Medical Device Incident Investigations: Recommendations

Safety Alert: Abbott Medisense Optium Xceed Diabetes Monitoring System

Abbott Diagnostics Division – Medisense Products meters are designed to show results in two different units of measure. This is dependent on country standards. In Australia, the correct unit of measurement is '**mmol/L**'. In other countries the standard may be '**mg/dL**'. If a user's meter is set up with the incorrect unit of measure they may have difficulty interpreting their result. The customer who uses mmol/L will believe their result is higher than the actual result if their meter is set in mg/dL and they assume a decimal point. For example, an actual glucose of 3.0mmol/L will read as 54 mg/dL (18 times the actual result), and may be interpreted by the customer as 5.4mmol/L. Alternatively, the customer may not assume a decimal and may interpret their result as 54mmol/L.

The consequence of interpreting a result in mmol/L is that the user or tester may administer an additional dose of insulin. In a worst-case scenario this may result in a hypoglycaemic coma.

Currently, the only way to change the unit of measure on Abbott Medisense meters is through a user-initiated change. Abbott has not received any reports about Medisense meters inadvertently changing units of measure when dropped or when there is a power failure.

To ensure that Abbott Medisense customers will only receive results in the Australian standard units, Abbott Diagnostic Division – Medisense Products is proactively taking the following steps to eliminate any chance of misinterpretation of results by the user.

In the near future, all Optium Xceed systems offered for use in Australia will have units of measure locked to the Australian standard unit of mmol/L.

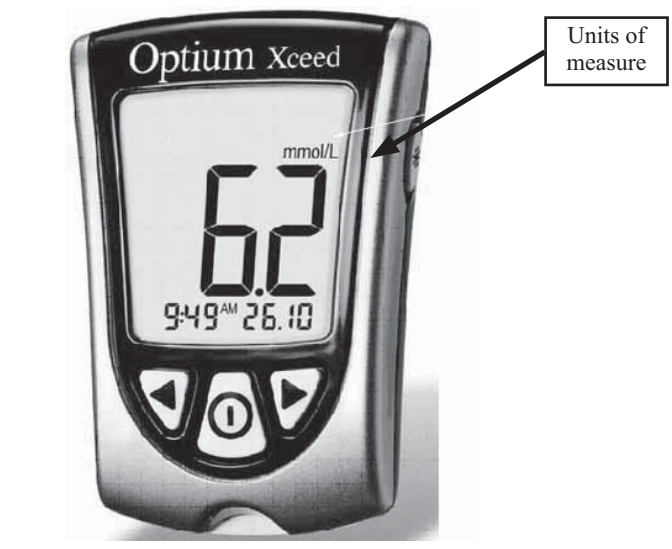
At the same time, the Optium Xceed meter User Manual will be revised to reflect these changes.

Recommended actions

To confirm that the Optium Xceed blood glucose meters are set to the correct units of measure follow these instructions.

Turn on the meter and the unit of blood glucose measure will appear in the top right hand corner on the result review display screen. In Australia the meter should read mmol/L.

If the unit of measure is incorrect, please follow these steps:



- See the user manual for meter set-up instructions.
- Review the quick reference guide.
- Call the customer service department on 1800 801 478.

If you have any questions, or if you have not received a copy of the Safety Alert from Abbott, please contact the Abbott Medisense Customer Service Department on 1800 801 478.

Safety Alert: CADD-Legacy® PLUS pump mistaken for CADD-Legacy® 1 pump

A clinician in Australia has mistaken a CADD-Legacy® PLUS pump for the CADD-Legacy® 1 pump. This mistake resulted in a large overdose of a cytotoxic drug.

As a result, Smiths Medical MD, Inc. ('Smiths') has recently issued a Safety Alert to provide information to customers, sales representatives, customer service representatives, clinical services, distributors and affiliates who use or distribute the CADD-Legacy® PLUS and CADD-Legacy® 1 Ambulatory Pumps.

The Safety Alert, which was issued in consultation with the TGA, highlights that there is a potential for serious injury or death if users are not aware of the following differences between the CADD-Legacy® PLUS and CADD-Legacy® 1 pumps:

Programming differences

- The CADD-Legacy® PLUS pump is designed to infuse medication in millilitres per hour only.
- When programming the infusion rate, the CADD-Legacy® PLUS pump display is in mL/hr.
- The CADD-Legacy® 1 pump is designed to infuse medication in millilitres per 24 hours only.
- When programming the infusion rate, the CADD-Legacy® 1 pump display is in mL/24 hr.

Pump keypad differences

- The CADD-Legacy® PLUS pump has a **BLUE keypad** with no label in the centre of the keypad.
- The CADD- Legacy® 1 pump has a **PURPLE keypad** with a label in the centre of the keypad that states "Rate is in mL/24 hours".
- The pump model name is clearly displayed on the bottom of each keypad.

Recommended actions

Please bring this Safety Alert to the attention of any staff operating either the CADD-Legacy® PLUS pump or the CADD-Legacy® 1 pump.

Please refer to the Operator's Manual that is provided with each device for a complete list of all warnings and precautions associated with the use of these devices.

Retained biliary stent within a duodenoscope

The TGA received a report about the retention of a biliary stent within a duodenoscope. The circumstances surrounding this report are as follows:

1. The patient required urgent intervention during the procedure, and the procedure was aborted.
2. The stent being used was a self-expanding biliary stent that had been released from its introducer when the scope was removed quickly from the patient; the stent adhered to the wall of the instrument channel.
3. The scope was removed and sent to be cleaned.
4. The cleaning staff were unaware that the patient did not receive the stent due to sudden deterioration in the patient's health during the procedure.
5. The device was cleaned as per the hospital protocol using brushes down all channels. The brushes used in the instrument channel appear to have passed through the stent. The scope was sterilised using ETO.
6. The instrument channel cannot be visualised at any time.

Since it cannot be easily detected, the retention of a biliary stent within a duodenoscope represents a risk of infection. During a 'typical' procedure this problem would not occur as the stent would have been inserted. However, this unusual incident could recur even with other brands of duodenoscopes when self-expanding stents are used and can only be prevented through operator awareness and vigilance.

Recommended actions

Surgical teams should have procedures for accounting for every medical device used (or in this case not used) during an operation. (Such procedures are commonplace in surgical operating theatres, but are less commonly used in, for example, endoscopy suites and catheterisation laboratories).

Surgical teams should ensure that such procedures are always followed, taking particular care when the operation is terminated abnormally.

Patient hoist failure due to poor maintenance

The TGA has received a report about a patient who was dropped while being manoeuvred from a bed using a Promed Skipper 175 hoist attached with a PWS300 weighing device. The patient was being supported by the sling when the device tipped and the patient was dropped.

A short time before the incident, the hoist had been serviced and modified. The sponsor, Invacare, has stated that the service agent used by the healthcare facility is not a recognised service agent for their products. The product literature supplied with Invacare devices states that they should only be serviced by agents accredited and recognised by Invacare.

The problems that lead to the tipping over of this patient hoist were:

- The load cell had a 450mm long cable attached. The original length of cable was 150mm.
- The suspension bolt for the load cell had been modified with a second hole for a locking pin.
- The pin used to lock the suspension bolt was of a soft metallic material. The original bolt supplied with the hoist was a hardened cell-lock pin.
- An end of a soft metallic pin was still in the load cell with no sign of a pin in the suspension bolt.
- Signs of damage, high pressure drag marks, were found on the suspension bolt of the load cell.
- A key ring used to secure the pin holding the transducer was not a standard fitting. The standard fitting is an 'R' clip.
- The guide bolt for the leg spreader actuator was not standard.

The Promed Skipper 175 conformed to Australian and International technical standards at the time of original purchase. The manufacturer is not sure if the modified hoist will conform to those same standards and the service agents did not test and certify to indicate that it did.

Conformity with technical standards is not a legal requirement. However conformity with technical standards is strongly recommended, because it is perhaps the easiest way to demonstrate or ensure that a product conforms to principles of safety and performance.

Recommended actions

- When servicing patient hoists and other similar types of devices ensure that the service agent is authorised to carry out the work.
- When contemplating modifications to a medical device, check with the original manufacturer as to whether modifications of the type sought can be done, and whether the modifications have any implications for the device's safety or performance.
- Follow the instructions for use for these devices when lifting a patient.

Imitation CIG (BOC) gas outlets on ICU pendants

A recent report of a faulty gas outlet has led to the discovery that the outlet was an imitation of the CIG (formerly BOC) Mark II Gas Outlet. The outlet's indexing ring, which prevents cross-connection of different gases, relied only on adhesive to keep it attached to the main outlet body. The adhesive failed on one outlet leaving only a ¼" BSP thread exposed. This would allow the connection of Medical Air rather than Oxygen. Another outlet was discovered to have a loose indexing ring.

Investigation by Draeger Medical Australia has revealed that Draeger Medical, Germany, once supplied blank pendants directly to a Victorian company, Hosquip, which is now in receivership. Hosquip installed these pendants in the Queen Elizabeth Hospital, Adelaide, **(and possibly in other places)** and fitted them out with gas and electrical outlets in accordance with Australian standards. However, it would appear that the gas outlets that were used are of unknown origin, having no markings and no manufacturer's labels. The outlets appear to be a copy of the well-known CIG (formerly BOC) Mark II outlet, but lack the CIG logo engraved on the coloured backing plate and the grub screw which anchors the genuine CIG indexing ring.

After their investigation, Draeger Medical Australia believes that the Queen Elizabeth Hospital in Adelaide is the only hospital in Australia that has both Draeger Pendants and these unbranded gas outlets. However the imitation outlets may also be present in other manufacturer's pendants, wall-mounted panels or bed-heads.

Recommended actions

Maintenance gas-fitters or biomedical engineers should inspect the gas outlets in their facility to ensure that they have genuine CIG products. Genuine CIG products can be identified by the letters 'CIG' engraved into the coloured ring at the base of the outlet. Inspection of the back (wall or pendant side) of genuine CIG gas outlets will also show manufacturer's markings and part numbers, while on the imitation outlets these markings are absent.

As a temporary measure, the indexing ring part of the imitation outlet can be secured by drilling and tapping the index ring to accept a locking grub screw. However, the safety and performance of these outlets from an unknown manufacturer and a supplier who is no longer in business cannot be guaranteed. The TGA recommends that any imitation gas outlets identified be destroyed and replaced.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/04/2005 to 30/09/2005

Total Number Received: 346

Cause of Problem[1]	
Biocompatibility	5
Component Failure	59
Contamination	7
Design	33
Diagnostic Inaccuracy	0
Electrical	15
Inadequate Instructions	6
Labelling	8
Maintenance	7
Manufacture	29
Material/Formulation Deficiency	12
Mechanical	22
Not Device Related	51
Other	37
Quality Assurance	9
Unknown	74
Wear/Deterioration	10

Effect	
Death	17
Serious Injury	61
Temporary Injury	85
No Injury	183
Source Category	
Medical Administrator	18
Specialist	12
General Practitioner	5
Coroner	4
Nurse	36
Blood Bank	4
Hospital Supply Service	18
Other	25
Sponsor	175
Overseas Advice	27
Biomed Engineer	15
Para Medical	1

Result of Investigation	
Bulletin Article	4
Company Warned	9
Compliance Testing	10
No Further Action	98
Not Investigated[2]	134
Other	20
Problem Not Confirmed	23
Product Improvement	28
Recall/Hazard Alert	6
Refer to GMP	2
Refer to Surveillance	1
Safety Alert	16
User Education	24

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are "Not Investigated" the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.