

**Important Supplemental Information to the
Urgent Field Safety Notice**
LINQ II™ Insertable Cardiac Monitoring Systems
Brady, Pause, & PVC Detections Disabled Following Partial Electric Reset
Notification

Affected Model Number	Model Description
LNQ22	LINQ II

<February 2022>

Medtronic Reference: FA979 phase III

Dear Healthcare Professional,

In mid-2021, Medtronic issued a Medical Device Correction for LINQ II™ Insertable Cardiac Monitors (ICMs); the two communications (dated June 2021 and August 2021) of this advisory are enclosed. This letter provides supplemental information to that advisory.

The June 2021 advisory notified customers of the potential for LINQ II ICMs that had experienced a partial electrical reset that disabled Brady, Pause, and PVC event detection and reporting to clinicians. In the event that Medtronic’s data indicated specific devices that had experienced a partial electrical reset, clinicians received a supplemental letter with the details of those devices.

Since June 2021, Medtronic has implemented continuous monitoring of all CareLink™ enrolled LINQ II patients for partial electrical resets as an assist to clinicians’ efforts to identify affected devices. As of <date>, we have identified one or more LINQ II devices associated with your hospital/clinic that have experienced a partial electrical reset and that are no longer detecting Brady, Pause, and PVC events as designed:

<Insert device model/device serial number>

If you have already identified one or more of the above devices and contacted Medtronic, no further action is needed for that device. Consult the original advisory and materials (enclosed) for more information about this issue, how to identify affected devices, and to review patient management recommendations.

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.

If you have any questions, please contact your local Medtronic Representative <XXXX>

Sincerely,

Local/BU Manager

Enclosures:

- June 2021 Medical Device Correction Notification
- August 2021 Update: Medical Device Correction Notification
- Identification of Updated LINQ II ICMs; TipCard to Compare GTINs