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URGENT MEDICAL DEVICE NOTIFICATION

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

13 April 2022

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Physician or Health Care Professional,

Medtronic is notifying health care professionals 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). The software is anticipated to receive regulatory approval in May of 2022. 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 local Medtronic field 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. 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 the described 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.

When the software is available in the respective region, please follow these recommendations:

- **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 local Medtronic field representative for assistance.

Please complete the enclosed Confirmation Form, following review of this letter, and hand or email back to your local Medtronic field representative.

Per your facility's standard medical device complaint procedures, report to your local Medtronic field representative any adverse reactions or quality problems if the quality issue described above has been observed.

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,

DocuSigned by:

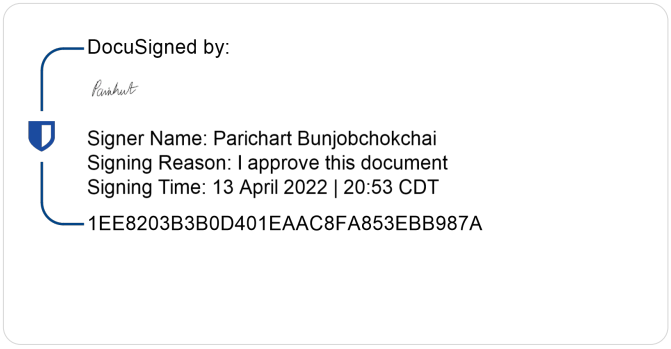
Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 13 April 2022 | 20:23 CDT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead
Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 13 April 2022 | 03:23 CDT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead
Indochina & Frontier Markets Plus



Medtronic QRA Lead
Thailand

Enclosures: Appendix A, Confirmation Form, Software Release Notes

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CLINICIAN CONFIRMATION FORM

SmartSync Device Manager Applications	Cobalt Models	Crome Models
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For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

By signing this form, I confirm that I have read the Urgent Medical Device Notification Letter, dated 13 April 2022 from Medtronic regarding Medtronic Cobalt™ and Crome™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and acknowledge the patient management recommendations.

Name (print): _____ Signature: _____ Stamp: _____ Date:_____

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact *your local Medtronic field representative.*

APPENDIX A

Medtronic Cobalt™ and Crome™ Implantable Cardioverter Defibrillators (ICDs)

and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

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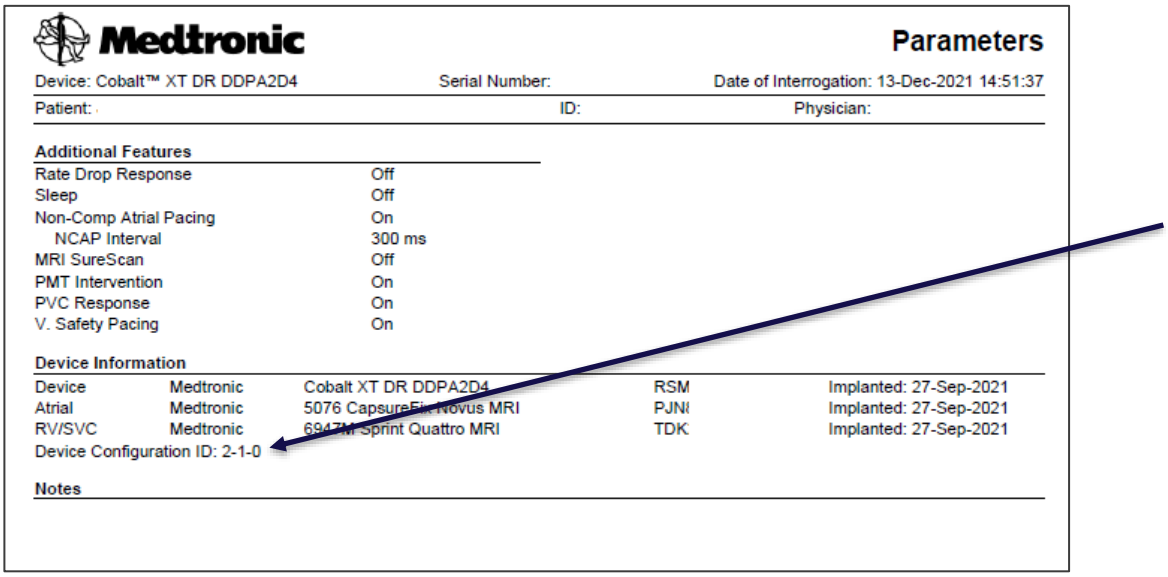
How to Confirm a Patient's Device Has Received the Update?

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.



Medtronic

Parameters

Device: Cobalt™ XT DR DDPA2D4 Serial Number: Date of Interrogation: 13-Dec-2021 14:51:37

Patient: ID: Physician:

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

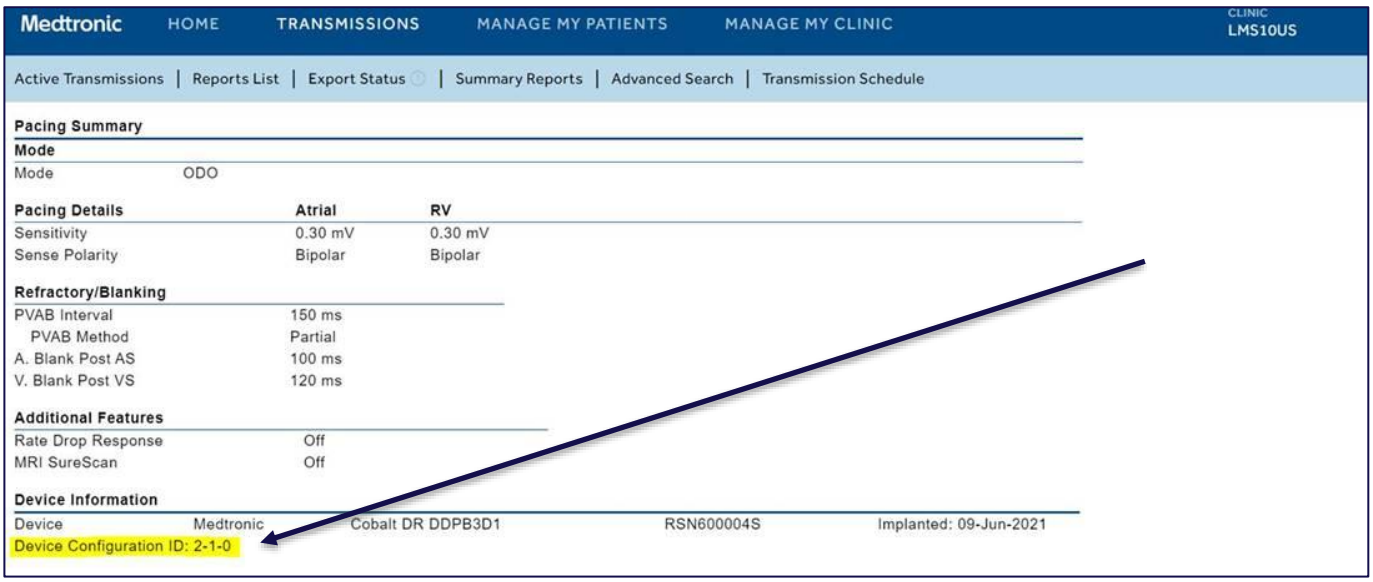
Device	Medtronic	Cobalt XT DR DDPA2D4	RSM	Implanted: 27-Sep-2021
Atrial	Medtronic	5076 CapsureFix Novus MRI	PJN	Implanted: 27-Sep-2021
RV/SVC	Medtronic	6947M Sprint Quattro MRI	TDK	Implanted: 27-Sep-2021

Device Configuration ID: 2-1-0

Notes

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

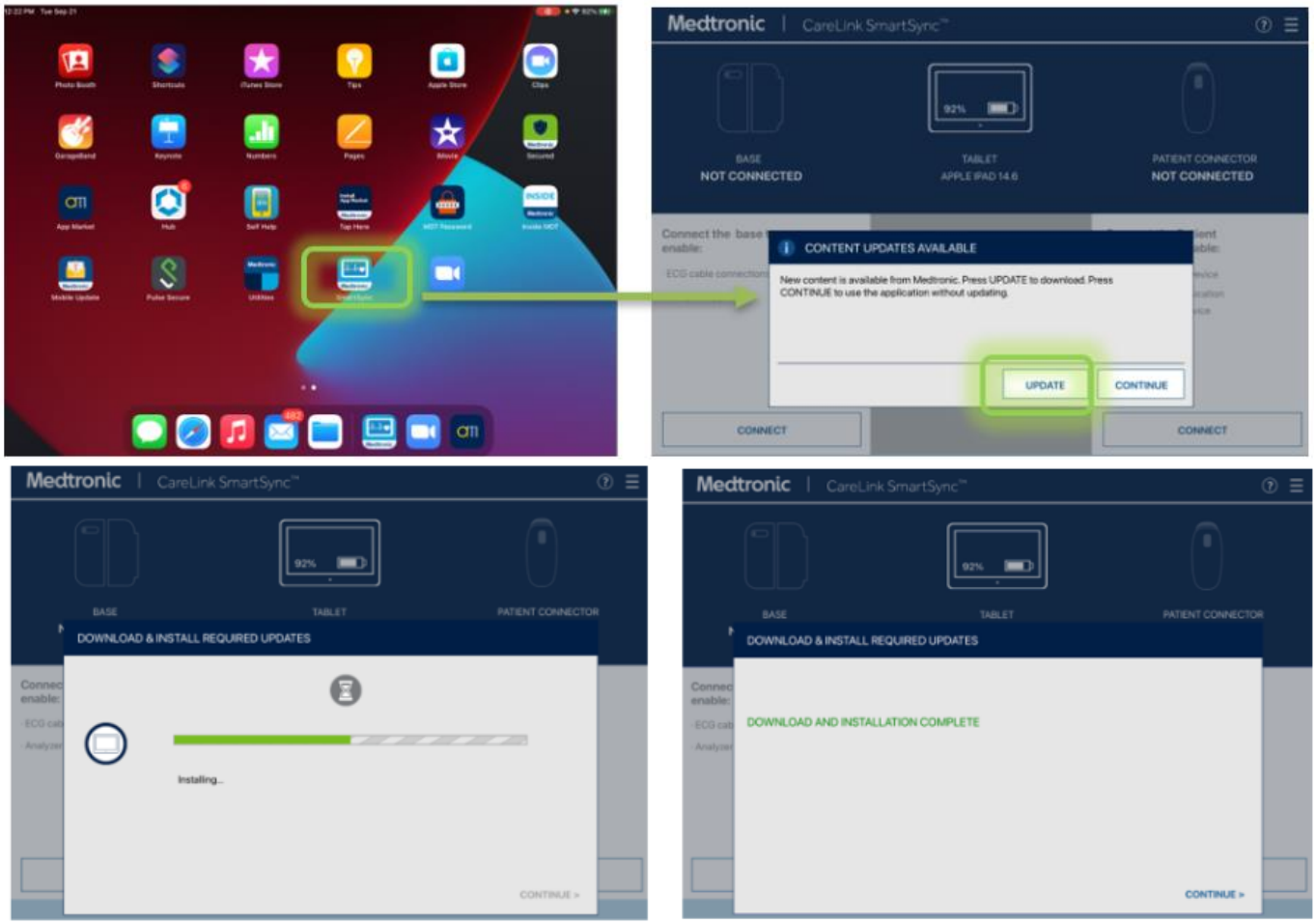
Device	Medtronic	Cobalt DR DDPB3D1	RSN600004S	Implanted: 09-Jun-2021

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.



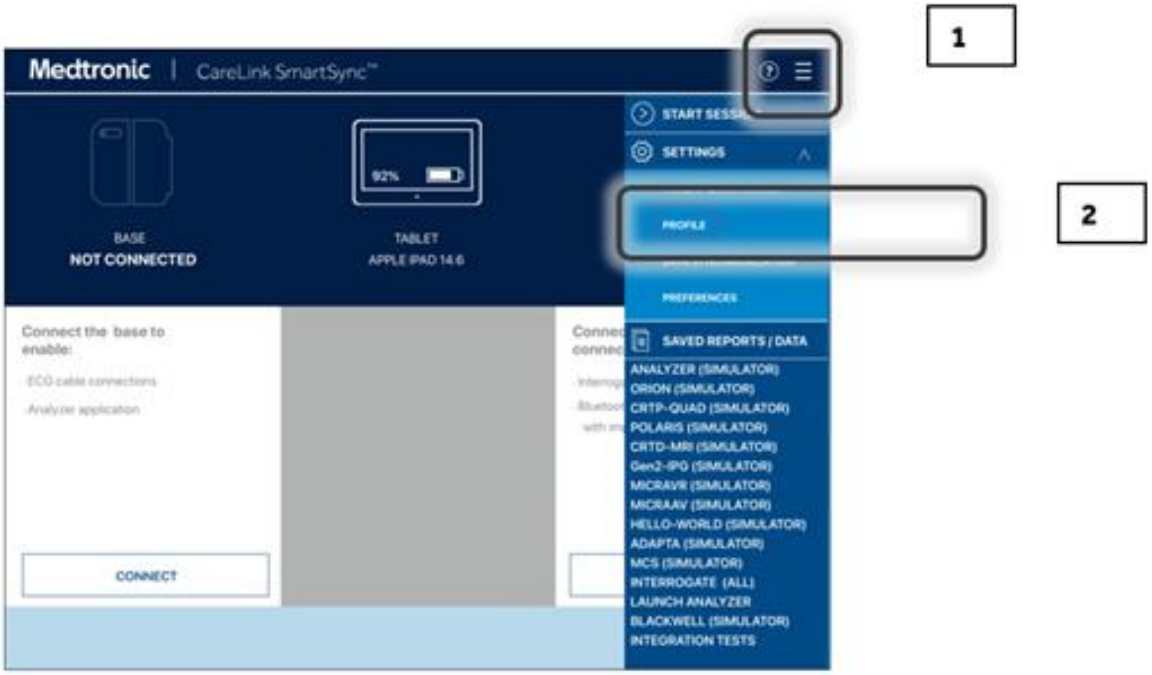
How do I confirm if a SmartSync tablet has already been installed with the updated software?

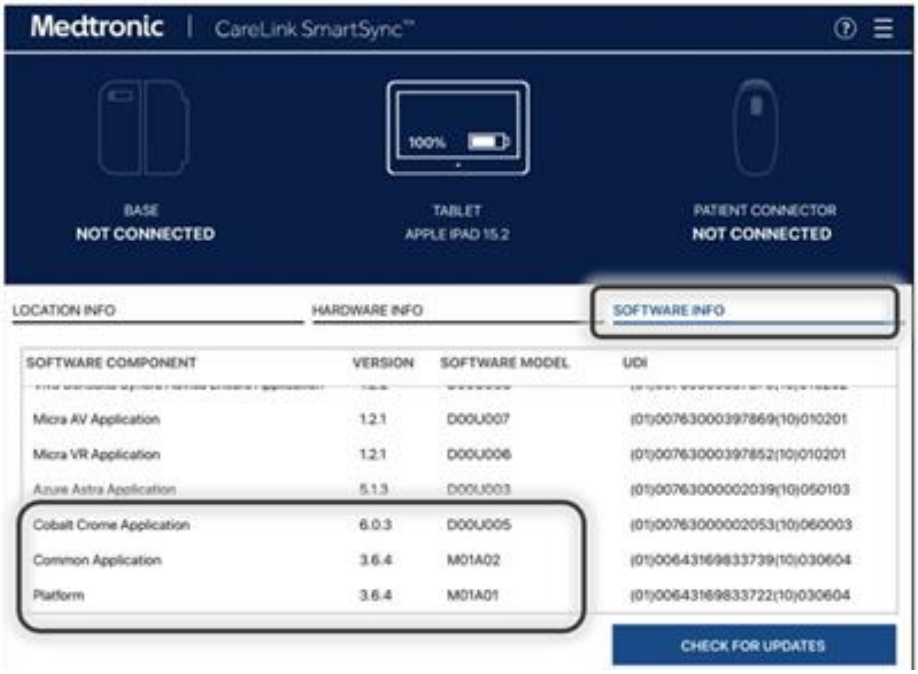
On any tablet, you can confirm the application software version for any device family by:

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)





3 - Updated application versions