

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.

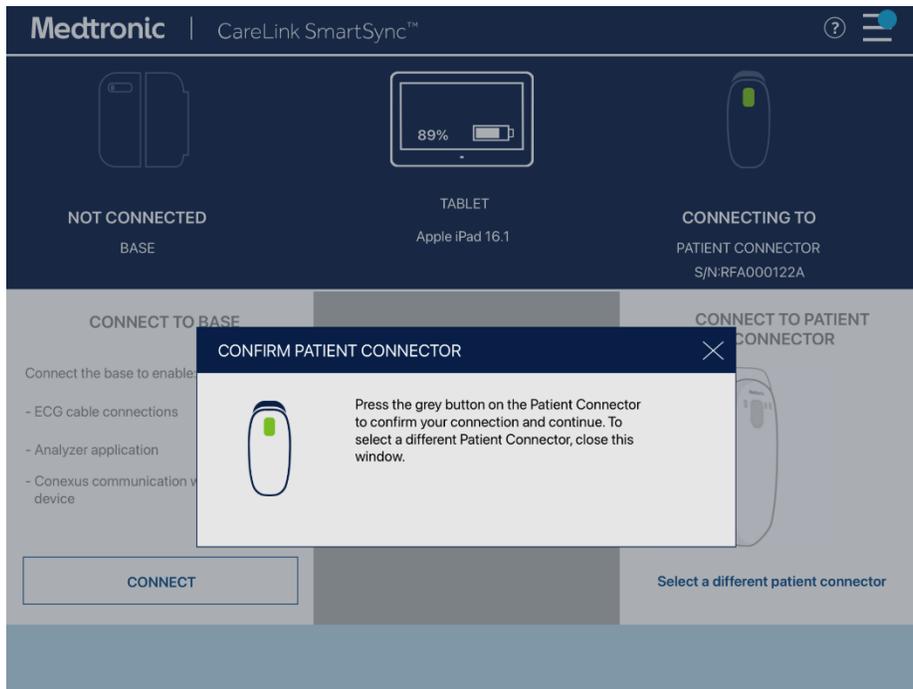
Sincerely,

Local / OU Manager

Enclosure:
June 2021 Communication

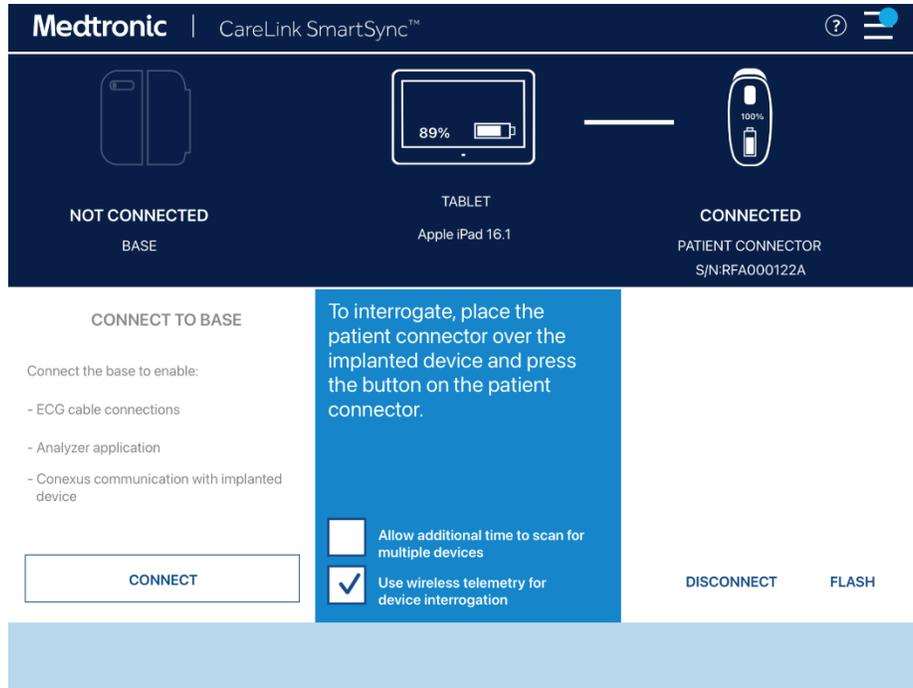
APPENDIX A: Updating LINQ II ICM device software with SmartSync

1. 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.



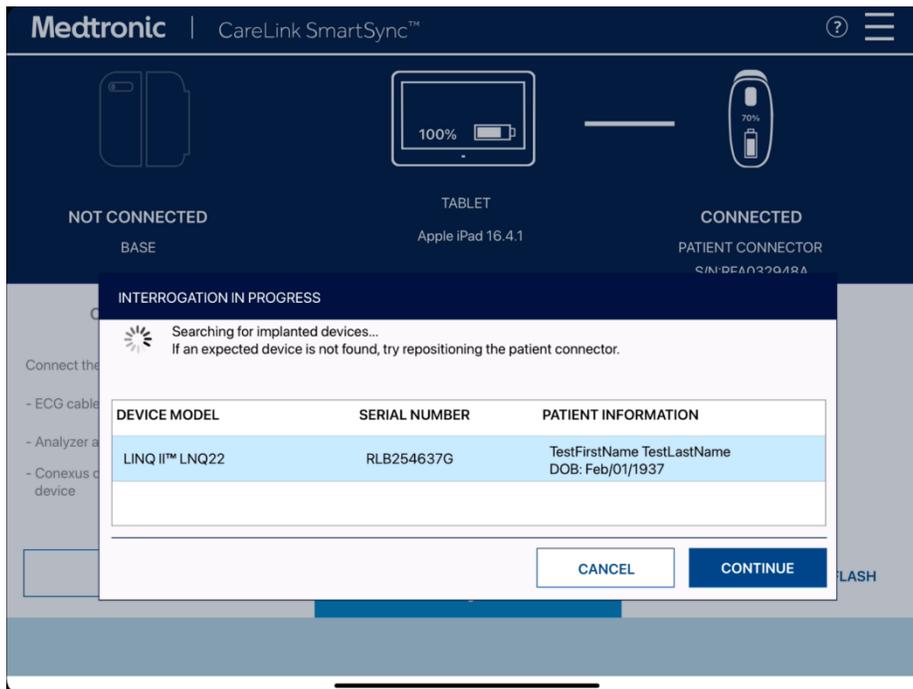
3. Once connection with the Patient Connector is established, SELECT "Use Wireless telemetry for device interrogation"

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



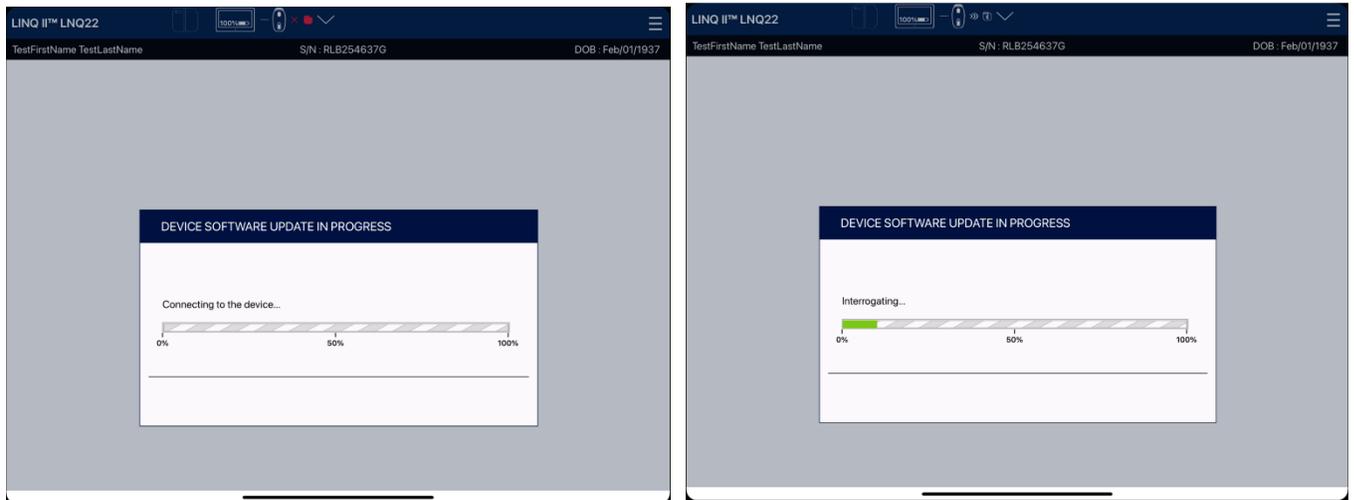
5. PRESS the grey button on the patient connector.

6. The app will start searching for the available LINQ II ICM.



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.

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



- A confirmation screen will appear indicating the successful download of the LINQ II device software (see image below).

