

Cardiac Rhythm Device Battery Life



CV Watch

Novation®

Overview

Implantable cardiac resynchronization therapy devices with integrated defibrillators provide life-saving therapy by slowing the progression of heart failure. However, CRT-D devices must be replaced when their battery life ends, historically every three to seven years. Thus it is not unusual for patients to require several costly device replacements over a patient’s lifetime. As the United States’ large baby boomer population ages and patients receive implantable cardiac defibrillators or CRT-D devices earlier in the course of their disease, their increased life expectancy means even more device replacements become necessary.

As battery technology continues to advance, manufacturers are leveraging those improvements to dramatically extend their devices’ longevity, as well as introduce new devices that are expected to operate twice as long as their equivalent current devices. Today’s CRT-D devices have up to twice the battery capacity as their predecessors, are as energy-efficient as a pacemaker, and utilize a lithium manganese dioxide battery chemistry that is not plagued with the mid-life charge time issues associated with lithium silver vanadium oxide battery chemistry.

These new devices have the potential to dramatically reduce health care costs by cutting the number of expensive device change-out procedures in half. Having fewer device change-outs benefits patients because there are fewer surgeries, resulting in lower costs as well as reduced risk of infections and complications from surgery.

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Technology Summaries

How long should a CRM device battery last?

CRM patients are generally told to expect about five years of battery life from their CRT-D devices, and perhaps up to seven or eight years from their ICDs. But more often than not, the device does not last as long as projected. For example, according to Medtronic's November 2011 Product Performance Report, only 40 percent of CRT-Ds released into the market in 2007 were still in service after 4.4 years.¹ CRT-D devices with features like continuous pacing, remote monitoring and anti-tachycardia pacing therapy during charging can deplete battery life more quickly.

Battery technology in general is rapidly evolving based on increasing demand for miniaturization and longer life of cellular communications technologies as well as medical devices.

Newly introduced ICD and CRT-D devices with advanced battery technology are reported as lasting almost twice as long.² In its most recent analysis, Boston Scientific projected that its CRT-D devices will last an average of eight years on a single battery and with lower power consumption. The supplier projects an average of 10 to 12 years for its dual- and single-chamber ICDs.³

Evolving Demographic and Intervention Trends

Between 35 and 45 percent of patients with an ICD or CRT-D are under the age of 65. Recent data have demonstrated that earlier intervention with biventricular pacing and CRT-D therapy can significantly decrease heart failure hospitalization in high-risk class I and II patients.⁴

In the MADIT-CRT study, investigators found that in the high-risk* New York Heart Assessment class I and II patients with left bundle branch block, early CRT-D intervention reduced the relative risk of all-cause mortality or first heart failure event by 57 percent when compared with ICD therapy ($p < 0.001$).** In another study, Dr. Robert Hauser from the Minneapolis Heart Institute evaluated primary prevention patients at his institution and found that 70 percent of patients required at least one device change-out, and 40 percent of patients were still living 10 years after ICD implantation.⁵ As the trend to treat primary prevention patients with CRT-D therapy earlier in their disease process continues, patients are likely to live longer, and the number of patients who would benefit from a device that lasts more than three to five years will continue to increase.

In light of the trend toward earlier intervention, the increasing number of younger ICD/CRT-D patients, and average U.S. life expectancy of 76 years for men and 81 years for women, the average patient could expect to receive two to four device change-outs over their lifetime.

* High-risk is defined as QRS width ≥ 130 ms, LVEF ≤ 30 percent, and left bundle branch block.

** Left bundle branch block was not an inclusion parameter for the MADIT-CRT trial. However, a significant interaction between treatment and bundle branch block morphology was detected. Further analyses revealed that LBBB is an objective discriminator of patient benefit from CRT-D regardless of other baseline characteristics.

Patient Impact

The decreased frequency of device replacement procedures associated with increased battery life offers clinical as well as economic benefits to CRM patients. In a recent study from Leiden University, 9 percent of patients experienced complications following device change-out. Investigators found that ICD replacement is associated with a doubled risk for pocket-related surgical re-interventions, and the need for re-intervention increased with every consecutive replacement.⁶

Additional studies indicate a higher rate of infection among patients whose devices are changed more frequently.^{7,8,9} While device infection occurred in less than 1 percent of patients following the initial implant, infection rates increased substantially (2 to 7 percent) following device replacement, and device replacement is the most common cause of device infection.^{10,11} When device infection occurs, the American Heart Association and Heart Rhythm Society recommend removal of both the device and leads.^{10,11} Treating a device infection is complex, costly and associated with higher mortality.^{12,13,14}

A 2011 survey conducted among ICD and CRT-D patients found 73 percent were concerned about battery life and device longevity.¹⁵ The confidence level of patients facing an implantation or replacement procedure could also increase as a result of improved battery life.

Economic Impact

Device longevity has a direct effect on cost management for the health care industry as well as for individual patients. For the growing younger patient population, the cost difference between a device that lasts four to five years versus eight to 10 years would be substantial.^{16,17} Dr. Ramachandra from the Cleveland Department of Veterans Affairs Hospital evaluated the costs associated with device change-outs and estimates a large number of device infections and change-outs could have been avoided if the devices had a longer battery life. In addition, he modeled the potential cost savings for devices that lasted seven to nine years, and projected this change could reduce direct health care expenditures for device replacements by \$190 million to \$296 million in 2005 Medicare dollar costs to the health care system over a 15-year period.¹⁸

Imagine a 54-year-old patient with class II heart failure who is indicated for a CRT-D, and who receives a device with a 4.4-year battery life. This patient would need five device replacements by the age of 80, for a total of six surgeries. Data from the ICD registry estimate procedure and device replacement cost is about \$37,000,¹⁴ not including physician or anesthesia fees. Six ICD surgeries over this patient's lifetime could therefore easily exceed \$220,000, a portion of which would be out-of-pocket expenses for the patient, who also must endure the six procedures. In this scenario, if device longevity could be doubled to more than eight years, the number of surgeries required — and the cost to the patient and the health care system — could be cut in half.

Younger patients who are not yet eligible for Medicare are typically covered by private insurance. They are experiencing not only an increase in their insurance premiums, but also more costs shifted to the patient because insurance companies implement cost-sharing programs — including higher co-pays, co-insurance and higher deductibles.¹⁹

An example can be demonstrated in preferred provider organization, or PPO, health plans. PPOs are the most common type of private insurance program in the United States, with an average deductible of \$1,521 for a family plan in 2011.¹⁹

High-deductible health savings accounts and health reimbursement arrangements have become quite popular with large employers, but in 2011 these plans had an average deductible of \$3,666 for family coverage¹⁹, an average co-insurance rate of 17 percent, an average co-pay for hospital admission of \$246, and an average hospital deductible of \$627.¹⁹ Using the estimated cost of an ICD or CRT-D replacement from the ICD registry — \$32,000 for an ICD and \$37,000 for a CRT-D (no infection)⁵ — a 17 percent co-insurance would add \$5,440 to \$6,290 to the patient's bill.

New Battery Technology

Most cardiac rhythm management device manufacturers develop and make their own batteries. However, due to the proprietary nature of battery technology, obtaining detailed information on performance characteristics of the batteries is difficult. The only measurement is through projections of longevity and reliability in the manufacturers' respective device warranties. Reliability in battery discharge testing serves as the foundation for the longevity projections on their devices. A battery's reliability provides better patient benefit due to the increase in device warranty.

In the CRM market, Boston Scientific appears to have taken the lead in developing a longer-lasting ICD and CRT-D battery. The company began development of its current battery technology in 2002 and has a state-of-the-art battery manufacturing facility. The advanced battery technology developed by Boston Scientific for its Incepta™ and Energen™ lines of ICD and CRT-D systems has up to

a 10-year warranty. These batteries offer nearly twice the battery capacity as some ICDs and CRT-Ds, yet require the same low power consumption as a pacemaker. More battery capacity and increased energy efficiency are reasons why these devices are projected to last up to twice as long as other devices. In addition, the company moved away from the silver vanadium oxide battery chemistry that has historically troubled the industry with mid-life charge-time challenges. Instead, Boston Scientific uses lithium manganese dioxide, which has no mid-life increase in charge times, even when run down in seven-year real-time testing.

Novation commends manufacturers like Boston Scientific for continuing to develop longer-lasting and enhanced therapy devices. We challenge CRM manufacturers not only to extend their warranty life, but also to change their prorated warranties and offer full warranties with minimum coverage of five years.



INCEPTA™ and ENERGEN™ ICD and CRT-D

Boston Scientific's new line of premium level ICDs and CRT-Ds that feature the 4-SITE™ DF4 connector system

- ▶ Designed to last up to twice as long as other devices with a 10-year warranty^{2,3}
- ▶ Built on the RELIANCE® lead platform, which has more than 99 percent lead survival probability at seven years¹⁹
- ▶ The RELIANCE 4-SITE lead and DF4 connector system that makes the smallest, thinnest high-energy device system in the world even smaller
- ▶ Offers AcuShock™, an advanced technology that can distinguish between a potentially lethal heart arrhythmia and a non-lethal arrhythmia within seconds
- ▶ Remote monitoring of weight and blood pressure (LHFM) included with the purchase of these new devices
- ▶ Offers LATITUDE® LeadCheck™, a comprehensive suite of 10 alerts in LATITUDE, useful in monitoring lead integrity

Footnotes

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