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URGENT FIELD SAFETY NOTICE

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

Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event

Software update

CareLink™ SmartSync™ Device Manager Application	**Implantable Device Models**
CareLink™ SmartSync™ Device Manager application software D00U005	All Cobalt XT, Cobalt and Crome Models

August 2022

Medtronic reference: FA1225

Dear Health Care Professional:

A software release for CareLink™ SmartSync™ Device Managers (SmartSync) is now available for installation onto all SmartSync tablets. This software update (**application D00U005 version 7.1.1**) was previously announced as part of an advisory communication Medtronic issued in June 2022 (see enclosed letter). The software will deploy a device update to Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) to prevent the potential for an intermittent, second-phase Short Circuit Protection (SCP) event during high-voltage (HV) therapy delivery.

Medtronic representatives are available to work with you to ensure all SmartSync tablets in your facility are updated with application software D00U005 version 7.1.1 (or higher). The software can be installed by connecting each SmartSync tablet to the internet, opening the SmartSync App and accepting the on-screen prompts; refer to Appendix A of this letter.

Actions:

As disclosed in the June 2022 patient management recommendations (attached), patients will require an in-clinic visit for the update to be installed into their device via interrogation with an updated SmartSync tablet. Once installed, the update will allow devices to deliver the full programmed shock energy. Programming B>AX pathway and Active Can enabled is still required. We have added on-screen messaging to the SmartSync software to reinforce these programming recommendations. Additionally, this programming mitigates the theoretical risk for proarrhythmia if a low-level current pathway develops in the HV circuitry.

Clinicians can identify if a patient's device has successfully received the update by viewing the displayed

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Configuration ID and confirming the first number in the sequence is as indicated below:

- **11**-1-0 for Cobalt/Crome VR devices
- **10**-1-0 for Cobalt/Crome DR and CRT-D devices

The Device Configuration ID can be found under the "Device Information" section of the SmartSync *Parameters* Report, or for CareLink patients, under the *Transmission Details* page by selecting <More Reports > 'Parameters.' Refer to Appendix A for examples.

Pending local regulatory approvals, for new device implants, clinicians can identify if a device received the update on the manufacturing line through the presence of a "Product Version Number" of 01 – located under the bar code of the device packaging.

Note: If the device packaging does not contain a "01" for the version number, during implant the device will automatically receive the update via interrogation with any SmartSync tablet that has been updated to D00U005 version 7.1.1 or higher.

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

We regret any difficulties this issue may cause you and 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. If you have any questions regarding this communication, please contact your local Medtronic representative.

Sincerely,

Digitally signed by
Dirk Gey Van Pittius
Date: 2024.06.25
15:57:37 +02'00'

Dirk Gey Van Pittius
Medtronic Africa
Quality and Regulatory Affairs

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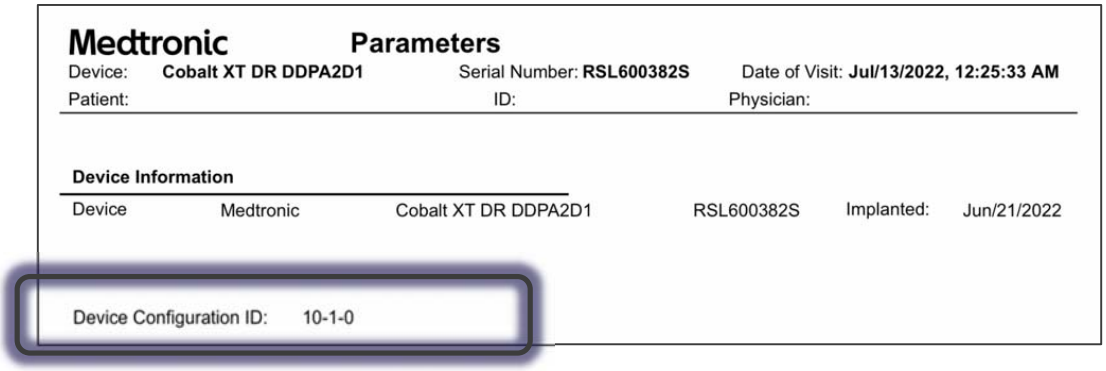
APPENDIX A

How do I confirm a patient's device has received the update?

To confirm if a device has been updated, locate the Device Configuration ID on the *Parameters Report* either via SmartSync interrogation, or via CareLink (after interrogation by an updated SmartSync tablet).

SmartSync-generated Parameters Report showing updated Device Configuration ID for CRT-D and dual-chamber (DR) ICDs.



Medtronic **Parameters**

Device: **Cobalt XT DR DDPA2D1** Serial Number: **RSL600382S** Date of Visit: **Jul/13/2022, 12:25:33 AM**

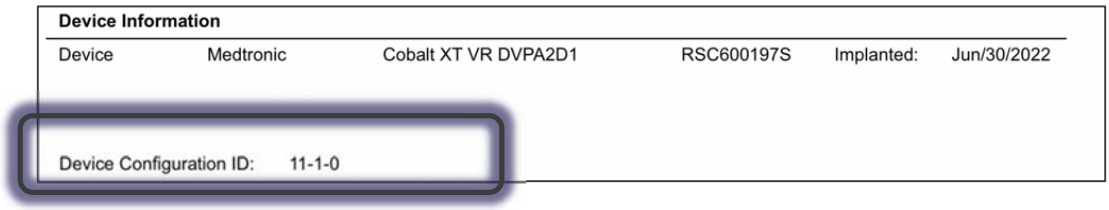
Patient: ID: Physician:

Device Information

Device	Medtronic	Cobalt XT DR DDPA2D1	RSL600382S	Implanted:	Jun/21/2022

Device Configuration ID: 10-1-0

SmartSync-generated Parameters Report showing updated Device Configuration ID for single-chamber (VR) ICDs.

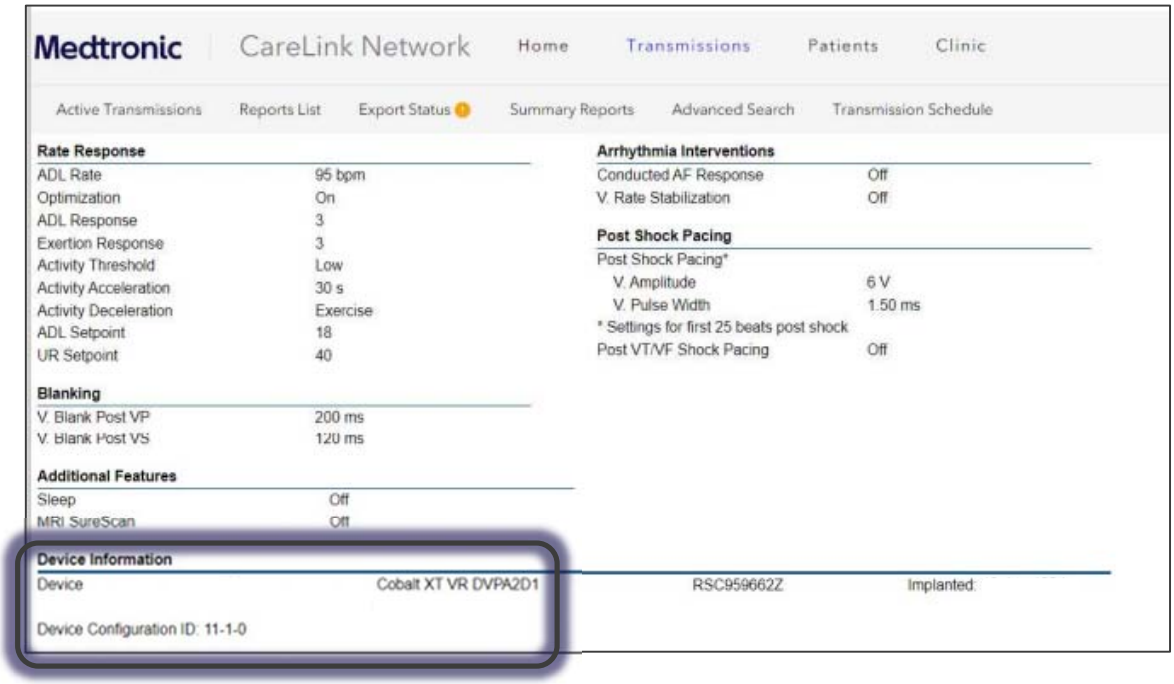


Device Information

Device	Medtronic	Cobalt XT VR DVPA2D1	RSC600197S	Implanted:	Jun/30/2022

Device Configuration ID: 11-1-0

CareLink-generated Parameters Report; available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'



Medtronic CareLink Network Home Transmissions Patients Clinic

Active Transmissions Reports List Export Status Summary Reports Advanced Search Transmission Schedule

Rate Response

ADL Rate	95 bpm
Optimization	On
ADL Response	3
Exertion Response	3
Activity Threshold	Low
Activity Acceleration	30 s
Activity Deceleration	Exercise
ADL Setpoint	18
UR Setpoint	40

Blanking

V. Blank Post VP	200 ms
V. Blank Post VS	120 ms

Additional Features

Sleep	Off
MRI SureScan	Off

Arrhythmia Interventions

Conducted AF Response	Off
V. Rate Stabilization	Off

Post Shock Pacing

Post Shock Pacing*	
V. Amplitude	6 V
V. Pulse Width	1.50 ms
* Settings for first 25 beats post shock	
Post VT/VF Shock Pacing	Off

Device Information

Device	Cobalt XT VR DVPA2D1	RSC959662Z	Implanted:

Device Configuration ID: 11-1-0

How do I update my SmartSync™ application software for the issue?

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 if you need assistance.

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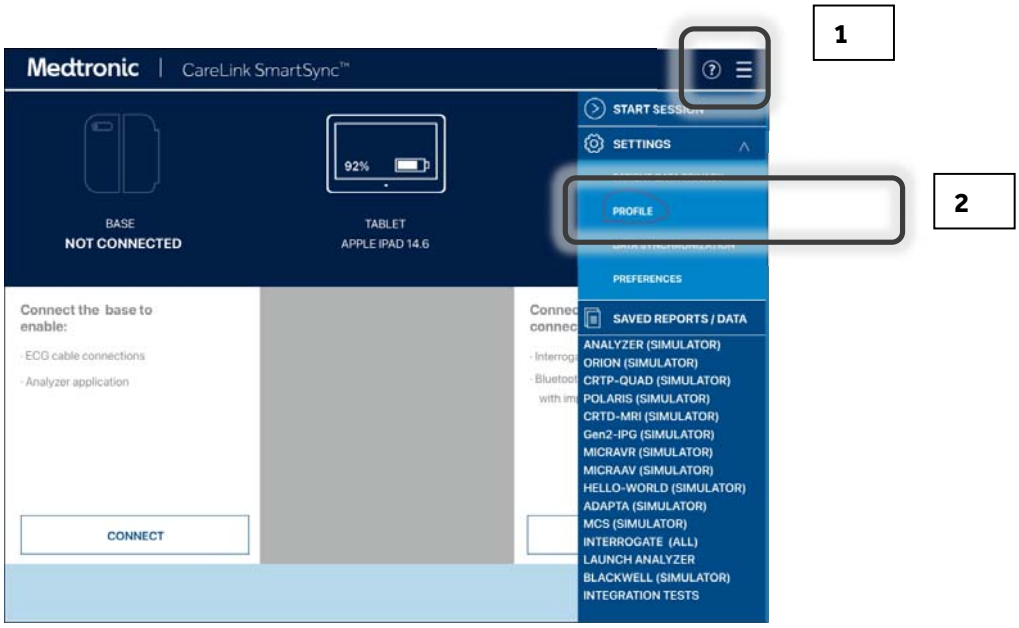
How do I confirm if a SmartSync tablet has already been installed with the updated software?

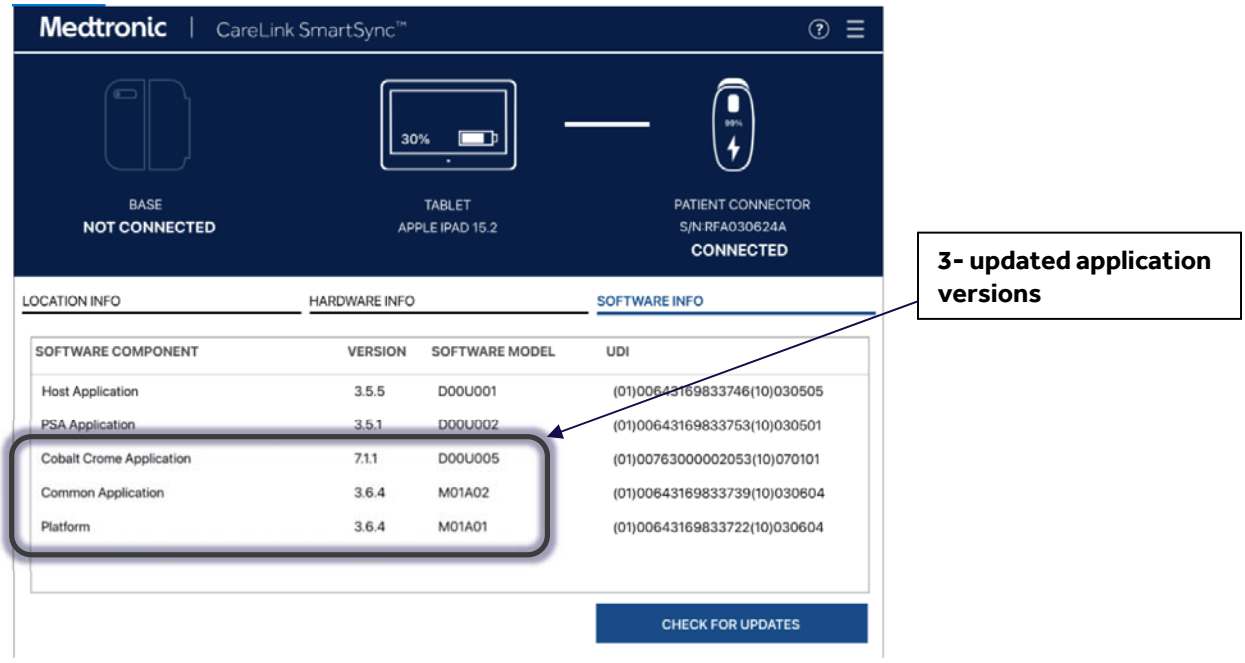
On any tablet, you can confirm the application software version for any device family by:

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 Cobalt/Crome application version is 7.1.1 (or higher)





If the tablet does not show Cobalt Crome Application at version 7.1.1 or higher after following these instructions, contact your local Medtronic representative.