Medtronic

Medtronic Ireland Limited
T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

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 P2

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional, Risk Manager:

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 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. 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.

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.

VAT: IE9513488W
Registered in Ireland No. 275799

Sincerely,

Keith Taverner
Principal Regulatory Affairs Specialist UK & Ireland

Enclosure: May 2023 communication

Customer Acknowledgement Form Below

Medtronic

FA1326 Phase II: Customer Acknowledgement Form - Response is required.

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SMARTSYNC SOFTWARE UPDATE

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Hospital / Account Name:_____

Country:_____

- I have read and understand the instructions provided and acknowledge receipt of the **FA1326 November Notification** regarding the SmartSync Software and updated IFU release by signing below.
- I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed as required.
- I confirm that all SmartSync tablets have been updated to version 3.13.3. Number of systems SmartSync tablets updated: _____

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL ACKNOWLEDGEMENT TO:

rs.regulatoryuk-ire@medtronic.com