

Urgent Field Safety Notice

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

Software Update Available to Correct Potential for SmartSync Telemetry Error

SmartSync Device Manager Applications	Cobalt Models	Crome Models
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 HF: DTPB2D4, DTPB2D1 Cobalt XT HF Quad: DTPA2QQ, DTPA2Q1 Cobalt HF Quad: DTPB2QQ, DTPB2Q1	Crome VR: DVPC3D1, DVPC3D4 Crome DR: DDPC3D1, DDPC3D4 Crome HF: DTPC2D4, DTPC2D1 Crome HF Quad: DTPC2QQ, DTPC2Q1

April 2022

Medtronic reference: FA1236

Dear Physician or Risk Manager,

Medtronic is notifying Physicians and Risk Managers of **a software update for CareLink SmartSync™ Device Managers** (SmartSync) that will address a telemetry error that may occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds). Specifically, **software application D00U005 version 6.0.3 will deploy an update** to implanted devices that will correct the potential for temporary suspension of some device features (details below) due to a telemetry error involving inductive (non-Bluetooth) telemetry. As of 22 March 2022, 0.3% of devices have experienced this issue. No serious adverse events or permanent harms have been reported due to this error.

Medtronic representatives will work with you to ensure all SmartSync tablets in your facility are updated with application software D00U005 version 6.0.3 or higher. Once the software has been installed on a tablet, a patient’s device will automatically receive an update (to prevent the telemetry error) during their next SmartSync session.

Details:

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.

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 "???" Longevity estimates will be unavailable for approximately 82 weeks. 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 Medtronic Representative Ing.Jiří Exner at 602 294 729 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. The issue is unlikely to result in clinical impact to the patient given the features listed above can be restored with an in-clinic SmartSync programmer session.

Devices manufactured after July 2021 have already received the software update and are not susceptible to this behavior. Refer to Appendix A and Software Release Notes for details on how to identify which Cobalt/Crome devices have already received the update.

Patient Management Recommendations:

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends continuing normal follow-up frequency per local clinic protocol:

- **Patients routinely seen in the clinic** will automatically receive the update during their next interrogation using an updated SmartSync tablet (D00U005 version 6.0.3 or higher). No additional programming of the device is required.
- **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 (D00U005 version 6.0.3 or higher). No additional programming of the device is required.

Note: If a patient's device displays a grey longevity estimator bar with "???", the device may have a persistent session-active flag. Contact your Medtronic Representative Ing.Jiří Exner at 602 294 729 for assistance.

Medtronic has notified all applicable regulatory agencies about this matter. We regret any difficulties this issue may have caused you or your patients. We remain dedicated to ensuring the highest level of quality and will continue to monitor performance of our products to ensure we meet your needs and those of your patients.

Sincerely,



Michal Vondraš
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Enclosures: Appendix A, Software Release Notes, Consignee Form

APPENDIX A

Medtronic Cobalt™ and Crome™ Implantable Cardioverter Defibrillators (ICDs)
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How to Confirm a Patient's Device Has Received the Update?

Each device will display a Device Configuration ID after interrogation by an updated SmartSync tablet, or after transmitting to CareLink. The Device Configuration ID can be found via the Parameters Report as noted below:

For SmartSync - the following is available from the Parameters Report PDF file.

The image shows a sample SmartSync-generated Parameters Report. At the top left is the Medtronic logo. To the right of the logo, the word "Parameters" is displayed in a large, bold font. Below the logo, the report header includes: "Device: Cobalt™ XT DR DDPA2D4", "Serial Number:", and "Date of Interrogation: 13-Dec-2021 14:51:37". Below this, there are fields for "Patient:", "ID:", and "Physician:". The report is divided into sections: "Additional Features", "Device Information", and "Notes". The "Additional Features" section lists various settings such as Rate Drop Response (Off), Sleep (Off), Non-Comp Atrial Pacing (On), MRI SureScan (Off), PMT Intervention (On), PVC Response (On), and V. Safety Pacing (On). The "Device Information" section is a table with five columns: Device, Manufacturer, Model, Lead, and Implanted Date. A blue arrow points from the "Device Configuration ID: 2-1-0" row in the "Device Information" table to the "ID:" field in the report header. The "Notes" section is currently empty.

Additional Features		
Rate Drop Response		Off
Sleep		Off
Non-Comp Atrial Pacing		On
NCAP Interval		300 ms
MRI SureScan		Off
PMT Intervention		On
PVC Response		On
V. Safety Pacing		On

Device Information				
Device	Medtronic	Cobalt XT DR DDPA2D4	RSM	Implanted: 27-Sep-2021
Atrial	Medtronic	5076 CapsureFix Novus MRI	PJNi	Implanted: 27-Sep-2021
RV/SVC	Medtronic	6947M Sprint Quattro MRI	TDK	Implanted: 27-Sep-2021
Device Configuration ID: 2-1-0				

Image: Sample SmartSync-generated Parameters Report showing updated Device Configuration ID.

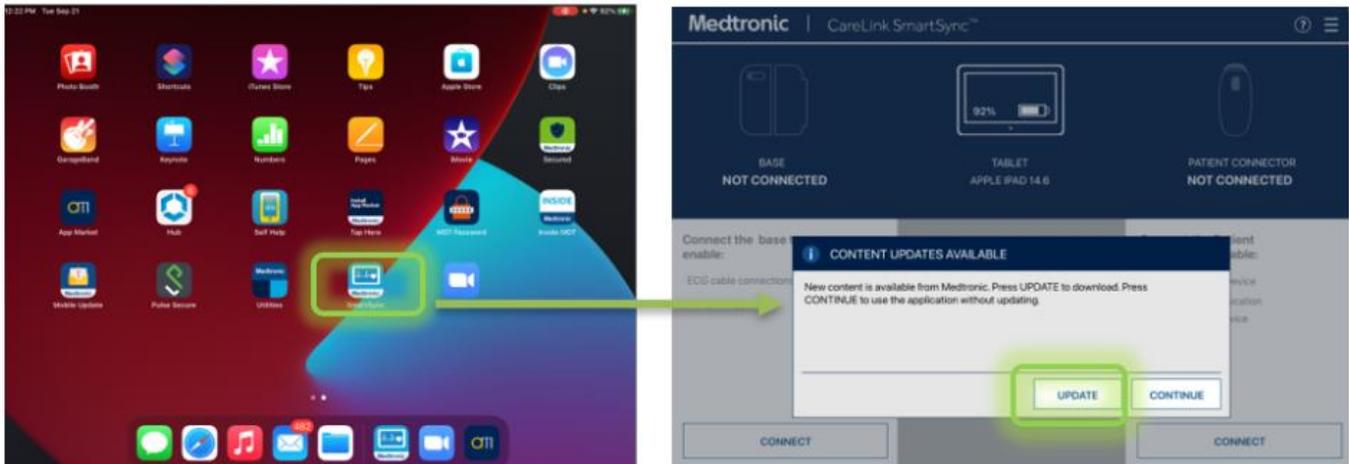
For CareLink - the following is available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'

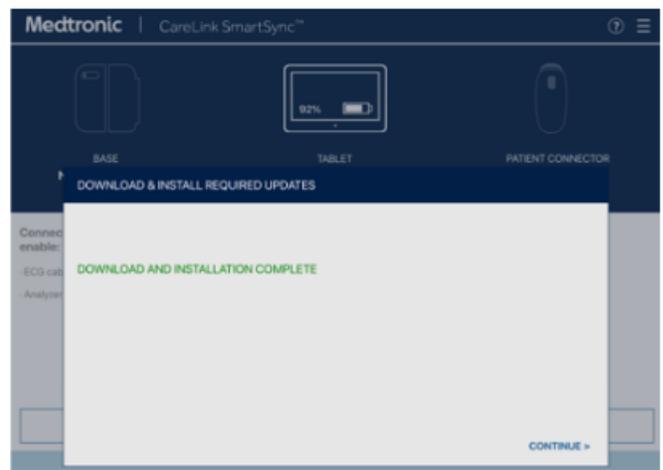
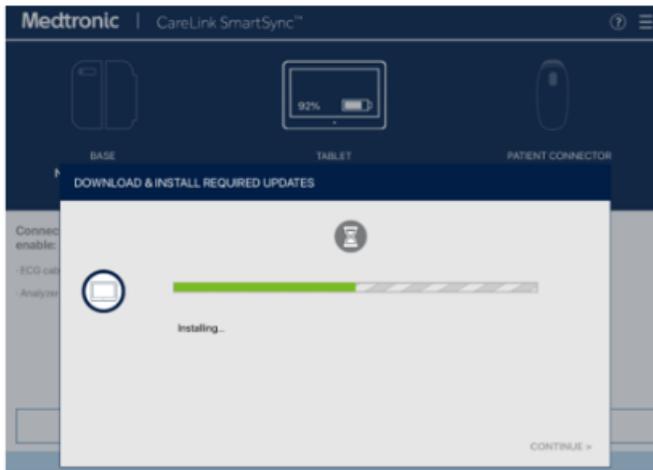
Medtronic				
HOME	TRANSMISSIONS	MANAGE MY PATIENTS	MANAGE MY CLINIC	CLINIC LMS10US
Active Transmissions Reports List Export Status Summary Reports Advanced Search Transmission Schedule				
Pacing Summary				
Mode				
Mode	ODO			
Pacing Details				
	Atrial	RV		
Sensitivity	0.30 mV	0.30 mV		
Sense Polarity	Bipolar	Bipolar		
Refractory/Blanking				
PVAB Interval	150 ms			
PVAB Method	Partial			
A. Blank Post AS	100 ms			
V. Blank Post VS	120 ms			
Additional Features				
Rate Drop Response	Off			
MRI SureScan	Off			
Device Information				
Device	Medtronic	Cobalt DR DDPB3D1	RSN600004S	Implanted: 09-Jun-2021
Device Configuration ID:	2-1-0			

Image: Sample CareLink Parameters Report showing updated Device Configuration ID.

How do I update my SmartSync™ application software for the issue described in the April/May 2022 communication?

On any tablet, you can update to the most recent version for all applications resident on that tablet by simply connecting to the internet and either **automatically discover** if new software is available by launching the SmartSync App (see images below), OR **manually discover** if new software is available by navigating to the Software Information screen and perform "Check for Updates." Contact your local Medtronic representative or Medtronic Technical Services (insert programmer support number here) if you need assistance.





How do I confirm if a SmartSync tablet has already been installed with the updated software?

On any tablet, you can confirm the application software version for any device family by:

- 1) Selecting the MENU in the upper right corner of the SmartSync App [1]
- 2) Selecting PROFILE [2]
- 3) Selecting the SOFTWARE tab and scrolling through the SOFTWARE INFO list [3]

If the software update for this issue has already been installed, you will see the following versions listed:

- The Common/Platform application version is 3.6.4 (or higher)
- The Cobalt/Crome application version is 6.0.3 (or higher)



The screenshot displays the Medtronic CareLink SmartSync™ interface. At the top, there are three status indicators: 'BASE NOT CONNECTED', 'TABLET APPLE IPAD 15.2' (with a 100% battery icon), and 'PATIENT CONNECTOR NOT CONNECTED'. Below these are three tabs: 'LOCATION INFO', 'HARDWARE INFO', and 'SOFTWARE INFO'. The 'SOFTWARE INFO' tab is active, showing a table of software components. A red box highlights the 'Cobalt Chrome Application' row. At the bottom right of the software info section is a 'CHECK FOR UPDATES' button.

SOFTWARE COMPONENT	VERSION	SOFTWARE MODEL	UDI
Micra AV Application	1.2.1	D00U007	(01)00763000397869(10)010201
Micra VR Application	1.2.1	D00U006	(01)00763000397852(10)010201
Azure Astra Application	5.1.3	D00U003	(01)00763000002039(10)050103
Cobalt Chrome Application	6.0.3	D00U005	(01)00763000002053(10)060003
Common Application	3.6.4	M01A02	(01)00643169833739(10)030604
Platform	3.6.4	M01A01	(01)00643169833722(10)030604

3 - Updated application versions