Medtronic

Urgent Field Safety Notice

Potential for Rapid Battery Depletion due to Lithium Plating
In a Subset of ICD and CRT-D Devices

January 2020

Medtronic Reference: FA900

Dear Health Care Professional,

In November 2019 Medtronic issued a Performance Note regarding a rare failure mechanism in the battery design of specific implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) models that could result in rapid battery depletion. The rapid depletion is caused by a latent shorting mechanism resulting from lithium plating between the anode and cathode elements of the battery. At the request of the Danish Medicines Agency (DKMA), Medtronic is reissuing this content below to provide clarifying information in their requested format. It is important to note this is not a new safety issue.

In rare cases (0.003%), a device encountered End of Service (EOS) within 1 day of the Recommended Replacement (RRT) alert. Reaching EOS does not necessarily equate to loss of functionality or device failure. As previously conveyed, **if rapid depletion occurs, the device may not meet expected longevity or provide at least three months of device operation between the (RRT) and (EOS).** Per Instructions for Use, once a device reaches its EOS battery voltage threshold it should be replaced immediately.

Content from the Performance Note issued in November 2019 is reiterated below:

Approximately 607,800 ICD and CRT-D devices distributed worldwide are susceptible to this rare failure. Refer to the attached copy of this Performance Note for complete details.

Through November 8, 2019, approximately 0.04% of the devices identified have exhibited premature battery depletion due to lithium plating. The battery continues to perform within projected estimates. As a result of our understanding of this phenomenon, Medtronic implemented battery design enhancements. All products currently in distribution contain the battery enhancement.

There have been no reports of permanent harm to patients as a result of this issue. This Performance Note, like others previously issued, is provided for transparency and can also be accessed from the CRHF Product Performance Report at http://wwwp.medtronic.com/productperformance/advisories.html

Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend prophylactic replacement of any ICD or CRT-D devices manufactured prior to the battery enhancement. Physicians can continue normal patient follow-up in accordance with standard practice.

- Where possible, take advantage of the CareLink™ home monitoring system and the low battery voltage wireless CareAlert to assist with remote management of patients.
- As always, remind patients to seek medical attention if they hear a device audible alert (shipped On with high urgency toning for low battery voltage indicator).
- At each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Monitor changes in device longevity and note any unexpected device status indicators such as RRT and/or EOS, the inability to interrogate the device or to transmit data.
- As with all unexpected events, including a rapid unexplained voltage drop, inform a Medtronic representative immediately if any of the above behaviors are observed. Further device analysis may be warranted to determine if immediate replacement is necessary.
- If there is evidence of rapid battery voltage drop, patients may need to have their devices replaced urgently as device failure may lead to intended therapy not being delivered

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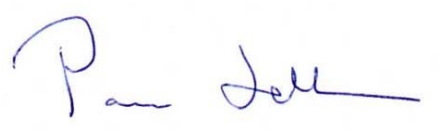
Review the attached Performance Note and contact your Medtronic Representative if you have any questions.

Sincerely,

Medtronic Danmark A/S



Pany Lauha
Country Director Nordic Countries

Enclosures:
November 2019 CRHF Performance Note