Medtronic

Urgent Field Safety Notice

Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q Pacemakers
Software Update

September 2019

Medtronic reference: FA857 Phase II

Dear Implanting Physician, Risk Manager, Biomedical Engineering Manager,

In January 2019, Medtronic issued an urgent Field Safety Norice letter regarding a subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names **Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q series** (see enclosed letter). Devices in the affected subset, when programmed to a dual chamber mode with atrial-sensing, may experience a pacing pause due to a circuit error.

This letter is a courtesy notification that Medtronic has received approval to distribute a software update to address the potential for a pacing pause in these devices (software models SW003 v8.2 Adapta/Versa/Sensia, SW010 v8.2 Relia, SW043 v8.2 Attesta/Sphera, VSF20 v8.2 Vitatron and VSF21 v8.2 Vitatron). No action is required on your part. Follow-up physicians are also receiving a notification regarding the software update with Patient Management Recommendations.

Medtronic Representatives or authorized personnel will be updating all Medtronic CareLink™ 2090 and CareLink Encore™ 29901 Programmers.

We are committed to patient safety and are providing this notification as a courtesy for your information.

If you have any questions, please contact your Medtronic Representative.

Sincerely,

Enclosure:
- January 2019, Urgent Field Safety Notice letter
- Updating a Pacemaker to Correct the Dual Chamber Circuit Error tip card.