

Urgent Field Safety Notice

Medtronic Conexus™ Telemetry: Update to June 2020 Communication Software Update Phase 3

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

April 2021

Medtronic reference: FA844 Phase V

Dear Healthcare Professional,

Medtronic is writing to inform you of the third and final phase of cybersecurity improvements to address vulnerabilities related to Medtronic Conexus™ Telemetry. Medtronic received regulatory approval for software updates which are now available 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). For background information, including a list of devices subject to this communication, see the Security Bulletin at <http://www.medtronic.com/security>.

As of 02 March 2021, there have been zero (0) complaints reported due to this issue. No serious adverse events or patient harm have been reported.

Once the software update is available (expected from end of April/beginning of May 2021), 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, 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. As part of the Phase 3 software installation, all Phase 1 and Phase 2 applications will be installed if they were not previously installed.

Phase 1	Phase 2	Phase 3 (Final)
Viva-Brava-Evera (SW016) v8.3 Evera MRI (SW033) v8.4 - includes Primo MRI, Mirro MRI	Visia AF, Visia AF MRI (SW035) v8.2 Claria-Amplia-Compia (SW034) v8.4, v8.5	Protecta, Cardia, Egida (SW009) v8.3

Table 1: Phases of software updates for Conexus Telemetry

Please share this notice with those who need to be aware within your organization or with any organization where devices may have been transferred. 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. If you have any questions regarding this information, please contact your Medtronic Representative.

Sincerely,
Medtronic (Schweiz) AG