

CARDIAC RHYTHM AND HEART FAILURE PERFORMANCE NOTE

POTENTIAL FOR PREMATURE BATTERY DEPLETION IN
A SUBSET OF ICD AND CRT-D DEVICES

Medtronic

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Battery Enhancements Implemented

Medtronic identified 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. As a result of our understanding of this phenomenon, Medtronic implemented battery design enhancements. All products currently in distribution contain the battery enhancement, however approximately 607,800 devices distributed worldwide were manufactured prior to implementing the battery enhancement and were distributed under the following brand names¹:

- Claria MRI™/Amplia MRI™/Compia MRI™ CRT-Ds
- Viva™/Brava™ CRT-Ds
- Visia AF™/Visia AF MRI™ ICDs
- Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs

Potential for Premature Battery Depletion in subset ICD and CRT-D devices prior to battery enhancement

Approximately 0.04% of devices exhibit this behavior. The battery continues to perform within projected estimates. There have been no reports of permanent harm to patients as a result of this issue.

Under rare circumstances, a small percentage of ICD and CRT-D devices manufactured prior to the battery enhancement may develop lithium plating. If lithium bridges between a positive (cathode) and a negative (anode) element in the battery, an internal short will develop and the battery will deplete rapidly. If this occurs, the device may not meet expected longevity or provide at least three months of device operation between the Recommended Replacement Time (RRT) and End of Service (EOS).

All events have occurred during the mid-portion of device life; typically, 1-4 years after implant. Note, there have been no reports of this issue occurring after RRT has triggered under normal conditions. Therefore, when a device reaches RRT based on its programmed settings and use conditions, the device is likely performing as expected and time between RRT and EOS should be as labeled.

Continue to Follow Normal Clinical Practice per Instructions for Use –Pay Attention to Unexpected RRT or Unexpected Changes in Longevity

- 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.

Additional Details

Contact Medtronic Technical Services if you have concerns on a specific patient. A serial number look-up to assist with identifying if an ICD or CRT-D was manufactured prior to the battery enhancement is available at: <https://www.medtronic.com/productperformance/>

Confirmed premature battery depletions, regardless of cause, are reported in our semi-annual Product Performance report under the confirmed "Malfunctions" section for each device model. Product Performance information can be accessed directly at: <http://www.medtronic.com/productperformance/>

Q1) Can any ICD or CRT-D battery that uses lithium experience this rare, latent shorting mechanism?

Yes. Industry-wide, every ICD or CRT-D battery that uses lithium has the potential for plating to develop under normal use conditions and create an internal short. Lithium plating leading to an internal short is influenced by a number of factors including the battery design. There are differences in the battery design (e.g. layout and insulation) for each manufacturer. Note that the lithium plating phenomenon described in this Performance Note is different, and more rare, than lithium "cluster" formations that result from high current pulsing (charging) as has been described in literature.^{2,3,4}

Q2) Are all device models equally susceptible to this rare failure mechanism?

Devices with higher use conditions (such as CRT-D devices) are less susceptible to the failure mode. This is because the free electrolyte element of the battery, which contributes to lithium plating, is consumed by the cathode more rapidly under high current conditions. Additionally, devices that reach RRT as expected, based on programmed settings and use conditions, are also not likely to experience lithium plating since the electrolyte is consumed as part of the normal discharge process of the battery.

¹Device models vary by geography; not all models are available in all geographies.

²Aggarwal, A, et. al. Accelerated Implantable Defibrillator Battery Depletion Secondary to Lithium Cluster Formation: A Case Series. PACE 2016;39:375-7.

³Pokorney, SD, et. al. Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter defibrillators. Heart Rhythm 2014;11:2190-5.

⁴Hayashi, Y, et. al. A case of unexpected early battery depletion caused by lithium cluster formation in implantable cardioverter-defibrillator. J Cardiol Cases 2017;15:184-6.