

Urgent Field Safety Notice

CFx Longevity Estimator Software Error

SOFTWARE UPDATE AVAILABLE FOR SUBSET OF AFFECTED DEVICES

Affected Programmers & Remote Monitoring Software Apps	Affected Devices
2090 CareLink™ Programmer 29901 Encore™ Programmer CareLink Network Application Software 2491 CareLink SmartSync™ Device Manager MyCareLink Heart™ Mobile Application	Subset of the following devices: Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava™ CRT-Ds Visia AF™/Visia AF MRI™/Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs Azure™/Astra™ IPGs Percepta™/Serena™/Solara™ CRT-Ps Micra™ TPS

June 2020

Medtronic Reference: FA887 Phase II

Dear Healthcare Professional and Risk Manager,

This letter is to inform you of the availability of software updates that will correct the issue disclosed in a communication sent in October 2019. The original communication described the potential for Medtronic programmers and remote monitoring systems to display an inaccurate longevity estimate for a well-defined subset of approximately 53,100 implanted cardiac devices worldwide; and that prophylactic device replacement is not recommended, as device functionality and the RRT indicator are not impacted by the inaccurate longevity estimate.

Two phases of software releases will be required to address the issue (refer to Table 1 below). Device families listed under Phase 1 are receiving the software update at this time. Device families listed under Phase 2 will be addressed in future software releases, anticipated to be approved in late calendar year 2020.

Software Update Phase 1 – June 2020	Software Update Phase 2 – Late 2020
Azure™/Astra™ (SW030) v 8.1 Serena™/ Solara™/ Percepta™ (SW040) v 8.3 Visia AF™/ Visia AF™ MRI (SW035) v 8.2	Viva™/Brava™/ Evera Evera™ MRI/ Primo™ MRI/ Mirro™ MRI Micra™ VR TPS Claria™/Amplia™/Compia™

Table 1: Device family updates by phases

As of 5 June 2020, the Medtronic CareLink™ Network has been updated, and longevity estimates displayed through CareLink for devices in Phase 1 will reflect the correct longevity estimate. Azure IPG and Percepta/Serena/Solara CRT-P patients remotely monitored via the MyCareLink Heart™ mobile app will automatically receive an updated longevity estimate on their mobile app with their next scheduled transmission, or within 92 days, whichever comes first.

Actions for devices in Software Update Phase 1

The Independent Physician Quality Panel recommends routine follow up in accordance with standard practice for these devices, as RRT function is normal and the battery longevity is unaffected. There is no need to schedule patients to come in outside of their planned, scheduled visits due to this issue. The corrective fix is implemented in programmers, CareLink, and other systems which display device longevity. The patient's device does not require an update. Follow the steps below as applicable to your clinic or hospital. A local Medtronic Representative can assist in updating Model 2090/Encore programmers and SmartSync Device Managers in your facilities.

- Model 2090 and Encore™ Programmers
 These programmers will require new software to be installed to correct the displayed longevity estimator error. The software applications and version are listed in Table 1 above and can be installed via Medtronic Software Distribution Network (SDN) or via secure USB.

- **SmartSync™ Device Managers**
These tablet-based programmers will require a software update to be installed via the internet - refer to Appendix A for detailed instructions on how to download and install the updated application software. The software is available for installation as of 10 June 2020.

Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions. Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will work with your facility as requested to complete the updates.

Note: Once a programmer is updated, the correct longevity estimate will display at the patient's next regularly scheduled clinic visit. Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, a difference in longevity estimates between programmers and CareLink Network-displayed longevity may be observed.

Recommendations for devices in Software Update Phase 2

Continue to follow the patient management recommendations from the October 2019 communication (excerpted below) for the subset of patients within the affected population who are not included in the Phase 1 software updates.

Patient Management Recommendations (October 2019)

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel, Medtronic provides the following guidance:

- ***Prophylactic device replacement is not recommended, as device functionality and the RRT indicator are not impacted by the inaccurate longevity estimate.***

Until the software update becomes available:

- *Continue normal patient follow-up in accordance with standard practice.*
- *Per labeling, continue to use the RRT notification to identify when device replacement should be scheduled. Where available, utilize the low battery voltage RRT audible alert or wireless CareAlert™.*
- *At any time, if a lower-than-expected remaining longevity estimate occurs, contact Medtronic Technical Services for assistance – additional analysis of stored device information will be required to assess if the decreased longevity estimate is due to this issue.*

The Competent Authority of your country has been notified of this action. Please share this notification as appropriate with others in your organization or to any organization where these devices may have been transferred.

Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Majed Matraji
Business Manager, CRHF, APS

APPENDIX A – UPDATING SMARTSYNC™ DEVICE MANAGER

Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, you may observe a difference in longevity estimates between these programmers and CareLink-displayed longevity.

Updating Medtronic SmartSync™ Device Managers:

- 1) Connect tablet to internet and open the SmartSync App.
 - a. The SmartSync App automatically checks for available updates each time it is opened.

- 2) If your tablet does not contain the most recent software, you will automatically receive a notification that a new version of the SmartSync App is available (3.2.01):
 - If pop-up messages appear with the option to “cancel” or to “update”, **select “update”**.
 - **Medtronic Managed Tablets:** If the App closes, find the Medtronic App Catalog, and **select “Install”** to initiate the download.
 - **Customer Owned Tablets:** If the App closes, navigate to the AirWatch App Catalog or App Store and **select “Install”** to initiate the download.
 - If you do not receive a notification that a new version of the SmartSync App is available, skip to Step 3.

- 3) Once you confirm the newest version of the SmartSync App is on your tablet, re-open the SmartSync App.
 - The app will automatically provide pop-up notifications informing you if there are new versions of *device* software applications that must be installed (see table below).
 - Select CONTINUE for each pop-up window that appears. If you do not receive any pop-up notifications when you open the SmartSync App, then your tablet contains the most recent versions of all available software.

Device Family	SmartSync Application SW Version
Azure™/Astra™ DR and SR	D00U003, Version 3.2.02
Percepta™/Serena™/Solara™	D00U004, Version 3.2.02