MEDICAL DEVICE CORRECTION

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

June 2020

Dear Risk Manager/Practice Manager,

Medtronic is writing to inform you of software updates available for CareLink 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 the CareLink SmartSync Device Manager to address this issue. 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 your staff on the SmartSync update process as needed. Medtronic will notify all applicable regulatory agencies and competent authorities about this matter.

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. Questions regarding this information should be directed to the local Medtronic Representative or Medtronic Programmer Technical Services at 800-638-1991.

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,

Kirk Hauge
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm and Heart Failure