 45502
SVN# 307408460
Low Battery Alert & Frozen Screen

Medtronic

Within the analysis of the device it is stated :

"Power Graph Analysis confirmed Low Battery Alarms and an abnormal Loaded Voltage (Loaded Vlith) at the Power Management Graph due to connector resistance at J6/PCB 1"

Please explain if this would have led to the customer complaint. If not please provide a valid explanation as to the customers compliant.

Indeed, the connector resistance anomaly could cause unexpected Low Battery Alarms, which would confirm the customer's complaint of Low Battery Alarm.

If this could have led to the customer complaint, please provide the following;

1. How many other devices in the market might have this potential issue.

For the time-period of November 11, 2015 and April 12, 2017, there have been 195 complaints received regarding short battery life and Low Battery Alarm. All of the complaint devices have been returned for analysis and 160 have been confirmed to have connector resistance at J6/PCB 1 anomaly. There have been no reported adverse events or serious injuries associated with the anomaly.

Region	Year	# of confirmed cases	Install base	Rate
Australia	2015	1	3,567	0.0280%
	2016	10	8,176	0.1223%
	2017	1	10,269	0.0097%
Worldwide*	2015	1	25,048	0.0040%
	2016	159	49,937	0.3184%
	2017	23	56,135	0.0410%

***Worldwide does not include Australia.**

2. What actions do you intend to take to alert users of this potential issue.

As part of our ongoing post-market surveillance process, Medtronic Diabetes continues to monitor and analyze the trends and the signals of complaint associated with Low Battery Alarm and initiate investigations upon detection of any new unfavorable signals.

All product complaints and returns for commercially available Medtronic Diabetes devices are reviewed by Medtronic Diabetes using the Control Chart Statistical Program (Control Chart Program). The Control Chart Program is a validated statistical software that is used with our company's main database and business operating system. It is used to statistically monitor complaints and returns for statistical signals (statistical outliers, trends and shifts).

The Control Chart Program is used to analyze all complaints and returns received for trends, shifts, or outliers and identify unfavorable statistical signals above the upper control limit.

A trend, shift or outlier is considered a "signal." These signals are reviewed to determine if they are previously identified and assessed or addressed. If a signal had not been identified previously, or had not been adequately investigated, or if an assessment or corrective action was not previously performed.

From: s22 [redacted]
To: s22 [redacted]
Cc: s22 [redacted]
Subject: RE: Corrections to 47915 & 47914 [SEC=UNCLASSIFIED]
Date: Wednesday, 22 November 2017 4:30:15 PM

Thank you for this additional information. The report has been updated.

Kind regards

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)
Email: IRIS@health.gov.au
Phone: 1800 809 361
Fax: 02 6232 1713
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers can use the online Medical Device Incident Reporting (MDIR) system using a TGA Business Service (TBS) user name and password. The MDIR system allows sponsors and manufacturers to submit initial, follow-up and final reports and to review reports already submitted to the TGA. A user guide and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.

If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TBS, please click on the following link to access the appropriate forms:
http://www.tga.gov.au/form/ebusiness-services-forms
If you have any issues please contact TBS on 1800 010 624 or email: eBS@health.gov.au

Online reporting ~
Sponsors / Manufacturers: http://www.tga.gov.au/safety/problem-device-report-industry.htm
Medical Device Healthcare Professionals/Users: http://www.tga.gov.au/safety/problem-device-report-user.htm

---

From: s22 [redacted] [mailto:s22 [redacted]@medtronic.com]
Sent: Friday, 17 November 2017 5:45 PM
Subject: Corrections to 47915 & 47914 [SEC=No Protective Marking]

Hi,

Unfortunately I have just been informed by the manufacturer that the information provided for similar incidents for 2 Final DIR reports earlier this month, was incorrect. Please note the following corrections:

DIR 47915
Other Similar Events Manufacturer / Sponsor Aware of: *
The following data relates to similar incidents involving high blood glucose hospitalization, with a failed HP test.

Region	Year	# of Similar Events	Install Base

Worldwide (including Australia)	2015	0	11,851
	2016	0	39,124
	2017 (to date)	7	59,192
Australia	2015	0	1,946
	2016	0	5,913
	2017 (to date)	2	10,901

Countries Where These Similar Adverse Events Occurred:
Netherlands

-

DIR 47914

Other Similar Events Manufacturer / Sponsor Aware of: *
The following data relates to similar incidents involving keypad unresponsive / button error alarm, no hospitalisation.

Region	Year	# of Similar Events	Install Base
Worldwide (including Australia)	2015	76	11,851
	2016	435	39,124
	2017 (to date)	470	59,192
Australia	2015	21	1,946
	2016	54	5,913
	2017 (to date)	81	10,901

Countries Where These Similar Adverse Events Occurred:
Chile, Czech Republic, Denmark, Estonia, Finland, Germany, Hong Kong, Hungary, Iceland, Ireland, Kuwait, Netherlands, Norway, Singapore, Slovakia, Slovenia, South Africa, Sweden, Switzerland, United Kingdom

I appreciate if you could please update your records accordingly and apologise for any inconvenience caused.

Kind Regards

s22 [redacted]
Senior Regulatory Affairs Specialist | Quality and Regulatory Affairs

Medtronic
Medtronic Australasia Pty Ltd
5 Alma Road | Macquarie Park, NSW, 2113 | Australia
Office: s22 [redacted] | Mobile: s22 [redacted] | Fax: s22 [redacted]
s22 [redacted] @medtronic.com
medtronic.com.au | Facebook | LinkedIn | Twitter | YouTube

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER



This message has been marked as Medtronic Controlled

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From: s22
To: IRIS
Subject: RE: DIR 60932 - Questionnaire Letter - response due 15 April 2020 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Wednesday, 15 April 2020 2:00:25 PM
Attachments: DIR 60932 - Questionnaire 15.4.2020.pdf

Hi s22

Please find attached completed questionnaire for DIR 60932.

Should you have any further questions, please do not hesitate to contact me.

Kind Regards

s22

From: IRIS <IRIS@health.gov.au>
Sent: Wednesday, 18 March 2020 1:55 PM
To: s22 @medtronic.com>
Subject: [EXTERNAL] DIR 60932 - Questionnaire Letter - response due 15 April 2020 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22

Please see the attached **Questionnaire Letter** for action.

Please note that the form provided must be completed and return to TGA as an attachment by COB, 15 April 2020.

Kind regards

s22
Administrative Officer
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring Section
Medical Devices Branch
Email: IRIS@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted]@medtronic.com

File Reference: E20-45930
Sent by email

Dear s22 [redacted]

DEVICE INCIDENT REPORT DIR 60932 - ARTG # 95763 - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 15/04/2020.

Please send responses via email to IRIS@health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8777 or email: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

18/03/2020

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 18/03/2020

DIR: 60932 Manufacturer Name: Medtronic Minimed [40022]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG:** 95763
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:		**YES** / **NO**
a) To the Australian Market		X /
b) For Export		/
3) How many of this model have been supplied 1 Jan 2017 - 31 March 2020	In Australia:	5,782
	Worldwide:	360.168
4) How many of this batch (if applicable) have been supplied:	In Australia:	N/A – Product is serialised
	Worldwide:	N/A – Product is serialised
5) Are you aware of this problem, as reported?		X /
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?		X /
7) Have you had any other reports of similar* problems with this product in Australia?		/ X
If **YES**, how many:		
If **YES**, please give details:		

The following data is based on a search for allegations over Possible Over Delivery Anomaly.

Australia:
2017: 0 similar incidents / 0 units sold
2018: 0 / 404
2019: 0 / 5,006
2020 (to date): 0 / 372

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? [X] Document 84 [ ]

If **YES**, how many:

If **YES**, please give details:

The following data is based on a search for allegations over Possible Over Delivery Anomaly.

Worldwide:
2017: 13 similar incidents/ 73,157 sold worldwide
2018: 72/ 113,938
2019: 70 / 159,734
2020: (to date): 18 / 13,339

9) Please provide details of any action you have taken, or intend to take, regarding this problem

All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test.
The test P-cap locks properly in the reservoir compartment.
The following physical damages were noted but did not impact the insulin pump's performance: a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- [ ] Sample of the product/device
- [ ] Product Specifications
- [ ] Descriptive product promotional documentation
- [ ] Instructions for use, as supplied with the device
- [ ] Device Packaging with printed instructions
- [ ] Operator's manual
- [ ] Technical Service Manual
- [ ] Clinical training manual in printed or video form
- [ ] In-house training documentation
- [ ] Evidence of compliance with the Essential Principles
- [ ] A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- [ ] Service History, and Safety and Performance Test Results
- [ ] Configuration Information and Documentation
- [ ] HHE (Health Hazard Evaluation)

12) Additional Information required:

Please explain the rates supplied in more detail.
Are they for low blood glucose, hospitalisation, over-delivery or all together?"

The Similar Incident data provided is based on a search for allegations over 'Possible Over Delivery Anomaly.' The hypoglycemia and hospitalisation were not factored into the calculations.

This customer complaint reported physical damage to the pump, an allegation of over delivery of insulin, and hospitalisation due to hypoglycemia. Similar incident data below is provided on the basis of other complaints containing this combination of codes.

When all four keywords are included in the search - 'Possible Over Delivery Anomaly', 'Physical/Cosmetic Damage', 'hypoglycemia' and 'hospitalisation', the similar incident data is as follows:

Australia:

2017: 0 / 0 units

2018: 0 / 404

2019: 1* / 5,006

2020 (to date): 0 / 372

Worldwide**:

2017: 0 / 73,157 units

2018: 3 / 113,938

2019: 3 / 159,734

2020 (to date): 2 / 13,339

*The only incident matching this criteria is the complaint associated with this report.

**All worldwide complaints occurred in the United States. Worldwide data is inclusive of Australia.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name	s22 [redacted]	Phone	s22 [redacted]
Signature	s22 [redacted]	Fax	
Position	BP Program Management Spec	Email	s22 [redacted]@medtronic.com

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed.

Reporter Reference #: CASE-2019-00840457 / 8 /9

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
03/03/2020

ARTG #:
95763

Brand Name:
Minimed 670G pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1782K

Serial #:
NG1784493H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: (02) 9857-9000

Email: s22 [redacted] @medtronic.com

Fax:

Reporter:
s22 [redacted]
PMV Manager
Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park NSW 2113

Confidential: N/A

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted] @medtronic.com

Clinical Event Information:
Medtronic was notified of a customer hospitalized for low blood glucose. The customer was using the auto feature on their 670G pump (continuous glucose monitoring).
No troubleshooting was performed as the customer refused.
Medtronic has requested that the pump be returned for analysis.

As of today 03/03/2020- more detailed description of the event:

Customer called and reported that they were hospitalized due to low blood glucose on s22 [redacted] with blood glucose of 20 to 32 mg/dl at the time of the incident.
The customer's blood glucose was 144 mg/dl at the time of the call. The customer was given glucose and intravenous fluids to treat.
The customer did not mention any symptoms. The customer was wearing the insulin pump during the incident. The Auto Mode on the insulin
pump was active and automatically adjusting insulin delivery during the event. The customer reported pump physical damage.
The customer suspected the pump was over delivering. Troubleshooting was not completed as the customer declined.

Patient Outcome/Consequences:

Device Analysis Results:
The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test,
Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test.
The test P-cap locks properly in the reservoir compartment.
The following physical damages were noted but did not impact the insulin pump's performance: a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads.

Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:
Australia:
2017: 0 similar incidents / 0 units sold
2018: 0 / 404
2019: 0 / 5,006
2020 (to date): 0 / 372

Worldwide:
2017: 13 similar incidents/ 73,157 sold worldwide
2018: 72/ 113,938
2019: 70 / 159,734
2020: (to date): 18 / 13,339

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Canada, Sweden, United Kingdom, United States.

From: RS ANZ PMV
To: s22
Subject: RE: DIR 61609 - Request For Information (RFI) Letter - Response due COB 17 June 2020 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Monday, 29 June 2020 2:26:44 PM
Attachments: RI Response - 61609.pdf

Dear s22

Please find attached Medtronic's response to your below request. The rates provided now include all potential over-delivery and hypoglycaemia cases.

Kind Regards

s22

From: s22 @health.gov.au>
Sent: Monday, 22 June 2020 12:00 PM
To: s22 @medtronic.com>
Subject: [EXTERNAL] RE: DIR 61609 - Request For Information (RFI) Letter - Response due COB 17 June 2020 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22

I am investigating DIR 61609. Please provide the rates for the over-delivery and hypoglycaemia regardless of the patient treatment and outcome.

Please provide the response by COB 06 July 2020.

Thanks & Regards,

s22
Departmental Officer
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s22 [redacted] @medtronic.com>
Sent: Wednesday, 3 June 2020 12:20 PM
To: s22 [redacted] @health.gov.au>
Subject: RE: DIR 61609 - Request For Information (RFI) Letter - Response due COB 17 June 2020 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted]

I have confirmed with the manufacturer that the search criteria used for similar incidents in this case was for 'over-delivery', 'hypoglycaemia' and 'no hospitalisation'. The user reported that they treated themselves without being hospitalized, nor calling emergency medical services.

For the other cases noted on your database, I believe they will indicate that hospitalisation was involved.

The manufacturer has confirmed that, for accuracy, they try to match similar incidents as closely as possible to the case in question.

Kind Regards

s22 [redacted]

From: s22 [redacted]
Sent: Wednesday, 20 May 2020 1:29 PM
To: s22 [redacted]
Subject: [EXTERNAL] DIR 61609 - Request For Information (RFI) Letter - Response due COB 17 June 2020 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted]

Please see the attached **Request For Information (RFI) Letter** for action.
*Please note the due date for a response is COB 17 June 2020.

Kind regards,

s22 [redacted]

-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au
Phone: **DST** s22 [redacted]
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609



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Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via 02 6289 4642 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

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TGA
RB Reference: 61609
SVN: 310732899

640G Over-delivery anomaly

Medtronic

Thank you for your inquiry. The responses to your questions are presented below.

TGA asks:

TGA DIR: 61609	CASE-2020-00020427	Event Date: 8-Jan-20		
ARTG: 95763	**GMDN: 35983**	**CFN: 95763**	**Product Description:** Minimed 640G pump	**Serial Number: NG1437260H**
Year	**Similar Incidents Australia**	**Number sold AUS**	**Similar Incidents Worldwide**	**Number sold Worldwide**
2017	2	7,185	23	83,260
2018	0	8,128	24	124,525
2019	2	4,953	73	111,395
2020 (to date)	1	1,302	19	35,389

Manufacturer's Investigation

Manufacturer's analysis results:	The insulin pump passed functional testing including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test, and Displacement Accuracy Test. No over-delivery anomaly was noted during testing. The following physical damages were noted but did not impact the insulin pump's performance: a scratched case, and scratched display window. Analysis testing identified the insulin pump met specifications.
Countries where similar events occurred	Austria, Belgium, Colombia, Czech Republic, Denmark, Finland, France, Germany, Guatemala, Hungary, Ireland, Italy, Netherlands, Norway, Saudi Arabia, Spain, Sweden, Switzerland, United Kingdom.
Event Description	Information received by Medtronic indicated the user alleged the insulin pump over-delivered insulin. Blood glucose reading at the time of the event was 3.1 mmol/l. The user did not mention any symptoms. The user treated with glucose tablets. The user was neither in ER, nor admitted into hospital, nor was EMS dispatched as a result of low BG.
Corrective Action	All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

From: s22
To: IRIS; s22
Subject: Medtronic Response - DIR 67426 - Request For Information Letter 18-May-2021
Date: Tuesday, 18 May 2021 9:00:22 AM
Attachments: Medtronic Response - DIR 67426 - Request For Information Letter 18-May-2021.pdf

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Dear s22

Thank you for your query relating to DIR 67426, please see attached for Medtronic's response. Should you have any further questions, please do not hesitate to contact me.

Best Regards,

s22
s22 | Quality and Regulatory Affairs

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 22 April 2021 3:22 PM
To: s22 @medtronic.com>
Cc: s22 @medtronic.com>
Subject: [EXTERNAL] DIR 67426 - Request For Information Letter *Response due 21/05/2021* [SEC=OFFICIAL, ACCESS=Personal-Privacy]

Dear s22

Please see the attached Request For Information Letter for action. **Please note the due date for a response is 21 May 2021.**

Kind regards,

-
s22
-

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609



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Medtronic Australasia Pty Ltd
ABN 47 001 162 661
2 Alma Road
Macquarie Park, NSW 2113
Australia
www.medtronic.com.au
Tel: 02 9857 9000
Fax: 02 9878 5100

18th May 2021

s22 [redacted]

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health
136 Narrabundah Lane
Symonston ACT 2609

Re: DIR 67426 - Request For Information Letter

Dear s22 [redacted]

Please see below for similar incident data based on the clinical event description, i.e. hospitalization due to DKA.

Year	Similar Incidents (Australia)	Sales (Australia)	Incident Rate
2018	0	474	0%
2019	0	5,006	0%
2020	4	4,094	0.0977%
2021 (to date)	0	369	0%

Year	Similar Incidents (Worldwide excluding AU)	Sales (Worldwide excluding AU)	Incident Rate
2018	399	113,938	0.3502%
2019	968	159,734	0.6060%
2020	907	145,532	0.6232%
2021 (to date)	172	10,097	1.7035%

Best Regards,

s22 [redacted]
s22 [redacted] | Quality and Regulatory Affairs

Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
s22 [redacted]
s22 [redacted]@medtronic.com

From: s22
To: s22 ; IRIS
Cc: s22
Subject: Medtronic Response - s41JA Requirement for Information for DIR letter 67426
Date: Thursday, 3 June 2021 2:53:20 PM
Attachments: Medtronic Response - s41JA Requirement for Information for DIR letter 67426.pdf

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Dear s22

Thank you for your inquiry. Please see attached for Medtronic's response.
Should you have any further questions, please do not hesitate to contact me.

Best Regards,

s22
s22 | Quality and Regulatory Affairs

From: s22 @health.gov.au>
Sent: Tuesday, 18 May 2021 3:03 PM
To: s22 @medtronic.com>; s22
s22 @medtronic.com>
Subject: [EXTERNAL] TGA s41JA Requirement for Information for DIR letter 67426 [SEC=OFFICIAL]

Dear s22

Please find attached a Request for Information Letter for your action. **A response is due 4 June 2021.**

Please send your response to : IRIS@health.gov.au

Kind regards,

s22
Departmental Officer
Devices Post Market monitoring Section
Medical Devices Surveillance Branch

Phone: s22
Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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Fax: 02 9878 5100

03 June 2021

s22
Departmental Officer
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch
Therapeutic Goods Administration
Department of Health

Re: TGA s41JA Requirement for Information for DIR letter 67426

Dear s22

Thank you for your inquiry dates 18th May 2021. Please see below for Medtronic's response to your question.

> "In your response dated 18 May 2021, it states the similar event code used was "hospitalization due to DKA". The similar event rates in 2020 were noted to be four and similar events to date for 2021was zero. The TGA has received only 2 reports of diabetic ketoacidosis in 2020 and 4 reports of diabetic ketoacidosis in the last 6 months. The information provided in your response is not consistent with the IRIS database. Please provide the overall rates for all similar events of diabetic ketoacidosis regardless of extra codes (i.e. hospitalization)."

Our similar incidents calculation is based on reportable complaints where the customer mentioned having Diabetic Ketoacidosis that required hospitalization documented on the 670G insulin pump specifically. The 4 reports of diabetic ketoacidosis in the last 6 months may have been related to other pump models (640G,770G) or other devices such as infusion sets or sensors.

The following table shows the four complaints (including the complaint related to this inquiry) that were identified per this search scope.

Notified Date	DIR Number	Harm	Treatment
12-Jun-2020	63917	Diabetic Ketoacidosis	Hospitalization
08-Oct-2020	65977	Diabetic Ketoacidosis	Hospitalization
28-Nov-2020	66917	Diabetic Ketoacidosis	Hospitalization
22-Dec-2020	67426	Diabetic Ketoacidosis	Hospitalization

Medtronic

The similar incidents calculation based on reportable complaints where the customer mentioned having Diabetic Ketoacidosis documented on the 670G insulin pump (excluding extra codes i.e. hospitalization) included one additional case involving a death.

The following table shows the incident rates calculated based on our 670G insulin pump install base.

Year	Reportable Complaints	Incident Rates
2018	0	0.0000%
2019	0	0.0000%
2020	5	0.0623%
2021	0	0.0000%

Best Regards,

s22 [redacted]
s22 [redacted] | Quality and Regulatory Affairs

Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
s22 [redacted]
s22 [redacted] @medtronic.com

From: s22
To: IRIS
Cc: s22 ; s22
Subject: RE: DIR 76971 - **URGENT ACTION REQUIRED** - Request for Action Reminder Letter under s41JA - Response due 11/08/2022 [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Tuesday, 9 August 2022 3:08:00 PM
Attachments: image002.png
RI-DIR 76971 Response.docx

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Hi IRIS Team,

Please find the response from our manufacturer attached.
Just a reminder, for future requests in regards to DIR information requests, please email to rs.anzpmv@medtronic.com.

Kind Regards,

s22
s22 | Quality and Regulatory Affairs
Medtronic
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
Office s22 |
s22 @medtronic.com
medtronic.com.au | Facebook | LinkedIn | Twitter | YouTube

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 28 July 2022 3:36 PM
To: s22 @medtronic.com>
Subject: [EXTERNAL] DIR 76971 - **URGENT ACTION REQUIRED** - Request for Action Reminder Letter under s41JA - Response due 11/08/2022 [SEC=OFFICIAL, ACCESS=Personal-Privacy]

Dear s22

Please see the attached **Request For Action under s41JA** for your urgent action.

Please note the due date for a response is **COB 11 August 2022.

Kind regards,

s22

s22 [redacted]
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)

Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Australian Government, Department of Health and Aged Care

Email: IRIS@health.gov.au
Phone: **DST** s22 [redacted]
Phone: **IRIS** 1800 809 361
Post: 27 Sherger Drive, Canberra Airport, ACT 2609
Courier: 1 Tindal Lane, Canberra Airport, ACT 2609

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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MDIR Technical assistance is available via 02 6289 4642 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

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Medtronic

Diabetes
1800 Devonshire St.
Northridge, CA 91325-1219
USA

www.medtronic.com

August 4, 2022

Subject: DIR 76971, CASE-2022-00116776

To Whom it May Concern:

Thank you for your request with respect to above referenced report number. Please find answers to your questions below.

TGA Request:

Q1: We received this report as a Final. However the Clinical Event Information section is unclear. In order to help with the Therapeutic Goods Administration (TGA) investigation of this report, could you please provide some more information in regards to the clinical event description for this DIR ? The Clinical event in the DIR states the user contacted regarding a crack in the device, however they were hospitalised due to Diabetic Ketoacidosis.

R1: The customer called the Medtronic 24-hour helpline on the morning of s22 [redacted]. The customer reported they were hospitalized with Diabetic Ketoacidosis. Blood glucose value on admission was 44mmol/L and ketones were 6.6. The customer was treated with IV insulin therapy and manual injections. It is unknown if pump, sensor or Auto Mode were used at the time of the incident. s22 [redacted], customer reported a crack in the battery compartment. There was no damage to the Retainer Ring.

Q2: The rates are provided, however it is not clear if these rates are for a crack in the device in the device or hospitalised due to Diabetic Ketoacidosis. Please ensure that the similar event

information provided relates to the actual event reported in the Clinical Event Information field of this report, not the root cause of the event.

R2: Please see below for similar events where the user was hospitalized or required emergency medical assistance involving the 670G insulin pump which were considered reportable due to Diabetic Ketoacidosis during 2019-2022 for Australia and Worldwide.

Year	Region	Similar Events
2019	Australia	0
	Worldwide (not including Australia)	929
2020	Australia	4
	Worldwide (not including Australia)	969
2021	Australia	4
	Worldwide (not including Australia)	738
2022 (till June 30)	Australia	11
	Worldwide (not including Australia)	189

Sincerely,
Medtronic Diabetes

DIR Number	Licence ID	Initial Device Description	Model No	Initial report Date	Published Event Description (DAEN)	Details of Similar Events	Investigated
88755	308140	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1762K	30/06/2023	Pump not working.	In Australia 3 similar events from 4233 units (0.07087%) sold in CY2020; 4 similar events from 3534 units (0.11319%) sold in CY2021; 17 similar events from 1877 units (0.9057%) sold in CY2022; 4 similar events from 671 units (0.59613%) sold in CY2023; WorldWide 1019 similar events from 146968 units (0.69335%) sold in CY2020; 723 similar events from 77745 units (0.92996%) sold in CY2021; 617 similar events from 47122 units (1.30937%) sold in CY2022; 261 similar events from 16194 units (1.61171%) sold in CY2023; Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported being hospitalized due to Hyperglycemia and Diabetic Ketoacidosis.	No
87843	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	25/05/2023	Customer called notifying that Pump was not delivering insulin. ended having high BG and 4.9 DKA was rush to hospital. remove cannula and cannula is kinked but pump did not alert any blockage.	In Australia 3 similar events from 5888 units (0.05095%) sold in CY2020; 14 similar events from 3135 units (0.44657%) sold in CY2021; 3 similar events from 465 units (0.64516%) sold in CY2022; 2 similar events from 66 units (3.0303%) sold in CY2023; WorldWide 970 similar events from 103728 units (0.93514%) sold in CY2020; 665 similar events from 48250 units (1.37824%) sold in CY2021; 567 similar events from 54423 units (1.04184%) sold in CY2022; 247 similar events from 11557 units (2.13723%) sold in CY2023; Similar incidents are calculated based on reportable incidents on the 640G insulin pump which the user reported being hospitalized due to Hyperglycemia and Diabetic Ketoacidosis.	No
87651	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782KL	18/05/2023	Hyperglycemia, diabetic ketoacidosis.	Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported being hospitalized due to Hyperglycemia and Diabetic Ketoacidosis. In Australia 4 similar events from 4233 units (0.0945%) sold in CY2020; 5 similar events from 3533 units (0.14152%) sold in CY2021; 19 similar events from 1876 units (1.01279%) sold in CY2022; 4 similar events from 581 units (0.68847%) sold in CY2023; WorldWide 1612 similar events from 146968 units (1.09684%) sold in CY2020; 1328 similar events from 77758 units (1.70786%) sold in CY2021; 923 similar events from 47169 units (1.95679%) sold in CY2022; 411 similar events from 12806 units (3.20943%) sold in CY2023;	No
87450	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	11/05/2023	ICU hospitalisation due to ketones, Diabetic ketoacidosis and nausea.	Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported being hospitalized due to Diabetic Ketoacidosis. In Australia 4 similar events from 4233 units (0.0945%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 17 similar events from 1876 units (0.90618%) sold in CY2022; 4 similar events from 581 units (0.68847%) sold in CY2023; WorldWide 957 similar events from 146968 units (0.65116%) sold in CY2020; 772 similar events from 77758 units (0.99282%) sold in CY2021; 618 similar events from 47169 units (1.31018%) sold in CY2022; 228 similar events from 12806 units (1.78042%) sold in CY2023;	No

87169	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	28/04/2023	Hospitalisation as patient reportedly experienced hyperglycemia with a blood glucose value of 29.7 mmol/L.	Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported being hospitalized due to Hyperglycemia and Diabetic Ketoacidosis. In Australia 4 similar events from 4233 units (0.0945%) sold in CY2020; 5 similar events from 3533 units (0.14152%) sold in CY2021; 19 similar events from 1876 units (1.01279%) sold in CY2022; 4 similar events from 581 units (0.68847%) sold in CY2023; WorldWide 1612 similar events from 146968 units (1.09684%) sold in CY2020; 1328 similar events from 77758 units (1.70786%) sold in CY2021; 923 similar events from 47169 units (1.95679%) sold in CY2022; 411 similar events from 12806 units (3.20943%) sold in CY2023;	No
86342	308140	Infusion pump, insulin, ambulatory	MMT-1782K	28/03/2023	Patient experienced high blood glucose.	Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported Hyperglycemia and Diabetic Ketoacidosis. In Australia 3 similar events from 4233 units (0.07087%) sold in CY2020; 4 similar events from 9683 units (0.04131%) sold in CY2021; 16 similar events from 9389 units (0.17041%) sold in CY2022; 3 similar events from 9275 units (0.03235%) sold in CY2023; WorldWide 1022 similar events from 146968 units (0.69539%) sold in CY2020; 727 similar events from 289991 units (0.2507%) sold in CY2021; 628 similar events from 279282 units (0.22486%) sold in CY2022; 178 similar events from 274958 units (0.06474%) sold in CY2023;	No
86159	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	22/03/2023	Customer experienced hyperglycaemia and diabetic ketoacidosis.	Similar incidents are calculated based on reportable incidents on the 670G insulin pump which the user reported Hyperglycemia and Diabetic Ketoacidosis. In Australia 3 similar events from 4233 units (0.07087%) sold in CY2020; 4 similar events from 9683 units (0.04131%) sold in CY2021; 16 similar events from 9389 units (0.17041%) sold in CY2022; 3 similar events from 9275 units (0.03235%) sold in CY2023; WorldWide 1022 similar events from 146968 units (0.69539%) sold in CY2020; 727 similar events from 289991 units (0.2507%) sold in CY2021; 628 similar events from 279282 units (0.22486%) sold in CY2022; 178 similar events from 274958 units (0.06474%) sold in CY2023;	No
85851	95763	640G Insulin Pump -Infusion pump, insulin, ambulatory	MMT-1711K	09/03/2023	A crack and chip were found alongside the battery compartment.	In Australia 2 similar events from 6183 units (0.03235%) sold in CY2020; 10 similar events from 3453 units (0.2896%) sold in CY2021; 2 similar events from 473 units (0.42283%) sold in CY2022; 0 similar events from 40 units (0%) sold in CY2023; WorldWide 40 similar events from 143033 units (0.02797%) sold in CY2020; 63 similar events from 76260 units (0.08261%) sold in CY2021; 66 similar events from 63874 units (0.10333%) sold in CY2022; 10 similar events from 5359 units (0.1866%) sold in CY2023; Similar incidents are calculated based on reportable incidents on the 640G insulin pump which the user reported Hyperglycemia and Diabetic Ketoacidosis.	No

83959	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711KL	14/12/2022	Medtronic received information from a customer that a HCP noticed a crack on the pump, located on the battery compartment. Patient was hospitalized due to DKA with a 7.4 result in ketones test.	Hospitalization due to DKA: In Australia 23 similar events from 6183 units (0.37199%) sold in CY2020; 21 similar events from 3453 units (0.60817%) sold in CY2021; 6 similar events from 473 units (1.2685%) sold in CY2022*; 0 similar events from 40 units (0%) sold in CY2023 Worldwide 98 similar events from 143033 units (0.06852%) sold in CY2020; 116 similar events from 76260 units (0.15211%) sold in CY2021; 83 similar events from 63874 units (0.12994%) sold in CY2022; 14 similar events from 5359 units (0.26124%) sold in CY2023. Physical damage to the pump including cracks: In Australia 0 similar events from 6183 units (0%) sold in CY2020; 3 similar events from 3453 units (0.08688%) sold in CY2021; 2 similar events from 473 units (0.42283%) sold in CY2022*; 1 similar events from 40 units (2.5%) sold in CY2023 Worldwide 17064 similar events from 143033 units (11.93011%) sold in CY2020; 15819 similar events from 76260 units (20.74351%) sold in CY2021; 4170 similar events from 63874 units (6.52848%) sold in CY2022; 394 similar events from 5359 units (7.35212%) sold in CY2023. Includes this event, DIR 83959	No
82741	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	24/10/2022	Patient death due to diabetic ketoacidosis.	In Australia 1 similar events from 3239 units (0.03087%) sold in CY2020; 0 similar events from 3453 units (0%) sold in CY2021; 1 similar events from 473 units (0.21142%) sold in CY2022 (includes this event, DIR 82741) Worldwide 161 similar events from 91169 units (0.1766%) sold in CY2020; 156 similar events from 76260 units (0.20456%) sold in CY2021; 176 similar events from 63875 units (0.27554%) sold in CY2022;	No
82624	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-943AT	18/10/2022	A patient reported having hypoglycemic and hyperglycemic events.	In Australia 3 similar events from 4233 units (0.07087%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 20 similar events from 1876 units (1.0661%) sold in CY2022; Worldwide 1879 similar events from 146968 units (1.27851%) sold in CY2020; 1475 similar events from 77758 units (1.89691%) sold in CY2021; 1061 similar events from 47169 units (2.24936%) sold in CY2022;	No
81853	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782KL	13/09/2022	Patient could smell insulin and reported a crack on the middle button of the pump.	In Australia 2 similar events from 5512 units (0.03628%) sold in CY2019; 6 similar events from 4233 units (0.14174%) sold in CY2020; 7 similar events from 3533 units (0.19813%) sold in CY2021; 21 similar events from 1408 units (1.49148%) sold in CY2022* Worldwide 2535 similar events from 155617 units (1.629%) sold in CY2019; 2664 similar events from 146968 units (1.81264%) sold in CY2020; 1995 similar events from 77758 units (2.56565%) sold in CY2021; 1264 similar events from 38106 units (3.31706%) sold in CY2022. *Includes this event, DIR 81853	No

81793	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	09/09/2022	Patient with a Medtronic pump had deceased.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 2 similar events from 3533 units (0.05661%) sold in CY2021; 1 similar events from 1408 units (0.07102%) sold in CY2022* Worldwide 78 similar events from 155617 units (0.05012%) sold in CY2019; 143 similar events from 146968 units (0.0973%) sold in CY2020; 140 similar events from 77758 units (0.18005%) sold in CY2021; 92 similar events from 38106 units (0.24143%) sold in CY2022. Includes this event, DIR 81793	No
80974	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	05/08/2022	Customer reportedly hospitalised due to high blood sugar levels and diabetic ketoacidosis.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 4 similar events from 4233 units (0.0945%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 13 similar events from 1408 units (0.9233%) sold in CY2022; WorldWide 922 similar events from 155617 units (0.59248%) sold in CY2019; 959 similar events from 146968 units (0.65252%) sold in CY2020; 745 similar events from 77758 units (0.9581%) sold in CY2021; 287 similar events from 38106 units (0.75316%) sold in CY2022;	No
80978	308140	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	05/08/2022	Crack on the battery side of the device.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 4 similar events from 4233 units (0.0945%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 12 similar events from 1408 units (0.85227%) sold in CY2022; WorldWide 922 similar events from 155617 units (0.59248%) sold in CY2019; 959 similar events from 146968 units (0.65252%) sold in CY2020; 745 similar events from 77758 units (0.9581%) sold in CY2021; 286 similar events from 38106 units (0.75054%) sold in CY2022;	No
80377	95763	MiniMed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	12/07/2022	Patient had been experiencing low blood glucose levels and was hospitalized due to diabetic coma and severe brain injury.	In Australia 0 similar events from 5271 units (0%) sold in CY2019; 0 similar events from 3239 units (0%) sold in CY2020; 0 similar events from 3453 units (0%) sold in CY2021; 1 similar events from 297 units (0.3367%) sold in CY2022* Worldwide 27 similar events from 124490 units (0.02169%) sold in CY2019; 37 similar events from 91005 units (0.04066%) sold in CY2020; 11 similar events from 76107 units (0.01445%) sold in CY2021; 14 similar events from 38746 units (0.03613%) sold in CY2022. *The one event referenced is this event, DIR 80377	No
80261	308140	MiniMed 670G Insulin pump with CGM - Infusion pump, insulin, ambulatory	MMT-1782	07/07/2022	Pump casing has a crack.	-	No
79969	308140	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1782K	27/06/2022	The customer was hospitalized due to high blood glucose and diabetic ketoacidosis.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 8 similar events from 1044 units (0.76628%) sold in CY2022; WorldWide 924 similar events from 155151 units (0.59555%) sold in CY2019; 965 similar events from 146661 units (0.65798%) sold in CY2020; 734 similar events from 77617 units (0.94567%) sold in CY2021; 189 similar events from 25270 units (0.74792%) sold in CY2022;	No

79838	308140	Minimied 670G - Infusion pump, insulin, ambulatory	MMT-1782K	20/06/2022	Hyperglycaemia, advised faulty pump.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 9 similar events from 1044 units (0.86207%) sold in CY2022* Worldwide 924 similar events from 155151 units (0.59555%) sold in CY2019; 965 similar events from 146661 units (0.65798%) sold in CY2020; 734 similar events from 77617 units (0.94567%) sold in CY2021; 189 similar events from 25270 units (0.74792%) sold in CY2022. *Includes this event, DIR 79838	No
79624	308140	MiniMed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	10/06/2022	The customer was hospitalized due to high blood glucose and diabetic ketoacidosis.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 5 similar events from 4233 units (0.11812%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 15 similar events from 1044 units (1.43678%) sold in CY2022; Worldwide 1966 similar events from 155151 units (1.26715%) sold in CY2019; 1957 similar events from 146661 units (1.33437%) sold in CY2020; 1511 similar events from 77617 units (1.94674%) sold in CY2021; 404 similar events from 25270 units (1.59873%) sold in CY2022;	No
79178	95763	PUMP MMT-1711KL 640G V4.10 MM - Infusion pump, insulin, ambulatory	MMT-1711KL	23/05/2022	Customer reported pump not delivering properly leading to hospitalisation due to diabetic ketoacidosis.	In Australia 5 similar events from 5271 units (0.09486%) sold in CY2019; 2 similar events from 3239 units (0.06175%) sold in CY2020; 10 similar events from 3453 units (0.2896%) sold in CY2021; 2 similar events from 297 units (0.6734%) sold in CY2022; WorldWide 50 similar events from 124490 units (0.04016%) sold in CY2019; 26 similar events from 91005 units (0.02857%) sold in CY2020; 55 similar events from 76107 units (0.07227%) sold in CY2021; 16 similar events from 38746 units (0.04129%) sold in CY2022;	No
79005	308140	MMT-1782KL 670G MM RPL - Infusion pump, insulin, ambulatory	MMT-1782KL	16/05/2022	Patient was admitted to hospital for DKA.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 8 similar events from 1044 units (0.76628%) sold in CY2022; WorldWide 924 similar events from 155151 units (0.59555%) sold in CY2019; 965 similar events from 146661 units (0.65798%) sold in CY2020; 734 similar events from 77617 units (0.94567%) sold in CY2021; 189 similar events from 25270 units (0.74792%) sold in CY2022;	No
78905	95763	MiniMed 640G - Infusion pump, insulin, ambulatory	MMT-1711KL	11/05/2022	Patient unable to use 4 sets and was hospitalised with hyperglycaemia.	In Australia 5 similar events from 5271 units (0.09486%) sold in CY2019; 2 similar events from 3239 units (0.06175%) sold in CY2020; 10 similar events from 3453 units (0.2896%) sold in CY2021; 3 similar events from 297 units (1.0101%) sold in CY2022* Worldwide 50 similar events from 124490 units (0.04016%) sold in CY2019; 26 similar events from 91005 units (0.02857%) sold in CY2020; 55 similar events from 76107 units (0.07227%) sold in CY2021; 16 similar events from 38746 units (0.04129%) sold in CY2022. *Includes this event, DIR 78905	No

78650	95763	MiniMed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	29/04/2022	Patient was hospitalised due to DKA. Patient reported not getting any pump alerts.	In Australia 5 similar events from 5271 units (0.09486%) sold in CY2019; 2 similar events from 3239 units (0.06175%) sold in CY2020; 10 similar events from 3453 units (0.2896%) sold in CY2021; 3 similar events from 297 units (1.0101%) sold in CY2022* Worldwide 50 similar events from 124490 units (0.04016%) sold in CY2019; 26 similar events from 91005 units (0.02857%) sold in CY2020; 55 similar events from 76107 units (0.07227%) sold in CY2021; 16 similar events from 38746 units (0.04129%) sold in CY2022. *Includes this event, DIR 78650	No
78654	308140	MiniMed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	29/04/2022	Patient felt they were going to have a heart attack, sweating, cramps and thirst. Upon admission to hospital, blood glucose level was 39.0 mmol/L and ketones 6.7.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 3 similar events from 4233 units (0.07087%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 18 similar events from 1044 units (1.72414%) sold in CY2022* Worldwide 1866 similar events from 155151 units (1.2027%) sold in CY2019; 1872 similar events from 146661 units (1.27641%) sold in CY2020; 1425 similar events from 77617 units (1.83594%) sold in CY2021; 453 similar events from 25270 units (1.79264%) sold in CY2022. *Includes this event, DIR 78654	No
78468	95763	MiniMed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	21/04/2022	It was reported that a patient's insulin pump had an unknown pump error alarm.	In Australia 5 similar events from 5271 units (0.09486%) sold in CY2019; 2 similar events from 3239 units (0.06175%) sold in CY2020; 11 similar events from 3453 units (0.31856%) sold in CY2021*; 2 similar events from 297 units (0.6734%) sold in CY2022. Worldwide 50 similar events from 124490 units (0.04016%) sold in CY2019; 26 similar events from 91005 units (0.02857%) sold in CY2020; 55 similar events from 76107 units (0.07227%) sold in CY2021; 16 similar events from 38746 units (0.04129%) sold in CY2022. *Includes this event, DIR 78468	No
78348	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782KL	14/04/2022	Patient was hospitalized due to DKA.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 9 similar events from 1044 units (0.86207%) sold in CY2022* Worldwide 924 similar events from 155151 units (0.59555%) sold in CY2019; 965 similar events from 146661 units (0.65798%) sold in CY2020; 734 similar events from 77617 units (0.94567%) sold in CY2021; 189 similar events from 25270 units (0.74792%) sold in CY2022. *Includes this event, DIR 78348	No
78002	308140	PUMP MMT-1782KL 670G V4.10 BM MM - Infusion pump, insulin, ambulatory	MMT-1782KL	05/04/2022	Customer hospitalized due to high blood glucose level.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 2 similar events from 4233 units (0.04725%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 8 similar events from 1044 units (0.76628%) sold in CY2022; WorldWide 924 similar events from 155151 units (0.59555%) sold in CY2019; 965 similar events from 146661 units (0.65798%) sold in CY2020; 734 similar events from 77617 units (0.94567%) sold in CY2021; 189 similar events from 25270 units (0.74792%) sold in CY2022;	No

77388	308140	MMT-1782KL 670G MM RPL - Infusion pump, insulin, ambulatory	MMT-1782KL	22/03/2022	Unable to pair glucometer with continuous glucose monitor. Also discovered infusion cannula kinked at 2 points.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 5 similar events from 4233 units (0.11812%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 15 similar events from 1044 units (1.43678%) sold in CY2022; WorldWide 1966 similar events from 155151 units (1.26715%) sold in CY2019; 1957 similar events from 146661 units (1.33437%) sold in CY2020; 1511 similar events from 77617 units (1.94674%) sold in CY2021; 404 similar events from 25270 units (1.59873%) sold in CY2022;	Yes
76971	308140	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	11/03/2022	Hospitalised due to Diabetic Ketoacidosis	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 5 similar events from 4233 units (0.11812%) sold in CY2020; 6 similar events from 3533 units (0.16983%) sold in CY2021; 15 similar events from 1044 units (1.43678%) sold in CY2022; WorldWide 1966 similar events from 155151 units (1.26715%) sold in CY2019; 1957 similar events from 146661 units (1.33437%) sold in CY2020; 1511 similar events from 77617 units (1.94674%) sold in CY2021; 404 similar events from 25270 units (1.59873%) sold in CY2022;	No
76665	95763	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1711KL	04/03/2022	Report of under delivery. Patient was bolusing correctly but reading high. Changed the set, levels went drastically down. Patient experienced a hypoglycaemic seizure.	In Australia 2 similar events from 5271 units (0.03794%) sold in CY2019; 1 similar events from 3239 units (0.03087%) sold in CY2020; 6 similar events from 3453 units (0.17376%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 252 similar events from 124661 units (0.20215%) sold in CY2019; 215 similar events from 91155 units (0.23586%) sold in CY2020; 255 similar events from 76249 units (0.33443%) sold in CY2021; 27 similar events from 14471 units (0.18658%) sold in CY2022;	No
76599	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	03/03/2022	Infusion Flow Blocked alarm.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 4 similar events from 4233 units (0.0945%) sold in CY2020; 4 similar events from 3533 units (0.11322%) sold in CY2021; 11 similar events from 403 units (2.72953%) sold in CY2022; WorldWide 929 similar events from 155151 units (0.59877%) sold in CY2019; 966 similar events from 146660 units (0.65867%) sold in CY2020; 728 similar events from 77616 units (0.93795%) sold in CY2021; 168 similar events from 8405 units (1.99881%) sold in CY2022; Similar incident numbers were calculated based on reportable events involving the 670G insulin pump which resulted in hospitalization due to DKA.	No
76314	308140	MMT-1782KL 670G MM RPL - Infusion pump, insulin, ambulatory	MMT-1782KL	18/02/2022	Patient called in regarding assistance for pump programming re establishing settings for XMTR was disconnected due to pump is not being used.	In Australia 0 similar events from 5513 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 0 similar events from 3533 units (0%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 0 similar events from 155151 units (0%) sold in CY2019; 0 similar events from 146661 units (0%) sold in CY2020; 18 similar events from 77617 units (0.02319%) sold in CY2021; 10 similar events from 8406 units (0.11896%) sold in CY2022;	No

75998	308140	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	08/02/2022	Patient was admitted in emergency room due to high blood glucose.	In Australia 0 similar events from 5513 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 0 similar events from 3533 units (0%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 1413 similar events from 155151 units (0.91073%) sold in CY2019; 1280 similar events from 146661 units (0.87276%) sold in CY2020; 1425 similar events from 77617 units (1.83594%) sold in CY2021; 217 similar events from 8406 units (2.58149%) sold in CY2022;	Yes
76028	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	08/02/2022	It was found that the reservoir is showing less insulin than what is shown on the status screen.	In Australia 1 similar events from 5271 units (0.01897%) sold in CY2019; 0 similar events from 3239 units (0%) sold in CY2020; 3 similar events from 3453 units (0.08688%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 345 similar events from 124661 units (0.27675%) sold in CY2019; 603 similar events from 91155 units (0.66151%) sold in CY2020; 468 similar events from 76249 units (0.61378%) sold in CY2021; 42 similar events from 14471 units (0.29024%) sold in CY2022;	No
75859	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	03/02/2022	Reported high blood glucose levels.	In Australia 1 similar events from 5513 units (0.01814%) sold in CY2019; 5 similar events from 4233 units (0.11812%) sold in CY2020; 2 similar events from 3533 units (0.05661%) sold in CY2021; 7 similar events from 403 units (1.73697%) sold in CY2022; WorldWide 11280 similar events from 155151 units (7.27034%) sold in CY2019; 8891 similar events from 146661 units (6.06228%) sold in CY2020; 4985 similar events from 77617 units (6.42256%) sold in CY2021; 1080 similar events from 8406 units (12.84797%) sold in CY2022; Similar incidents include this event (DIR 75859)	No
75306	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782KL	20/01/2022	Patient reported insulin flow block alerts, called an ambulance and was hospitalised for DKA.	In Australia 0 similar events from 5513 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 0 similar events from 3533 units (0%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 925 similar events from 155151 units (0.59619%) sold in CY2019; 1771 similar events from 146661 units (1.20755%) sold in CY2020; 3359 similar events from 77617 units (4.32766%) sold in CY2021; 445 similar events from 8406 units (5.29384%) sold in CY2022;	No
75267	308140	INFST MMT-923A MIO 10PK 6MM23IN PINK - Infusion administration set, insulin pump	MMT-1782K	19/01/2022	Reported hyperglycemia.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 0 similar events from 3533 units (0%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 681 similar events from 155151 units (0.43893%) sold in CY2019; 423 similar events from 146660 units (0.28842%) sold in CY2020; 801 similar events from 77616 units (1.032%) sold in CY2021; 162 similar events from 8405 units (1.92742%) sold in CY2022;	No

75146	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	14/01/2022	Infusion Flow Blocked alarms.	In Australia 2 similar events from 5271 units (0.03794%) sold in CY2019; 1 similar events from 3239 units (0.03087%) sold in CY2020; 3 similar events from 3453 units (0.08688%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 251 similar events from 124661 units (0.20135%) sold in CY2019; 207 similar events from 91155 units (0.22709%) sold in CY2020; 186 similar events from 76249 units (0.24394%) sold in CY2021; 2 similar events from 14471 units (0.01382%) sold in CY2022; Similar incident calculations include this event (DIR 75146)	No
74676	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	07/01/2022	Reported insulin pump had a critical pump error alarm.	In Australia 0 similar events from 5270 units (0%) sold in CY2019; 1 similar events from 3239 units (0.03087%) sold in CY2020; 0 similar events from 3453 units (0%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 63 similar events from 124661 units (0.05054%) sold in CY2019; 287 similar events from 91155 units (0.31485%) sold in CY2020; 104 similar events from 76249 units (0.1364%) sold in CY2021; 0 similar events from 14471 units (0%) sold in CY2022; Similar incidents include this event (DIR 74676)	No
74678	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	07/01/2022	It was reported that the insulin pump had pump error alarms and physical damage at the reservoir lip ring.	In Australia 1 similar events from 5270 units (0.01898%) sold in CY2019; 0 similar events from 3239 units (0%) sold in CY2020; 0 similar events from 3453 units (0%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 32 similar events from 124661 units (0.02567%) sold in CY2019; 42 similar events from 91155 units (0.04608%) sold in CY2020; 159 similar events from 76249 units (0.20853%) sold in CY2021; 0 similar events from 14471 units (0%) sold in CY2022; Similar incidents include this event (DIR 74678)	No
74743	95763	640G Insulin Pump MMT-1711W - Infusion pump, insulin, ambulatory	MMT-1711W	31/12/2021	Reported a Power error Detected Alarm.	In Australia 0 similar events from 5271 units (0%) sold in CY2019; 0 similar events from 3239 units (0%) sold in CY2020; 0 similar events from 3453 units (0%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; World Wide 11 similar events from 124661 units (0.00882%) sold in CY2019; 11 similar events from 91155 units (0.01207%) sold in CY2020; 3 similar events from 76249 units (0.00393%) sold in CY2021; 0 similar events from 14471 units (0%) sold in CY2022;	No
74674	95763	Minimed 640G Minimed 640G Infusion pump, insulin - Infusion pump, insulin, ambulatory	MMT-1711K	24/12/2021	Reported DKA and was admitted to hospital as a result of insulin pump failure.	In Australia 3 similar events from 5270 units (0.05693%) sold in CY2019; 5 similar events from 3239 units (0.15437%) sold in CY2020; 6 similar events from 3453 units (0.17376%) sold in CY2021; 1 similar events from 172 units (0.5814%) sold in CY2022; WorldWide 261 similar events from 124661 units (0.20937%) sold in CY2019; 179 similar events from 91155 units (0.19637%) sold in CY2020; 190 similar events from 76249 units (0.24918%) sold in CY2021; 35 similar events from 14471 units (0.24186%) sold in CY2022; Similar incidents include this event (DIR 74674)	No

74085	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	01/12/2021	It was reported that there was issue with a persistent Insulin Flow Blocked alarm.	In Australia 0 similar events from 5512 units (0%) sold in CY2019; 0 similar events from 4233 units (0%) sold in CY2020; 1 similar events from 3533 units (0.0283%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 19 similar events from 155151 units (0.01225%) sold in CY2019; 0 similar events from 146660 units (0%) sold in CY2020; 0 similar events from 77616 units (0%) sold in CY2021; 0 similar events from 8405 units (0%) sold in CY2022; Similar incidents include this event (DIR 74085)	No
73971	308140	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1782K	25/11/2021	Reported hypoglycemia with a reading of 1.9 mmol/L.	In Australia 1 similar events from 5005 units (0.01998%) sold in CY2019; 0 similar events from 4093 units (0%) sold in CY2020; 2 similar events from 2731 units (0.07323%) sold in CY2021; 0 similar events from 220 units (0%) sold in CY2022; WorldWide 345 similar events from 159732 units (0.21599%) sold in CY2019; 603 similar events from 145149 units (0.41544%) sold in CY2020; 448 similar events from 55164 units (0.81212%) sold in CY2021; 28 similar events from 3302 units (0.84797%) sold in CY2022;	No
73704	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	12/11/2021	Reported that a blood glucose was low at 1.6 mmol/L.	In Australia 1 similar events from 5270 units (0.01898%) sold in CY2019; 0 similar events from 3239 units (0%) sold in CY2020; 1 similar events from 3453 units (0.02896%) sold in CY2021; 0 similar events from 172 units (0%) sold in CY2022; WorldWide 58 similar events from 124661 units (0.04653%) sold in CY2019; 47 similar events from 91155 units (0.05156%) sold in CY2020; 32 similar events from 76249 units (0.04197%) sold in CY2021; 1 similar events from 14471 units (0.00691%) sold in CY2022; Similar incident numbers include this event (DIR 73704)	No
73705	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	12/11/2021	Reported extreme low blood glucose incident. It was also reported the smell of insulin on the pump, but could not determine where it is coming from and no leaks on reservoir.	In Australia 1 similar events from 5512 units (0.01814%) sold in CY2019; 1 similar events from 4233 units (0.02362%) sold in CY2020; 3 similar events from 3533 units (0.08491%) sold in CY2021; 0 similar events from 403 units (0%) sold in CY2022; WorldWide 345 similar events from 155151 units (0.22236%) sold in CY2019; 603 similar events from 146660 units (0.41116%) sold in CY2020; 448 similar events from 77616 units (0.5772%) sold in CY2021; 40 similar events from 8405 units (0.47591%) sold in CY2022; Similar incidents include this event (DIR 73705)	No
73452	308140	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	02/11/2021	Customer reported unresponsive keypad issue, customer was admitted to hospital due to high BG and had symptoms of nausea and gut ache.	In Australia 0 similar events from 5005 units (0%) sold in CY2019; 0 similar events from 4093 units (0%) sold in CY2020; 0 similar events from 2731 units (0%) sold in CY2021; 0 similar events from 220 units (0%) sold in CY2022; WorldWide 2733 similar events from 159732 units (1.71099%) sold in CY2019; 3553 similar events from 145149 units (2.44783%) sold in CY2020; 3947 similar events from 55164 units (7.15503%) sold in CY2021; 222 similar events from 3302 units (6.7232%) sold in CY2022;	No

73462	308140	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1782k	02/11/2021	The customer reported that they went to emergency room due to hyperglycemia.	Australia: 0 similar events from 474 units (0%) sold in CY2018; 1 similar events from 5005 units (0.01998%) sold in CY2019; 0 similar events from 602 units (0%) sold in CY2020; 1 similar events from 332 units (0.3012%) sold in CY2021 (Includes this event). Worldwide: 278 similar events from 112872 units (0.2463%) sold in CY2018; 346 similar events from 159732 units (0.21661%) sold in CY2019; 602 similar events from 145149 units (0.41475%) sold in CY2020; 332 similar events from 44936 units (0.73883%) sold in CY2021.	No
73370	95763	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1711KL	28/10/2021	Patient advise that the pump seems to be not working, patient was hospitalized due to high BG and now it seems like BG is not going down even after changing the site.	Australia: 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953 units (0%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 1 similar events from 1273 units (0.07855%) sold in CY2021 (Includes this event). Worldwide: 12 similar events from 122660 units (0.00978%) sold in CY2018; 14 similar events from 110335 units (0.01269%) sold in CY2019; 33 similar events from 88292 units (0.03738%) sold in CY2020; 124 similar events from 49614 units (0.24993%) sold in CY2021.	No
73383	308140	Minimed 670G -Infusion pump, insulin, ambulatory	MMT-1782K	28/10/2021	Patients pump has been doing multiple rewinds, patient admitted to ICU.	In Australia 0 similar events from 5005 units (0%) sold in CY2019; 0 similar events from 4093 units (0%) sold in CY2020; 0 similar events from 2731 units (0%) sold in CY2021; 0 similar events from 220 units (0%) sold in CY2022; WorldWide 194 similar events from 159732 units (0.12145%) sold in CY2019; 550 similar events from 145149 units (0.37892%) sold in CY2020; 716 similar events from 55164 units (1.29795%) sold in CY2021; 51 similar events from 3302 units (1.54452%) sold in CY2022;	No
73129	95763	Medtronic MINIMED - Infusion pump, insulin, ambulatory	MMT-1711K	18/10/2021	Insulin pump was not working and had lines on the screen. Customer was hospitalized due to high blood glucose and diabetic keto acidosis.	Australia: 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953 units (0%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 0 similar events from 1273 units (0%) sold in CY2021 (Includes this event). Worldwide: 4 similar events from 122660 units (0.00326%) sold in CY2018; 1 similar events from 110335 units (0.00091%) sold in CY2019; 11 similar events from 88292 units (0.01246%) sold in CY2020; 80 similar events from 49614 units (0.16124%) sold in CY2021.	No
72993	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	13/10/2021	A patient was hospitalized due to diabetic ketoacidosis and high blood glucose level.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 1 similar events from 5005 units (0.01998%) sold in CY2019; 5 similar events from 4093 units (0.12216%) sold in CY2020; 2 similar events* from 1356 units (0.14749%) sold in CY2021; *Includes this event WorldWide 10621 similar events from 112872 units (9.40977%) sold in CY2018; 11299 similar events from 159732 units (7.07372%) sold in CY2019; 8917 similar events from 145149 units (6.14334%) sold in CY2020; 3784 similar events from 44936 units (8.42087%) sold in CY2021;	No

72869	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711KL	07/10/2021	Customer had chronic seizure and went to DKA.	Australia: 2 similar events from 8128 units (0.02461%) sold in CY2018; 3 similar events from 4953 units (0.06057%) sold in CY2019; 5 similar events from 3151 units (0.15868%) sold in CY2020; 5 similar events from 1273 units (0.39277%) sold in CY2021 (Includes this event). Worldwide: 246 similar events from 122660 units (0.20055%) sold in CY2018; 261 similar events from 110335 units (0.23655%) sold in CY2019; 178 similar events from 88292 units (0.2016%) sold in CY2020; 135 similar events from 49614 units (0.2721%) sold in CY2021.	No
72466	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711KL	15/09/2021	Patient was unable to set the pump temp basal to 200% when asked by the doctor. Patient was hospitalized with symptoms.	Australia: 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953 units (0%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 0 similar events from 1273 units (0%) sold in CY2021 (Includes this event). Worldwide: 0 similar events from 122660 units (0%) sold in CY2018; 0 similar events from 110335 units (0%) sold in CY2019; 1 similar events from 88292 units (0.00113%) sold in CY2020; 16 similar events from 49614 units (0.03225%) sold in CY2021.	No
71968	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	25/08/2021	Customer SG reading low causing the pump's insulin delivery to be suspended.	Australia: 2 similar events from 8128 units (0.02461%) sold in CY2018; 3 similar events from 4953 units (0.06057%) sold in CY2019; 5 similar events from 3151 units (0.15868%) sold in CY2020; 2 similar events from 1273 units (0.15711%) sold in CY2021 (Includes this event). Worldwide: 250 similar events from 122660 units (0.20382%) sold in CY2018; 265 similar events from 110335 units (0.24018%) sold in CY2019; 177 similar events from 88292 units (0.20047%) sold in CY2020; 131 similar events from 49614 units (0.26404%) sold in CY2021. Similar incident rates were determined using RFR code (Harm reported, with no Allegation of Device Deficiency - Z101) for the platform family type of product reported per subject event.	No
71872	308140	HYBRID CLOSED LOOP TECHNOLOGY - Infusion pump, insulin, ambulatory	670G	20/08/2021	Device ignored previous insulin doses resulting in insulin stacking.	-	No
71889	308140	MiniMed™ 670G Insulin pump - Infusion pump, insulin, ambulatory	MMT-1782K	20/08/2021	Customer admitted to hospital due to hyperglycemia with vomiting, nausea and positive results in ketones. Customer alleged the insulin pump was possibly under delivering insulin.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5005 units (0%) sold in CY2019; 2 similar events from 4093 units (0.48863%) sold in CY2020; 0 similar events from 3207 units (0%) sold in CY2021; WorldWide 344 similar events from 112872 units (0.30477%) sold in CY2018; 578 similar events from 159732 units (0.36185%) sold in CY2019; 810 similar events from 145149 units (0.55804%) sold in CY2020; 752 similar events from 44936 units (1.67349%) sold in CY2021;	No
71555	95763	640G Insulin Pump MMT-1711H Infusion pump, insulin, ambulator	MMT-1711H	05/08/2021	Patient was admitted to hospital due to high BG levels with reading discrepancies.	In Australia 2 similar events from 8128 units (0.02461%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 3 similar events from 3151 units (0.09521%) sold in CY2020; 2 similar events from 1273 units (0.15711%) sold in CY2021; WorldWide 188 similar events from 122661 units (0.15327%) sold in CY2018; 154 similar events from 110336 units (0.13957%) sold in CY2019; 86 similar events from 88293 units (0.0974%) sold in CY2020; 65 similar events from 49615 units (0.13101%) sold in CY2021;	No

71487	308140	MiniMed™ 670G Infusion pump, insulin, ambulatory	MMT-1782KL	03/08/2021	Patient was found deceased	Australia: 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5005 units (0%) sold in CY2019; 0 similar events from 4093 units (0%) sold in CY2020; 0 similar events from 1356 units (0%) sold in CY2021 (Includes this event). Worldwide: 298 similar events from 112872 units (0.26402%) sold in CY2018; 609 similar events from 159732 units (0.38126%) sold in CY2019; 763 similar events from 145149 units (0.52567%) sold in CY2020; 441 similar events from 44936 units (0.9814%) sold in CY2021. Similar incident rates were determined using RFR code (No Delivery/Occlusion Alarm During Therapy - AA21) for the platform family type of product reported per subject event.	No
71312	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	-	23/07/2021	Patient had chronic seizure and went to DKA, a crack on the battery cartridge was noted.	In Australia 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953units (0%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 1 similarevents from 1273 units (0.0785%) sold in CY2021; Worldwide 7 similar events from 122661 units(0.0570%) sold in CY2018; 7 similar events from 110336 units (0.0634%) sold in CY2019; 7 similar events from 88293 units (0.07928%) sold in CY2020; 6 similar events from 49615 units(0.01209%) sold in CY2021;	No
71155	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	15/07/2021	A patient reported ketones and high Blood Glucose.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5006 units (0%) sold in CY2019; 3 similar events from 4094 units (0.07328%) sold in CY2020; 0 similar events from 1356 units (0%) sold in CY2021; WorldWide 289 similar events from 112873 units (0.25604%) sold in CY2018; 640 similar events from 159733 units (0.40067%) sold in CY2019; 628 similar events from 145150 units (0.43266%) sold in CY2020; 341 similar events from 44937 units (0.75884%) sold in CY2021;	No
71156	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	15/07/2021	Patient was admitted to emergency due to high ketones and elevated Blood Glucose levels.	In Australia 1 similar events from 8128 units (0.0123%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 3 similar events from 1097 units (0.27347%) sold in CY2021; WorldWide 20 similar events from 124526 units (0.01606%) sold in CY2018; 43 similar events from 111396 units (0.0386%) sold in CY2019; 40 similar events from 89414 units (0.04474%) sold in CY2020; 24 similar events from 36561 units (0.06564%) sold in CY2021;	No
70724	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	24/06/2021	Nurse reported a patient's pump is not turning on, patient was admitted due to DKA.	In Australia 0 similar events from 8128 units (0%) sold in CY2018; 1 similar events from 4953 units (0.02019%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 0 similar events from 1097 units (0%) sold in CY2021; WorldWide 5 similar events from 235920 units (0.00212%) sold in CY2018; 3 similar events from 111396 units (0.00269%) sold in CY2019; 7 similar events from 89414 units (0.00783%) sold in CY2020; 6 similar events from 36561 units (0.01641%) sold in CY2021;	No

70617	95763	MiniMed® 640G - Infusion pump, insulin, ambulatory	MMT-1711K	18/06/2021	Customer experiencing unknown HIGH BG but suspects that the pump is not delivering insulin.	Australia: 1 similar events from 8128 units (0.0123%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 6 similar events from 1097 units (0.54695%) sold in CY2021 (Includes this event). Worldwide: 20 similar events from 235920 units (0.00848%) sold in CY2018; 43 similar events from 111396 units (0.0386%) sold in CY2019; 40 similar events from 89414 units (0.04474%) sold in CY2020; 34 similar events from 36561 units (0.093%) sold in CY2021.	No
70620	95763	MiniMed® 640G - Infusion pump, insulin, ambulatory	MMT-1711K	18/06/2021	Patient hospitalised due to hyperglycaemia and DKA.	Australia: 0 similar events from 8128 units (0%) sold in CY2018; 1 similar events from 4953 units (0.02019%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 1 similar events from 1097 units (0.09116%) sold in CY2021 (Includes this event). Worldwide: 13 similar events from 235920 units (0.00551%) sold in CY2018; 26 similar events from 111396 units (0.02334%) sold in CY2019; 44 similar events from 89414 units (0.04921%) sold in CY2020; 19 similar events from 36561 units (0.05197%) sold in CY2021.	No
70472	95763	Medtronic MiniMed™ 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711KL	11/06/2021	Patient hospitalised due to DKA when using new replacement pump.	Australia: 1 similar events from 8128 units (0.0123%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 0 similar events from 3151 units (0%) sold in CY2020; 6 similar events from 1097 units (0.54695%) sold in CY2021 (Includes this event). Worldwide: 20 similar events from 235920 units (0.00848%) sold in CY2018; 43 similar events from 111396 units (0.0386%) sold in CY2019; 40 similar events from 89414 units (0.04474%) sold in CY2020; 34 similar events from 36561 units (0.093%) sold in CY2021.	No
68922	308140	Medtronic 670G insulin pump - Infusion pump, insulin, ambulatory	670G	25/03/2021	Recurrent hypoglycaemia as the insulin pump began to self-deliver insulin boluses multiple times over a four day period uninitiated by the patient or carer.	-	Yes
68623	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	10/03/2021	Faulty pump, Customer alleges corrections seem not to be going through and that they had 3 set changes and noted no air bubbles.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5006 units (0%) sold in CY2019; 1 similar events from 4094 units (0.02443%) sold in CY2020; 0 similar events from 705 units (0%) sold in CY2021; WorldWide 7 similar events from 113938 units (0.00614%) sold in CY2018; 39 similar events from 159734 units (0.02442%) sold in CY2019; 40 similar events from 145562 units (0.02748%) sold in CY2020; 21 similar events from 21730 units (0.09664%) sold in CY2021;	No
68198	308140	Guardian CGM Infusion pump, insulin, ambulatory	Carelink Connect	17/02/2021	Alerts not provided by the CGM when levels go out of range.	-	Yes
68118	308140	Medtronic 670G & Guardian CGM - Infusion pump, insulin, ambulatory	670G	12/02/2021	Device pump showing 7.9, finger prick showing 23.2mmol.	-	Yes
67988	308140	Medtronic Insulin Pump 670G - Infusion pump, insulin, ambulatory	670G	04/02/2021	Complete pump failure due to water entering the pump via a hairline crack in the pump casing.	-	No

67426	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	01/01/2021	Patient was admitted to the hospital due to DKA.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5006 units (0%) sold in CY2019; 0 similar events from 4094 units (0%) sold in CY2020; 0 similar events from 369 units (0%) sold in CY2021; WorldWide 14 similar events from 113938 units (0.01229%) sold in CY2018; 71 similar events from 159734 units (0.04445%) sold in CY2019; 64 similar events from 145532 units (0.04398%) sold in CY2020; 11 similar events from 10097 units (0.10894%) sold in CY2021;	Yes
66917	308140	Minimed 670G - Infusion pump, insulin, ambulatory	MMT-1782K	04/12/2020	A customer was hospitalized due to series of DKA.	In Australia 0 similar events from 475 units (0%) sold in CY2018; 1 similar event from 5006 units (0.01998%) sold in CY2019; 4 similar events from 4094 units (0.0977%) sold in CY2020; 0 similar events from 204 units (0%) sold in CY2021; WorldWide 887 similar events from 113938 units (0.77849%) sold in CY2018; 1835 similar events from 159734 units (1.14878%) sold in CY2019; 1660 similar events from 145563 units (1.1404%) sold in CY2020; 46 similar events from 4896 units (0.93954%) sold in CY2021;	No
66790	95763	640G Insulin Pump MMT-1711K Infusion pump, insulin, ambulatory	MMT-1711K	27/11/2020	A patient was hospitalized due to DKA, High BG and Presence of Ketones.	In Australia 2 similar events from 8128 units (0.02461%) sold in CY2018; 10 similar events from 4953 units (0.2019%) sold in CY2019; 5 similar events from 3151 units (0.15868%) sold in CY2020; 0 similar events from 254 units (0%) sold in CY2021; WorldWide 68 similar events from 124526 units (0.05461%) sold in CY2018; 97 similar events from 111396 units (0.08708%) sold in CY2019; 55 similar events from 89414 units (0.06151%) sold in CY2020; 0 similar events from 3711 units (0%) sold in CY2021;	No
66605	95763	Guardian 3 and Medtronic 670G, Continous glucose monitoring system (sensor+transmitter) plus insulin pump)	-	18/11/2020	Noted the pump+sensor system, interferes with the ECG being performed.	-	Yes
66014	95763	PUMP MMT-1711KL 640G V4.10 BK SF MM - Infusion pump, insulin, ambulatory	MMT-1711KL	20/10/2020	A customer called to report that he was hospitalised due to high Blood glucose and vomiting.	In Australia 1 similar events from 8128 units (0.0123%) sold in CY2018; 2 similar events from 4953 units (0.04038%) sold in CY2019; 4 similar events from 3151 units (0.12694%) sold in CY2020; WorldWide 35 similar events from 124526 units (0.02811%) sold in CY2018; 69 similar events from 111396 units (0.06194%) sold in CY2019; 34 similar events from 89414 units (0.03803%) sold in CY2020;	No
65977	308140	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	18/10/2020	Diabetic ketoacidosis.	In Australia 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5006 units (0%) sold in CY2019; 3 similar events from 4094 units (0.07328%) sold in CY2020; WorldWide 304 similar events from 113938 units (0.26681%) sold in CY2018; 660 similar events from 159734 units (0.41319%) sold in CY2019; 594 similar events from 145562 units (0.40807%) sold in CY2020;	No

65754	308140	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	02/10/2020	Death due to diabetic ketoacidosis. Blood glucose was 306 mg/dL as the last reading in the pump.	In Australia: 0 similar events from 474 units (0%) sold in CY2018; 0 similar events from 5006 units (0%) sold in CY2019; 1 similar events from 4094 units (0.02443%) sold in CY2020 (Includes this event). Worldwide: 4 similar events from 113938 units (0.00351%) sold in CY2018; 11 similar events from 159734 units (0.00689%) sold in CY2019; 7 similar events from 145562 units (0.00481%) sold in CY2020.	No
65755	308140	Pump MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	02/10/2020	Hyperglycaemia	In Australia 0 similar events from 8128 units (0%) sold in CY2018; 0 similar events from 4953 units (0%) sold in CY2019; 1 similar events from 411 units (0.24331%) sold in CY2020; WorldWide 31 similar events from 124525 units (0.02489%) sold in CY2018; 43 similar events from 111395 units (0.0386%) sold in CY2019; 31 similar events from 13371 units (0.23185%) sold in CY2020;	Yes
65028	308140	Medtronic 670g insulin pump - Infusion pump, insulin, ambulatory	670g MMT-1782	25/08/2020	The maximum bolus will not allow beyond 25u of insulin.	-	Yes
64204	95763	640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	06/07/2020	User was hospitalized due to high blood glucose in spite of delivery of multiple boluses.	Similar events in Australia in the past 3 years: 3 Similar events worldwide (Australia excluded) in the past 3 years: 382696 Sales in Australia in the past 3 years: 22542 This correlates to a complaint rate of 0.0001% Sales worldwide (Australia excluded) in the past 3 years: 382696 This correlates to a complaint rate of 0.0003%	No
64004	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711KL	24/06/2020	s22 called in to report issue on patient pump as he was in ICU now after going as low as 0.6 mmol/L.	Similar events in Australia in the past 3 years: 0 Similar events worldwide (Australia excluded) in the past 3 years: 382696 Sales in Australia in the past 3 years: 22542 This correlates to a complaint rate of 0.00004% Sales worldwide (Australia excluded) in the past 3 years: 382696 This correlates to a complaint rate of 0.0001%	No
63917	95763	PUMP MMT-1782K 670G V4.11 MM - Infusion pump, insulin, ambulatory	MMT-1782K	19/06/2020	Patient required multiple hospitalisation due to DKA.	Similar events in Australia in the past 3 years: 0 Similar events worldwide (Australia excluded) in the past 3 years: 456450 Sales in Australia in the past 3 years: 8778 This correlates to a complaint rate of 0.0001% Sales worldwide (Australia excluded) in the past 3 years: 456450 This correlates to a complaint rate of 0.003%	No
63629	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	02/06/2020	Pump is not sending proper amount of insulin and patient was hospitalised due to High Blood Glucose (BG)/Under Delivery.	Similar events in Australia in the past 3 years (ie 1 Jan 2017 until today): 5 Similar events worldwide (Australia excluded) in the past 3 years: 74 Sales in Australia in the past 3 years: 21777. This correlates to a complaint rate of 0.023% Sales worldwide (Australia excluded) in the past 3 years: 358,187 This correlates to a complaint rate of 0.021%	No
63123	308140	Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory	670G	20/04/2020	There is one fault in the programming that has caused me to have a number of Hypos over the last three months, and a many instances where the pump delivered insulin when the BGL was close to the safe minimum.	-	Yes
62549	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	12/03/2020	Return of unused sensors	Similar events in Australia in the past 3 years: 1 Similar events worldwide (Australia excluded) in the past 3 years: 32 Sales in Australia in the past 3 years: 21777 This correlates to a complaint rate of 0.005% Sales worldwide (Australia excluded) in the past 3 years: 358187 This correlates to a complaint rate of 0.009%	No
62330	95763	Medtronic - 640G Insulin Pump - Infusion pump, insulin, ambulatory	640G	01/03/2020	The pump's retainer ring on the device is loose.	-	No
61609	95763	Minimed 640G pump - Infusion pump, insulin, ambulatory	MMT-1711KL	16/01/2020	Pump overdelivered insulin.	Similar events* in Australia in the past 3 years: 1 Similar events* worldwide (Australia excluded) in the past 3 years: 92 *Similar event data is generated using FDA Annex A code Sales in Australia in the past 3 years: 21568 This correlates to a complaint rate of 0.0046% Sales worldwide (Australia excluded) in the past 3 years: 354,569 This correlates to a complaint rate of 0.0259%	Yes

61530	95763	Medtronic 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711	13/01/2020	Unexpected delivery of insulin	-	Yes
61208	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	18/12/2019	It was reported that the insulin pump had blank display.	Australia: 2017: 0 similar incidents / 7,185 units sold 2018: 0 / 8,128 2019: 0 / 4,953 2020 (to date): 0 / 410 Worldwide: 2017: 3 similar incidents/ 83,206 sold worldwide 2018: 6 / 124,525 2019: 6 / 111,395 2020: (to date): 0 / 13,371	No
61072	95763	Minimed 670G pump - Infusion pump, insulin, ambulatory	MMT-1782K	12/12/2019	Hyperglycaemic episode.	Australia: 2017: 0 similar incidents / 0 units sold 2018: 0 / 404 2019: 0 / 5,006 2020 (to date): 0/ 372 Worldwide: 2017: 10 similar incidents/ 73,187sold worldwide 2018: 22 / 113,938 2019: 53 / 159,734 2020: (to date): 7 / 13,339	No
61081	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	12/12/2019	Customer hospitalized for high blood glucose.	Australia: 2017: 0 similar incidents / 7,185 units sold 2018: 0 / 8,128 2019: 0 / 4,953 2020 (to date): 0/ 411 Worldwide: 2017: 4 similar incidents/ 83,206 sold worldwide 2018: 1/ 124,525 2019: 6 / 111,395 2020: (to date): 0 / 13,371	No
60932	95763	Minimed 670G pump - Infusion pump, insulin, ambulatory	MMT-1782K	05/12/2019	Hypoglycaemic episode.	Australia: 2017: 0 similar incidents / 0 units sold 2018: 0 / 404 2019: 0 / 5,006 2020 (to date): 0 / 372 Worldwide: 2017: 13 similar incidents/ 73,157 sold worldwide 2018: 72/ 113,938 2019: 70 / 159,734 2020: (to date): 18 / 13,339	Yes
60132	308140	640G INSULIN PUMP	640G`	27/10/2019	My Daughters Medtronic 640g Insulin Pump, had a major failure, with extremely loud alarms, and had 10 errors.	-	Yes
59873	95763	Medtronic 640G - Infusion pump, insulin, ambulatory	640G	09/10/2019	Hairline fracture in pump housing leading to water immersion and pump failure.	-	No

59070	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	23/08/2019	Customer claims pump is under delivering insulin.	The following relates to similar incidents based on High Blood Glucose hospitalization with possible under delivery anomaly. Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 0 / 8128 = 0% 2019 (to date): 2 / 3412 = 0.06% Worldwide 2016: 0 similar incidents / 65 778 units sold = 0% 2017: 12 / 83 206 = 0.01% 2018: 20 / 124 525 = 0.02% 2019 (to date): 23 / 78 686 = 0.03%	No
58537	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	22/07/2019	Patient experiencing high BG. Trouble shooting was performed and the pump failed the high pressure test.	Similar incidents based on high blood glucose and failed High Pressure Test Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 1 / 8128 = 0.01% 2019 (to date): 1 / 3412 = 0.03% Worldwide 2016: 0 similar incidents / 65 778 units sold = 0% 2017: 1 / 83 206 = 0.00% 2018: 10 / 124 525 = 0.01% 2019 (to date): 14 / 78 686 = 0.02%	No
57426	95763	Medtronic Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	15/05/2019	Hospitalization for treatment of DKA. Symptoms include nausea, vomiting and abdominal pain.	2016: Australia - 2 similar incidents / 5,199 units sold = 0% Worldwide: 32 similar incidents / 65,778 units sold = 0% 2017: Australia - 0 similar incidents / 7,185 units sold = 0% Worldwide: 27 similar incidents / 83,206 units sold = 0% 2018: Australia - 1 similar incidents / 8,128 units sold = 0% Worldwide: 32 similar incidents / 124,525 units sold = 0% 2019 (to date): Australia - 2 similar incidents / 2,624 units sold = 0% Worldwide: 30 similar incidents / 61,694 units sold = 0%	No
57271	308140	Medtronic MiniMed 670G - Infusion pump, insulin, ambulatory	PUMP-1782K	06/05/2019	Customer presented to emergency department with low BG (1.2mmol).	2016: Australia - 0 similar incidents / 0 units sold = 0% Worldwide: 0 similar incidents / 0 units sold = 0% 2017: Australia - 0 similar incidents / 0 units sold = 0% Worldwide: 69 similar incidents / 72,692 units sold = 0.1% 2018: Australia - 0 similar incidents / 404 units sold = 0% Worldwide: 311 similar incidents / 113,864 units sold = 0.27% 2019 (to date): Australia - 1 similar incidents / 2,618 units sold = 0% Worldwide: 184 similar incidents / 71,661units sold = 0.25%	No
57230	95763	Medtronic MiniMed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	03/05/2019	Hospitalization due to DKA.	Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 0 / 8128 =0% 2019 (to date): 1 / 2624 = 0.04% Worldwide: 2016: 0 similar incidents / 65778 units sold = 0% 2017: 3 / 83206 = 0% 2018: 6 / 124525 = 0% 2019 (to date): 10 / 61694 = 0.02%	No
57139	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	26/04/2019	A customer was admitted to hospital with low BG. Customer claims they have had multiple low BG events within the month.	Australia 2016: 3 similar incidents / 5199 units sold = 0.06% 2017: 3 / 7185 = 0.04% 2018: 0 / 8128 = 0% 2019 (to date): 2 / 2624 = 0.08% Worldwide: 2016: 16 similar incidents / 65778 units sold = 0.02% 2017: 41 / 83206 = 0.05% 2018: 47 / 124525 = 0.04% 2019 (to date): 36 / 61694 = 0.06%	No

56506	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	22/03/2019	A patient was hospitalized for high BG and possible onset of DKA. The customer is alleging that the pump was under delivering insulin.	Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 0 / 8128 = 0% 2019 (to date): 1 / 2333 units sold = 0.04% Worldwide: 2016: 0 similar incidents / 65779 units sold = 0% 2017: 12 / 83207 = 0.01% 2018: 20 / 124526 = 0.02% 2019 (to date): 12 / 47653 = 0.03%	No
56509	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	22/03/2019	Repeated 'insulin flow blocked' alarms on device.	Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 0 / 8128 = 0% 2019 (to date): 1 / 2333 units sold = 0.04% Worldwide: 2016: 0 similar incidents / 65779 units sold = 0% 2017: 12 / 83207 = 0.01% 2018: 20 / 124526 = 0.02% 2019 (to date): 4 / 47653 = 0.01%	No
56344	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1751H	14/03/2019	Sponsor received a report that a customer was hospitalized (Emergency Room) due to high BG and ketones. The customer alleges that the pump did not alarm to indicate a flow block. The customer is also reporting concerns with the battery. Several alarms were received but customer states there was no 'low battery' alarm - only a 'replace now' alarm.	Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 0 / 7185 = 0% 2018: 0 / 8128 = 0% 2019 (to date): 1 / 2333 units sold = 0.04% Worldwide: 2016: 3 similar incidents / 65779 units sold = 0.00% 2017: 2 / 83207 = 0.00% 2018: 8 / 124526 = 0.01% 2019 (to date): 2 / 47653 = 0.00%	No
56276	95763	Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	12/03/2019	Patient hospitalized for high BG and DKA.	Australia 2016: 2 similar incidents / 5199 units sold = 0.04% 2017: 0 / 7185 = 0% 2018: 1 / 8128 = 0.01% 2019 (to date): 2 / 3014 = 0.07% Worldwide: 2016: 32 similar incidents / 65778 units sold = 0.05% 2017: 27 / 83206 = 0.03% 2018: 33 / 124525 = 0.03% 2019 (to date): 34 / 70727 = 0.05%	No
56185	95763	Minimed 640G Insulin Pump MMT-1711K - Infusion pump, insulin, ambulatory	MMT-1711K	07/03/2019	Medtronic has received a report of a patient who was hospitalized for low blood glucose.	Australia 2016: 0 similar incidents / 5199 units sold = 0% 2017: 1 / 7185 = 0.01% 2018: 0 / 8128 = 0% 2019 (to date): 1 / 2333 units sold = 0.04% Worldwide: 2016: 0 similar incidents / 65779 units sold = 0% 2017: 13 / 83207 = 0.02% 2018: 9 / 124526 = 0.01% 2019 (to date): 8 / 47653 = 0.02%	No
55626	308140	Medtronic Insulin pump 670G - Infusion pump, insulin, ambulatory	670G	03/02/2019	Injury to ankle sustained during a hypoglycaemic episode resulting from a device malfunction. Pump has been replaced 5 times in last 5 months due to malfunction.	-	Yes

55547	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711W	25/01/2019	Sponsor has been informed that a customer of an insulin pump was found deceased in bed.	Australia: 2016: 1 similar incident / 5199 units sold = 0.02% 2017: 0 / 7185 = 0% 2018: 0 / 8128 = 0% 2019 (to date): 1 / 333 = 0.30% Worldwide: 2016: 2 similar incident / 65,779 units sold = 0.00% 2017: 5 / 83,207 = 0.01% 2018: 8 / 124,526 = 0.01% 2019 (to date): 4 / 47,653 = 0.01%	Yes
54413	95763	Medtronic 640g Insulin Pump - Infusion pump, insulin, ambulatory	-	14/11/2018	My daughter is a type 1 diabetic and using a Medtronic 640g pump. Today I received notification from a friend about a product recall of the pump. And after going through the instructions discovered that the pump is in fact faulty and has to be replaced. Medtronic have not even sent a email about this recall.	-	Yes
54434	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	14/11/2018	Sponsor has received a complaint regarding an insulin pump with an unresponsive keypad. The customer states that the center button is not working, the numbers are not ramping on their own and the scroll bar is not moving with no input.	Australia 2016: 0 similar incidents AUS / 5199 units sold in AUS = 0% 2017: 0 / 7185 = 0% 2018: 1 / 8128 = 0% 2019 (to date): 0 / 566 = 0% Worldwide 2016: 46 similar incidents worldwide / 65778 number sold worldwide = 0.1% 2017: 25 / 83206 = 0% 2018: 9 / 124525 = 0% 2019 (to date): 0 / 13322 = 0%	No
54331	95763	Medtronic Minimed 640G Insulin Pump	MMT-1711K	08/11/2018	Sponsor has received a complaint regarding an insulin pump with an unresponsive keypad. The customer states that the numbers are not ramping on their own and that the scroll bar is not moving.	Australia 2016: 0 similar incidents / 5199 units sold in AUS = 0% 2017: 9 / 7185 = 0.1% 2018: 11 / 8128 = 0.1% 2019 (to date): 0 / 566 = 0% Worldwide: 2016: 12 / 65778 = 0.01% 2017: 693 / 83206 = 0.83% 2018: 1371 / 124525 = 1.10% 2019 (to date): 162 / 13322 = 1.22%	No
54333	95763	Medtronic Minimed 640G Insulin Pump	MMT-1711P	08/11/2018	Sponsor has received a complaint regarding an insulin pump with an unresponsive keypad. The customer states that the numbers are ramping on their own and that the scroll bar is moving with no input.	Australia 2016: 0 similar incidents in AUS / 5199 Number sold in AUS = 0% 2017: 9 / 7185 = 0.1% 2018: 11 / 8128 = 0.1% 2019 (To date): 0 / 566 = 0% Worldwide 2016: 12 similar incidents worldwide / 65778 number sold worldwide = 0% 2017: 693 / 83206 = 0.8% 2018: 1371 / 124525 = 1.1% 2019 (to date) : 162 / 13322 = 1.2%	No
54334	95763	Medtronic Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	08/11/2018	Sponsor has received a complaint regarding an insulin pump with an unresponsive keypad. The customer states that there is no response from any button on the keypad. The numbers are ramping on their own and the scroll bar is not moving with no input.	Australia 2016: 0 similar incidents / 5199 units sold in AUS = 0% 2017: 1 / 7185 = 0.01% 2018: 1 / 8128 = 0.01% 2019 (to date): 0 / 566 = 0% Worldwide 2016: 51 similar incidents worldwide / 65778 number sold worldwide = 0.08% 2017: 123 / 83206 = 0.15% 2018: 190 / 124525 = 0.15% 2019 (to date): 0 / 13322 = 0%.	No

54269	95763	640G Insulin Pump MMT 1711K - Infusion pump, insulin, ambulatory	MMT 1711K	06/11/2018	The customer reported that the up arrow button gets sticky.	Australia 2016: 0 similar incidents / 5199 number sold in AUS = 0% 2017: 9 / 7185 = 0.1% 2018: 11 / 8128 = 0.1% 2019 (to date): 0 / 566 = 0% Worldwide 2016: 12 similar incidents worldwide / 65778 number sold worldwide = 0% 2017: 693 / 83206 = 0.8% 2018: 1371 / 124525 = 1.1% 2019 (to date): 162 / 13322 = 1.2%	No
54112	95763	Medtronic Minimed 640G Insulin Pump	MMT-1711K	29/10/2018	Sponsor has received a complaint regarding an insulin pump with an unresponsive keypad. The customer states that the numbers are not ramping on their own and that the scroll bar is not moving. No response from any button.	Australia 2016: 0 similar incidents AUS / 5199 Number sold in AUS = 0% 2017: 9 / 7185 = 0.1% 2018: 11 / 8128 = 0.1% 2019 (to date): 0 / 566 = 0% Worldwide 2016: 12 similar incidents / 65 778 number sold worldwide = 0% 2017: 693 / 83206 = 0.8% 2018: 1371 / 124525 = 1.1% 2019 (To date): 162 / 13322= 1.2%	No
53645	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	26/09/2018	Medtronic has become aware of a customer who was hospitalized with high blood glucose. After performing some basic troubleshooting, it was confirmed that the pump failed the high pressure test.	Australia 2016: 3 similar incidents / 5199 number sold AUS = 0.1% 2017: 3 / 7185 = 0% 2018: 3 / 8128 = 0% 2019 (to date): 0 / 566 = 0% Worldwide 2016: 80 similar incidents worldwide /65778 number sold worldwide = 0.1% 2017: 117 / 83206 = 0.1% 2018: 197 / 124525 = 0.2% 2019 (to date): 21 / 13322 = 0.2%	No
53502	95763	Medtronic 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711K	19/09/2018	Pump failed to deliver basal insulin and no alarm was noted.	Australia 2016: 0 similar incidents/ 5199 number sold AUS = 0% 2017: 0/ 7185 = 0% 2018: 1/8128 = 0.01% 2019 (to date): 0/566 = 0% Worldwide 2016: 219 similar incidents/ 65778 Number sold worldwide = 0% 2017: 257/83206 = 0% 2018: 4329/124525 = 0.03% 2019 (to date) : 864/13322 = 0.06%	No
52486	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711P	09/07/2018	Patient admitted to hospital for high blood glucose. Patient reported that the pump is not delivering insulin. Insulin pump failed the HP Test.	Australia: 2015: 0 similar incidents / 4,397 units sold (0%) 2016: 0/5,199 (0%) 2017: 10/7,185 (0.139%) 2018 (to date): 17/5,295 (0.321%) Worldwide: 2015: 0/49,575 (0%) 2016: 3/65,778(0.005%) 2017: 51/83,206 (0.061%) 2018 (to date): 36/78,191 (0.046%)	No
52076	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	13/06/2018	Patient experienced a keypad anomaly with their pump. It has been reported that the scroll bar is moving without input and that the up and down buttons are stuck. The patient was admitted to hospital with low blood glucose.	Australia: 2015: 0 similar incidents / 4,397 units sold (0%) 2016: 0/5,199 (0%) 2017: 8/7,185 (0.111%) 2018 (to date): 4/5,295 (0.076%) Worldwide: 2015: 0/49,575 (0%) 2016: 0/65,778 (0%) 2017: 8/83,206 (0.010%) 2018 (to date): 7/78,191 (0.009%)	No
51398	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711B	27/04/2018	Customer hospitalized due to high blood glucose with ketones, with blood glucose of 540 mg/dl at the time of the incident.	Worldwide: 25 similar incidents/87,409 supplied = 0.029%. Australia: 8 similar incidents/17,735 supplied - 0.045%.	No
50984	95763	Insulin pump with CGM capability	640G	05/04/2018	Degraded battery performance with crack over battery compartment, from edge of clip retainer.	-	Yes
50334	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	26/02/2018	Insulin pump had a Keypad Anomaly. Insulin pump buttons were unresponsive and only the menu button was working.	Australia: 2015: 22/3,567*100=0.62%; 2016: 56/8,167*100=0.69%; 2017: 89/14,577*100=0.61%; 2018: 54/17,735*100=0.30%. Worldwide: 2015: 80/25,048*100=0.32%; 2016: 457/49,862*100=0.92%; 2017: 546/74,343*100=0.73%; 2018: 323/87,409*100=0.37%.	No

50182	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	14/02/2018	A customer is experiencing a keypad anomaly with their Medtronic Minimed 640G pump. It has been reported that the up, left, centre and down buttons are unresponsive.	35 (Number of similar events reported Australia from 2015 to current). 187 (Number of similar events reported Worldwide from 2015 to current). Number sold Australia (to date) 2018: 16,441. Number sold Worldwide (to date) 2018: 84,346.	No
50146	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711B	12/02/2018	A customer was hospitalized with high blood glucose and ketones. It is alleged that the pump basal program is not working. The customer was not aware of any alarms.	8 (Number of similar events reported Australia from 2015 to current). 18 (Number of similar events reported Worldwide from 2015 to current). Number sold Australia (to date) 2018: 16,441. Number sold Worldwide (to date) 2018: 84,346.	No
49918	95763	Minimed 640G insulin Infusion pump - Infusion pump, insulin, ambulatory	MMT-1711B	29/01/2018	Customer is experiencing a keypad anomaly with their 640G pump. The customer reports that there is no response from the down arrow key.	35 (Number of similar events reported Australia from 2015 to current). 187 (Number of similar events reported Worldwide from 2015 to current). Number sold Australia (to date) 2018: 16,441. Number sold Worldwide (to date) 2018: 84,346.	No
49919	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711W	29/01/2018	Customer is experiencing a keypad anomaly with their 640G pump. The customer reports that there is no response from the down and left arrow keys.	35 (Number of similar events reported Australia from 2015 to current). 187 (Number of similar events reported Worldwide from 2015 to current). Number sold Australia (to date) 2018: 16,441. Number sold Worldwide (to date) 2018: 84,346.	No
49337	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	14/12/2017	Medtronic has received a report that a customer is experiencing a keypad anomaly with their 640G pump. The customer reports that there is no response from any key.	The following data relates to similar incidents involving keypad anomalies with no hospitalization reported. Worldwide: 2015: 80 similar incidents / 25,048 install base = 0.32% 2016: 457 / 49,862 = 0.92% 2017 (until 19 December): 546 / 70,850 = 0.77% Australia: 2015: 22 / 3,567 = 0.62% 2016: 56 / 8,176 = 0.68% 2017 (until 19 December): 89 / 13,959 = 0.64%	No
49116	95763	Minimed 640G insulin infusion pump	MMT-1711H	30/11/2017	Medtronic has received a report that a customer is experiencing a keypad anomaly with their 640G pump. The Down arrow key is not responding.	The following data relates to similar incidents involving keypad anomalies with no hospitalization reported. Worldwide: 2015: 80 similar incidents / 25,048 install base = 0.32% 2016: 457 / 49,862 = 0.92% 2017 (until 21 December): 546 / 70,850 = 0.77% Australia: 2015: 22 / 3,567 = 0.62% 2016: 56 / 8,176 = 0.68% 2017 (until 21 December): 89 / 13,959 = 0.64%	No
48938	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711B	21/11/2017	Medtronic has received a report that a customer is experiencing a keypad anomaly with their 640G pump.	The following data relates to similar incidents involving keypad anomalies with no hospitalization reported. Worldwide: 2015: 80 similar events / 25,048 install base = 0.32% 2016: 457 / 49,862 = 0.92% 2017 (until 20 December): 546 / 70,850 = 0.77% Australia: 2015: 22 / 3,567 = 0.62% 2016: 56 / 8,176 = 0.68% 2017 (until 20 December): 89 / 13,959 = 0.64%	No
48917	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711P	20/11/2017	Medtronic has received a report that a customer is experiencing a keypad anomaly with their 640G pump. The keys & display have been frozen for approximately 1 week.	The following data relates to similar incidents involving keypad anomalies with no hospitalization reported. Worldwide: 2015: 80 similar incidents / 11,851 install base = 0.68% 2016: 457 / 39,124 = 1.17% 2017 (until 21 December): 546 / 60,251 = 0.91% Australia: 2015: 22 / 1,946 = 1.13% 2016: 56 / 5,913 = 0.95% 2017 (until 21 December): 89 / 11,179 = 0.80%	No

48491	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711P	24/10/2017	Medtronic has received a report that a customer is experiencing a keypad anomaly with their Minimed 640G pump. All keys are unresponsive.	The following data relates to similar incidents involving keypad anomalies with no hospitalization reported. Worldwide: 2015: 76 similar incidents / 11,851 install base = 0.64% 2016: 435 / 39,124 = 1.11% 2017 (until 28 November): 470 / 59,192 = 0.79% Australia: 2015: 21 / 1,946 = 1.08% 2016: 54 / 5,913 = 0.91% 2017 (until 28 November): 81 / 10,901 = 0.74%	No
48266	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	09/10/2017	A keypad anomaly. Several keypad issues experienced, specifically the middle key is not working.	The following data relates to similar incidents of keypad anomalies, with no hospitalisation. Worldwide (including Australia): 2015: 76 similar incidents / 11,851 install base 2016: 435 / 39,124 2017 (to date): 470 / 59,192 Australia: 2015: 21 / 1,946 2016: 54 / 5,913 2017 (to date): 81 / 10,901	No
48270	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711W	09/10/2017	A keypad anomaly with their insulin pump.	The following data relates to similar incidents of keypad anomalies, with no hospitalisation. Worldwide (including Australia): 2015: 76 similar incidents / 11,851 install base 2016: 435 / 39,124 2017 (to date): 470 / 59,192 Australia: 2015: 21 / 1,946 2016: 54 / 5,913 2017 (to date): 81 / 10,901	No
48248	95763	Minimed 640G Infusion pump, insulin, ambulatory	MMT-1711P	06/10/2017	A low blood glucose event and associated hospitalization (ER). It has been alleged that the pump administered a bolus that was not programmed. .	The following data relates to similar incidents of low blood glucose hospitalisation, with allegation of over delivery. Worldwide (including Australia): 2015: 0 similar incidents / 11,851 install base 2016: 0 / 39,124 2017 (to date): 12 / 59,192 Australia: 2015: 0 / 1,946 2016: 0 / 5,913 2017: 3 / 10,901	No
48092	95763	MiniMed Insulin Reservoirs	-	22/09/2017	Patient on third 640G pump. The first two failed in the first 15 months of use.	-	Yes
48018	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	20/09/2017	A keypad anomaly with their 640G pump.	The following data relates to similar incidents of keypad anomalies, with no hospitalization. Worldwide (including Australia) 2015: 76 similar incidents / 11, 851 install base 2016: 435 / 39,147 2017 (to date): 470 / 59,192 Australia: 2015: 21 / 1,946 2016: 54 / 5,913 2017 (to date): 81 / 10,901	No

47914	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711W	14/09/2017	Sponsor received a complaint regarding a keypad anomaly.	The following data relates to 'keypad unresponsive / button error alarm, no hospitalisation. Worldwide (including Australia) 2015: 10 similar events / 11,851 install base 2016: 104 / 39,147 2017 (to date): 1,638 / 52,412 Australia: 2015: 2 / 1,946 2016: 24 / 5,913 2017 (to date): 321 / 9,561 Sponsor update (21/11/2017): Previous details of similar events are incorrect. See the table to the right for the correct information.	No
47915	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711K	14/09/2017	Patient admitted to hospital for high blood glucose and ketones.	The following data relates to similar incidents involving high blood glucose hospitalization, with a failed HP test. Worldwide (including Australia): 2015: 0 similar incidents / 1,946 install base = 0% 2016: 1 / 5,913 = 0.017% 2017 (to date): 30 / 9,561 = 0.314% Australia: 2015: 0 / 11,851 = 0% 2016: 0 / 39,147 = 0% 2017 (to date): 5 / 52,412 = 0.010% Sponsor update (21/11/2017): The previous details of similar events was incorrect. Please see the table to the right for correct information.	No
47698	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711	31/08/2017	Low blood glucose and seizures. Self-test could not be completed due to a pump error.	The following similar event data relates to cases of 'low blood glucose hospitalization' and 'pump error'. Worldwide (including Australia) 2015: 14 similar incidents / 25,048 install base = 0.06% 2016: 37 / 49,937 = 0.07% 2017 (to date): 22 / 64,583 = 0.03% Australia 2015: 6 / 3,567 = 0.17% 2016: 9 / 8,176 = 0.11% 2017 (to date): 2 / 12,281 = 0.02%	No
47290	95763	Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1712K	04/08/2017	Medtronic has received a report that a customer has been hospitalized (intensive care) with High BG. The customer is claiming that the CGM sensor has a lower reading than the actual BG reading.	Worldwide (including Australia): 2015: 7 similar incidents / 25240 install base = 0.03% 2016: 62 / 55158 = 0.11% 2017 (to date): 34 / 72507 = 0.05% Australia: 2015: 0 / 3567 = 0% 2016: 0 / 8176 = 0% 2017 (to date): 1 / 11747 = 0.01%	No
47062	95763	Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory	MMT-1711P	20/07/2017	It is alleged that the pump was not delivering insulin and did not alarm.	The following similar incidents involve reported events of High Blood Glucose hospitalisation. Worldwide (including Australia) 2015: 29 incidents / 25048 install base (0.12%) 2016: 125/49937 (0.25%) 2017 (to date): 70/62441 (0.11%) Australia 2015: 11/3567 (0.31%) 2016: 33/8176 (0.40%) 2017 (to date): 11/11747 (0.09%)	No

46667	95763	Minimed 640G Insulin Pump	MMT-1711H	21/06/2017	Customer alleges that the pump delivered an unprogrammed bolus, resulting in a hypoglycemic event.	Worldwide (including Australia) 2015: 0/25048 = 0% 2016: 0/49937 = 0% 2017 (to date): 10/59330 = 0.017% Australia 2015: 0/3567 = 0% 2016: 0/8176 = 0% 2017 (to date): 2/11152 = 0.018%	No
46531	95763	Medtronic MiniMed 640G Insulin Infusion Pump	MiniMed	13/06/2017	Patient is unable to upload the data from their insulin pump.	-	Yes
46164	95763	Medtronic 640g insulin pump	640g	19/05/2017	Power error detected.	-	No
45702	95763	Medtronic Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711P	19/04/2017	The pump failed the High Pressure test.	Australia: 2015: 11 similar incidents / 3567 install base 2016: 33 similar incidents / 8176 install base 2017 (to date): 10 similar incidents / 9389 install base Worldwide: 2015: 29 similar incidents / 25048 install base 2016: 126 similar incidents / 49937 install base 2017 (to date): 39 similar incidents / 56060 install base	No
45703	95763	Medtronic Minimed 640G - Infusion pump, insulin, ambulatory	MMT-1711W	19/04/2017	The patient alleges that the pump was over delivering insulin.	Australia: 2015: 7 similar incidents / 3567 install base 2016: 9 similar incidents / 8176 install base 2017 (to date): 2 similar incidents / 9389 install base Worldwide: 2015: 15 similar incidents / 25048 install base 2016: 36 similar incidents / 49937 install base 2017 (to date): 9 similar incidents / 56060 install base	No
45502	95763	Insulin Pump	640g	03/04/2017	Insulin pump warned low battery approximately. A day later it alarmed warning battery critically now and to replace immediately. Replaced battery but insulin pump didn't recognise new battery. Tried 4 different batteries including a new sealed package. Contacted sponsor's helpline and outlined this error and asked to troubleshoot. By time call taker went through various prompts, eventually asked to go to a menu but the pump battery had failed and unable to select menu.	-	Yes

From: s22
To: s22 @medtronic.com
Subject: TGA completion letter for DIR 67426 [SEC=OFFICIAL]
Date: Thursday, 17 June 2021 9:27:29 AM
Attachments: image001.png
[D21-2738196] TGA Sponsor Complete Letter DIR 67426.PDF

Dear s22

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Please find attached the completion letter for DIR 67426.

Kind regards,

s22
Departmental Officer
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

File Reference: E21-284733
Sent by email

Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 @medtronic.com; s22 @medtronic.com

Dear s22

DEVICE INCIDENT REPORT DIR 67426 - ARTG # 308140 - Infusion pump, insulin, ambulatory

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on (02) 6289 4642 or send an email to: IRIS@health.gov.au

Yours sincerely

Signed electronically by

s22

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

17/06/2021

DIR 67426 - ARTG # 308140 - Infusion pump, insulin, ambulatory

Reporter Reference #:
CASE-2020-00922453/56/57

Date of Adverse Event:
s22 [redacted]

Date of Initial Report:
01/01/2021

ARTG #:
308140

Brand Name:
Minimed 670G - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1782K

Serial #:
NG2285129H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Fax:

Email: s22 [redacted] @medtronic.com;
s22 [redacted] @medtronic.com

Reporter:
s22 [redacted]
s22 [redacted]
Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park NSW 2113
Email: s22 [redacted] @medtronic.com

Confidential: N/A

Phone: s22 [redacted]
Fax:

Clinical Event Information:
According to a customer, patient was admitted to the hospital due to DKA.
Customer alleges that the pump was not delivering properly, they checked the settings and everything was accurate according to Diabetes Educator.
Patient's Blood Glucose was unknown because it was too high and did not register on the meter.
Patient experienced positive results in ketones test, Nausea, Vomiting, Abdominal pain, Difficulty breathing and DKA

Patient Outcome/Consequences:

Device Analysis Results:
The pump passed the functional tests, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08720 inches.

Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.

Details of Similar Events:
In Australia
0 similar events from 474 units (0%) sold in CY2018;
0 similar events from 5006 units (0%) sold in CY2019;
0 similar events from 4094 units (0%) sold in CY2020;
0 similar events from 369 units (0%) sold in CY2021;

WorldWide
14 similar events from 113938 units (0.01229%) sold in CY2018;
71 similar events from 159734 units (0.04445%) sold in CY2019;
64 similar events from 145532 units (0.04398%) sold in CY2020;
11 similar events from 10097 units (0.10894%) sold in CY2021;
Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Canada, Netherlands, Spain, United States

Clinical Signs (Level 1)

Hepatic and Biliary System

Clinical Signs (Level 2)

Health Impacts (Level 1)

Hospitalization or Prolonged

Health Impacts (Level 2)

Type of Problem (Level 1)

Infusion or Flow Problem

Type of Problem (Level 2)

Cause of Problem (Level 1)

No Device Problem Found

Cause of Problem (Level 2)

Outcome of Investigation

Reviewed, No Further Action Required

Summary of Investigation:
Review of the information provided by the sponsor confirmed that the pump passed all tests conducted on the returned device. Review of the instructions for use noted that Diabetic Ketoacidosis is included in the list of 'Risks related to insulin administration and pump use'. The TGA clarified the similar event rates provided by the sponsor and confirmed they are consistent with a search of the IRIS database.

Date Completed:
17/06/2021

***** End of DIR 67426 *****

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 @medtronic.com

File Reference: E20-45930
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 60932 - ARTG # 95763 - Infusion pump, insulin, ambulatory

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on (02) 6289 4642 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

s22

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

26/06/2020

DIR 60932 - ARTG # 95763 - Infusion pump, insulin, ambulatory

Reporter Reference #: CASE-2019-00840457 / 8
/9

Date of Adverse Event:
s22 [redacted]

Date of Initial Report:
05/12/2019

ARTG #:
95763

Brand Name:
Minimed 670G pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1782K

Serial #:
NG1784493H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: (02) 9857-9000

Fax:

Email: s22 [redacted] @medtronic.com

Reporter:
s22 [redacted]
PMV Manager
Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park NSW 2113
Email: s22 [redacted] @medtronic.com

Confidential: N/A

Phone: s22 [redacted]
Fax:

Clinical Event Information:
Medtronic was notified of a customer hospitalized for low blood glucose. The customer was using the auto feature on their 670G pump (continuous glucose monitoring).
No troubleshooting was performed as the customer refused.
Medtronic has requested that the pump be returned for analysis.

As of today 03/03/2020- more detailed description of the event:

Customer called and reported that they were hospitalized due to low blood glucose on s22 [redacted] with blood glucose of 20 to 32 mg/dl at the time of the incident.
The customer's blood glucose was 144 mg/dl at the time of the call. The customer was given glucose and intravenous fluids to treat.
The customer did not mention any symptoms. The customer was wearing the insulin pump during the incident. The Auto Mode on the insulin
pump was active and automatically adjusting insulin delivery during the event. The customer reported pump physical damage.
The customer suspected the pump was over delivering. Troubleshooting was not completed as the

customer declined.

Patient Outcome/Consequences:

Device Analysis Results:
The insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test,
Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test.
The test P-cap locks properly in the reservoir compartment.
The following physical damages were noted but did not impact the insulin pump's performance: a cracked
case corner of the belt clip rails near the battery compartment and cracked battery tube threads.
Corrective/Preventative Actions:
All complaints are monitored for trends and signals. Quality Review decides on formal investigations based on trending including signal detection and complaint data.
Details of Similar Events:
Australia:
2017: 0 similar incidents / 0 units sold
2018: 0 / 404
2019: 0 / 5,006
2020 (to date): 0 / 372

Worldwide:
2017: 13 similar incidents/ 73,157 sold worldwide
2018: 72/ 113,938
2019: 70 / 159,734
2020: (to date): 18 / 13,339
Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:
Canada, Sweden, United Kingdom, United States.

Type of Problem (Level 1) Type of Problem (Level 2)

Appropriate Term/Code Not Available

Cause of Problem (Level 1) Cause of Problem (Level 2)

No Findings Available

Outcome of Investigation

Reviewed, No Further Action Required

Summary of Investigation:
The manufacturer stated that they have conducted an analysis on the returned device. Review of their findings confirmed the insulin pump passed the functional tests, including the Self-Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and Displacement Accuracy Test. The test P-cap locks properly in the reservoir compartment. The device was also found to have a cracked case corner of the belt clip rails near the battery compartment and cracked battery tube threads. The manufacturer has confirmed that the physical damage noted in the analysis would not impact the device's performance. (what did you find or are you just going with what the manufacturer has stated is the issue)The sponsor has stated one similar event has been reported. This is consistent with a search of the TGA database.
No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:
23/06/2020

***** End of DIR 60932 *****

From: s22 [redacted]
To: IRIS
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 28 June 2019 5:50:46 PM
Attachments: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019.pdf

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Dear IRIS,

Thank you for your request for information.

The following is in answer to your questions:

1. Please provide a copy of the Coroner's report if available. **Due to patient privacy legislation, Medtronic are not given access to Coroner's reports. As such, we do not have a copy relating to this event.**
2. Please provide details of the patient so the TGA can obtain a Coroner's Report. **As requested, the patient's name is** s22 [redacted]

Should you have any further questions, please do not hesitate to contact me.

Kind Regards

s22 [redacted]
s22 [redacted] | Quality and Regulatory Affairs
Office: s22 [redacted] | Mobile: s22 [redacted] | Fax: s22 [redacted]
s22 [redacted] @medtronic.com

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 20 June 2019 9:03 AM
To: s22 [redacted] @medtronic.com>
Subject: [EXTERNAL] RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted]

Please delete and disregard the Request For Information letter attachment that was incorrectly sent to you yesterday titled under DIR 57560. Apologies for the confusion.
Please see the correct letter attached for DIR 55547.

Kind regards,

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: 1800 809 361

Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621, using a TGA eBusiness Service (eBS) user name and password.

User guidance and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting
Sponsors / Manufacturers: https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621
Medical Device Healthcare Professionals/Users:
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1267534111



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From: s22 [redacted] @medtronic.com]
Sent: Wednesday, 19 June 2019 4:30 PM
To: IRIS
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear IRIS,

It appears that this request may have been sent in error.

Kind regards,

s22 [redacted]
s22 [redacted] Quality and Regulatory Affairs

Medtronic
2 Alma Road | Macquarie Park NSW 2113 | Australia
Office s22 [redacted] | Mobile s22 [redacted] | Fax s22 [redacted]
s22 [redacted] @medtronic.com ; rs.anzpmv@medtronic.com

medtronic.com.au | Facebook | LinkedIn | Twitter | YouTube

LET'S TAKE HEALTHCARE

FURTHER, TOGETHER

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

This message has been marked as Medtronic Controlled

From: IRIS <IRIS@health.gov.au>
Sent: Wednesday, 19 June 2019 4:18 PM
To: s22 [redacted] @medtronic.com>
Subject: [EXTERNAL] DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted],

Please see the attached **Request For Information (RFI) letter** for action.
***Please note the due date for a response is no later than COB 17 July 2019.**

Kind regards,

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621, using a TGA eBusiness Service (eBS) user name and password.

User guidance and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting
Sponsors / Manufacturers: https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621
Medical Device Healthcare Professionals/Users:
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1267534111



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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 [redacted] @medtronic.com

File Reference: E19-579552
Sent by email

Dear s22 [redacted],

DEVICE INCIDENT REPORT DIR 55547 - Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the TGA database report is attached.

To assist in the evaluation and resolution of this report, could you please provide the information requested below referencing the above DIR number and return it to this office **within 20 working days of the date of this letter and no later than close of business 17/07/2019**.

1. Please provide a copy of the Coroner's report if available.
2. Please provide details of the patient so the TGA can obtain a Coroner's Report

Electronic submission of all information is preferred. Please send the requested information to email address: **IRIS@health.gov.au**

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report and Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device(s) to the TGA please follow the instructions via link:
https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

If you do not respond with the requested information or with a request for a reasonable extension to this timeframe within the twenty days, you will receive a letter under Section 41JA of the Therapeutic Goods Act requesting the information and no further extension of time will be granted.

Thank you for your cooperation. If you require further information please call (02) 6232 8777.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

19/06/2019

DIR 55547 - Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Reporter Reference #: CASE-2019-00044409

Date of Adverse Event:
s22 [redacted]

Date of Report:
13/06/2019

ARTG #:
95763

Brand Name:
Minimed 640G Insulin Pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
MMT-1711W

Serial #:
NG1263558H

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed

Sponsor:
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name:
s22 [redacted]

Phone:
(02) 9857-9000

Reporter:
s22 [redacted]
PMV Manager
Medtronic Australasia
2 Alma Road
Macquarie Park NSW 2113

Confidential: No

Phone: s22 [redacted]
Fax:

Email:
s22 [redacted]@medtronic.com

Clinical Event Information:
Medtronic has been informed that a customer of an insulin pump was found deceased in bed. The cause of death is unknown at this stage.

The pump will be returned for analysis.

Patient Outcome/Consequences:
Unknown.

***** End of DIR 55547 *****

From: s22
To: s22
Cc: s22
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 5 July 2019 6:59:37 PM
Attachments: image001.gif
Victorian Institute of Forensic Medicine_474318_19.02.2019.pdf

---

Hi s22

My apologies for the delay in getting this information back to you. I was unable to access the files that I was hoping to and so had to wait on a colleague to get back to me.

I believe s22 state is Victoria.

I thought the attached may be of assistance to you.

Kind Regards

s22
s22 | Quality and Regulatory Affairs
Office: s22 | Mobile: s22 | Fax: s22
s22 @medtronic.com

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

From: s22
Sent: Tuesday, 2 July 2019 8:24 PM
To: s22 @health.gov.au>
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Hi s22

I can confirm that s22 DOB is s22

Kind Regards

s22
Post Market Quality Operational Excellence Manager | Quality and Regulatory Affairs
Office: s22 | Mobile: s22 | Fax: s22
s22 @medtronic.com

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

From: s22 @health.gov.au>
Sent: Monday, 1 July 2019 11:35 AM
To: s22 @medtronic.com>
Subject: [EXTERNAL] RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

Thank you for providing the responses below.

Do you know what [redacted] birth date was?

Kind Regards

[redacted]

Registered Nurse (RN), GradCertEmergencyNursing
Departmental Officer
Devices Vigilance and Monitoring
Medical Devices Branch

Phone: [redacted]
Email: [redacted]@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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From: [redacted]@medtronic.com]
Sent: Friday, 28 June 2019 5:51 PM
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear IRIS,

Thank you for your request for information.

The following is in answer to your questions:

1. Please provide a copy of the Coroner's report if available. **Due to patient privacy legislation, Medtronic are not given access to Coroner's reports. As such, we do not have a copy relating to this event.**
2. Please provide details of the patient so the TGA can obtain a Coroner's Report. **As requested, the patient's name is** [redacted]

Should you have any further questions, please do not hesitate to contact me.

Kind Regards

s22 [redacted] | Quality and Regulatory Affairs
Office: s22 [redacted] | Mobile: s22 [redacted] | Fax: s22 [redacted]
s22 [redacted] @medtronic.com

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, 20 June 2019 9:03 AM
To: s22 [redacted] @medtronic.com>
Subject: [EXTERNAL] RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted]

Please delete and disregard the Request For Information letter attachment that was incorrectly sent to you yesterday titled under DIR 57560. Apologies for the confusion.
Please see the correct letter attached for DIR 55547.

Kind regards,

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621, using a TGA eBusiness Service (eBS) user name and password.

User guidance and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting
Sponsors / Manufacturers: https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621

Medical Device Healthcare Professionals/Users:
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1267534111

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From: s22 [redacted] @medtronic.com]
Sent: Wednesday, 19 June 2019 4:30 PM
To: IRIS
Subject: RE: DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear IRIS,

It appears that this request may have been sent in error.

Kind regards,

s22 [redacted]
s22 [redacted] | Quality and Regulatory Affairs

Medtronic
2 Alma Road | Macquarie Park NSW 2113 | Australia
Office s22 [redacted] | Mobile s22 [redacted] | Fax s22 [redacted]
s22 [redacted] @medtronic.com ; rs.anzpmv@medtronic.com

medtronic.com.au | Facebook | LinkedIn | Twitter | YouTube

LET'S TAKE HEALTHCARE FURTHER, TOGETHER

Please note that I only check my emails a few times each day. If your matter is urgent, kindly give me a call.

This message has been marked as Medtronic Controlled

From: IRIS <IRIS@health.gov.au>
Sent: Wednesday, 19 June 2019 4:18 PM
To: s22 [redacted] @medtronic.com>
Subject: [EXTERNAL] DIR 55547 - Request For information (RFI) Letter - response due COB 17 July 2019 [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 [redacted]

Please see the attached **Request For Information (RFI) letter** for action.
***Please note the due date for a response is no later than COB 17 July 2019.**

Kind regards,

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609
This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621, using a TGA eBusiness Service (eBS) user name and password.

User guidance and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting
Sponsors / Manufacturers: https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=2008494621
Medical Device Healthcare Professionals/Users:
https://apps.tga.gov.au/prod/mdir/udir03.aspx?sid=1267534111

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VICTORIAN INSTITUTE OF FORENSIC MEDICINE

Ref: 4743/18

Date: 19/02/19

s22
s22
Medtronic
2 Alma Road
Macquarie Park, NSW, 2113

Dear s22

I am writing to request an interrogation of an insulin pump and a report to be provided at request of the pathologist s22 is in charge of this case. Please return the pump if possible once the interrogation and report have been completed and provided to us.

RE: CASE s22 **DOB:** s22 **DOD:** s22

MEDTRONIC MINIMED 640G
S/N: NG1263558H
Ref: MMT-1711W

s22 was last seen alive at 2100hrs on s22 when she went to bed. She was found deceased at 04:30am on s22 by her husband. She was wearing her insulin pump at the time of her death and there are no reports to say there had been any issues with its function prior to s22 passing away.

Please do not hesitate to contact myself on s22 or my colleague s22 on s22 s22 if you have any further questions or require any additional information.

Kind Regards

s22
s22

s22

65 Kavanagh Street
Southbank VIC 3006
Australia
ABN 15 887 032 583

info@vifm.org
T +61 3 9684 4444
F +61 3 9682 7353
vifm.org

From: s22 on behalf of IRIS
To: s22
Subject: DIR 62330 - Sponsor Complete letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 5 March 2020 11:16:22 AM
Attachments: DIR 62330 - Sponsor Complete letter.pdf

Dear s22

Please see the attached letter in relation to the Device Incident Report (DIR) that has been submitted to the Therapeutic Goods Administration (TGA).

Kind regards

s22
Administrative Officer
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring Section
Medical Devices Branch
Email: IRIS@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Medtronic Australasia Pty Ltd
PO Box 945
NORTH RYDE BC NSW 1670
Email: s22 @medtronic.com

File Reference: E20-37937
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 62330 - ARTG # 95763 - Infusion pump, insulin, ambulatory

An incident report has been received by the Therapeutic Goods Administration from a healthcare professional/user for the above mentioned medical device and an investigation into the incident is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information. The Therapeutic Goods Administration is not requesting any action from you.

Should you have any further queries concerning this report please contact our team on (02) 6289 4642 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

05/03/2020

DIR 62330 - ARTG # 95763 - Infusion pump, insulin, ambulatory

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Initial Report:
01/03/2020

ARTG #:
95763

Brand Name:
Medtronic - 640G Insulin Pump - Infusion pump, insulin, ambulatory

Device Class:
Class IIb

Model #:
640G

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Medtronic Minimed [40022]

Sponsor:
Medtronic Australasia Pty Ltd [837]
PO Box 945
NORTH RYDE BC NSW 1670

Contact Name: s22 [redacted]

Phone: (02) 9857-9000

Fax:

Email: s22 [redacted] @medtronic.com

Reporter:

Confidential: Yes

Clinical Event Information:
Device is A Medtronic Insulin Pump 640G.

There is a known problem with the retainer ring that hold the insulin cartridge in place: (TGA Reference: RC-2019-RN-01694-1 MiniMed™ 640G: MMT-1711, MMT-1712 MiniMed™ 670G: MMT-1782). This known issue may lead to an over or under dose of insulin resulting in possible high or low blood sugar with one reported death overseas. The device has been recalled in the USA by the FDA. Medtronic have advised Australians to stop using the device if the retainer ring is loose and to contact Medtronic for a repair.

My pump's retainer ring is loose. I have been in contact with Medtronic. The issue is that Medtronic will only address the issue if the pump is within its 4 year warranty period. My pump is 4.5 years old but I am still using it as I am waiting for the release of new insulin pumps.

My view is that the pump is dangerous in its current state and Medtronic should replace or repair the pump (with the same model is acceptable).

I would like to see the TGA force Medtronic to address the issue regardless of the age of the pump if the pump is still in use.

Patient Outcome/Consequences:
Possible death from overdose of insulin. Possible hign or low blood sugar as a result of incorrect insulin dose.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Recall Number:
RC-2019-RN-01694-1

Type of Problem (Level 1)	Type of Problem (Level 2)
Material Integrity Problem	Material Separation
Cause of Problem (Level 1)	**Cause of Problem (Level 2)**
Mechanical Problem Identified	Stress Problem Identified

Outcome of Investigation

Reviewed, for Trending Purposes Only

Summary of Investigation:

The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to):

- the commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc.
- the individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Should you require further information or clinical assistance related to the use of this medical device and your individual health circumstances, please contact your treating medical professional, hospital or health care service.

Assistance and information regarding product refunds, returns or product compensation should be addressed with the Australian Competition and Consumer Commission (ACCC) via https://www.accc.gov.au/consumers/complaints-problems or 1300 302 502.

If you would like to lodge a complaint regarding the clinical practice of an Australian healthcare professional you should contact the Australian Health Practitioner Regulation Agency (AHPRA) via https://www.ahpra.gov.au/notifications/make-a-complaint.aspx, or the Health Care Complaints Commission within your State or Territory. More information on the respective State and Territory health complaint organisations can be accessed via https://www.ahpra.gov.au/notifications/further-information/health-complaints-organisations.aspx.

Date Completed:
04/03/2020

***** End of DIR 62330 *****

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24/12/2021
SIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 45 - ID : 535466

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
74678		CASE-2019-00729153	Final

ARTG: 95763

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	07/01/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
07/04/2022	07/01/2022		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
11/04/2022			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

It was reported that the insulin pump had pump error alarms and physical damage at the reservoir lip ring.

Clinical Event Information:

It was reported that the insulin pump had pump error alarms and physical damage at the reservoir lip ring. The reservoir does not lock into place. Blood glucose was 22 mmol/L at the time of the incident. The caller stated they were able to clear the alarm and complete the rewind process. Customer also stated the device failed by not giving insulin and continuously asking for a rewind. Customer performed displacement test and self test which passed. It was also reported that the customer was hospitalized on s22 s22 at 4:00 PM due to high blood glucose and ketones. Blood glucose was 26.3 mmol/L at the time of admission.

Pump Error 63 Alarm confirmed in the Pump History due to software error.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Computer Software Problem -> Application Program Problem -> ;
Mechanical Problem -> Structural Problem -> Difficult to Open or Close

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Investigations and Diagnostic Tests -> Hyperglycemia ->

Health Impact

Recorded Health Impacts:

Unexpected Medical Intervention -> Additional Device Required -> ;
Unexpected Medical Intervention -> Medication Required ->

Patient Information

Sex:	Weight:	Age:
		s

Patient Focused Corrective Action Taken:

Customer was treated with potassium and manual injection. The customer was advised that the insulin pump needed to be replaced and was advised to refer to the backup plan.

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

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Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: Temporary Injury

Consequence:

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: $2

Reporter #:

Preferred Contact Method:

Reporter Title: $

First Name: $22

Surname: $2

Position: Post Market Vigilance Specialist

Company/Institution: Medtronic Australisa Pty Ltd

Address 1: 2 Alma Road

Address 2:

Town/Suburb: Macquarie Park

State: NSW

Country: Australia

Postcode: 2113

Phone: $22

Fax:

Mobile:

Email: $22

Last External Submission By: 113429_837 - 07/04/2022 11:52

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG: 95763

Device ARTG #: 95763

Therapeutic Licence Type: Medical Device

Product Licence Category: Included

Device Class: Class IIb

GMDN / UMDN Code: 35983

GMDN / UMDN Text: Infusion pump, insulin, ambulatory

Brand Name: Minimed 640G - Infusion pump, insulin, ambulatory

Initial Device Description: Minimed 640G - Infusion pump, insulin, ambulatory

Usage of Device: Reuse of Reusable

Software Version:

Model #: MMT-1711K

Serial #: NG1307997H

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

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Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	18/07/2003	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Medtronic Minimed		40022	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	s22		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Rate considered low at this stage	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
24/12/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22	

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Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	2 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	11/04/2022	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	**Yes - manufacturer HAS documented issues or complications of this type**		No	Screening only	**Screening only**
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**1. Recalls for similar incidents in Australia have occurred within the past 12 months**			Final; low rates. There could be potential wear and tear with device.	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	Yes		No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	Yes	**2 incidents**			Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:	
				No	Final; low rates. There could be potential wear and tear with device.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitivities identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
					Yes	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:

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s22		Level 10	68 Pitt Street
State:	Postcode:	Phone:	Fax:
NSW	2000	s22	

Email:

s22 @medtronic.com; s22 @medtronic.com; s22 @medtronic.com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

S/W 2.9D

Pump passed the functional tests, including the Self Test, Sleep Current Measurement, Active Current Measurement, Rewind Test, Prime/Seating Test, Basic Occlusion Test, Occlusion Test, Force Sensor Test, Displacement Test and DAT at 0.08700 inches. The test P-cap locks properly in the reservoir compartment noted. No unexpected Pump Error 130 Alarm or Pump Error 19 Alarm noted. However, Pump Error 63 Alarm (VariableInfo=9) confirmed in the Pump History due to software error.
Pump received with scratched case, pillowing keypad overlay, cracked select button keypad overlay, cracked case behind the pump at the battery compartment and minor scratched LCD window.

Corrective/Preventative Actions:

No corrective action. Monitoring and trending this type of event.

Details of Similar Events:

In Australia
1 similar events from 5270 units (0.01898%) sold in CY2019;
0 similar events from 3239 units (0%) sold in CY2020;
0 similar events from 3453 units (0%) sold in CY2021;
0 similar events from 172 units (0%) sold in CY2022;

WorldWide
32 similar events from 124661 units (0.02567%) sold in CY2019;
42 similar events from 91155 units (0.04608%) sold in CY2020;
159 similar events from 76249 units (0.20853%) sold in CY2021;
0 similar events from 14471 units (0%) sold in CY2022;

Similar incidents include this event (DIR 74678)

Additional Details (use for tables):



CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Report Closed 11-04-2022.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

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Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Computer Software Problem	Application Program Problem		
Mechanical Problem	Structural Problem	Difficult to Open or Close	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Investigations and Diagnostic Tests	Hyperglycemia		

Health Impact

Details			
Level 1	Level 2	Level 3	
Unexpected Medical Intervention	Medication Required		

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Unexpected Medical Intervention	Additional Device Required		

Investigation Findings

Finding Details			
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
Material and/or Chemical Problem Identified	Degradation Problem Identified		

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to Component Failure			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
RC-2021-RN-01995-1 - The MiniMed 600 series insulin pump is designed with a pump retainer ring to lock the reservoir in the insulin pump. There have been reported incidents of a loose reservoir that can no longer be locked into the pump. The reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock. The retainer ring can be broken as a result of excessive dropping or bumping the pump on a hard surface. If the retainer ring is damaged, loose or missing, and the user inserts the reservoir back in while the infusion set is still connected to the body, it could result in rapid infusion of insulin, which could cause hypoglycemia. Medtronic first communicated this issue as a Safety Alert in November 2019 with a follow-up reminder in July 2020 (TGA Reference RC-2019-RN-01694-1)	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

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Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

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Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 330165

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
330165	DIR-REQ		Closed	s22	OPR Administration User	11/04/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	11/04/2022 09:21:31	
Comment		