



The Cardiac Society  
of Australia and  
New Zealand

Level 6 Suite 601  
1 Castlereagh Street  
Sydney NSW 2000  
Ph 61 2 9226 7900  
E [info@csanz.edu.au](mailto:info@csanz.edu.au)  
[www.csanz.edu.au](http://www.csanz.edu.au)  
ABN 23 003 635 505

## **ANZCDACC Advisory Notice 7<sup>th</sup> March 2016**

### **Device: Medtronic Medtronic Reveal LINQ™ Insertable Cardiac Monitor (ICM) Model LNQ11 8042, 8042B, 8042U**

**Advisory Grade TGA:** Hazard Alert  
**ANZDACC Advisory Grade:** Low risk

**Number at risk in Australia and New Zealand:** Numerous

**Risk:** There is the potential for an issue with the sensitivity of an algorithm used in the Reveal LINQ ICM that may prematurely trigger the RRT (Recommended Replacement Time). As of February 12, 2016, Medtronic has observed an occurrence rate of 0.45% of devices experiencing this issue. Battery capacity is not affected and the device will continue to support data collection and manual data transmissions. At 30 days after RRT status is reached, Reveal LINQ devices will display an End of Service (EOS) status at which time the device disables automatic wireless alerts and transmissions. Patients will still be able to transmit remote manual transmissions allowing clinics to receive alerts and stored device data. Due to the design of the RRT algorithm, devices are not susceptible to this issue until 200 days (6.5 months) post-implant.

**Description:** Medtronic has identified a performance issue that affects the RRT alert which occurs prematurely in of a small subset of these devices. This occurs when there is sufficient battery longevity and the device will continue to function but requires manual transmissions when RRT changes to EOS.

**Presentation:** Patients will not present independently however interrogation by CARE link will highlight premature RRT. The patient will be required to transmit manually as automatic transmissions will no longer work at EOS

**Advice:** The device is functioning normally and should not be replaced. The patient's management should continue normally as before. Medtronic will release a software update to prevent and correct the issue.