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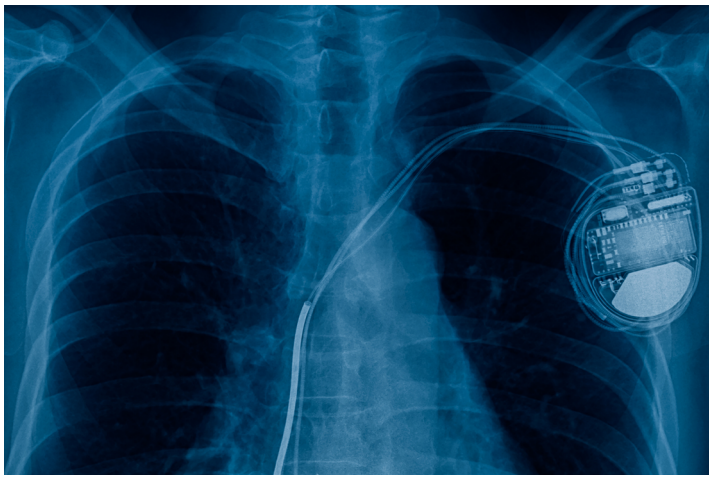
When Reliability is Paramount: Selecting Capacitors for Life-Critical Applications

INTRODUCTION

As technology advances in the medical device space, electronics design is constantly adapting to meet industry needs. Capacitors are one of the many components that need to meet the demands of innovation. Strict guidelines place more weight on reliability grade, size, and durability over other common parameters of importance for consumer devices and electronics. Here we begin to explore regulation, testing procedure, and supplier considerations to help you choose the best components for your medical application.



The advent of minimally invasive medical procedures and advances in biocompatibility and power management have aided in the rapid development of implantable devices.

MEETING DEMANDS IN MEDICAL INNOVATION

Technological innovation in the medical device space has continued to superminiaturize electronic circuits and advance capacitor materials and design; medical implantables, in particular, have seen rapid development over a short time span. Advances in implantable medical devices continue to improve patient outcomes in a range of applications from pace makers to pain management and glucose monitoring.

The electronics industry is continually tasked with responding to the demand for new products, and reduced size, while meeting the expectations for functionality and reliability necessary in life-critical applications. It takes a specialty components manufacturer with a commitment to innovation to drive improvements in patient safety and quality of life. In order to help you choose the right capacitor for your implantable medical device, this white paper discusses key reliability specifications, testing guidelines, and use cases for capacitors in life-critical applications.

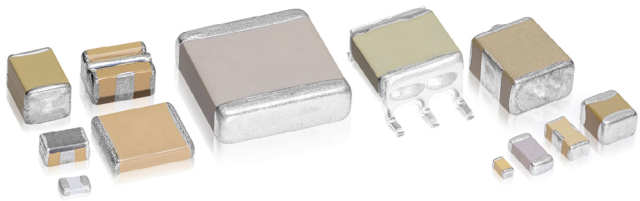
REQUIREMENTS FOR MEDICAL GRADE CAPACITORS

Between material, leakage resistance, stability, and price among others, there are numerous factors steering capacitor choices; medical applications add another layer of consideration. Strict guidelines place more weight on reliability grade, size, and durability over other common parameters of importance in consumer devices and electronics.

MIL-PRF-55681 is the most widely used SCD specification in the field of high reliability capacitors, and by extension, medical implantable devices. It defines a mid-K stable dielectric designated as BX. The BX specification has voltage temperature limits in addition to temperature limits of capacitance. The BX dielectric is limited to ±15% maximum change in capacitance between 25°C and -55°C or +125°C and also has a voltage restriction of +15% / -25% maximum change in capacitance between 25°C and -55°C or +125°C at rated voltage.

Regulatory bodies, such as the International Standards Organization (ISO) or the U.S. Food and Drug Administration (FDA), require this SCD specification to be met as part of their many efforts to maintain the highest level of reliability in all phases of development and manufacture for medical applications.

MIL-PRF-123 is another widely used SCD specification in the medical device space. Capacitors covered by this specification may be used in two main applications. This includes: 1) Critical frequency determining applications and other applications where absolute stability is required (BP and BG), like cardiac pacing devices that utilize timing circuits and 2) Applications where there are variations in capacitance with respect to temperature, voltage, frequency, and life can be tolerated (BX and BR). Many life sustaining devices require this kind of variation. These specifications are not limited to implanted devices.



Selecting the right MLCC capacitors for medical applications requires researching specifications, reliability, pricing, and availability, among many other considerations.

Applications for high reliability products include aerospace, airborne, and various military applications where consumer use requires more substantial safety margins than conventional products.

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. 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, and 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°wC • 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.

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 for medical applications. When designing medical implantables, 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.

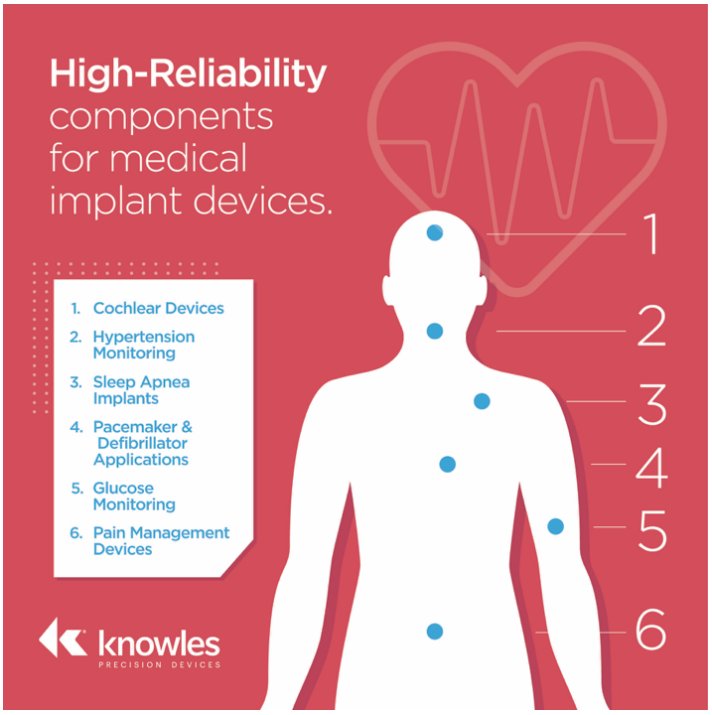
Table 2: Depending on individual SCD requirements, Group B, Group C, and Qualification testing, referred to in MIL-PRF-55681 and MIL-PRF-123, might be necessary to perform as an additional level of environmental testing.

MEDICAL GRADE CAPACITORS IN PRACTICE

Since implantable medical devices must be embedded into the body, one of the main goals is to reduce physiological burden by minimizing the need for invasive surgeries. Developing devices smaller in size and higher in reliability and service life contributes to the solution from the very foundation of the device.

MLC chip capacitors in Ultra stable EIL Class I C0G/ NP0 feature nickel barrier terminations that are suitable for solder wave, reflow solder board attachment and vapor phase attachment for part sizes 2225 or smaller. Silver-palladium terminations can be adapted for hybrid use with conductive epoxy. These chips are used in precision circuitry requiring Class I stability due to their linear temperature coefficient, low loss and stable electrical properties with time, voltage and frequency.

MLC chip capacitors in Stable EIA Class II feature the same terminations and reliability standards; however, Class II X7R chips are used as decoupling, by-pass, filtering and transient voltage suppression elements. They exhibit a +/-15% temperature coefficient and predictable variation of electrical properties with time, temperature and voltage. These components are burned in at elevated voltage and temperature and are 100% physically and electrically inspected to meet strict performance and reliability criteria. At KPD, units may be tested in accordance with MIL-PRF-55681, MIL-PRF-123, MIL-PRF-49467, or customer SCD.



KPD partners with engineering and product development teams on a variety of medical device applications.

Aside from implantables, the demand for portable and wearable technology has increased as medicine begins to move away from its conventional setting. Traditionally bench top devices are becoming miniaturized, and increasingly wearable and implantable to improve quality of life for patients. Knowles Precision Devices (KPD) offers high reliability, extensively tested parts as small as 0201.

While it depends on the application, most implantable devices use 0402, 0504, and 0805 sizes. For example, a typical cochlear implant utilizes 0402 and 0603. A high reliability capacitor is one of the many important

components that allow cochlear implants to provide a sense of sound to deaf or severely hard-of-hearing patients. In this size range, utilizing a more compact, high reliability product is required. If a device is to deliver a lifesaving or sustaining function, it must be reliable all the way down to its foundational components.

CONSIDERATIONS FOR CHOOSING A SUPPLIER

While choosing the right capacitor for a medical application is critical, you also need to choose the right supplier. An experienced supplier becomes a trusted partner that can advise your engineering team early in the development process to avoid costly, or potentially life threatening, mistakes.

Knowles Precision Devices 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 in the military, aerospace, and medical space where reliability is paramount. Our team of experts can help you work through your toughest development challenges and find components that meet demanding specifications.

ABOUT KNOWLES PRECISION DEVICES

Having worked in the field of medical grade capacitors for over two decades, we understand the details. Testing and quality assurance provided by KPD is tightly controlled. The KPD Hi-Rel Catalog details an exhaustive list of testing that can be applied across high reliability capacitors.

We work closely with both mature and start-up medical companies to help create, or fine tune, SCD governing the capacitors supplied. KPD has extensive experience partnering with medical device manufacturers and understands the wide span of customer needs. Regardless of the project, our goals remain the same: maintain quality and drive innovation with reliable component performance. At KPD, we provide extensive resources to accommodate custom designs and unique application needs for medical applications to do our part in pushing the field forward.

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