

Urgent Field Safety Notice **CFx Longevity Estimator Software Error**

CARELINK NETWORK UPDATE RELEASED 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

September 2020

Medtronic Reference: FA887 Phase III

Dear Healthcare Professional and Risk Manager,

This letter is to inform you of a **CareLink™ Network update** (version CLN18) that was recently released to address the CFX longevity estimator display error described in an October 2019 customer communication. The original communication described the potential for Medtronic programmers and CareLink monitoring systems to display an inaccurate longevity estimate for a well-defined subset of approximately 53,100 implanted cardiac devices worldwide.

The first phase of CareLink Network updates occurred in June 2020 and corrected the longevity estimation display error for the following device models. Prior communications related to this advisory are posted on the CRHF Product Performance eSource <http://productperformance.medtronic.com> under Customer Communications.

- Azure™/Astra™ pacemakers
- Percepta™/Serena™/Solara™ CRT-Ps
- Visia AF™/Visia AF MRI™ ICDs
- Amplia MRI™/Claria MRI™/Compia MRI™ CRT-Ds

UPDATE: As of September 2020, the second phase of **CareLink™ Network** updates have been deployed worldwide, and accurate longevity estimates are now being displayed through CareLink for the following device models:

- Viva™/Brava™ CRT-D
- Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs
- Micra™ VR TPS

Model 2090 and Encore Programmer software updates to correct the longevity estimation display error for the Phase 2 devices listed above are currently under submission with worldwide regulatory bodies/notified bodies. Once these programmer software updates are approved, Medtronic employees will update Model 2090 and Encore programmers in your accounts. These programmer updates will then conclude all activities associated with the October 2019 advisory. Devices included in this second phase of updates are not currently supported by Medtronic SmartSync™ Device Manager.

The Competent Authority of your country has been notified of this action. Medtronic records indicate you are following one or more patients with an affected device. Please share this notification as appropriate with others in your organization or to any organization where these devices may have been transferred.

Important Note: Until all programmers are updated, a difference in displayed longevity estimates between programmers and the CareLink Network may be observed. If you have questions regarding the accuracy of any longevity estimate, please contact your Medtronic Representative directly or via Tel no: 01 511 1400

Sincerely,



Keith Taverner, Regulatory Affairs Manager UK & Ireland