

### URGENT FIELD SAFETY NOTICE

#### Medtronic LINQ II Insertable Cardiac Monitoring Systems

Re: Brady, Pause & PVC Detections Disabled Following Partial Electrical Reset

CareLink™ SmartSync™ Device Manager Application	Implantable Device Models	
LINQ II ICM Application D00U024 v. 1.4.0 (or higher)	LNQ22	

#### SOFTWARE UPDATE AVAILABLE

February 2024

#### Medtronic Reference FA979

< For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019977>

Dear Risk Manager / Health Care Professional,

This is a follow-up to the Medtronic June 2021 advisory for LINQ II™ (LNQ22) insertable cardiac monitors (ICMs) distributed prior to July 2021 which described inhibited Brady, Pause, and PVC detection following a partial electrical reset. The June 2021 customer advisory letter is enclosed. LINQ II ICMs distributed starting July 2021 are not subject to this partial electrical reset behavior.

A software update is now available for identified LINQ II ICMs and can be assessed through updated CareLink SmartSync Device Managers (SmartSync). Once LINQ II ICMs are updated, they will no longer be susceptible to the described partial electrical reset behavior. An in-person clinic visit is required for the software update.

- For patients monitored on CareLink, Medtronic will monitor monthly through 1 August 2024 for instances of a reset and provide awareness to your clinic in the event of a reset event so clinicians may consider installing a software update.
- For patients not monitored on CareLink consider bringing your patient into clinic to install this software update.

See Appendix A for instructions on using an updated SmartSync to load new software on LINQ II ICMs. Once LINQ II ICMs are updated, they will no longer be susceptible to the described partial electrical reset behavior. If needed, Medtronic representatives are available to work with you to install or update the SmartSync application(s) on your tablet.

Please share this information with clinicians in your facility who provide follow-up care for patients with LINQ II ICMs released prior to July 2021 and complete the enclosed Confirmation Form to acknowledge receipt of this notification.

We regret any difficulties this issue may have caused you or your patients. If you have questions regarding this communication, please contact your local Medtronic representative.

Sincerely,

Local / OU Manager

Enclosure: June 2021 Communication

#### APPENDIX A: Updating LINQ II ICM device software with SmartSync

- Confirm that the prerequisite SmartSync App version 3.15.3 or higher is installed, and all updates have been accepted. Refer to the latest Software Release Notes (August 2023 or later) for instructions. Note that SmartSync versions prior to 3.15.3 may result in a lock out - do not use prior SmartSync version with LINQ II.
- 2. PRESS the grey button on the Patient Connector to confirm your connection and continue.

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	89%	
NOT CONNECTED BASE	TABLET Apple iPad 16.1	CONNECTING TO PATIENT CONNECTOR S/N:RFA000122A
CONNECT TO BASE	TIENT CONNECTOR	CONNECT TO PATIENT
- ECG cable connections - Analyzer application - Conexus communication v device	Press the grey button on the Patient Connec to confirm your connection and continue. To select a different Patient Connector, close th window.	tor is
CONNECT		Select a different patient connector

3. Once connection with the Patient Connector is established, SELECT "Use Wireless telemetry for device interrogation"

4. PLACE the patient connector on top of the LINQ II ICM.



- 5. PRESS the grey button on the patient connector.
- 6. The app will start searching for the available LINQ II ICM.

Medtr	<b>ronic</b>   CareLir	nk SmartSync™		?
NOT	CONNECTED BASE	TABLET Apple iPad 16.4.1	CONNECTED PATIENT CONNECTOR	
C Connect the - ECG cable	Searching for impl	RESS anted devices ice is not found, try repositioning the pati	ent connector.	
- Analyzer a - Conexus c device	LINQ II <sup>™</sup> LNQ22	RLB254637G	TestFirstName TestLastName DOB: Feb/01/1937	
			CANCEL CONTINUE	LASH

7. Once connected, the available LINQ II ICM will appear on the list. SELECT the LINQ II ICM from the list and SELECT "Continue" to pair.

8. The software update will download to the LINQ II ICM, and the progress bar will indicate when the installation is complete.

LINQ II™ LNQ22		≡	LINQ II™ LNQ22		≡
TestFirstName TestLastName	S/N : RLB254637G	DOB : Feb/01/1937	TestFirstName TestLastName	S/N : RLB254637G	DOB : Feb/01/1937
	DEVICE SOFTWARE UPDATE IN PROGRESS			DEVICE SOFTWARE UPDATE IN PROGRESS	
	Connecting to the device			Interrogating	
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9. A confirmation screen will appear indicating the successful download of the LINQ II device software (see image below).

LINQ II™ LNQ22		100%=D - (°) »»			≡	
TestFirstName TestLastNa	ame		S/N : RLB254637G	DOB	: Feb/01/1937	
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Detient	lama	. TeatFirstName	Testi estNeme			
DOB	Patient Name : TestFirstName TestLastName					
Device	Device : LINO ITM LNO22					
S/N	S/N : RLB254637G					
Device 0	Configuration ID	: 1-0-0				
The dev	ce software update l	has been successfi	ul.			
To change	programming, view diag	nostics and all other in	nformation GO TO MANAGE LINQ (LMM) app.			
60		(1 MM)		END SESSION		
	TO MANAGE LING		VIEW OPDATE REPORT	END SESSION		
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