



The Cardiac Society  
of Australia and  
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## **ANZDACC Advisory Notice: 30 August 2016**

### **Device: Medtronic Viva Cardiac Resynchronisation Therapy Defibrillators and Evera Implantable Cardioverter Defibrillators**

Note: The advisory has only been issued for one particular batch of these generators consisting of 78 devices worldwide. No other Viva or Evera devices are affected.

**Advisory Grade: TGA: Hazard Alert**  
**ANZCDACC: Urgent**

### **Number at risk in Australia 3 and New Zealand 0: 3 (all Evera VR devices)**

**Risk:** Unpredictable abrupt battery failure in subset of devices as a result of component failure of the telemetry module resulting in loss of function of the implantable cardioverter defibrillator. The current confirmed failure rate of the affected batch is 9% (7 of 78 devices) with overall failure predicted to be 17% (13 of 78 devices). There is no way of predicting which devices may fail.

**Description:** The component was inappropriately flexed during production and subsequently cracks and shorts through the circuit boards. This results in a low resistance path in the circuit that has been reported to cause battery depletion in less than 7 days in some cases.

**Presentation:** Patients have presented with shortness of breath, pocket heating and low heart rates requiring early generator change. Patients who are pacing dependent are expected to present with pre syncope and/or syncope.

On interrogation of affected devices the following may be observed:

- One or more electrical resets displayed as observation on the programmer
- No pacing or defibrillation therapy output
- No telemetry
- Programmer screen display of "SERIOUS DEVICE MEMORY FAILURE"

Patient audible alerts and CareAlerts may not function as a result.

**Advice:** The treating physicians of the three identified patients in Australia have been notified. As the rate of predicted failure in this group is high (17% predicted overall failure rate) and as such device replacement should be strongly considered. The Committee acknowledges however this needs assessment on an individual basis and ultimately is the decision of the patient and primary care physician. However the Committee recommends patients who are pacing dependent and have a secondary prevention indication for implantable cardioverter defibrillator or recent therapies for ventricular arrhythmias should have early device replacement due to the unpredictable nature of the component failure.

Patients who are not suitable for device replacement require more intensive follow up. Patients should have their audible alarm for Low battery Voltage RRT programmed “On High”, however it should be noted that the alarm may not sound if the battery is depleted.

All patients should be monitored with remote monitoring with at least weekly transmissions scheduled.

Alternatively, or in combination patients can place a supplied magnet (free of charge from Medtronic) over the device to check the audible tone confirming either normal device function or an alarm requiring immediate review. If no audible tone is emitted then immediate review is required. This application needs to be performed on a daily basis.

Patients should be informed of possible new symptoms or symptom progression associated with device failure and importance of regular transmission and/or magnet application.

ANZCDACC will continue to advise if the issue becomes more widespread.