

UPDATE TO URGENT FIELD SAFETY NOTICE

CARELINK™ 2090 AND CARELINK™ ENCORE 29901

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

2 July 2026

Dear Device Customer/Distributor/Health Care Professional, Risk Manager:

In May of 2023, Medtronic communicated on the *Increased Potential for Reduced-Energy or No Energy Delivered During High Voltage Therapy When Programmed AX>B* in devices with a glassed feedthrough design. As detailed in the enclosed original communication, Medtronic indicated that programmer platforms and device Instructions For Use would be updated to align with the patient management recommendations.

Effective May 2026, Medtronic CareLink™ 2090 or CareLink™ Encore 29901 programmers not already updated to Desktop software version 3.2 or higher (2090) or 9.2 or higher (Encore) will not be updated.

Issue Description:

Medtronic CareLink™ 2090 and CareLink™ Encore 29901 programmers have a variety of software certifications that require periodic renewal to enable future updates while maintaining the integrity of the programming system. On 4 April 2026, one of these certificates expired. As a result, any programmer that remains on a Desktop software version lower than 3.2 (2090) or 9.2 (Encore) can no longer be updated in the field. There is no patient risk associated with continuing to use a programmer with an expired certificate, devices should continue to be programmed in the B>AX configuration for all high-voltage therapy pathways.

- Medtronic will be transitioning away from the older 2090/Encore technology and working to expand access to the more current tablet-based CareLink™ SmartSync Device Manager (SmartSync) programmer platform which has or will have programmer software that aligns with the patient management recommendations for these devices.

Patient Management Recommendations:

- Manage all ICD and CRT-D patients with SmartSync or a previously updated 2090 or Encore programmer (refer to Appendix A to identify programmer software version)
- In locations where SmartSync and/or updated programmers are not available, continue to program all high-voltage therapy pathways to the B>AX configuration (as detailed in the enclosed letter).

Customer Actions:

- Complete the enclosed Customer Acknowledgement Form review of this letter and return it to Medtronic to confirm receipt.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred
- Please maintain a copy of this notice in your records.

Additional Information:

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

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Mai
Faied

Digitally
signed by Mai
Faied
Date:
2026.07.02
17:35:44 
+03'00'

Mai Faied
Regulatory Affairs Specialist

Enclosed:

- Appendix A
- May 2023 communication
- Customer Acknowledgement Form

Appendix A

To view the Desktop software version on the 2090 or Encore programmer

1. Press the **Programmer** icon, and then select **Software**

- a. Look at the "Vision Release" Information

Programmers at versions below 3.2 (2090) and 9.2 (Encore) remain functional, but will no longer be able to be updated.

2. For each device model with software loaded on the programmer, the screen displays the software version number next to the model number. Updated software will have the **minimum version** (or higher) listed below:

- a. Press the **Programmer** icon, and then select **Software**

Brand Name	SW Model #	Minimum SW Version
Viva/Brava/Evera	SW016	8.5
Claria/Amplia/Compia	SW034	8.6
Visia AF	SW035	8.3
Evera MRI	SW033	8.6

3. To confirm a SmartSync Tablet has the latest Software:

- a. 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)

- b. If the software update has already been installed, you will see the **minimum version** (or higher) listed below

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

