Medtronic

Urgent Field Safety Notice

SmartSync Device Managers supporting Azure™ pacemakers, and Percepta™, Serena™, Solara™ CRT-pacemakers

Software Update

June 2020

Medtronic Reference: FA917

Dear Risk Manager/Practice Manager,

Medtronic is writing to inform you of software updates available for SmartSync Device Managers supporting Medtronic Azure™ pacemakers, and Percepta™, Serena™, Solara™ cardiac resynchronization therapy pacemakers (CRT-P).

This update addresses a rare communication sequence during the first device interrogation with a SmartSync Device Manager that may result in the temporary suspension of some device features (i.e., battery measurements, Capture Management™, Atrial Lead Position Check™, EffectivCRT™ algorithms, and AdaptivCRT™). This rare interaction results in temporary suspension of automatic threshold testing and output adjustments, and suspension of auto-optimization of CRT therapy. The issue is unlikely to result in clinical impact to the patient, and features are restored upon next programmer device interrogation or presence of a magnet.

As of 8 May 2020, Medtronic has received sixteen (16) complaints due to this issue. The predicted rate of occurrence for this issue is 0.03% on first interrogation of an Azure, Percepta, Serena, or Solara device with a SmartSync programmer. No adverse events or patient harm have been reported. Based on consultation with the Independent Physician Quality Panel and considering that the issue is unlikely to result in clinical impact to the patient, routine patient follow-up in accordance with standard practice is recommended.

Updates are available for CareLink SmartSync™ Device Manager to address this issue as of 10 June 2020. The SmartSync Device Manager software version 3.2.01 update can be obtained by connecting the tablet to the internet and requesting all application downloads. The software update will modify the SmartSync Device Manager to prevent this issue from occurring; no patient actions are required.

A local Medtronic Representative can assist or advise you on the SmartSync update process as needed.

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

If you have any questions, please contact your Medtronic Representative . Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

Sincerely,

Majed Matraji

Business Manager, CRHF, APS