

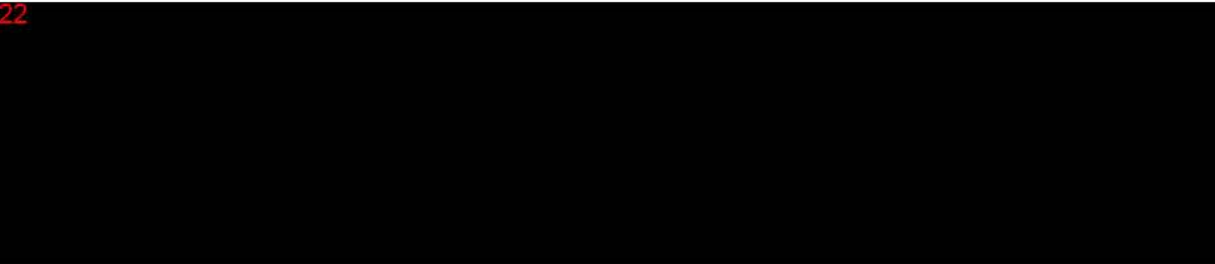
From: [Recalls](#)  
To: [Recalls](#)  
Subject: FW: {External} AGREED: RC-2024-RN-01116-1 [SEC=OFFICIAL]  
Date: Monday, 26 May 2025 4:25:50 PM  
Attachments: [image001.png](#)  
[image003.png](#)

From: s22 <[REDACTED]@bsci.com>  
Sent: Thursday, 19 December 2024 2:40 PM  
To: Recalls <Recalls@health.gov.au>  
Cc: ANZ\_Incident\_Report <ANZ\_Incident\_Report@bsci.com>  
Subject: RE: {External} AGREED: RC-2024-RN-01116-1 [SEC=OFFICIAL]

Hi s22,

Table 2 within the Customer Letter displays the total number of devices belonging to the advisory population, globally.

The number of devices belonging to the advisory population that have been supplied to the Australian market is 1661.



Any further questions please let me know.

Best regards,

s22



From: Recalls <Recalls@health.gov.au>  
Sent: Thursday, December 19, 2024 11:42 AM  
To: s22 <[REDACTED]@bsci.com>  
Subject: RE: {External} AGREED: RC-2024-RN-01116-1 [SEC=OFFICIAL]

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Hi s22,

Can you please confirm that the table listed in the customer letter is the *implantation total* of devices in the Australian population?

Table 2: ACCOLADE High Battery Impedance Advisory Population and Performance

Therapy-Battery	Occurrence rate according to implant duration				Confirmed Malfunctions	Population
	6yr	7yr	8yr	9yr		
DR-SL	0.1%	0.3%	0.6%	0.6%	436	123,000
DR-EL	0.02%	0.1%	0.2%	0.4%	83	59,000
CRT-P-EL	0.2%	0.9%	1.6%	2.0%	178	21,000
Total					697	203,000

If this is not the total implantation population, are you able to please advise on this value?

Thank you and kind regards,

s22  
Recall Coordinator - Recalls Section  
Manufacturing Quality Branch  
s22

Medical Devices and Product Quality Division | Health Products Regulation Group  
Australian Government Department of Health and Aged Care  
T: (02) s22 | E: recalls@health.gov.au  
Location: 160 Ann Street, Brisbane City, QLD 4000  
PO Box 100, Woden ACT 2606, Australia  
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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