

Urgent Field Safety Notice

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

Brady & Pause Detections Disabled Following Partial Electrical Reset
Software Update Available

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

November 2021

Medtronic Reference: FA978 Phase II

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 (the original June 2021 communication is enclosed).

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 June 2021 communication. Reveal LINQ ICMs distributed from mid-October 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.

The Competent Authority of your country has been notified of this action.

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. If you have questions, please contact your Medtronic Representative.

Sincerely,

[Local / BU Manager](#)

Enclosure:

- Appendix A
- June 2021 Field Safety Notice

APPENDIX A

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

Brady & Pause Detections Disabled Following Partial Electrical Reset

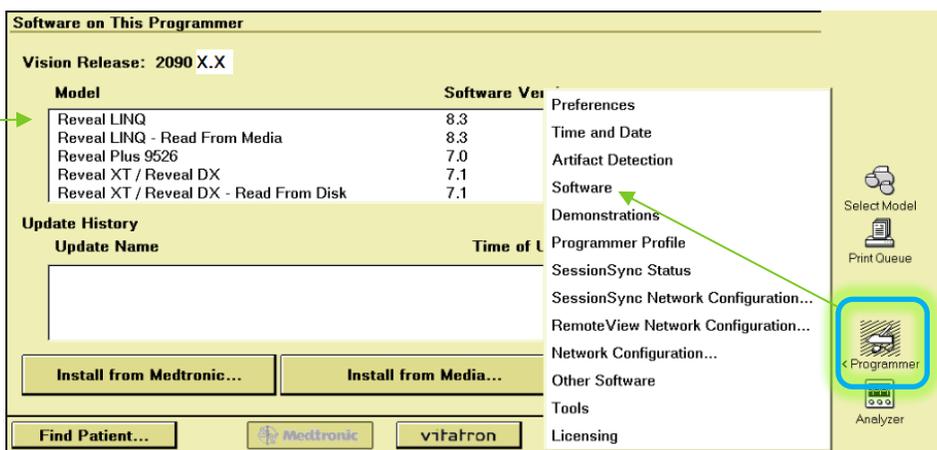
Software Update Available

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			
Symptom	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 DateTime		25-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 LINQ11	RLA511585S
Device Configuration ID	0-0-0-1		
Implanted: 23-Mar-2021			
History			