

UPDATE TO URGENT FIELD SAFETY NOTICE

SOFTWARE UPDATE NOW AVAILABLE

Re: Increased Potential for Reduced-Energy or No Energy Delivered During High Voltage Therapy
When Programmed AX>B

Devices Include the Following Models:

A subset of: Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava™ CRT-Ds

A subset of: Visia AF™/Visia AF MRI™/Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs

July 2024

Dear Health Care Professional, Risk Manager:

Software updates for the CareLink™ 2090 and CareLink Encore™ 29901 programmers, and CareLink™ SmartSync Device Managers are now available. These updates align nominal settings and programming screens with the May 2023 patient management recommendations (see enclosed letter).

Ensure that all Medtronic programmers and device managers are updated with the version numbers listed in Appendix A.

Medtronic representatives can assist as necessary. Device Instructions For Use (IFU) have been updated and can be found online at <http://manuals.medtronic.com>.

There are no new patient management recommendations with this notification. With the previously communicated programming recommendations implemented, Medtronic devices return to historical safety and reliability performance. Status updates for the May 2023 communication are posted online at <http://productperformance.medtronic.com> under Customer Communications.

Following review of this letter, sign and return the enclosed Customer Acknowledgement Form.

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

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,

Local / OU Manager

Enclosure:
May 2023 communication

APPENDIX A

Ensure that each software application is at the listed version number or higher as locally approved.

On any CareLink™ 2090/CareLink™ 29901 Encore programmer, you can confirm the software version by:

- 1) From the programmer home screen, press the **Programmer** icon
- 2) Select **Software**

For each device model with software loaded on the programmer, the screen displays the software version number next to the model number. Verify the following versions have been successfully loaded:

Software Name	SW Model #	SW Version #
Viva/Brava/Evera	SW016	8.5
Evera MRI (Primo MRI/Mirro MRI)	SW033	8.6
Claria/Amplia/Compia	SW034	8.6
Visia AF	SW035	8.3

SmartSync Tablets

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
- 2) Selecting **PROFILE**
- 3) Selecting the **SOFTWARE** tab and scrolling through the SOFTWARE INFO list

If the software update for this issue has already been installed, you will see the following versions listed:

SmartSync Application	SmartSync App Model #	Minimum Version*	Current Version
Viva/Brava/Evera	D00U012	2.1.0	2.2.3
Evera MRI	D00U010	2.1.0	2.2.3
Claria/Amplia/Compia	D00U009	2.1.0	2.2.3
Visia AF	D00U011	2.1.0	2.2.3
Cobalt/Crome	D00U005	8.1.0	8.2.3