ANZCDACC Advisory Notice 9th July 2018

Device: Medtronic Entrust VR/DR/AT ICDs.
Models: D154ATG; D154VRC

TGA Reference: RC-2018-RN-00833-1
Australian Register of Therapeutic Goods (ARTG): 119254; 119256

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Semi-Urgent

Description:
Under certain circumstances, the device may display an immediate End of Life (EOL) Observation with no prior ERI alert. Though no ERI alert is triggered, there may not be enough remaining battery capacity to charge the high voltage circuits, resulting in an excessive charge time EOL Observation, leading to a loss of high voltage and anti-tachycardia pacing therapy. Bradycardia therapies will continue to operate as expected.

- This is not due to the battery losing charge at a higher rate. A device near end of life operating under low current drain conditions may not sufficiently decrement battery voltage enough to satisfy the ERI criteria (three (3) consecutive nightly measurements of < 2.614V), however battery capacity continues to be consumed through everyday use. Eventually the battery capacity reaches a point where it can still support bradycardia therapies, has not met ERI criteria but no can longer charge the HV capacitors within the time window allowed by the device before disabling the charging circuits. In EnTrust devices, the charging circuits are disabled (along with ATP therapies) if the charge time exceeds 30 seconds on three consecutive charge attempts.

Through 15 June 2018, Medtronic has confirmed 25 charge timeout events related to this issue, with no (0) patient deaths or complications. All events occurred during routine capacitor formation or in-clinic charge testing. Twenty-one (21) events occurred with no ERI alert; four (4) events followed an ERI alert. Time from implant to the devices experiencing the issue ranges from 7.9 – 11.7 years.

Number of devices affected in Australia and New Zealand:
Numbers are still being finalised.
There are 470 potentially active devices although the number of devices which remain active are likely to be substantially less based on the device projected longevity and implant date.

Presentation:
If this issue has occurred, an “EOL: replace device immediately” observation will be displayed on the QuickLook report on the programmer or on a manual (inductive) remote follow-up transmission on Carelink (this is not a wireless device).

Patients may present with this issue before or after the Elective Replacement Indicator (ERI) alert;

1. as an 'Excessive Charge Time End of Life (EOL)' alert from;
    a. a routine capacitor formation with an auditory device alert if turned on (nominally off)
    b. OR following a manual in-clinic charge test
    c. OR as a coincidental finding on a routine review (if the alert is off or the patient did not hear or respond to the alarm).
2. With the clinical presentation of an untreated ventricular arrhythmia including presyncope, syncope, serious injury and sudden death.

Rate of occurrence:
EnTrust ICDs were last manufactured in 2010. Approximately 25,000 sold devices globally are in-scope of this advisory, with an estimated 2,770 of those devices remaining actively implanted worldwide. The rate of occurrence in remaining active devices is estimated to be 0.00098 in single chamber ICDs and 0.00005 in dual chamber devices.

Recommendation:

- Schedule an in-office patient follow-up as soon as possible to assess the potential for this issue per the steps described below.
- Ensure the 'Excessive Charge Time EOL' and the 'Low battery Voltage ERI' patient alerts have been programmed to "On-High".
- *Demonstrate the alert tone in clinic to make the patient aware of it.
- Instruct patients to contact their follow up clinic if they hear device alert tones.
- **If this issue has occurred,** an "EOL: replace device immediately" observation will be displayed on the QuickLook report. **Schedule device replacement immediately.**

Additionally, the following actions are recommended to help ensure patient safety and effective high voltage therapy remain as the battery voltage approaches its nominal **2.61 ERI threshold**:

If Battery Voltage ≤ 2.64V:	
Prophylactic device replacement should be strongly considered since the device is near its elective replacement and additional programming would provide only minimal additional months of service. For patients for whom it is determined that delaying replacement is clinically desirable, contact Medtronic Technical Services to discuss further risk mitigation.	
If Battery Voltage > 2.64V:	
Step 1:	If the Auto-Cap Formation Interval is set to "Auto", reprogram the value to "6". The change from an "Auto" value to a fixed numeric value will ensure that the first excessive change time will trigger an audible patient alert rather than the second (1 month later)
Step 2:	Conduct an in-clinic manual high voltage charge. DO NOT Dump the test charge as it will dissipate on its own and allow for capacitor reformation to occur.

Step 3: Retrieve Data after the test charge:

- **If charge time is less than 16 seconds**, no further immediate action is required. Review the charge time every 6 months, this may need to be manually performed if follow-ups are scheduled more frequently. 6 monthly charge time review is especially important if the patient can't hear the alert tone. Continue with routine follow-up per clinic practice.
- **If Charge Time is 16 seconds or longer,** or an "EOL" observation is displayed, schedule device replacement immediately.

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@moh.govt.nz
Fax 04 819 6806