**ANZCDACC Report: Medtronic Cobalt™ and Crome™ Product Defect Correction (October 2021)**

**Device:**
All Medtronic Cobalt™ and Crome™ ICDs and CRTDs.

Namely:
Cobalt™:
Cobalt XT VR: DVPA2D1, DVPA2D4; Cobalt VR: DVPB3D1, DVPB3D4; Cobalt XT DR: DDPA2D1, DDPA2D4; Cobalt DR: DDPB3D1, DDPB3D4; Cobalt XT HF: DTPA2D4, DTPA2D1; Cobalt XT HF Quad: DTPA2QQ, DTPA2Q1; Cobalt HF: DTPB2D4, DTPB2D1; Cobalt HF Quad: DTPB2QQ, DTPB2Q1
Crome™:
Crome VR: DVPC3D1, DVPC3D4; Crome DR: DDPC3D1, DDPC3D4; Crome HF: DTPC2D4, DTPC2D1; Crome HF Quad: DTPC2QQ, DTPC2Q1

**TGA /Medsafe Reference:**
Australian Register of Therapeutic Goods (ARTG): 313620
Medsafe Reference: 28468

**Advisory grade TGA:**
Not listed on TGA website but likely Class II
(Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not class I.)

**ANZDACC Advisory Grade:** Routine

**Description:**
A small number of SmartSync interrogation sessions, or CareLink network transmissions may fail for Cobalt or Crome devices when the current session diagnostic data includes any VT/VF episode type with multiple therapy sequences and three or more data recording suspensions. For these specific episodes, the software is unable to decode and process the data. SmartSync will display a message indicating an "Unexpected error occurred", and the application software requires restarting. Within CareLink, the current transmission processing may fail, and the information will not be viewable. For both of these scenarios contact your Medtronic representative, they can assist clinicians with retrieving stored device information for the failed transmission.

Note: Cobalt/Crome devices are only supported by the SmartSync programmer. Accordingly, the Model 2090 and Encore programmers cannot be used as an alternative.

No permanent patient harm has occurred. No device operations are affected by the software interrogation issue. All device features and therapies continue to operate as programmed. Risks associated with an interrogation failure are potential for unnecessary device replacement, and/or delays in patient care due to missed CareAlerts, or inability to access stored device diagnostic information in a timely manner.

SmartSync software release D00U005 version 5.0.0 (or higher) will correct this issue and is now available. A CareLink software update is anticipated to be released in mid-2022.

**Number of devices affected in Australia and New Zealand:** 1756 total (936 CRTDs, 820 ICDs)

**Presentation:**
During an in-clinic check, this issue would present as an error message on the SmartSync (ipad) programmer stating: "Unexpected error occurred"

**No alert would be received through Carelink for any "VT/VF episode type with multiple therapy sequences and three or more data recording suspensions" . A manual transmission will only send**

**data since the time of the failed alert transmission. I.e. The CareLink transmission containing the episode with "multiple therapy sequences with three or more data recording suspensions" will not be processed, and therefore not viewable to the clinic**.

**Rate of occurrence:**
Through 24 Sep 2021, Medtronic has confirmed 22 reports of a software interrogation failure due to this issue out of approximately 48,700 devices distributed worldwide (0.045%).

**Recommendation:**

1. Ensure all SmartSync programmers are updated with the latest software now that it has become available.
2. ANZCDACC and Medtronic recommends that normal clinical practices are followed given these devices will continue to operate as programmed.
3. If a failure to interrogate a Cobalt or Crome device occurs with a SmartSync programmer, ensure it is updated with the latest software update (SmartSync software release D00U005 version 5.0.0 (or higher) will correct this issue). Re-interrogate the device following the software update. Select "Interrogate => Interrogate all" once the platform has loaded to ensure all episodes are displayed. Contact your Medtronic representative if further assistance is required.
4. If a CareLink transmission is attempted, but the transmission is not viewable on the CareLink network (i.e., the transmission is missing from the transmission list for the patient), contact your Medtronic representative for assistance. This team can help with retrieving the transmission data and/or provide additional troubleshooting guidance that may be needed. Missing transmissions can also occur due to connectivity or other issues and may be unrelated to the software decode error described in this letter. Alternatively, these patients could be invited into clinic and have their device interrogated with an updated SmartSync programmer.

**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 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