



Urgent Field Safety Notice
CareLink™ Monitor - Model 2490C
Important Device Information

April 2016

Medtronic reference: FA705

Dear Healthcare Professional,

This letter is to inform you that Medtronic has identified an issue with a recent software update for the Model 2490C CareLink™ Monitor which may prevent a subset of these home monitors from connecting to the CareLink™ Network through traditional (analogue) landline phone service. According to Medtronic's records, you are currently following one or more patients with home monitors that have received this update and, as a result, are impacted by this issue.

Issue Description: Medtronic has determined that a recent software update was distributed with incorrect telephone number information used by the home monitor to contact the CareLink Network. Monitors that have received this update may no longer be able to connect to the CareLink Network as a result of this error. This inability to connect will prevent the monitor from transmitting implanted device data, including CareAlerts, to the clinic and from receiving future software updates.

This issue does not impact home monitors currently using a cellular or internet accessory (e.g. WireX) to connect to the CareLink Network. Medtronic has included a list of serial numbers impacted by this issue (see appendix A). This data is based on available records until 7 March 2016.

Customer Actions for facilities with patients using impacted 2490C CareLink Monitors: Medtronic advises to resolve this issue by connecting a WireX Cellular Adaptor or WireT Ethernet Adaptor to the patients' existing monitor. This adaptor will restore monitor connectivity with the CareLink Network.

- o WireX adaptors require that patients place the monitor within a cellular network coverage area.
- o WireT adaptors require that patient have internet service.

Your Medtronic representative is available to assist you in ordering a WireX Cellular Adaptor or WireT Ethernet Adaptor to connect to the patients' existing monitor.

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

Medtronic has halted further distribution of this software update and notified the Competent Authority of your country of this communication.

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.

Sincerely,