WHITEPAPER

PRECISION DEVICES knowles

COMPEX • DLI • JOHANSON MFG
NOVACAP • SYFER • VOLTRONICS

The Price of Reliability: Considerations for Buyers

INTRODUCTION

Capacitors are one of the many components that contribute to the overall longevity of an implantable medical device; making a small component change could extend its reliability, and even its lifespan, by preventing battery related complications. Here we begin to explore the cost of device failures and how proper reliability testing and supplier considerations can help you navigate capacitor sourcing for your medical device application.

THE COST OF FAILURE

Advances in medical devices and medical implantables continue to improve patient outcomes in a range of applications from pace makers to pain management. Building and designing health solutions that stay in step with innovation takes dedication from research and development, regulatory and operations among others. When applying the business lens, balancing value and reliability is a constant consideration. Patient safety is paramount; however, making effective cost decisions becomes increasingly complex when other factors are on the line.

When implantable devices fail, everyone pays a price—including patients. For example, cardiac resynchronization therapy, or CRT, is a clinically proven heart failure treatment option for certain heart failure patients. It's designed to improve the heart's ability to pump blood and oxygen by sending small electrical impulses to the ventricles of the heart to restore a synchronized pattern. In combination with a complete therapy program, CRT has the potential to improve quality of life for patients by reducing symptoms of heart failure and increasing exercise capacity.

With all of the positive considerations for CRT, there are risks as well. Infection at the surgical site, sensitivity to device material, failure to deliver therapy when needed or even receiving extra, unneeded, therapy are all possible complications. There are similar concerns for many implantable devices, including, for example, implantable cardioverter defibrillators (ICDs).

Patients, especially with complex medical backgrounds, can experience psychological stress and anxiety related to implantable devices. They face a perceived choice between fear of, in the case of ICDs and CRTs, sudden

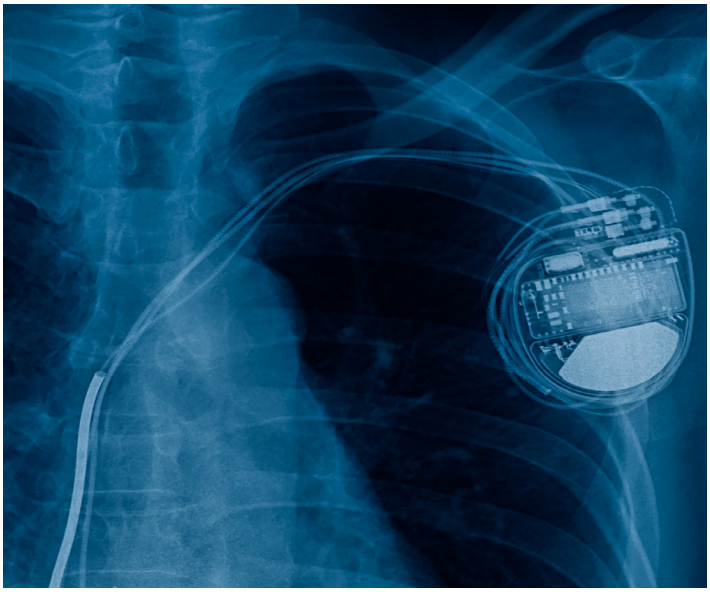
cardiac death and fear of post-implant complications, shocks and device malfunction. While all these concerns cannot be resolved directly by manufactures, high reliability devices remove some of that uncertainty and lessen the possibility of malfunctions, recalls and replacement surgeries.

FDA RECALLS – LEARNING FROM THE PAST

The U.S. Food and Drug Administration (FDA) uses the term "recall" when "a manufacturer takes a correction or removal action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health." You can access the FDA Medical Device Recalls database at any time. The following sections explore reviews of a few of many cases regularly submitted to the FDA.

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)

A systematic review of cardiac implant recall information across the PubMed, ScienceDirect and Scopus databases between 2004 and 2014, found 42 recalled implantable cardioverter defibrillator (ICD) reports. Of those, 50% had battery problems, 23.8% had problems related to therapy delivery, and 21.4% were associated with software malfunctions. One isolated report was related to data output express issues, and another was related to connection issues.



Ten out of the 21 reported battery-related recalls were due to capacitor issues. Accelerated degradation of the capacitors, causing battery depletion at a faster rate, triggered the recall because of the heightened risk of faulty therapy delivery.

CARDIAC RESYNCHRONIZATION THERAPY (CRT)

In an effort to understand the lessons that can be learned from a decade of cardiac implants, Shixuan Zhang and team also included 13 recall reports of Cardiac resynchronization therapy (CRTs) in a recent review. Nine of the thirteen reports detailed recalls due to battery issues, two reports were triggered by software problems, and two reports noted therapy delivery concerns. Of the nine reported battery issue recalls, six had capacitor malfunctions, and two experienced

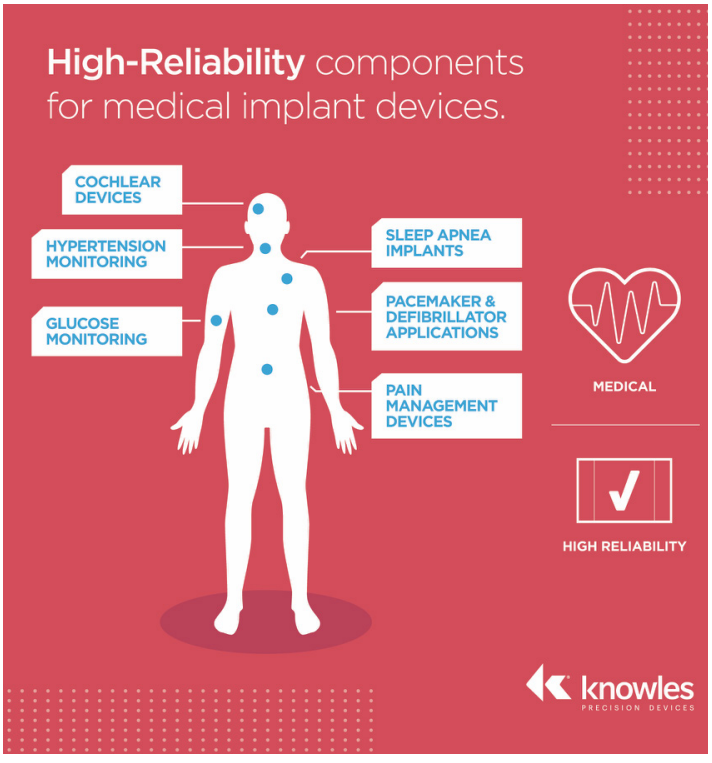
premature battery depletion. The review discusses a recall that was issued by Federal Institute for Drugs and Medical Devices (BfArM) in Aug. 2013. A total of approximately 264,000 identified devices had been distributed and implanted; a subset of 38,500 devices, manufactured prior to December of 2009, experienced a higher number of low voltage (LV) capacitor malfunctions. The recall was initiated because the manufacturer identified a capacitor component in some devices, which may lead to diminished performance after as few as two years from the time of implantation.

Patient safety is paramount, but the economic impact of recalls is important to note as well. Recalling large numbers of medical devices results in economic losses for the industry and the health care consumer. Further, the negative impact of recalls can reduce industry market shares. It is estimated that Medtronic's Fidelis recall cost Medicare some $287 million over five years for monitoring or replacing the leads. In 2010, *Johnson & Johnson* recalled a variety of products due to quality concerns. Consequentially, they suffered significant losses with a decrease of 7.7% in revenue over the previous year.

TWENTY-FIRST CENTURY PITFALLS

With medical devices becoming more complex, supply chains more global, and competition more widespread, recalls and device malfunctions are possible outcomes.

Medical devices incorporate an increasing amount of technology; mobile capabilities and complicated software continues to change the way devices are designed. In addition, companies are pursuing cost-competitive supplier options, and often weave intricate webs of suppliers from around the world to meet strict cost goals. These dense global supply networks present logistical challenges for component management, among others. Medical device engineers and manufacturers are also under a lot of pressure from consumers and shareholders to beat their competition to market with the most advanced option. Innovation propels the medical device industry, but in order to prioritize patient safety, these pitfalls should be considered.



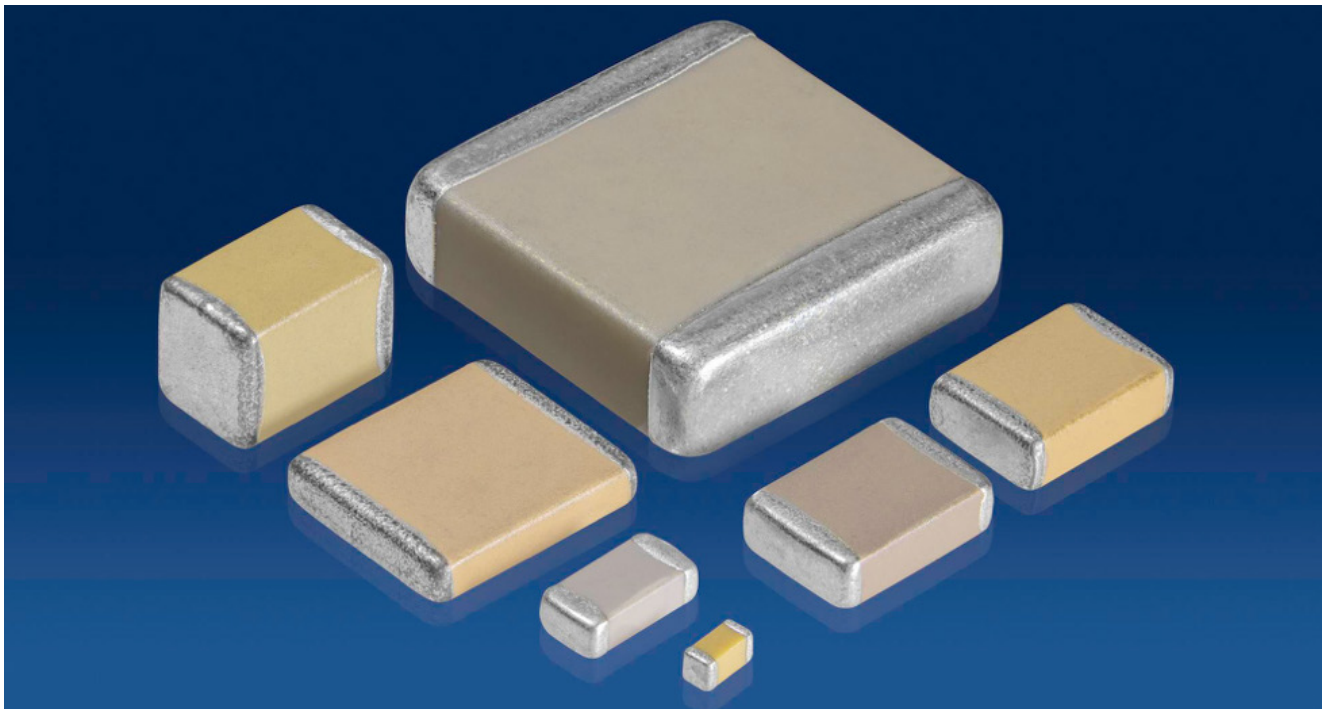
KPD partners with engineering and product development on numerous medical applications where high reliability is a key restraint.

DESIGNING FOR LONG TERM RELIABILITY

The demand for new products and reduced size, while meeting high expectations for reliability, drives change in the electronics industry. When patient safety and quality of life are key metrics, it takes a specialty components manufacturer, committed to innovation, to drive these types of improvements. The following sections discuss reliability specifications, testing guidelines, and key considerations for choosing the most reliable components and supplier.

REQUIREMENTS FOR MEDICAL GRADE CAPACITORS

There are numerous factors steering capacitor choices; material, leakage resistance, stability and price among others. Strict guidelines in the medical device space place more weight on reliability grade, size, and durability over other common parameters of importance in consumer devices and electronics. Regulatory bodies, such as the International Standards Organization (ISO) or FDA, require additional specifications to maintain reliability in all phases of development and manufacture for medical applications.



Choosing the right MLCC capacitor for a high reliability design, particularly in medical applications, requires a breadth of considerations from specifications to pricing and availability.

TESTING GUIDELINES AND CONSIDERATIONS

Each and every high reliability capacitor should be 100% electrically inspected and burned-in at elevated voltage and temperature levels to precondition the parts and comply with the established performance criteria. Military performance specifications are designed and written for specific voltage/capacitance ratings; these strict specifications easily transfer to life-critical applications. Each of the tests, detailed in Table 1, requires specialized equipment, tooling and significant time investment from the Quality Assurance engineering team. These performance specifications outline exactly how tests should be carried out; manufacturers require extensive resources to accommodate these additional standards and protect patients.

Specification	Description	Requirements
MIL-PRF-55681 (Group A)	General purpose military high reliability specification for surface mount sizes 0805 through 2225 in 50V and 100V.	• Voltage Conditioning • 100 Hrs, 2X VDCW, 125°C • DWV, IR, 125°C IR, CAP, DF Test • Visual & Mech. Inspection (Aql Sample Plan) • Solderability, Sample 13(0) • 8% PDA Maximum
MIL-PRF-123 (Group A)	The specification affords an increased reliability level over MIL-PRF-55681 for space, missile and other high reliability applications such as medical implantable or life support equipment. The specification covers surface mount sizes 0805 through 2225 in 50V rating and various radial / axial leaded products in 50V, 100V and 200V ratings.	• Thermal Shock, 20 Cycles • Voltage Conditioning 168/264 Hrs, 2X Vdcw, 125°C • DWV Ir, 125°C IR, CAP, DF Test • Visual & Mech. Inspection Sample 20(0) • DPA(1) • PDA, 3% (0.1%), 5% (0.2%) Max(2)

Table 1: Group A testing ensures no maverick lots escape and utilizes strict military specifications to validate capacitors in life-critical applications.

Additional testing, such as the Environmental Inspections in Table 2, can be performed on a lot basis according to SCD requirements. Life Sample Testing, performed at accelerated electrical and environmental conditions, is another important consideration when working with medical applications. Minimizing the need for invasive surgery is imperative, and additional testing is critical to determine the long-term reliability of a device.

Environmental Test	Description
Group B	Group B environmental testing for product group HS shall consist of the tests specified in table XII of MIL-PRF-123 and shall be performed on sample units from lots that have been subjected to and have passed group A inspection. Copies of Group B data shall be forwarded to purchaser with parts. Parts may not be shipped until the conclusion of life test.
Group C	Group C environmental testing shall consist of the tests specified in table XI of MIL-PRF-55681 for product groups HB and HK. Testing shall consist of the tests specified in table XIII of MIL-PRF-123 for product group HS. Tests shall be performed on sample units from lots that have been subjected to and have passed group A inspection. Copies of Group C data shall be forwarded to purchaser with parts. Parts may not be shipped until the conclusion of life test.

Table 2: Depending on individual SCD requirements, Group B, Group C, and Qualification testing, referred to in MIL-PRF-55681 and MIL-PRF-123, might be necessary to perform as an additional level of environmental testing.

CONSIDERATIONS FOR CHOOSING A SUPPLIER

Choosing the right supplier is just as imperative as choosing the right capacitor for a life-critical application. An experienced supplier should have a long reliability history and deep knowledge of reliability and safety guidelines. Partnering with a knowledgeable supplier, as early as the development process, will help you infuse these factors into your design.

Knowles Precision Devices (KPD) is the premier global source for manufacturing high performance multi-layer ceramic capacitors. We have a long heritage of helping clients with mission-critical applications including military, aerospace, and medical device where reliability is paramount. Our team of experts is ready to help you work through your toughest development challenges and find components that meet demanding specifications.

THE VALUE OF PROPRIETARY DESIGNS

Designing high reliability capacitors requires adopting some new rules that go beyond the typical MLCC designs. These design rules build performance margin directly into components. For example, to minimize the chance of electrical breakdown, our engineering

team built in a safety margin for dielectric thickness. Capacitors should not be up-screened to meet requirements. With patients in mind, these standards should be met and exceeded. KPD has iterated these designs over the last two decades to help customers prevent battery failures and extend the lifespan of implantable devices; that's why a leading medical device manufacturer considers us the gold standard when it comes to reliability.

ABOUT KNOWLES PRECISION DEVICES

KPD has provided capacitors to implantable device manufacturers for 25 years; in that time, our product has not been involved in any recalls. The operational processes, testing procedures and quality assurance efforts provided by KPD are guided by a long reliability history. We will not compromise on quality and safety. Our experts help medical device companies engineer solutions that factor in reliability and cost over the lifetime of a device to avoid fatal mistakes down the line.

Visit Website **Contact Us**