ANZCDACC Product Notification Notice 22nd November 2019

Device:

Product	ARTG
Claria MRI™ CRT-Ds	280183; 280186 ; 281607; 281608
Amplia MRI™ CRT-Ds	280182; 280184 ; 281606
Compia MRI™ CRT-Ds	280181 ; 280185
Viva™ CRT-Ds	203210 ; 203211; 203212; 203840; 219221; 219222; 230204
Brava™ CRT-Ds	219220
Visia AF™ ICDs	280351; 280352; 280353
Visia AF MRI™ ICDs	280354; 280355; 282960; 282961
Evera™ ICDs	206324; 208024; 208025; 208026; 208027; 208028; 208029; 208030
Evera MRI™ ICDs	208030; 230019; 230020; 230021; 230022; 281609; 281610; 281611; 281612
Primo MRI™ ICDs	312640 ; 312641; 312642; 312643
Mirro MRI ™ ICDs	Not sold in Australia

TGA Reference: RC-2019-RN-01641-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand: TBA

Description:

Medtronic identified a rare failure mechanism in the battery design of specific implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) models that could result in rapid battery depletion. The rapid depletion is caused by a latent shorting mechanism resulting from lithium plating between the anode and cathode elements of the battery. If lithium bridges between a positive (cathode) and a negative (anode) element in the battery, an internal short will develop and the battery will deplete rapidly. If this occurs, the device may not meet expected longevity or provide at least three months of device operation between the Recommended Replacement Time (RRT) and End of Service (EOS).
In response to this potential issue, Medtronic implemented battery design enhancements. All products currently in distribution contain the battery enhancement.

All events have occurred during the mid-portion of device life; typically, 1-4 years after implant. Note, there have been no reports of this issue occurring after RRT has triggered under normal conditions. Therefore, when a device reaches RRT based on its programmed settings and use conditions, the device is likely performing as expected and time between RRT and EOS should be as labelled.

Risk:

Approximately 607,800 devices distributed worldwide were implanted. Approximately 0.04% of these devices exhibit this behaviour. The battery continues to perform within projected estimates. There have been no reports of permanent harm to patients as a result of this issue.

Presentation:

Patients may present with symptoms related to pacemaker failure from bradycardia, loss of CRT pacing or untreated ventricular arrhythmia.

The battery longevity estimates, and voltage measurement may show a rapid unexpected drop in between routine follow up. This may also present as a low battery voltage alert on remote monitoring or as the inability to interrogate the device / transmit data.

Advice:

1. Identify. Identify the patients in your clinic who may be affected by this issue by searching their serial number at the following website: https://wwwp.medtronic.com/productperformance/

2. Evaluate risk*. Patients who are pacemaker dependent, those with secondary prevention indications and/or those who have experienced previous therapy for ventricular arrhythmias are at an increased risk.

Additionally, those who are unable to hear the device alarm and are not on remote monitoring are also at an increased risk.

Medtronic and ANZCDACC do not recommend prophylactic replacement.

3. Follow-Up.

a) Where possible, add these patients onto remote monitoring, especially those at higher risk*.

b) During the next follow-up visit, demonstrate the low battery alert tone and confirm whether the patient can hear it or not. Ensure this alert is turned on in the device (shipped On with high urgency toning for low battery voltage indicator). If they can't hear their device alert, remote monitoring is highly recommended.

c) Remind patients to promptly contact their physician if alert tones are heard from their ICD as this may be an indication of impending battery failure.

d) Consider 3 monthly follow up for those who will not be on remote monitoring, can't hear the device alert tones and are at higher risk*.

e) At each follow up, document the battery measurements and longevity estimates. Monitor for unexpected changes and contact a Medtronic representative immediately if there are any concerns or the described behaviour is observed. Further device analysis may be warranted to determine if immediate replacement is necessary.

f) Respond to device alert tones as a matter of urgency to minimise the risk of battery failure.

g) If there is evidence of rapid battery voltage drop, patients may need to have their devices replaced urgently as device failure may lead to intended therapy not being delivered.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA;

Online	https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe;

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email	devices@moh.govt.nz
Fax	04 819 6806

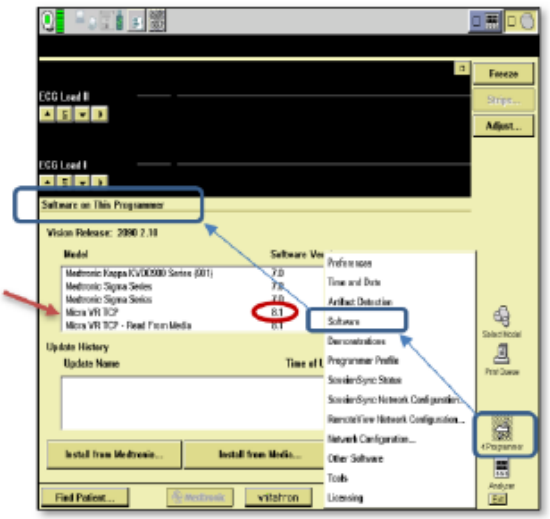
Appendix A: Programmer User Screens

Software Installation History Screen
Correct software: Micra VR TCP version 8.1 (or higher)

From the Programmer start-up screen CANCEL out of the Find Patient window and Select the Programmer icon along the right-hand side of the programmer display:

- Select Software (see image 1)
- Scroll through the list of available Software Models in the top selection box until you locate the Micra selection
- Verify the Software Micra VR TCP Version is 8.1

Image 1



Battery/Device Measurements Report Software ID Information

Any CareLink transmission completed after 17 January 2019 will report the updated remaining longevity estimate. For in-clinic patients who have been interrogated via a programmer, the clinician can view the Battery and Device Measurements Report (Images 2a and 2b) and verify that the Software Application Model ID located in the lower-left corner of the report indicates "SW022 Software Version 8.1".

- Select Reports (see image 2a)
- Select Battery/Device Measurements
- Click Print Now
- Verify the software version printed on the lower left-hand corner is "SW022 Software Version 8.1"

Images 2a and 2b