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Urgent Field Safety Notice

Smart Sync Error Message on Device Interrogation

Software Update

Affected Programmer	Related Cobalt™ Devices and Model Numbers
CareLink SmartSync™ Device Manager application software D00U005	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

October 2021

Medtronic Reference: FA1191

Dear Risk Manager or Healthcare professional,

Medtronic is notifying you of the potential for a small number of **CareLink SmartSync™ Device Manager (SmartSync) interrogation sessions, or CareLink network transmissions** to fail due to a software error. The issue described below can only occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds) when the *current session* data includes diagnostic episodes with a specific type of VT/VF therapy sequences.

An update for the SmartSync Cobalt/Crome application software (D00U005 version 5.0.0) is anticipated to receive regulatory approval by November 2021. Smart Sync tablets must be connected to internet to receive the update. Once it becomes available, Medtronic Representatives can assist with installing this update on SmartSync tablets in your account based on your facility's needs and accessibility.

ISSUE DETAILS

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 Medtronic representative can assist clinicians with retrieving stored device information for the failed transmission.

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%). No permanent patient harms have 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 anticipated to be available early/mid-November 2021. A CareLink software update is anticipated to be released in the mid-2022.

PATIENT MANAGEMENT RECOMMENDATIONS

We realize that each patient requires unique clinical considerations. Medtronic recommends physicians follow normal clinical practices given these devices will continue to operate as programmed:

- If a failure to interrogate a Cobalt or Crome device occurs with a SmartSync programmer, contact your Medtronic representative for assistance with retrieving the session data.

  Note: Cobalt/Crome devices are only supported by the SmartSync programmer; these devices are not supported by the Model 2090 and Encore programmers.

- 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. They can help with retrieving the transmission data and/or provide additional troubleshooting guidance that may be needed with troubleshooting the transmission failure and for further instruction if needed. Missing transmissions can occur due to connectivity or other issues and may be unrelated to the software decode error described in this letter.

ACTIONS

- Share this notice with those who need to be aware within your organization, or with any organization where SmartSync programmers may have been transferred.
- Share this information with electrophysiologists who implant or follow Cobalt and Crome patients as you deem appropriate.
- Please start updating your SmartSync tablets when the software is available:
    - To update a SmartSync tablet, connect to the internet and select Settings, Profile, Software Info, then Check for Updates.
    - Based on your facility's needs and accessibility, Medtronic Representatives can assist with installing this update on SmartSync tablets in your account.

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative directly or via Tel No: 01 511 1400

Sincerely,

Keith Taverner

Regulatory Affairs Manager UK & Ireland.