Attachment A: Serial No of Medical Device

Batch No.
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RLA148317G
RLA148278G
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RLA142236G
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RLA190062G
RLA180822G
RLA187483G
RLA178435G
RLA164300G
RLA178440G
RLA164299G
RLA159803G

APPENDIX B: Customer Communication letter

Medtronic

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Medical Device Correction

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems
Brady & Pause Detections Disabled Following Partial Electrical Reset

2nd June 2021

Attention: Risk management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Affected Model Number	Model Description
LNQ11	Reveal LINQ with TruRhythm

2nd June 2021

Dear Risk Manager or 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 Reveal LINQ™ with TruRhythm™ insertable cardiac monitors (ICMs).

This letter is to inform you that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events to clinicians. Medtronic estimates that **0.049%** of Reveal LINQ with TruRhythm ICMs have experienced a partial electrical reset resulting in the inability to detect Brady and Pause events. While there is a 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 and Pause episode types will not be reported to the clinician.

- Currently implanted/distributed Reveal LINQ with TruRhythm ICMs will receive a future software update to correct this issue delivered via the Model 2090 and Encore™ programmers. The corrective fix is anticipated to be available. Availability of the software will be communicated once Medtronic has obtained the necessary regulatory approvals.

- There will be an update for future manufactured Reveal LINQ with TruRhythm ICMs, which is anticipated to be available beginning late calendar year 2021. Medtronic will inform physicians once this manufacturing update is implemented into newly manufactured Reveal LINQ with TruRhythm ICMs.

ISSUE DESCRIPTION

Medtronic has identified that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause 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 Reveal LINQ with TruRhythm ICMs currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 87 complaints related to an electrical reset. The projected rate of a Reveal LINQ with TruRhythm ICM experiencing a partial electrical reset that results in the inability to detect Brady and Pause events is 0.056% 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 and Pause events, and an explant procedure.

If a partial electrical reset occurs, CareLink™, Model 2090 and Encore programmer software and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady and Pause 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.

HOSPITAL RISK MANAGER ACTIONS

1. 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).
2. Complete the enclosed Confirmation Form and provide to your Medtronic representative.

PATIENT MANAGEMENT RECOMMENDATIONS

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 Representative 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 or Pause 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 your Medtronic Representative.

Patients with a <u>confirmed</u> 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 or Pause events, 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 patients require monitoring for Brady and/or Pause events, and it is not acceptable to wait for the software update to become available (see details below), consider device replacement. Recognize that exposure to EMI could introduce this issue for new device implants that occur before the manufacturing update is implemented anticipated late calendar year 2021.

- As a reminder, per the Reveal LINQ with TruRhythm ICM's Instructions for Use, contact your Medtronic representative anytime an electrical reset occurs.

FUTURE SOFTWARE UPDATE AVAILABILITY

Medtronic is developing a programmer-delivered software update to correct this issue for Reveal LINQ with TruRhythm ICMs currently implanted or in distribution. Anticipated availability is early calendar year 2022 ; Medtronic representatives will inform you of the availability and work with you to install the software onto clinic and hospital 2090 and Encore programmers. LMM application software will be unable to deliver the software update for this issue. In order for patients with Reveal LINQ with TruRhythm ICMs to receive the update, the device will need to be interrogated with an updated 2090 or Encore programmer.

Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate.

Please notify your Medtronic representative of any adverse events or quality problems associated with your use of this product.

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

Sincerely,

Sincerely,
Diana Teo
Medtronic QRA Head
Singapore and Malaysia

Sincerely,
Chloe Tan
Medtronic QRA Head
Indochina and Frontier Market Plus

Sincerely,
Parichart Bunjobchokchai
Medtronic QRA Senior Manager
Thailand

Enclosure: Customer Confirmation Form

Medtronic

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Customer Confirmation Form

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Physician / HCP/Distributor :	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

In the event you no longer implant and/or manage patients with Reveal LINQ™ please provide a detailed explanation in the space below so that Medtronic's records can be updated accordingly. Thank you

Note: The addressee may continue to receive reminders of this notice until a response is received.

By signing this form, I confirm that I have read the Medical Device Correction Notification Letter, listed below dated 2nd June 2021 from Medtronic and taken appropriate action for Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems - Brady & Pause Detections Disabled Following Partial Electrical Reset

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____