Medtronic

Urgent Field Safety Notice

Medtronic Conexus™ Telemetry: Update to March 2020 Communication

Software Update

Product Name	Model Number
CareLink™ 2090 Programmer	2090; All Serial Numbers
CareLink Encore™ 29901 Programmer	29901; All Serial Numbers

June 2020

Medtronic reference: FA844 Phase IV

Dear Risk Manager/ Practice Manager,

Medtronic is writing to inform you of cybersecurity improvements to address vulnerabilities related to Medtronic Conexus™ Telemetry. Medtronic has regulatory approval to release a series of updates to address these vulnerabilities.

Conexus telemetry is a proprietary radio frequency wireless communication protocol between Medtronic programmers and certain Medtronic ICDs (implantable cardioverter defibrillators) and CRT-Ds (implantable cardiac resynchronization therapy defibrillators). On 21 March 2019, Medtronic posted a Security Bulletin regarding these vulnerabilities and in March 2020 notified customers about a series of planned updates to address these vulnerabilities. For background information, including a list of devices subject to this communication, see the Security Bulletin at http://www.medtronic.com/security.

A local Medtronic Representative can assist in installing the Conexus™ Telemetry update on programmers in your account. Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions.

During device interrogation with an updated programmer at implant or the next regularly scheduled clinic visit, a patient's device will automatically receive the updated software. There is no need to schedule patients to come in outside of their planned, scheduled visits, as no patient harm has been reported due to this issue. See below the software updates for Conexus Telemetry.

Software updates for Conexus Telemetry
Viva-Brava-Evera (SW016) v8.3
Evera MRI (SW033) v8.4
- includes Primo MRI, Mirro MRI
Visia AF, Visia AF MRI (SW035) v8.2

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 have been transferred.

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

Sincerely,

Medtronic (Schweiz) AG