Australia New Zealand Cardiac Device Advisory and Complication Committee (ANZCDACC)

Product Hazard Alert December 2023

ANZCDACC Statement and Update to May 2023 Medtronic Hazard Alert - increased potential for reduced energy or no energy delivered during high voltage therapy when programed AX > B

Device:
Cobalt™ XT/Cobalt™/Crome™ ICDs and CRT-Ds A subset of: Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava™ CRT-Ds A subset of: Visia AF™/Visia AF MRI™/Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs

TGA Reference:
RC-2023-RN-00433-1

Advisory grade TGA:
Class I

Committee Members:
Paul Gould (Chair), Rajesh Subbiah, Paul Weatherley, Nigel Lever, Jason Davies, Susan Sinclair, Justin Phan

Update:

To enable the desired programming to mitigate the above advisory Medtronic has released a software update for the CareLink™ SmartSync™ Device Manager (SmartSync). This SmartSync update aligns nominal settings and programming screens with the May 2023 advisory document. ANZCDACC advises implanting physicians to install the software update as soon as possible once updates for CareLink Encore™ and CareLink™ 2090 programmers are released and regulatory approvals have been received. Medtronic will help to ensure all SmartSync tablets in your facility are updated.

The updated software models are as detailed below:

Application	Software Model	Version
Carelink SmartSync™ Viva Evera App	D00U012	2.2.1
Carelink SmartSync™ Claria Amplia App	D00U009	2.2.1
Carelink SmartSync™ Visia AF App	D00U011	2.2.1
Carelink SmartSync™ Evera MRI App	D00U010	2.2.1
Carelink SmartSync™ Cobalt / Crome App	D00U005	8.2.1

With the programming recommendations implemented, Medtronic has stated devices return to historical safety and reliability performance. Status updates for the advisory are posted online at http://productperformance.medtronic.com under Customer Communications. ANZCDACC suggests implanting physicians stay abreast of developments in this advisory.

Statement:

The ANZCDACC has noted concerns in the implanting physician community regarding this advisory. The Committee is currently observing the performance of the suggested programming mitigation and will update if issues become known. Please inform ANZCDACC and the TGA with any concerns.

The Committee also would advise implanting physicians (as is standard for active device advisories) to inform patients with existing implanted devices or patients undergoing de novo implantation regarding the advisory and required programming.

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@health.govt.nz**