UPDATE TO MEDICAL DEVICE CORRECTION
Software Update Now Available via MyCareLink™ Patient Monitor
Reveal LINQ™ Insertable Cardiac Monitor (ICM)
Model LNQ11

November 2016

Dear Physician or Healthcare Professional,

In May 2016, Medtronic issued an Update to Medical Device Correction communication that indicated Medtronic was ready to begin applying a software update to Reveal LINQ™ Insertable Cardiac Monitors (ICMs). This update, applied via Encore and 2090 Programmers, addressed a performance issue that affects the Recommended Replacement Time (RRT) alert. This original communication also explained that Medtronic was working on functionality to allow patients the ability to receive this update via their MyCareLink™ Patient Monitor. This update through the MyCareLink Monitor is now ready for deployment.

What is the purpose of this software update?
This MyCareLink Monitor functionality will allow a patient to receive the updated Reveal LINQ RRT software via their home monitor without the need to come into a clinic. Once installed on a Reveal LINQ ICM, this software update will reset RRT & End of Service (EOS) status and re-enable wireless transmissions for devices that have experienced premature RRT / EOS. The update will also prevent the occurrence of premature RRT alerts due to this issue.

How do clinics apply this update to Reveal LINQ ICMs?
During the course of their normal monitoring and follow-up care, patients’ devices can receive the update via a programmer interrogation or home monitor manual transmission. Once the update has been installed on patients’ MyCareLink Monitor, the monitor itself will automatically apply the update to their Reveal LINQ ICM during a subsequent manual transmission. If your patient’s Reveal LINQ ICM is at RRT / EOS, instruct them to complete the following activities to order to receive the update as quickly as possible:

1.) Unplug the MyCareLink Patient Monitor from the wall outlet, wait 10 seconds, and then plug it back in.

2.) Leave your MyCareLink Patient Monitor plugged in and untouched for 24 hours to allow software updates to be successfully installed.

3.) After 24 hours have elapsed, complete a manual transmission using your MyCareLink Patient Monitor.

Patients who are not actively monitored using a MyCareLink Monitor or are using an analogue adaptor to connect to the CareLink Network will need to come into the clinic for interrogation by a programmer that has previously been loaded with the RRT software update.

How can I get more information on this update?
Additional information, including direction on how to apply this update, can be found at MedtronicDiagnostics.com/us/linq-software-update or by contacting your Medtronic Representative. Medtronic Diagnostic Patient Services is available to assist patients at 800-929-4043. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Diagnostic Technical Services at 800-929-4043.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure
UPDATE TO MEDICAL DEVICE CORRECTION
Software Update Now Available
Reveal LINQ™ Insertable Cardiac Monitor (ICM)
Model LNQ11

May 2016

Dear Physician or Healthcare Professional,

In February 2016, Medtronic issued a Medical Device Correction communication that indicated Medtronic Reveal LINQ™ Insertable Cardiac Monitors (ICMs) could experience a performance issue that affects the Recommended Replacement Time (RRT) alert. This original communication, which has been attached for reference, also explained that Medtronic was awaiting regulatory approval of a software update to address this issue.

Medtronic has now obtained the necessary regulatory approvals and is ready to begin applying this software update to all Reveal LINQ ICMs.

What is the purpose of this software update?
Once installed on a Reveal LINQ ICM, this software update will reset RRT & End of Service (EOS) status and re-enable wireless transmissions for devices that have experienced premature RRT /EOS. The update will also prevent the occurrence of premature RRT alerts due to this issue. Refer to the original communication for additional details.

How do clinics apply this update to Reveal LINQ ICMs?
During the course of their follow-up care, patients’ devices can receive the update via a programmer interrogation. Clinics with Reveal LINQ ICM patients will be contacted by Medtronic with instructions on how to install the update via the CareLink™ 2090 or Encore™ Programmer. Once programmers are updated, clinics will be provided further direction by their Medtronic Representative to contact patients who have experienced a premature RRT/EOS status in order to apply the update to individual Reveal LINQ ICMs. For new implants, the updated software will automatically be loaded on the Reveal LINQ ICM during interrogation of the device using a programmer that has previously been loaded with the new software.

Medtronic is also working on functionality to allow patients the ability to receive this update via their MyCareLink™ Monitor. More information will be provided regarding this update method as it becomes available.
How can I get more information on this update?

Additional information, including direction on how to apply this update, can be found at MedtronicDiagnostics.com/us/linq-software-update or by contacting your Medtronic Representative. Medtronic Diagnostic Patient Services is available to assist patients at 800-929-4043. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Diagnostic Technical Services at 800-929-4043.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure
February 2016

Dear Physician or Healthcare Professional,

Our records indicate that you have one or more patients with a Medtronic Reveal LINQ™ Insertable Cardiac Monitor (ICM). Medtronic has identified a performance issue that affects the Recommended Replacement Time (RRT) alert of a small subset of these devices. Medtronic has not received any reports of patient complications or injury related to this issue. No other Medtronic devices are affected.

**Issue Description:** Medtronic has identified an issue with the sensitivity of an algorithm used in the Reveal LINQ ICM that may prematurely trigger the RRT alert in some devices. As of February 12, 2016, Medtronic has observed an occurrence rate of 0.45% of devices experiencing this issue. Battery capacity is not affected and the device will continue to support data collection and manual data transmissions. As stated in Reveal LINQ labeling, the typical device will experience an average of 3 years longevity (refer to the device labelling for the corresponding use conditions). As part of the normal behavior of the device, 30 days after RRT status is reached, Reveal LINQ devices will display an End of Service (EOS) status at which time the device disables automatic wireless alerts and transmissions. Thereafter, patients will still be able to send remote manual transmissions allowing clinics to receive alerts and stored device data. Due to the design of the RRT algorithm, devices are not susceptible to this issue until 200 days (6.5 months) post-implant. As of February 12, 2016 the earliest reported occurrence of RRT is 7.3 months post-implant, with median implant to RRT duration of 16.5 months.

Medtronic is preparing a regulatory submission for a software update to prevent and correct this issue in the field. For those devices that have experienced this issue, the update will reset RRT & EOS status as well as re-enable wireless transmissions. Further information will be communicated once it becomes available. If Reveal LINQ device software is not updated, Medtronic projects that a small percentage of the total patient population (approximately 4%) may experience this issue with their device.

**Patient Management Guidance:** In consultation with our Independent Physician Quality Panel (IPQP), the following patient management guidance is provided:

- Prophylactic device replacement is not recommended and clinicians may continue to monitor Reveal LINQ patients per their clinic’s normal practice for devices that have not triggered an RRT alert.
- After premature RRT alert has been confirmed (directions for confirmation are noted below) and EOS status is displayed, options to continue ongoing monitoring include requesting remote manual transmissions or bringing the patient in for a programmer interrogation until the software update is made available.
- Explant of devices that have experienced a premature RRT alert is not recommended unless the clinician determines that the loss of daily wireless transmissions outweighs the potential complications associated with device replacement.

For assistance with determining if an RRT alert is due to the algorithm sensitivity issue, contact Medtronic Diagnostics Technical Services at 800-929-4043.

- To assess battery voltage status and provide a remaining-longevity estimate, Medtronic Diagnostic Technical Services will require a manual transmission file (obtained via the CareLink® Network or a 2090 Programmer).

Medtronic will offer a supplemental warranty for affected Reveal LINQ devices. Contact your Medtronic representative for information on Warranty Terms and Conditions.

Medtronic has notified appropriate regulatory agencies regarding this communication. We regret any difficulties this may cause you and your patients. Medtronic Diagnostic Patient Services is available to assist patients at 800-929-4043. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Diagnostic Technical Services at 800-929-4043.
Sincerely,

Tim Samsel  
Vice President, Quality and Regulatory  
Medtronic Cardiac Rhythm Heart Failure