# Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter-defibrillators

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**BACKGROUND** Battery failure is an uncommon complication of implantable cardioverter-defibrillators (ICDs), but unanticipated battery depletion can have life-threatening consequences.

**OBJECTIVE** The purpose of this study was to describe the prevalence of a novel mechanism of battery failure in St. Jude Medical Fortify and Unify ICDs.

**METHODS** Cases of premature Fortify battery failure from a single center are reported. A search (January 1, 2010 through November 30, 2013) for Fortify and Unify premature batter failure was conducted of the Food and Drug Administration's Manufacturer and User Facility Device Experience Database (MAUDE). These findings were supplemented with information provided by St. Jude Medical.

**RESULTS** Premature battery failure for 2 Fortify ICDs in our practice were attributed to the presence of lithium clusters near the cathode, causing a short circuit and high current drain. The prevalence of this mechanism of premature battery failure was 0.6% in our practice. A MAUDE search identified 39 cases of Fortify (30) and Unify (9) premature battery depletion confirmed by the manufacturer, representing a 0.03% prevalence. Four additional Fortify and 2 Unify cases were identified in MAUDE as suspected premature battery depletion, but in these cases the pulse generator was not returned to the manufacturer for evaluation. St. Jude Medical identified 10 cases of premature battery failure due to lithium clusters in Fortify devices (9) and Unify devices (1), representing a 0.004% prevalence.

**CONCLUSION** The deposition of lithium clusters near the cathode is a novel mechanism of premature battery failure. The prevalence of this problem is unknown. Providers should be aware of this mechanism for patient management.

**KEYWORDS** Implantable cardioverter-defibrillator; Battery failure; Short circuit; St. Jude Medical; Lithium clusters; Manufacturer and User Facility Device Experience Database (MAUDE)

**ABBREVIATIONS** **FDA** = Food and Drug Administration; **ICD** = implantable cardioverter-defibrillator; **MAUDE** = Manufacturer and User Facility Device Experience Database; **SVO** = silver vanadium oxide

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## Introduction

Battery failure is an uncommon device complication, but battery failure can have lethal consequences for patients dependent on pacing or lifesaving high-voltage shocks. The potentially devastating consequences of battery failure make battery reliability an important characteristic when selecting a device.[1]

There are multiple battery failure mechanisms. This report is of a novel mechanism of premature, accelerated battery failure in St. Jude Medical Fortify Assura implantable cardioverter-defibrillators (ICDs), first noted in routine clinical practice at our center. The premature battery failure appeared to be caused by lithium cluster formation between the battery cathode and anode, causing a short circuit and rapid battery depletion. The same battery is used in the Fortify ICDs and the Unify cardiac resynchronization therapy defibrillators. This battery is not known to be used by other manufacturers or in other devices. A search of

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Fortify and Unify devices was subsequently conducted in the Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience Database (MAUDE) to identify additional cases of lithium cluster. The aim of this report and the MAUDE search is to describe this novel mechanism of premature battery failure and the potential prevalence of this problem.

## Methods

### Fortify and Unify

The first generation of Fortify and Unify devices received FDA approval on May 12, 2010. The Fortify Assura and Unify Assura devices received FDA approval through a supplement pathway on May 8, 2012. The Assura devices changed from lithium silver vanadium oxide (SVO) batteries to combined SVO and carbon monofluoride Q high rate (QHR) batteries (Greatbatch Medical, Clarence, NY).

### Duke experience

There were 2 premature battery failures in Fortify devices noted at 2 institutions in our practice. The devices were explanted and sent to St. Jude Medical for analysis. A count of the number of Fortify and Unify devices implanted within the Duke University Health System and the Durham VA Hospital from 2010 through 2013 was used to calculate the prevalence of the premature battery failure. An Institutional Review Board (IRB) exemption was issued for this research.

### FDA MAUDE database

The MAUDE database consists of voluntary reports of medical device adverse events collected since June 1993. Medical providers are under no obligation to report adverse events. The database is freely accessible to the public. Multiple searches conducted on January 2, 2014, identified reported cases of premature battery failure. The combination of searches produced 430 Fortify entries and 459 Unify entries. Each of these entries was reviewed to identify events of premature battery failure (Online Supplementary Table 1).

### St. Jude Medical data

St. Jude Medical analyzed the 2 explanted pulse generators from our institution. Devices in the MAUDE database and from outside the United States were also sent to St. Jude Medical for analysis. In order to ensure the accuracy of the findings presented in this study, the preliminary data from our MAUDE search was shared with St. Jude Medical, which provided the details of the confirmed cases of lithium cluster–induced battery failure.

## Results

### Patient 1

The first case at our institution was a 74-year-old patient with a history of ischemic cardiomyopathy, coronary artery bypass grafting, and placement of a left ventricular assist device in 2009. The patient received a primary prevention ICD in 2003 with a Guidant 4470 atrial lead and a Guidant 0158 ventricular lead. The patient had a generator change on January 9, 2012, and a Fortify DR (model CD2231-40) was implanted at that time. The patient performed a remote monitoring download on December 11, 2013, and the battery was middle of life with charge time of 8.8 seconds and current 13 μA. The estimated longevity of the device had fallen to 1.7 years despite never receiving tachy-therapy (Figure 1). The patient noted an alert signal on December 18, 2013, and he presented to the clinic later that day for further evaluation. His device was noted to be at end of life, and an interrogation was not possible because the programmers were unable to communicate with the device. The device was explanted on December 23, 2013.

Manufacturer analysis demonstrated that telemetry communication with the device was not possible due to battery depletion (1.5 V), which was confirmed to have occurred prematurely. The device's microelectronics were normal, and there were no abnormalities in the circuitry despite testing with fluctuations in temperature and high humidity conditions. The battery was then returned to the battery manufacturer for further analysis. When the battery was cut open and inspected, 2 lithium clusters were noted in proximity to the battery cathode (Figure 2).

### Patient 2

The second case was a 67-year-old patient with a history of 3-vessel coronary artery disease, ischemic cardiomyopathy, and ejection fraction of 30%. The patient had a primary prevention Fortify VR ICD (Model CD1231-40Q) implanted on December 15, 2010, with a St. Jude Medical Durata 7120Q right ventricular lead (Figure 1). The patient was seen for routine follow-up in July 2011. He then had 2 remote transmissions that did not send appropriately, and the patient was not seen in the clinic for 2 years. He was seen in the clinic for routine follow-up in September 2013, and communication with the device could not be established. The device was explanted on September 6, 2013. The patient had never received any tachy-therapy.

Manufacturer analysis demonstrated that telemetry communication with the device was not possible due to battery depletion (1.1 V), which was confirmed to have occurred prematurely. The microelectronics of the device were normal. A high current state could not be induced despite testing with fluctuations in temperature and high humidity conditions. The battery was then returned to the battery manufacturer for further analysis. Upon inspection, 4 lithium clusters were noted in close proximity to the battery cathode.

### Single-practice prevalence

There were a total of 348 Fortify and Unify devices implanted within our clinics from 2010 through 2013: 74 in 2010, 120 in 2011, 107 in 2012, and 47 in 2013. Two cases of premature battery failure have been noted as of December 31, 2013. The prevalence of Fortify and Unify premature battery failure within this experience was 0.6%.

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