

Urgent Field Safety Notice

LINQ II™ Insetable Cardiac Monitoring Systems

Brady, Pause & PVC Detections Disabled Following Partial Electric Reset
Patient Management Recommendations and Retrieval

Affected Model Number	Model Description
LNQ22	LINQ II

June 2021

Medtronic Reference: FA979

Dear Healthcare Professional,

Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).

This letter is to inform you that LINQ II™ insertable cardiac monitors (ICM) that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause, and PVC events to clinicians. Medtronic estimates that 0.21% of LINQ II ICMs have experienced a partial electrical reset resulting in the inability to detect Brady, Pause, and PVC events. While there is potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady, Pause, and PVC episode types will not be reported to the clinician.

- A correction for currently implanted LINQ II ICMs is not available.
- We are requesting that hospitals quarantine all LINQ II ICMs on hospital shelves. Physicians should cease implanting any remaining LINQ II ICMs that may remain in shelf stock and return any unused product to Medtronic.
- There will be an update for future manufactured LINQ II ICMs, which is anticipated to be available mid calendar year 2021.

This letter contains a description of the information known to date and patient management recommendations.

ISSUE DESCRIPTION

Medtronic has identified that LINQ II ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause, and PVC events. A partial electrical reset is normal behavior that can occur when the device detects a possible issue with the device software. However, an error in the partial electrical reset implementation is causing this unintended behavior.

All LINQ II ICM devices currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 37 complaints related to an electrical reset. The projected rate of a LINQ II ICM experiencing a partial electrical reset that results in the inability to detect Brady, Pause, and PVC events is 0.73% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady, Pause, and/or PVC events, and an explant procedure.

If a partial electrical reset occurs, CareLink™ and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady, Pause, and PVC events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing and mark symptoms.

Tachy and AT/AF detections are not affected by a partial electrical reset.

ACTIONS

Medtronic is requesting customers with affected product on hand to take the following actions:

1. Identify and quarantine all unused affected Medtronic LINQ II ICMs.
2. Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
3. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).

PATIENT MANAGEMENT RECOMMENDATIONS

If an electrical reset has never occurred, all detection criteria are being monitored and recorded as programmed. Continue with normal follow-up per local clinic protocols for these patients.

All patients, including those on CareLink, should be carefully monitored for reports of an electrical reset condition.

Follow instructions below.

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. **Note:** Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady, Pause, or PVC events. Review the Brady lifetime episode counter:
 - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
 - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Representative directly or via Tel No: 01 511 1400 for assistance.

Patients with a confirmed partial electrical reset:

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady, Pause, or PVC events, device replacement may be appropriate. Consider the following before device replacement:
 - It is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue.
 - If replacement is desirable, consider Reveal LINQ with TruRhythm™ or alternative ICM. While Reveal LINQ devices are also susceptible to this issue (see correction notice, *Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems Brady & Pause Detections Disabled Following Partial Electrical Reset*), the observed rate is 0.049% for Reveal LINQ with TruRhythm ICMs compared to 0.21% for LINQ II ICMs.

Note: Implanted Reveal LINQ with TruRhythm ICMs have the ability to receive a future software update to correct this issue, which will be implemented via the Model 2090 and Encore™ programmers and is anticipated to be available early calendar year 2022.
 - Future manufactured LINQ II devices will have a correction for this issue implemented during manufacturing pending regulatory approval of the corrective fix, but initial supply may be limited.
- As a reminder, per the LINQ II ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

The Competent Authority of your country has been notified of this action. Please share this notification with others in your organization as appropriate.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have questions regarding the accuracy of any longevity estimate, please contact your Medtronic Representative directly or via Tel No: 01 511 1400

Medtronic

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland