



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 Physician or Healthcare Professional,

In January 2019, Medtronic issued an Urgent Field Safety Notice letter regarding a subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brands **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.

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

Patient Management Recommendations

After the new software is installed on the Medtronic CareLink™ 2090 and CareLink Encore™ 29901 programmers, pacemakers will automatically receive the update at the next in-clinic interrogation. This one-time pacemaker update process may result in a slightly longer interrogation time and is likely to temporarily interfere with the real-time waveform display. **Pacing operation is not impacted.**

Following receipt of the software update, pacemakers that were programmed to a pacing mode specifically to avoid a circuit error may be reprogrammed to any pacing mode. Once a device is updated, if the circuit error were to occur, the pacing cycle will automatically reset; this may be observed as a single dropped beat.

Physicians should use medical judgement to prioritize the scheduling of patients to receive the update based on their unique clinical conditions. Consider prioritizing patients who were not able to tolerate programming to a non-susceptible pacing mode and either; have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs.

Additional Information and Actions

Directions for applying these software updates to patient pacemakers and to Medtronic programmers can be found on the enclosed [Updating a Pacemaker to Correct the Dual Chamber Circuit Error](#) tip card.

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. Please share this notification with others in your organization as appropriate.

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

Sincerely,

Local / BU Manager

Enclosure:

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