

Medtronic

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UPDATE TO A MEDICAL DEVICE CORRECTION

Software Update Available

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

Brady & Pause Detections Disabled Following Partial Electrical Reset

Programmers / Application Software	Affected Product
2090 CareLink™ Programmer	Reveal LINQ™ with TruRhythm
29901 Encore™ Programmer	
Application Software SW026	

09 March 2022

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

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 of **the availability of a Medtronic CareLink (2090) and Encore (29901) Programmer software update, SW026 version 8.3**, to correct a low rate of occurrence issue with Reveal LINQ ICMs (0.049%) where Brady and Pause detections are disabled following a partial electrical reset.

Reveal LINQ ICMs that are interrogated in-office with an updated 2090 or Encore programmer will automatically receive a corrective fix and will no longer be susceptible to this issue. This software update cannot be delivered with the Reveal LINQ™ Mobile Manager (LMM). Until the update is installed, future partial electrical resets may disable Brady and/or Pause detections as described in the 02 June 2021 communication. Reveal LINQ ICMs manufactured from September 2021 on have already received the software update.

Please work with your local Medtronic Representative to update all 2090 and Encore device programmers. In addition, Medtronic requests you follow the below patient management recommendations.

Patient Management Recommendations:

- Reveal LINQ ICMs with a confirmed partial electrical reset will receive the corrective fix for this issue immediately by the device clinician completing the following steps:
 - a. Interrogate the ICM with an updated 2090 or Encore programmer (software application SW026 version 8.3). The corrective fix is automatically installed during initial interrogation. To confirm an ICM has successfully received the update, refer to Appendix A.
 - b. Per the Instructions for Use (IFU), following any electrical reset, verify ICM parameters are set appropriately for the patient and reprogram if necessary.

- For Reveal LINQ ICMs that have not experienced a partial electrical reset, an update will occur during the next in-clinic visit in which an updated Model 2090 or Encore programmer installed with software application SW026 version 8.3 is used to interrogate the ICM. Partial electrical resets will disable Brady and/or Pause detections as described in the June 2021 communication until the update is installed on to the patient's ICM.
 - For patients who are actively followed on CareLink, continue routine monitoring for CareAlerts and verify notification settings for electrical resets.
 - Per the IFU, notify your Medtronic representative if an electrical reset occurs. If a partial electrical reset is confirmed, the patient's ICM will require reprogramming.
 - During the programmer session, the corrective fix will be installed automatically.

Please complete the enclosed Confirmation Form, and hand or scan then email back to your local Medtronic representative.

Medtronic has notified all applicable regulatory agencies about this matter.

Per your facility's standard medical device complaint procedures, report to your local Medtronic representative any adverse reactions or quality problems if the quality issue described above has been observed.

We regret any difficulties this issue may have caused you or your patients. We remain dedicated to ensuring the highest level of quality and will continue to monitor ICM performance to ensure we meet your needs and those of your patients.

Sincerely,



Diana Teo
Medtronic QRA Lead
Singapore and Malaysia



Chloe Tan
Medtronic QRA Lead
Indochina and Frontier Market Plus



Parichart Bunjobchokchai
Medtronic QRA Lead
Thailand

APPENDIX A

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

SOFTWARE UPDATE AVAILABLE

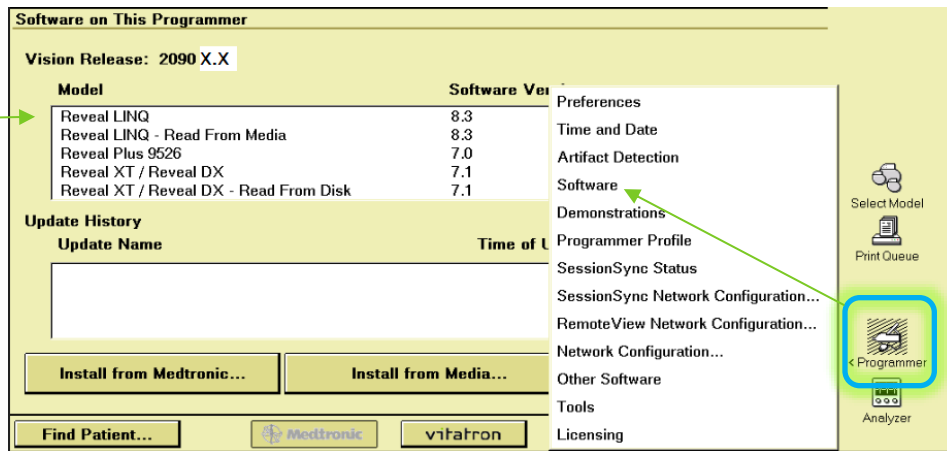
Brady & Pause Detections Disabled Following Partial Electrical Reset

How do I update my Model 2090 and Encore programmers with the Reveal LINQ with TruRhythm software described in the November 2021 communication)?

Software update SW026 version 8.3 can be installed onto all Model 2090 or Encore programmers through either the Medtronic Software Distribution Network (SDN) or via a USB. Medtronic representatives will work with you to install the software.

How do I confirm if a Model 2090 or Encore programmer has already been installed with the updated software (SW026 v8.3)?

From the *Find Patient* screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.



How do I confirm if a patient's Reveal LINQ ICM has received the software update?

Clinicians can confirm if a patient's ICM has received the software update by verifying the Device Configuration ID via a 2090 or Encore programmer (LMM will not display the Configuration ID). To locate the Device Configuration ID, enter a follow-up session and Print the Parameters Report. All Reveal LINQ ICMs that have received the software update will have their Configuration ID ending in a "1" (e.g. X-X-X-1).

NOTE: The Reveal LINQ Device Configuration ID can be viewed on CareLink beginning January 2022 after a manual transmission is completed by the patient.

Parameters			
Symptom	Four 7.5 min Episodes		
Detection	Interval (Rate)	Duration	
Tachy	Off	340 ms (176 bpm)	16 beats
Brady	Off	2000 ms (30 bpm)	4 beats
Pause	Off		3 sec
AT/AF Detection			
AT/AF Detection	Off		
Sensing			
Sensitivity	0.035 mV (35 µV)		
Blank after Sense	300 ms		
Sensing Threshold Decay Delay	200 ms		
Device Data Collection			
Reason for Monitoring	Suspected AF		
Device Date/Time	26-Aug-2021 06:44		
Wireless Transmission Time	00:00		
Wireless Data Priority	Pause, Tachy, Brady		
Device Data Collection	On		
Device Information			
Device	Medtronic REVEAL LINQ LNO11 RLA511585S Implanted: 23-Mar-2021		
Device Configuration ID	0404-1		
History			

Confirmation Form

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29901 Encore™ Programmer	
Application Software SW026	

PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Distributor/HCP:	Name:
Address:	Contact:
Phone no:	Email:
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.

Programmer Model	Serial Number	Remarks

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

Thank you for providing previous confirmation for Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems - Brady & Pause Detections Disabled Following Partial Electrical Reset.

By signing this form, I confirm that I have read the following communications related to Reveal LINQ with TruRhythm ICMs;

- The original 02 June 2021 notification of the issue
- The notification that updated software is available, dated 09 March 2022

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

For questions, contact your local Medtronic Field Representative.

Use this page *****ONLY IF***** the space in the previous page is not enough

Programmer Model	Serial Number	Remarks

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

Use this page *****ONLY IF***** the space in the previous page is not enough