

Urgent Field Safety Notice

SmartSync™ Longevity Estimation Software Error Percepta™, Serena™, Solara™ CRT-Ps Software Update

Affected Programmers and Remote Monitoring Software Apps	Affected Devices
CareLink SmartSync™ Device Manager	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: FA972

Dear Healthcare Professional,

This letter is to inform you of the upcoming availability of a software update for CareLink SmartSync™ Device Managers (SmartSync) supporting Medtronic Percepta™, Serena™, Solara™ cardiac resynchronization therapy pacemakers (CRT-P). This update addresses a SmartSync software issue that results in an overestimation in the displayed longevity of these devices during an approximate 6-month window of time before the device triggers its Recommended Replacement Time (RRT).

Through 09 March 2021, Medtronic has received four (4) complaints due to this issue. No adverse events or permanent patient harm have been reported related to this issue. If the software update is not applied to SmartSync, 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 SmartSync software application uses measured battery voltage to detect when the device is within approximately 6 months of its RRT voltage threshold. It is during this period prior to RRT that the software incorrectly calculates remaining longevity due to an error in the software algorithm.

An overestimation error only occurs when the device is interrogated with SmartSync and the device is within approximately 6 months of its RRT indicator. Correct remaining longevity estimates will be reported through interrogations done via a Model 2090 or Encore programmer, and through CareLink remote monitoring transmissions. Note, other devices supported by SmartSync are not affected by this error.

Software updates will be available for SmartSync to correct this programmer display issue (Percepta™ /Serena™ / Solara™, D00U004, version 4.0). Clinicians may update their SmartSync App by connecting their tablet to the internet and accepting the update. Based on your facility's needs and accessibility, once the software is available, a Medtronic Representative or authorized personnel may assist with updating SmartSync tablets in your account.

Once updated, SmartSync longevity estimates for these devices will no longer be affected by this issue. No change in patient management is necessary. There is no need to schedule patients to come in before their next regularly scheduled follow-up visit. The patient's device does not require an update.

Please share this notice with those who need to be aware within your organization or with any organization where these 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. Questions regarding this information should be directed to your Medtronic Representative.

Sincerely,

Majed Matraji,

Business Manager