

ANZCDACC Advisory Notice 29th November 2017

Device: Medtronic MyCareLink Remote Monitors: Models 24950 and 25000

TGA Reference: RC-2017-RN-01009-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Description:

Remote monitoring a patient with multiple (2 or more) Medtronic Cardiac Implantable Electronic Devices (CIEDs) can be inconsistent / unreliable.

This may mean a patient in this case;

1. is unable to transmit the data with their remote monitor from **any** of the CIEDs or
2. could transmit device data unintentionally from one of the CIEDs when attempting to transmit from another device implanted in the same patient.

In-clinic interrogation of multiple Medtronic CIEDs in the same patient can continue to be done reliably via a programmer (Model 2090 or Encore). i.e. The inability to reliably communicate with multiple Medtronic CIEDs impacts remote monitoring systems only.

Risk:

No permanent injury or death has been reported as a result of this issue.

Presentation:

These potential impacts could lead to missed remote monitoring alert transmissions or device follow up reports.

Advice:

Medtronic and the ANZCDACC do not recommend the use of remote monitoring for patients with multiple implanted Medtronic CIEDs and clinicians should take this into account when implanting an additional Medtronic CIED or preparing a patient for remote monitoring.

For example, if a Medtronic pacemaker is implanted in a patient with an existing Reveal LINQ Insertable Cardiac Monitor (ICM), you may not be able to monitor either device remotely. In this example, if a physician determines that it is appropriate, removal of the Reveal LINQ ICM will allow for remote monitoring of the Medtronic pacemaker.

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 dprgould@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@moh.govt.nz

Fax 04 819 6806