

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 Risk Managers:

Medtronic is notifying Risk Managers of a **software update for CareLink™ SmartSync™ Device Managers** (SmartSync) that will address an advisory from June 2022 (enclosed) related to Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). The attached Software Release Notes provide details associated with the newly released software **application D00U005 version 7.1.1**.

You can install the software by connecting each SmartSync tablet to the internet, opening the SmartSync App, and accepting the on-screen prompts (refer to Appendix A). Medtronic Representatives or authorized personnel can assist with installing this update on SmartSync tablets in your account, based on your facility's needs and accessibility.

Actions:

- **Update** all SmartSync tablets in your facility.
- **Please complete the enclosed Customer Acknowledgement Form and email to <XXXXX>**
- Share this notice with those who need to be aware within your organization, or with any organization where SmartSync programmers may have been transferred.

Medtronic has notified the Competent Authority of your country of this action. 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. If you have any questions regarding this communication, please contact your local Medtronic representative at **<XXXXX>**.

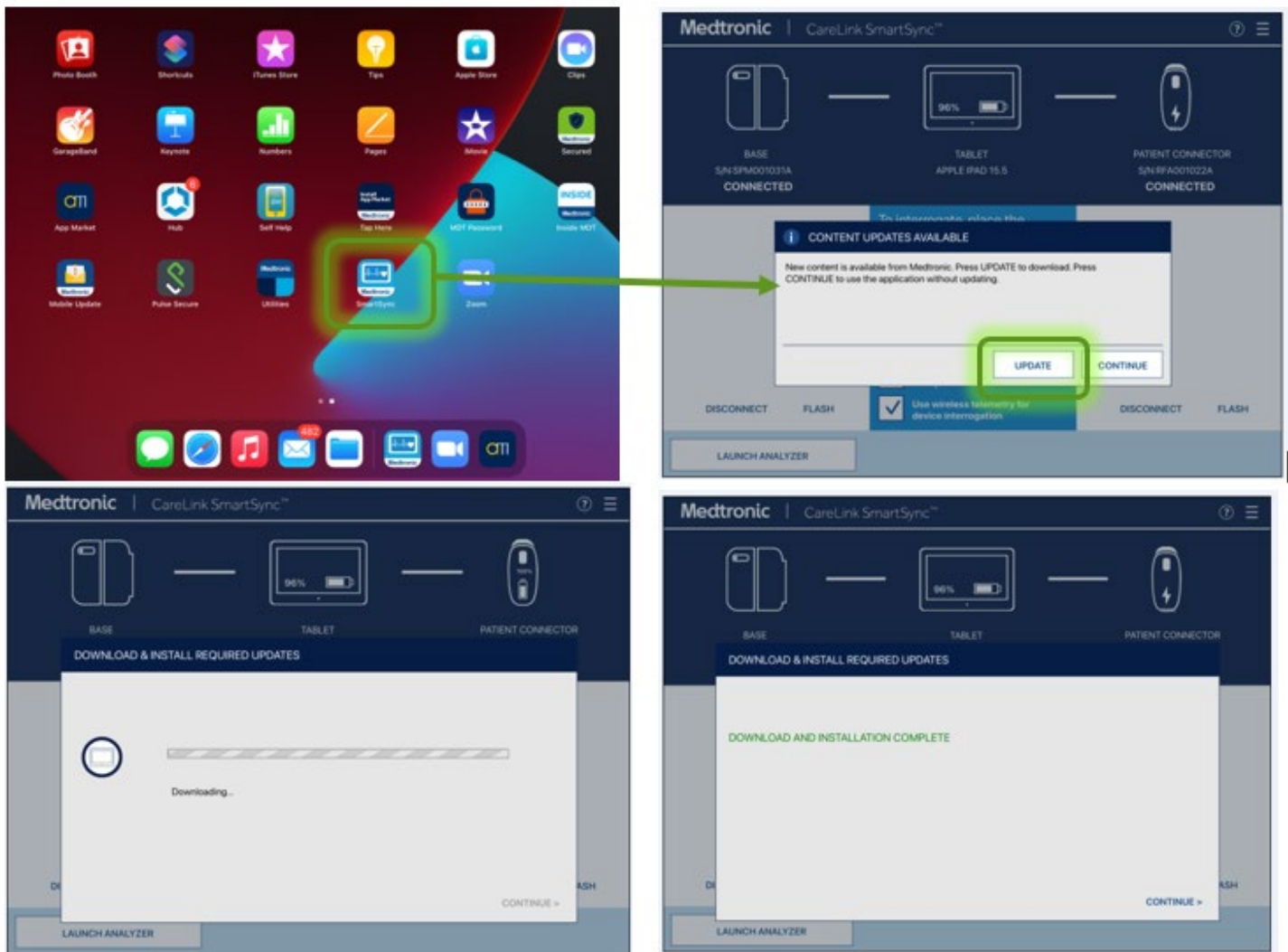
Sincerely,

Local / OU Manager

APPENDIX A

1. 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.



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

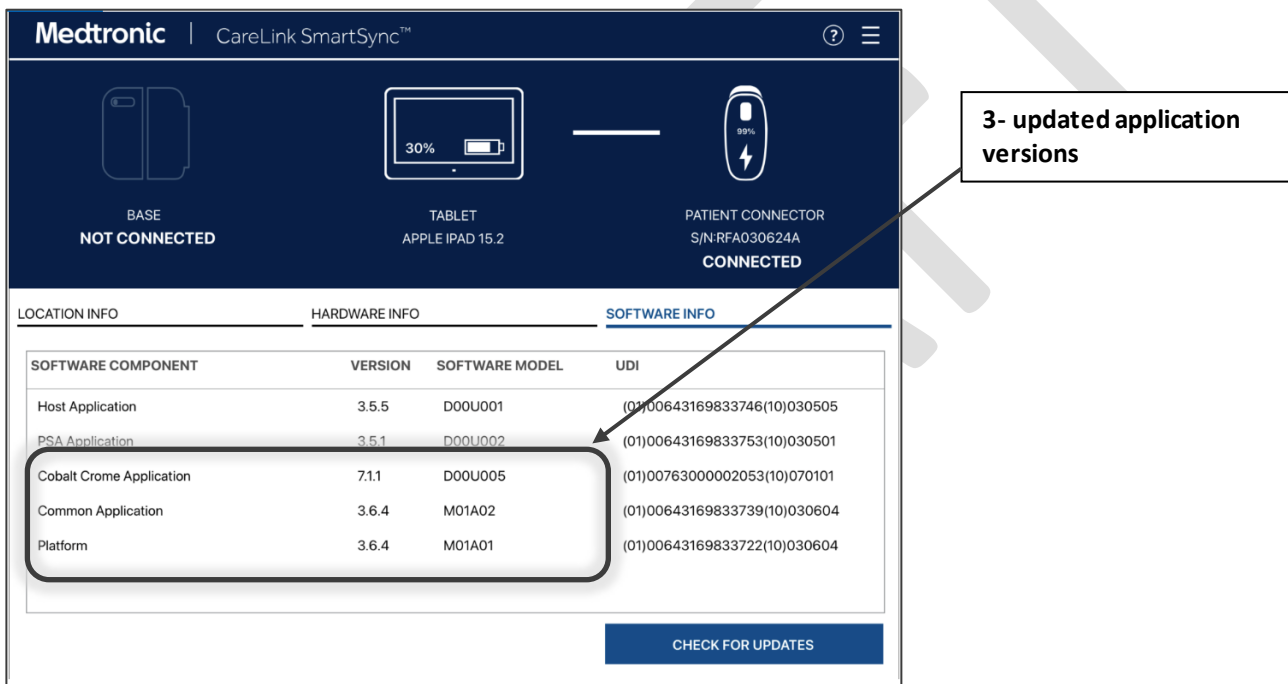
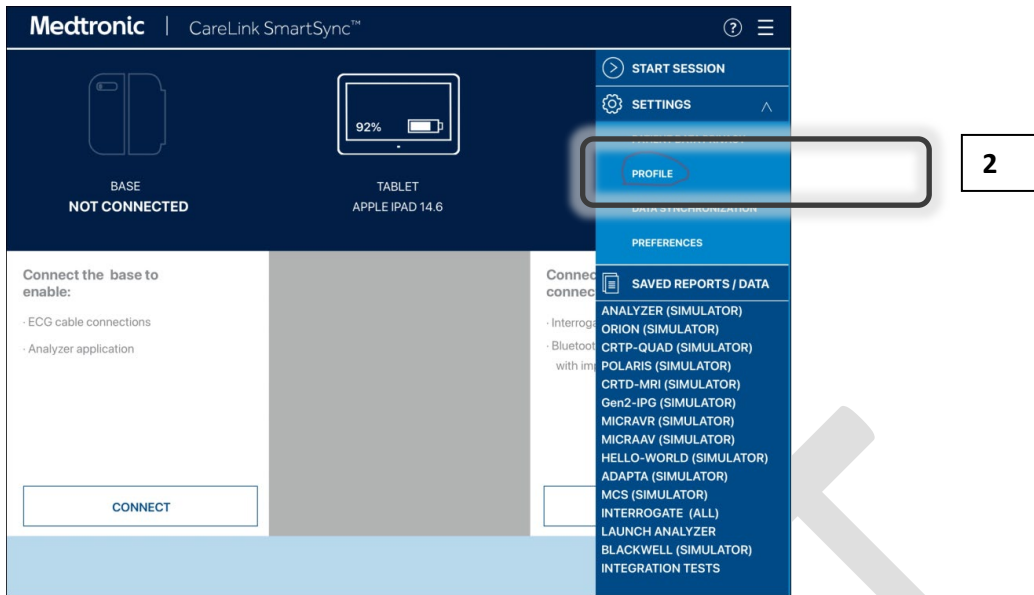
On any tablet, you can confirm the application software version for any device family by:

- 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 SOFTWAREINFO 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 version 7.1.1 (or higher) after following these instructions, contact your local Medtronic representative.