ANZCDACC Product Hazard Alert November 2023 - Medtronic LINQ II

Device:
Medtronic LINQ II Implantable Cardiac Monitor (LNQ22)

TGA Reference:
RC-2023-RN-00930-1

Australian Register of Therapeutic Goods (ARTG):
391830 and 355313

Medsafe Notification Reference:
#32047 200218-WAND-6U5Z2T

Advisory grade TGA:
Class II

Description:
A population of LINQ II insertable cardiac monitors (ICM), manufactured prior to September 2022, underwent a manufacturing process that may allow for moisture to impact electrode performance. This may lead to amplified noise and/or signal reduction, and may interfere with the recording of cardiac rhythm.

Number of devices affected in Australia and New Zealand:
595

Presentation:
This manufacturing defect may lead to amplified noise, which is different from occasional noise due to device positioning, patient activity of external electromagnetic interference. This may lead to missed diagnosis and / or delayed medical intervention.

Rate of occurrence:
As of August 2023, Medtronic has analysed and confirmed 7 returned devices, which have exhibited these characteristics. The potential for this behaviour is limited to 30074 device manufactured prior to September 2022, 595 of which were implanted in Australia and New Zealand.

Based on CareLink transmission data, the manufacturer estimates that this issue may affect 1.26% of these devices over a 4.5 year period.

Recommendation:
Where possible, enrollment in the Medtronic CareLink program is suggested. This will allow Medtronic to apply recurring algorithmic searches for the characteristic noise pattern, and will allow for earlier notification to the clinician. No further action is required for patients regularly transmitting to CareLink.

Consider removal and/or replacement of the device if this behaviour is encountered frequently.

Devices susceptible to this behaviour can be identified via serial number search on the manufacturers website at http://productperformance.medtronic.com/.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA:
Online: **https://www.tga.gov.au/reporting-problems**

In New Zealand, report to Medsafe:
Post: **Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145**
Email: **devices@health.govt.nz**