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Medtronic

Urgent Field Safety Notice

MyCareLink™ Patient Monitor
Model 24950

May 2016

Medtronic reference: FA719

Dear Physician or Healthcare Professional,

This letter is to inform you that Medtronic has identified an issue with a recent software update for the Model 24950 MyCareLink™ Monitor. According to Medtronic's records, you are currently following one or more patients with MyCareLink™ Monitors that have received this software update and, as a result, are impacted by this issue.

Issue Description: Recently, a new software version was automatically sent to a subset of Model 24950 MyCareLink Monitors. After release, Medtronic identified an issue with the software that prevents implanted device data from being available to clinicians on the CareLink™ Network. While the transmission appears successful to the patient, the transmitted data, including CareAlerts, are not visible to the clinic.

Upon discovering this issue, Medtronic discontinued further distribution of this software update.

Only MyCareLink Monitors associated with Implantable Cardioverter Defibrillator (ICD) or Cardiac Resynchronization Therapy Defibrillator (CRT-D) patients that received the software update are affected by this issue. This issue does not impact the operation of implanted ICD and CRT-D devices.

Customer Actions: In order to restore your ability to receive transmitted data from your affected patients, **Medtronic recommends replacing your patients' MyCareLinkMonitors immediately**. The list of impacted MyCareLink Monitors is attached to this letter. Your Medtronic Representative will be able to assist you with ordering replacement devices.

After receiving the new monitor, clinicians should request that patients perform a manual transmission in order to verify that the monitor is properly transmitting information and that previous device observations are received by the clinic.

In-clinic programmer interrogation may be utilized in the interim until monitor functionality is restored.

Medtronic has notified the Competent Authority of your country of this action.

We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative directly or via Tel No: +353 1 5111400

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

Appendix A: List of impacted serial numbers attached.