

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 Phase II

<[For use in countries that follow EUMDR: EU Manufacturer Single Registration Number \(SRN\): US-MF-000019977](#)>

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 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.

Please complete the enclosed Customer Acknowledgement Form and email to <XXXXXX>.

Please forward this notice to all those who need to be aware within your organization. Additionally, if any affected devices have been distributed to other organizations, please forward this notice to those entities.

Additional information

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 at <XXXXXX>.

Sincerely,

Local / OU Manager

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 | | | | | |

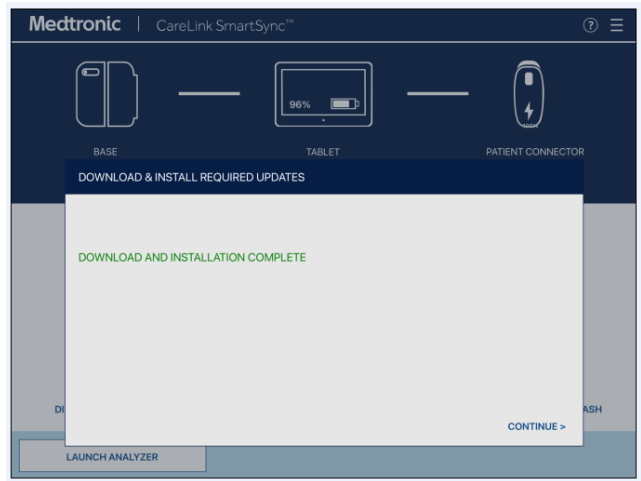
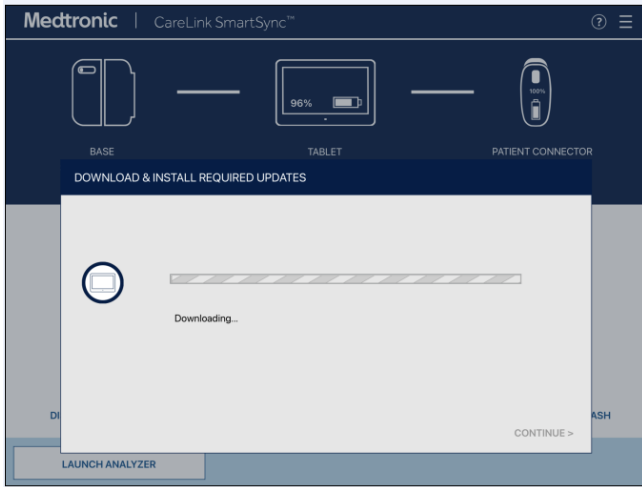
CareLink-generated Parameters Report; available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'

| Medtronic | | CareLink Network | | Home | Transmissions | Patients | Clinic |
|---------------------------------|----------------------|--|-----------------|---------------------------------|-----------------------|----------|--------|
| Active Transmissions | Reports List | Export Status | Summary Reports | Advanced Search | Transmission Schedule | | |
| Rate Response | | | | Arrhythmia Interventions | | | |
| ADL Rate | 95 bpm | Conducted AF Response | Off | | | | |
| Optimization | On | V. Rate Stabilization | Off | | | | |
| ADL Response | 3 | Post Shock Pacing | | | | | |
| Exertion Response | 3 | Post Shock Pacing* | | | | | |
| Activity Threshold | Low | V. Amplitude | 6 V | | | | |
| Activity Acceleration | 30 s | V. Pulse Width | 1.50 ms | | | | |
| Activity Deceleration | Exercise | * Settings for first 25 beats post shock | | | | | |
| ADL Setpoint | 18 | Post VT/VF Shock Pacing | Off | | | | |
| UR Setpoint | 40 | | | | | | |
| Blanking | | | | | | | |
| V. Blank Post VP | 200 ms | | | | | | |
| V. Blank Post VS | 120 ms | | | | | | |
| Additional Features | | | | | | | |
| Sleep | Off | | | | | | |
| MRI SureScan | 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.





DRAFT

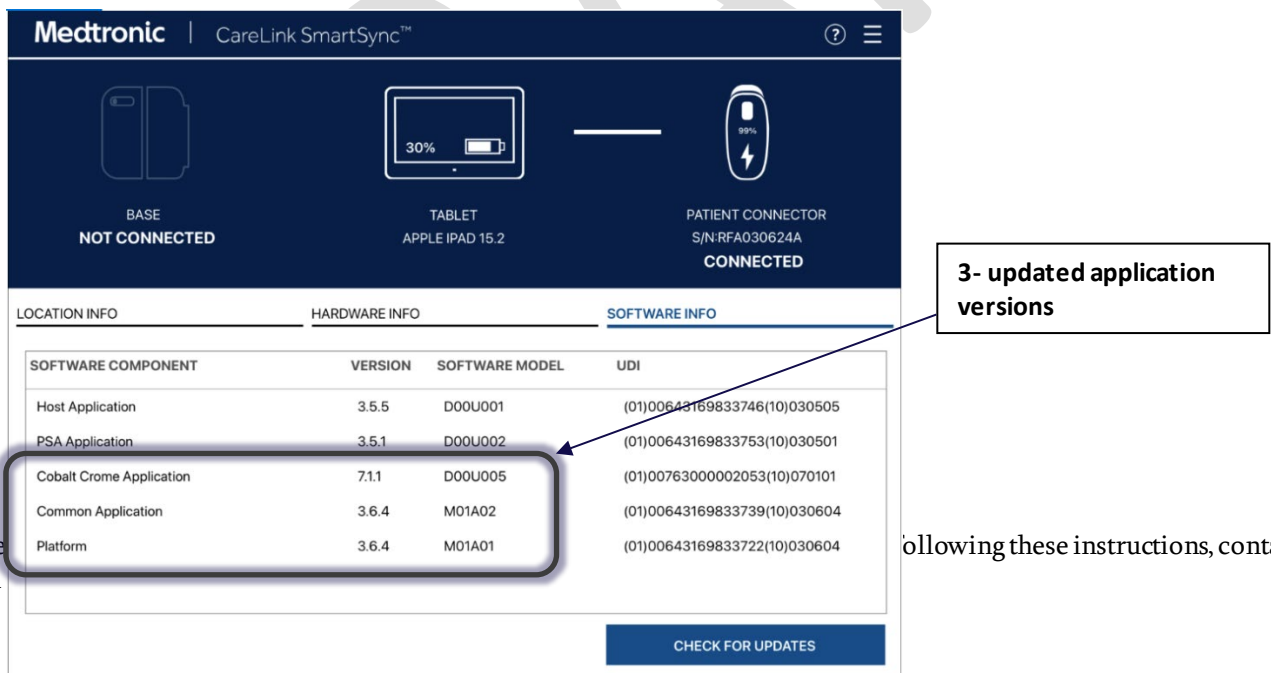
How do I confirm if a SmartSync tablet has already been installed with the updated software?

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 local

following these instructions, contact your