

## UPDATE TO URGENT FIELD SAFETY NOTICE

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

**Devices Include the Following Models:**

Cobalt™ XT/Cobalt™/Crome™ ICDs and CRT-Ds

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

### SMARTSYNC SOFTWARE UPDATE NOW AVAILABLE

November 2023

Medtronic Reference: FA1326

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019977>

Dear Health Care Professional:

A software update for the CareLink™ SmartSync™ Device Manager (SmartSync) is now available. This SmartSync update aligns nominal settings and programming screens with the May 2023 patient management recommendations (see enclosed letter). Devices managed with an updated SmartSync tablet are no longer in scope of the May 2023 communication.

**Install the software update as soon as possible.** Follow the instructions to install SmartSync version 3.13.3 and the updated software will be automatically installed - or - connect the SmartSync tablet to the internet, open the SmartSync application and accept the on-screen prompts. Medtronic representatives will work with you to ensure all SmartSync tablets in your facility are updated. Device Instructions For Use (IFU) have been updated and can be found online at <http://manuals.medtronic.com/> and are in process of being distributed. Medtronic representatives may assist you in obtaining updated IFUs.

With the 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. Updates for CareLink Encore™ and CareLink™ 2090 programmers will be released once applicable regulatory approvals have been received and a communication will be sent at that time.

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