



Medtronic

Cardiac Rhythm Heart Failure
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URGENT FIELD SAFETY NOTICE

MyCareLink™ Patient Monitor
Model 24950

May 2016

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.

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: Medtronic has enclosed a list of MyCareLink Monitors associated with your affected patients. In order to restore your ability to receive transmitted data from your affected patients, **Medtronic recommends replacing these MyCareLink Monitors immediately.**

[<Insert local geography instructions for device replacement, recommending a 24950J unit if available.>](#)

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.

Upon discovering this issue, Medtronic discontinued further distribution of this software update. Regulatory agencies have also been notified regarding this situation. We regret any difficulties this may cause you and your patients. Medtronic [<Insert Local Department or Organization>](#) is available to assist patients at [<Insert Local or Toll Free Number>](#). If you have any questions, or if we can be of further

assistance, please contact your local Medtronic Representative or Medtronic [<Insert Local Department or Organization>](#) at [<Insert Local or Toll Free Number >](#).

Sincerely,

[<Country/Region Contact>](#)