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Urgent Field Safety Notice

Unipolar Longevity Estimation Software Error Azure™, Astra™ IPGs and Percepta™, Serena™, Solara™ CRT-Ps

Software Update

Affected Programmers and Remote Monitoring Software Apps	Affected Devices
2090 CareLink™ Programmer 29901 Encore™ Programmer CareLink SmartSync™ Device Manager CareLink™ Network Application Software 2491 MyCareLink Heart™ Mobile Application	**IPGs:** Azure™ XT DR MRI SureScan™, Azure™ S DR MRI SureScan™, Azure™ XT SR MRI SureScan™, Azure™ S SR MRI SureScan™, Astra™ XT DR MRI SureScan™, Astra™ XT SR MRI SureScan™ **CRT-Ps:** Percepta™ CRT-P MRI SureScan™, Percepta™ Quad CRT-P MRI SureScan™, Serena™ CRT-P MRI SureScan™, Serena™ Quad CRT-P MRI SureScan™, Solara™ CRT-P MRI SureScan™, Solara™ Quad CRT-P MRI SureScan™

April 2021

Medtronic reference: FA971

Dear Healthcare Professional,

This letter is to inform you of the availability of software updates to address a potential inaccurate longevity estimate that may occur with the Azure™ and Astra™ family of pacemakers (IPGs) and the Percepta™, Serena™, Solara™ family of cardiac resynchronization therapy pacemakers (CRT-Ps). A longevity estimation error may occur in the early years of device life when a unipolar pacing vector is programmed in the right atrial (RA) lead and/or the right ventricular (RV) lead. No other device features or therapies are impacted. For devices programmed to bipolar pacing in both the RA and RV chambers, the longevity estimates are not affected by this issue.

Through 05 March 2021, Medtronic has received 13 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue. If the software update is not applied to the programmer, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention. Battery performance is not affected by this programmer display error. RRT will alert appropriately, and if patients are followed per standard clinical practice, the risk to patients is minimal.

The longevity estimation error associated with unipolar pacing configurations occurs only in the first half of the device life (prior to 50% depletion of the battery). During this phase, the estimator algorithm utilizes lead impedance as an input. When a unipolar pacing configuration is programmed, the algorithm incorrectly uses the bipolar lead impedance as input (rather than the appropriate unipolar pacing lead impedance). As a result, the algorithm will over-estimate the remaining longevity during this phase. At all times, RRT, Elective Replacement Indication, and End of Service will accurately display on programmers – even if the software update has not yet been installed.

Once the software update is available, a local Medtronic Representative can assist in installing the software on all Medtronic model 2090, Model 29901 Encore programmers, and SmartSync to correct this programmer display issue (see Table 1 below).

Medtronic 2090 and Encore Programmer Software Update	Medtronic SmartSync Software Update
Azure™/Astra™ (SW030) v 8.2 Percepta™/Serena™/ Solara™ (SW040) v 8.4	Azure™/Astra™ (D00U003) v 4.0 Percepta™/Serena™/ Solara™ (D00U004) v 4.0

Table 1: Software updates by device family and programmer

As of 26 March 2021, Medtronic CareLink network has been updated and will display correct longevity estimates for devices affected by this issue. Azure IPG and Percepta/Serena/Solara CRT-P patients remotely monitored via the

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MyCareLink Heart™ mobile app will automatically receive an updated longevity estimate on their mobile app with their next scheduled transmission or within 92 days of their last longevity update, whichever occurs first.

No change in patient management is necessary. Per labeling, the RRT notification can be used to identify when device replacement should be scheduled. There is no need to schedule patients to come in before their next regularly scheduled follow-up visit. The corrective fix for this error is implemented in programmers and the CareLink network. The patient's implanted device does not require an update.

Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will assist with installing software on programmers in your account. Until all SmartSync and Model 2090 and Encore programmers are updated, a difference in longevity estimates may be displayed between programmers and the CareLink network due to this software error.

Please share this notice with those who need to be aware within your organization or with any organization where programmers may have been transferred. The Competent Authority of your country has been notified of this action.

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

Sincerely,

Local/BU Manager