Medtronic Cobalt™ and Crome™ ICDs and CRT-Ds (May 2022)

ANZCDACC Hazard Alert May 2022

Device:

Medtronic Cobalt™ and Crome™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds)

TGA Reference: RC-2022-RN-00608-1

Australian Register of Therapeutic Goods (ARTG):
339481, 339482, 339483, 339484, 339485, 339486, 339487, 339488, 339489, 339490, 339491, 339492, 341547, 341548, 341549, 341551, 341552, 341555, 341556, 341557, 341558, 341553, 341550, 341554

Wand Notification:
200109-WAND-6TXFRQ, 200109-WAND-6TXFSH, 200109-WAND-6TXFVH, 200109-WAND-6TXFTE, 200109-WAND-6TXFTX, 200109-WAND-6TXG78, 200109-WAND-6TXFST, 200109-WAND-6TXFU9, 200109-WAND-6TXFT3, 200109-WAND-6TXG6G, 200109-WAND-6TXFTO, 200109-WAND-6TXG7J, 200109-WAND-6TXFPN, 200109-WAND-6TXFO3, 200109-WAND-6TXFJ5, 200109-WAND-6TXFOK, 200109-WAND-6TXFQB, 200109-WAND-6TXFQ1, 200109-WAND-6TXFOZ, 200109-WAND-6TXFP9, 200109-WAND-6TXFQO, 200109-WAND-6TXFN0, 200109-WAND-6TXFKX, 200109-WAND-6TXFNA

Advisory grade TGA:

Class II
(Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not class I.)

Description:

Some Cobalt and Crome devices may encounter a persistent “session-active” flag following the use of inductive telemetry. The persistent session-active flag is the result of a telemetry connection error that can occur when intermittent or disrupted signals manifest while communicating with the device at the end of the telemetry session. Inductive telemetry with a Cobalt/Crome device typically occurs during device interrogation with a CareLink Express™ Mobile reader head. A persistent session-active flag will result in temporary suspension of the following features (if available in the device) until the flag is cleared:

- Battery voltage measurements
- Capture Management™
- Atrial Lead Position Check™
- AdaptivCRT™, EffectivCRT™ diagnostic, and EffectivCRT™ During AF
- Wavelet™ template management
- Battery conditioning charges

Potential risks include loss of pacing or inadequate CRT support, and/or loss of Recommended Replacement Time (RRT) indicator.

The pacing outputs and AdaptivCRT™ configuration will remain at the programmed value prior to the suspension of Capture Management™. Loss of capture resulting from the "persistent session-active flag," would only occur if the capture threshold increased beyond previously set pacing outputs, after the "persistent session-active flag" occurred, and pacing was required.

When battery measurements are suspended for more than seven days, the longevity estimator cannot calculate a value and the estimator will display a grey bar with "???."
A device that experiences a persistent session-active flag can be manually cleared via a specific sequence of steps, using a non-Bluetooth SmartSync telemetry session. Contact Your Local Medtronic Representative for further instruction. After the persistent flag is manually cleared, the above features will automatically be restored. Remaining longevity estimates will resume approximately 82 weeks after the date the flag is cleared.
Devices manufactured after July 2021 have already received the software update and are not susceptible to the described behaviour.
Refer to Appendix A and Software Release Notes for details on how to identify which Cobalt/Crome devices have already received the update.

Number of devices affected in Australia and New Zealand:

1133 in Australia and New Zealand

Presentation:

2-6 days after the persistent session active flag has occurred, the battery voltage measurements will not be dated within 24 hours. The Capture Management™ will also have been disabled, so the device will stop plotting threshold measurements.
7 days after the persistent session active flag has occurred, the longevity estimator will display a grey bar with "???". This indicator will be available at the subsequent in-clinic check / remote monitor transmission.

Rate of occurrence:

As of 22nd of March 2022, 0.3% of devices have experienced this issue. No serious adverse events or permanent harms have been reported due to this error.

Recommendation:

Each patient requires unique clinical considerations.

1. Ensure all SmartSync tablets are updated with the latest software (D00U005 version 6.0.3 or higher). (See appendix for details)
2. Check the "Device Configuration ID" on all Medtronic Cobalt™ and Crome™ devices in your clinic, either from a programmer generated report from the last check, or on Carelink™ to identify those that require updating.

3. Patients routinely seen in the clinic will automatically receive the update during their next interrogation using an updated SmartSync tablet. No additional programming of the device is required. An earlier appointment is ideal but not required.
4. Where practical, patients followed remotely who do not have regularly scheduled in-clinic sessions should have their next follow-up session conducted in clinic using an updated SmartSync tablet. No additional programming of the device is required.
5. For patients in this group, the ANZCDACC suggests regular remote monitoring for evidence of a "persistent session-active flag" for those who will find it difficult to attend an in-clinic check such as those who have poor mobility and/or live a long distance from the closest clinic. This should continue until the device is updated.
6. For those patients who receive their follow-up via Carelink Express™ clinics, consider sending the remote site an updated SmartSync tablet. The remote site could then interrogate the Cobalt™/Crome™ device first with the SmartSync tablet to update the software, then send a Carelink Express™ transmission to allow the Hub site to both check the device and confirm the software was successfully updated.

Use the instructions in Appendix A or Contact your local Medtronic Representative for assistance if you discover a patient with a "persistent session-active flag".

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

Download Appendix A here (pdf)