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Component Specifications for Medical Products

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Abstract

The need for component-level specifications for medical applications has been long identified; the existing process today is inconsistent. There are no medical industry specifications for the qualification of components or their suppliers. Thus every component that is purchased for high-reliability medical products today must be individually qualified. Component suppliers have no industry standard to which they can turn, but instead, must develop their own suites of tests, some of which may not be relevant to medical applications. For an industry standard, both a clear understanding of the failure mechanisms of critical components is required, and the reliability and performance requirements of the critical components in medical devices must be considered. This report summarizes the work conducted by the iNEMI project team to identify relevant critical components and then, using a case study of a specific critical component, to assess the level of understanding and technical knowledge needed to develop a relevant specification for that component that would be appropriate for medical devices.

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Introduction

The need for the development of industry-wide component-level specifications for medical electronics products has been highlighted by the industry in recent years. In particular, in relation to implantable electronic devices, the 2011 iNEMI Roadmap Medical Product Emulator Group (PEG) chapter stated, "the unique application and reliability performance expectations of active implantable medical devices are not adequately represented in existing industry-standard reliability test methods for components. Standardized reliability test methods and reliability expectations for active implantable medical devices may increase the diversity of component suppliers by providing clear and consistent requirements for participation in the implantable medical device market" [1]. The topic of component specifications has also been flagged and prioritized in the feedback from the medical electronics community's participation in iNEMI-run workshops and focus groups in 2010 and 2011. To date, there has not been a concerted effort across the electronics manufacturing supply chain and standards bodies to address this issue for electronic components. There are no industry-wide medical specifications for the qualification of components or their suppliers. Thus, every component that is purchased for high-reliability medical products today must be individually qualified.

Project Motivation

The purpose of this project was to identify and define a set of component-level reliability qualification methods (screens and tests) for critical electronic components used in implantable and wearable medical devices. These tests and screens were to be identified from relevant existing test methodologies and standards available in the electronics industry at large, where possible.

The result of this work should inform the development of industry-wide specifications that can be accepted by medical device OEMs and supported by component suppliers. In particular, it should identify common approaches to tests that would reduce the resources expended presently on testing to unique requirements. This approach would enhance communication along the supply chain and enable the faster introduction of new components and suppliers. These advances are essential in this fast growing market, in which reliability and performance are critical.

Methodology

Survey

From the start of the project, it was understood that covering all electronic component types in a single iNEMI project would be hard to achieve. As a consequence, the first task was to prepare an online survey, open to the industry, to prioritize component types with respect to reliability.

The goal of the survey was to provide answers for four questions posed in the Statement of Work (SOW):

- Were unexpected or early component failures observed or anticipated?
- Are certain component types used in a critical manner (i.e., failure of the components has the potential to directly cause malfunction of the entire medical device)?

- Are certain component types prone to supply chain changes (e.g., relocation of Original Component Manufacturers (OCM) manufacturing sites, alternate suppliers)?
- Are certain component types used in either very large or very small numbers?

The four key questions were broken into more detailed questions that were suitable to be answered in an online survey. Most questions were multiple choice or ranking questions. Open text fields were also used to allow survey participants the opportunity to provide specific input to the project. In addition to the four key questions mentioned above, the survey also gathered information regarding respondent demographics.

The online survey was open to industry for a number of weeks. Altogether, 67 participants from across the industry participated. The participants were drawn from a mix of stakeholders on the global supply chain for medical devices. A presentation summary of the survey results is available at: http://thor.inemi.org/webdownload/Pres/Medical/Medical_Components_012913.pdf

Analysis

The survey results were reviewed by the team in late 2012 to determine components to be covered in Task 2 of the project. This review was conducted using statistical evaluation of the ranking questions, together with experience and expertise of project participants.

The following five critical components were identified, for the following reasons:

- Tantalum capacitors
    - Identified as the most critical passive component type in the survey.
- Connectors
    - Very widespread use, good potential for a collaborative effort.
- Feedthroughs
    - Important component in most implantable medical electronic devices.
- Analog and mixed-signal ICs
    - High ranking in active electronic components. Custom semiconductors ranked higher, but the team agreed that they were not suitable for a collaborative effort.
- Flex circuits
    - Widespread use in medical devices, when combined with rigid-flex; high priority / criticality in the survey.

An open industry webinar was held to assess which components to use in a case study. The webinar presented the survey results, along with demographics and additional findings.

Results

<u>Methodology</u>

One of the primary objectives of the team was to develop a methodology for establishing a component specification for a medical grade component. Based on the experience of this team, a summary of the recommended methodology is outlined below:

- Create a clear problem statement / rationale regarding why a specific component requires a common specification
- Compile a multi-disciplinary team, involving at least:

  - A “third-party” project moderator (e.g., iNEMI)
  - Companies that use components in marketed medical products (“end equipment manufacturers”)
  - Companies that serve as consultants or service providers to medical device OEMs
  - Research institutions with significant expertise in the field
  - Efforts should be made to involve medical component manufacturers in the team
- Conduct a thorough analysis of the existing state of the art Compile public domain information, e.g., scientific literature, suppliers’ datasheets, application notes, standards relating to known failure modes, triggers for failure
  - Seek to obtain input from experts not participating in the project
- Identify potential synergies or gaps with regard to the state of the art
- Provide a recommendation on how to proceed in order to obtain a common component specification. Possible methods include:
  - Standards organization
    - Initiate new standard
    - Contribute to ongoing standard work
  - Scientific publication
  - Industry pre-competitive validation

The original objective was to form a number of focused subgroups of experts to study new critical components identified in the survey. Following the survey, several attempts to enlist additional medical device original equipment manufacturers (OEMs) and suppliers were undertaken. As there was not sufficient response to these requests, the project team decided to focus on tantalum capacitors, the component for which there was most interest and expertise within the team.

As a first step, the project team contacted a number of component manufacturers. Due to competitive concerns and resource issues, no original component manufacturers (OCMs) joined the project. However, one agreed to present to the team their approach to testing tantalum capacitors.

It was also decided to invite external experts from non-participating organizations to an “interview-style” project call. These external experts were provided with a brief summary of the project and some specific questions / topics which were agreed on prior to inviting the expert to discuss the topic with the team. These external experts also had an opportunity to present non-proprietary information relevant to tantalum capacitors to the project team.
Such interviews were held with the following experts:

- AVX – Tantalum capacitor division (Allen Mayar, Bob Fairey, Brian Brunette)
- NASA (Alexander Teverovsky)

Further information was gathered by searching the scientific literature base, standards (including ongoing work items), and reviewing the experience of project participants. An effort was made to identify all relevant international, military, professional, and as available, company-specific standards.

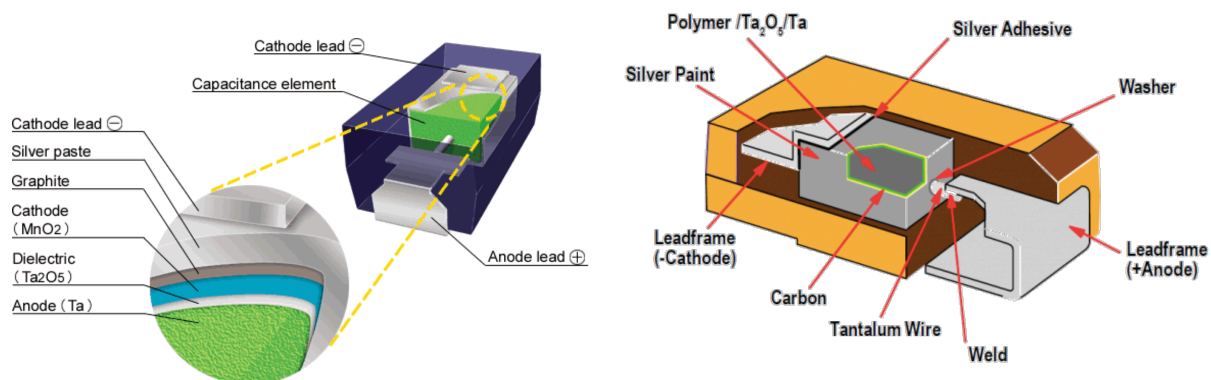
Outcomes and recommendations of the project team’s assessment of the tests and screens for tantalum capacitors are provided in the following section on tantalum capacitors in this report.

Case Study: Tantalum Capacitors

Tantalum (Ta) capacitors offer the highest volumetric efficiency of any commercially available conventional capacitor technology (excluding newer ‘supercapacitors’). In medical device applications they may be designed as a reservoir across a battery in an implantable medical device or in a charge pump circuit to increase voltage levels above the battery voltage. They might also be used in sample and hold circuits, where low equivalent series resistance (ESR) is required, such as a power rail. Typically, as tantalum is expensive, its use is reserved for applications requiring either small sizes or high power. Typical capacitance values range from 100nF to 1mF [2].

Tantalum capacitors are known to be more reliable than liquid aluminum electrolytic capacitors. Not only do tantalum capacitors not suffer from the risk of electrolyte leakage or loss, but they also have improved performance stability over temperature and frequency. Unlike the widely used multi-layer ceramic capacitors (MLCCs), tantalum capacitors do not exhibit a piezoelectric effect. They do, however, offer higher capacitances per unit volume.

Tantalum capacitors can be manufactured using two different methods. The first uses a solid tantalum capacitor, where a thin dielectric layer of Ta_2O_5 (tantalum pentoxide) is formed from the tantalum in the anode, and the cathode is made from manganese dioxide. In the second typical construction, a polymeric material replaces the manganese dioxide in the cathode.



Figures 1 & 2: Typical Tantalum Capacitor Structures

Tantalum capacitors are capable of 'self-healing’, and can recover from the effects of a damaged dielectric. As a result of this phenomenon, tantalum capacitors are often reported to have no known ‘wear out’ mechanisms. This fact is corroborated by field experience, which indicates very few failures, with almost all of those failures occurring immediately after turn-on. These failures occur due to the initiation of thermal runaway within the dielectric when subjected to surge currents, such as those the capacitor is subjected to during turn-on. Moreover, the few turn-on failures (usually measured in parts per million) are predominantly the result of impurities and defects introduced in the dielectric during fabrication, which in turn, can be exacerbated due to soldering-related or other thermal stresses. This failure mechanism is well understood and usually mitigated by introduction of screening techniques, ‘scintillation’ conditioning (electrical pre-conditioning) at the manufacturer end and by de-rating the operating voltages of tantalum

capacitors at the operator end. Newer polymer tantalum capacitors, in which the MnO_2 is replaced with conductive polymer electrolytes, do not exhibit this failure mechanism. These newer polymer tantalum capacitors are, therefore, even more reliable than the conventional tantalum capacitors.

Most tantalum capacitors usually fail short, in other words, they fail due to an increase in leakage current. Such capacitor failure may be induced by exceeding the rated conditions of forward DC voltage, reverse DC voltage, surge voltage, surge current, power dissipation, or temperature [3]. In most cases, both elevated temperatures and voltages (electric field) are required to induce failure. A leaky tantalum will result in shorter battery life. This scenario can be life critical for a patient in the worst case and could be a major issue for a company's viability.

The primary underlying failure mechanisms that could result in high leakage are dielectric breakdown and metal migration. There are several possible origins of breakdown including:

- Manufacturing (intrinsic) defects
  - Mechanical dielectric defect
  - Impurities included in the dielectric
  - Oxide crystallization sites in dielectric
- Thermal excursions
- Surge current conditions

Failure mechanisms that could cause the capacitor to fail open include cathode delamination or anode break. Such failure occurs due to the thermal expansion mismatches between the various layers in the capacitor. The following fish bone diagram (Figure 3) details typical failure modes and root causes and is a useful tool to see if the screens and tests are addressing the relevant failure modes.

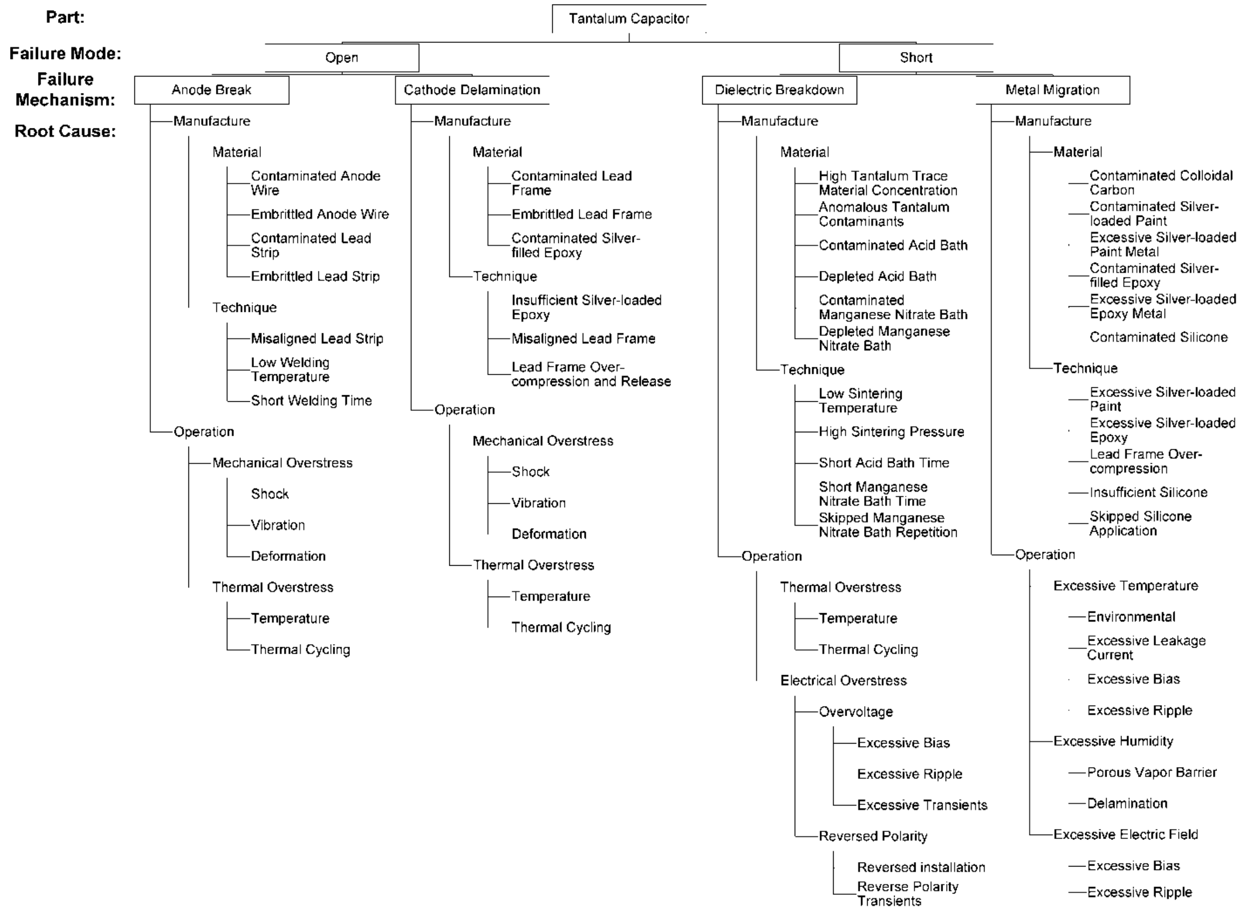


Figure 3: Failure modes and mechanisms in tantalum capacitors [4]

Screens and Tests for Tantalum Capacitors

The types of testing that can be performed on tantalum capacitors are given in Table 1. The majority of tests for components reference Military Standards (MIL STD) and not industry-wide developed standards. In particular, there are no industry standards specific to medical applications. In addition, as Table 1 shows, there are a couple of potential test needs that have no standards associated with them. Companies have been developing in-house tests to meet these needs.

Table 1: Typical testing required for tantalum capacitors.

Test Type	Typical Standard and Method
Mounting for testing	MIL-PRF-55365H method 4.7.1
Destructive analysis	MIL-PRF-55365H method 4.7.3
Visual inspection	MIL-PRF-55365H method 4.7.4
Flammability	MIL-STD-202, Method 111A
Stability at low and high T and damp heat	Already covered by “moisture resistance” and “temperature stability” (*see below*)
DC leakage	MIL 55365H, Method 4.7.6
Capacitance	MIL-STD-202, Method 305
Dissipation factor	MIL 55365H, Method 4.7.8
Seal Tests (hermeticity)	MIL-STD-202, Method 112, Condition D
Radiographic inspection	ASTM E1742 / E1742M [5]
Shock	MIL-STD-202, Method 213
Vibration	MIL-STD-202, Method 204
Thermal shock	MIL-STD-202, Method 107
Immersion	MIL-STD-202, Method 104
Solderability	MIL-STD-202. Method 208
Terminal strength (Pull)	MIL-STD-202, Method 211
Terminal strength (Twist)	MIL-STD-202, Method 211
Moisture resistance	MIL-STD-202, Method 106, J-STD-020
Case insulation dielectric strength	Company specific
Case insulation resistance	Company specific
Temperature stability	MIL-PRF-55365H Method 4.7.16
Surge current	MIL 55365H Method 4.7.18
Storage life	IPC/JEDEC J-STD-020D
Resistance to solvents	MIL-STD-202. Method 215
Resistance to soldering heat	MIL-STD-202, Method 210

At present, the qualification and screening procedures adopted by the main tantalum capacitor OCMs for medical device applications are largely based on the MIL-PRF-55365H standard, *General Specification for Capacitor, Fixed, Electrolytic (Tantalum), Chip, Established Reliability, Non-established Reliability, and High Reliability*. The screening tests are performed on all the capacitors before release to market and the qualification tests are performed on a sample from a lot to confirm that the lot (or the process) is acceptable [5,6,7 & 8].

Several publications have pointed out deficiencies and inconsistencies of these methods. In particular Teverovsky *et al.*, in their studies on tantalum capacitors for high-reliability aerospace applications, pointed out several deficiencies of MIL-PRF-55365H screening and qualification methods [9 & 10]. These deficiencies or inconsistencies are summarized in Tables 2 and 3.

Table 2: Deficiencies of MIL-PRF-55365H Screening Tests

	Method	Description	Deficiency / Inconsistency Noted
Screening	4.7.6	DC Leakage	Existing requirements for maximum acceptable DC leakage current (DCL) values are too loose and the test conditions, as they are specified in MIL-PRF-55365, might not be optimal to reveal and reject outliers. Longer electrification time before leakage current read out should be allowed. The effectiveness of revealing defects could be increased substantially if measurements would be made at 1.33 Vrate and 85°C. Assumption of normal distribution is not adequate and statistical analysis should be refined.
	4.7.10	Reflow Conditioning	No post-conditioning measurements required by the standard. Only one cycle is required, not reflecting assembly conditions for a large group of applications when parts are used on double-sided boards, thus experiencing solder reflow stress two times.
	4.7.14	Equivalent Series Resistance (ESR)	Since ESR can be degraded by surge current testing, it should be measured after surge current testing.
	4.7.18	Surge Current	Test conditions are not well defined. Test should performed at V> Vrated to add safety margin.
	4.7.20	Weibull Grading	Current limit (1 or 2 A) is too high and scintillation/self-healing events could remain undetected. Current limit should be reduced by 1 order of magnitude at least.

Table 3: Deficiencies of MIL-PRF-55365H Qualification Tests

	Method	Description	Deficiency / Inconsistency Noted
Qualification	4.7.11 4.7.12	Thermal Shock (unmounted/mounted)	Does not guarantee that tantalum capacitors can withstand multiple cycling, even within a relatively narrow operating temperature range. The number of cycles should be increased.
	4.7.13	Resistance to Soldering Heat.	ESR measurement after test is not required by the standard. 5% failure rate limit is too high.
	4.7.15	Moisture Resistance	Low voltage characterization should be performed after this test.
	4.7.19	Life Test	Test conditions not stressful enough to demonstrate target operating life.

The industry is aware of these deficiencies and efforts are being made to address them. AVX, for example, adopts a so-called "Q-process" comprising statistical screenings at various temperatures before and after burn-in, optimized 125°C burn-in, enhanced in-line reflow profile, and Maverick or outliers lot screening [11].

Kemet has developed a proprietary screening method (Simulated Break-Down Screening) based on the analysis of the capacitance charge characteristics when voltage exceeding average Break-Down Voltage (BDV) is applied to the tested capacitor with a high series resistor limiting the current in the circuit [12]. The test is reported to be capable of effectively screening low break-down voltage parts without any damage of the capacitor population.

Vishay offers customized screening and testing beyond MIL-PRF-55365H for medical applications, e.g., high-temperature DC leakage testing [13].

While these proprietary and/or customized screening strategies may be effective, they pose two major drawbacks for the customers: increased price due to non-standard requirements, and the inherent impossibility of having second sources. It would be more cost efficient for the industry if some standards screen tests could be used.

It should be noted that the use of outdated and discontinued methods is still employed by some OCMs. A prominent example is the handbook, MIL-HDBK-217, which is still being used to get a figure of merit for the reliability of tantalum capacitors [14]. There is strong discussion in the industry, which discourages the use of this handbook, because it provides no contextual results regarding product, technology or use conditions and does not address failure modes and mechanisms. The US Army regulation 70-1 emphasizes that "MIL–HDBK–217 or any of its derivatives are not to appear in a solicitation as it has been shown to be unreliable, and its use can lead to erroneous and misleading reliability predictions" [15-18].

Key Test Information

There are a number of existing standard screening and qualification tests available to the industry that address the key failure modes in tantalum capacitors. Designers need to consider both final device applications and capacitor manufacturing processes when evaluating the data from these tests. An understanding of the coupling between the failure mechanisms and the intended device storage and operating conditions is important. There are occasions, due to specific conditions, when the OCMs do not need to perform every specialized test. However, it is necessary to have, at a minimum, the following information to judge the applicability of the test of an application.

We recommend that 11 required test elements should be considered in any test standard/procedure/method (Table 4).

Table 4. Required Elements of a Test Procedure/Standard/Method

Key Test Element	Description
Stress level/test conditions	Applicable stress levels (e.g., temperature extremes) and the rates of changes (e.g., ramp up/down rate) should be provided.
Duration	Duration includes the number of testing cycles and/or the time duration of the test
Pre-test analysis	Pre- and post-test analyses may include visual, functional, mechanical and electrical testing before and after the test procedure. Results should be documented for future reference.
Test equipment	The test equipment section should include a description of the required specifications of the test equipment with the necessary tolerance limits. It may also include the auxiliary devices required to carry out the test.
Data acquisition	Details of the pre-test, post-test and any analysis during the course of the testing, need to be included along with the procedure. Inclusion of a flow chart or schematic will further aid this process.
Identification of units under test (UUT)	Units subjected to test may be system-level, assembly-level or component (subassembly)-level items.
Test procedure	Test procedure should be clear and unambiguous.
Sample size	The number of units under test.
Failure criteria	Failure criteria are the parameter thresholds beyond which the unit is deemed to have failed.
Acceptance criteria	Applicable for acceptance of the lot.
Post-test analysis	Same as pre-test analysis above.

Medical Device Standards

In the research of the various standards applicable to components for medical products, it was noted that the context of use is significantly different than that of other industries. Specifically, in a traditional standards context, a component may be designed following a single component

standard, and be used in a variety of products with minimal additional analysis and testing on the part of the end-equipment manufacturer. However, for medical devices, the concept of risk management has been introduced through a normative reference to *ISO 14971, Application of Risk Management to Medical Devices*. This standard provides end-product manufacturers with great flexibility in designing and offering new and novel products without waiting for a formal standard. However, this is a two-edged sword. Although medical device manufacturers have great flexibility in designing and offering new products, they must identify and manage the risks that may also be new and novel. Clearly, the end-product manufacturers' risk management processes for new and novel devices also have implications for component manufacturers, as their efforts cascade through the supply chain.

The goal of the end-equipment manufacturer risk management efforts must be to ensure that their device performs its clinical function properly. For example, performance may be absolute (a life supporting device such as a ventilator), or degradable (the image quality of an ultrasound device). Incorrect performance in either case would typically represent an unacceptable risk to the user. That is, cessation of function of a lung ventilator may lead directly to death; improper imaging for an ultrasound may result in a misdiagnosis of a condition by a physician.

Because medical device manufacturers may be designing new and novel products, they may require component specifications that are unique. As our team considered the implications of these facts, we noted that, as the end-equipment manufacturers perform risk analysis and, then, translate the needed performance into component specifications for outsourced components, there is a potential for blind spots. These blind spots strongly depend on the perspective of the parties involved, for example:

- End-equipment manufacturers may be unfamiliar with the limitations of certain components, and exactly which feature of the component may be critical to preserving basic safety and the clinical function of the device, as the component is applied within their application.

- Component manufacturers may be unaware of end-equipment application needs, and are focusing on creating "off-the-shelf" parts with universal applications (i.e. industries other than medical devices).

- Design engineers may be unfamiliar with production issues and limitations, particularly as they relate to their counterpart end-equipment or component manufacturer.

- Production engineers may be unfamiliar with changes that potentially impact design performance, particularly as it relates to their counterpart end-equipment or component manufacturer.

All of the above permutations may be extended through all tiers of the supply chain. In view of this, the project team believes that we have identified a need for greater and improved communication between all parties having some part to play in bringing a medical device to market. Risk management will help to drive this communication. However, additional research is warranted in uncovering "blind spots" and developing risk mitigation approaches.

Conclusions

There is a definite need for component-level standards for medical applications. A number of relevant screens and test methods are typically utilized, but they do not all consider the unique requirements of medical device applications. A methodical approach and commitment of resources are required, particularly on the part of the end equipment or medical device manufacturer, to communicate with the component suppliers and to consult experts in other high-reliability fields to relate the testing required to the application of the component. A starting point for this process has been to consider the standards being used in other high-reliability applications, such as aerospace, and to correlate those standards with the high-reliability requirements of medical devices and applications. Ideally, manufacturers in key areas of medical devices, e.g., implantable, should leverage their resources and influence with the supply base to work together to define a standard testing specification that would eliminate the need and cost of unique testing by the OCMs.

Understanding and engaging in a risk management process for medical device manufacturing is an important point that has to be considered not just by the device manufacturers but by the suppliers also. The survey showed limited knowledge by suppliers, in particular, of the ISO 14971 standard. Suppliers must not only be familiar with this standard, but should work proactively with their customers as part of the risk management process. For example, changes in processes should determine if the screening and testing should be reviewed; changes in manufacturing locations should also be assessed and communicated as an inherent part of the process.

For tantalum capacitors in particular, the team found that a number of screens and qualification tests exist that can be used as the basis of a component-level specification for medical devices. It should be noted that the severity of the tests used should be governed by the intended application, e.g., electrical testing at high temperature is not relevant to implanted devices as a screening test. However, elevated temperature testing is a standard technique for accelerating the aging process during qualification. We, nevertheless, note that reliability studies of tantalums capacitors used in other critical application areas have helped identify weaknesses in certain tests.

In addition, while MIL-PRF-55365 may be a starting point for screen and test for tantalum capacitors, it has to be kept in mind that it was developed specifically for military purposes.

- Tests are not always relevant to medical electronics applications.
- Tests may not be adequate for high-reliability medical applications.
- Test ranges may be overly broad for specific medical device applications, slowing progress and miniaturization in particular areas.

In the main, there are sufficient screens and tests available to ensure the reliability performance of tantalum capacitors in medical devices if the end use of the devices is well understood and considered at the design and manufacturing stage. However, failure mechanisms relevant to those end uses, as well as environmental conditions, must be known and directly traceable to test conditions.

Recommendations

There needs to be increased engagement between end use manufacturers and component suppliers focused on medical devices applications and their specific needs.

Collaborative development of specific standardized testing for different applications in medical electronics is recommended. For example, implanted device manufacturers should develop a specification focused on their needs and applications. This approach has been used in automotive and other industries. The methodology and results outlined in this project could be used as a starting point.

Contributors

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- Peter Lampacher, MED-EL
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- Boston Scientific (USA)
- CALCE (USA)
- Cochlear (Australia)
- DfR Solutions (USA)
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- MED-EL (Austria)
- Micro Systems Technologies (USA)
- NIST (USA)
- Underwriters Laboratories (USA)

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- AVX – Tantalum capacitor division (Allan Mayar, Bob Fairey, Brian Brunette)
- NASA (Alexander Teverovsky)

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iNEMI Medical Components Bibliography
Tantalum Capacitors

Description	***Brief Summary***
Failure modes of tantalum capacitors made by different technologies P. Vasina, T. Zednicek , J. Sikula*, J. Pavelka* AVX Czech Republic s.r.o., Dvorakova 328, 56301 Lanskroun, Czech Republic *CNRL TU Brno, Technicka 8, 60200 Brno, Czech Republic	According to V-A characteristics, a solid tantalum capacitor made with either MnO2 or conductive polymer technology can be considered as an MIS (metal-insulator-semiconductor) diode, and its reverse mode corresponds to an MIS diode operated in a forward direction. With MnO2 as the cathode material, thermal breakdown in the normal mode follows electrical breakdown due to energy dissipation. However, in the reverse mode, breakdown is initiated by an increase of the electrical conductance by Joule heating. The V-A characteristic of the conductive polymer capacitor, on the other hand, has a first section, the low intensity region, that is described as a square law dependency. It is related to the current injection into the insulating layer with trap-fillet-limit. This is consequently followed by a section of quadratic dependence due to space charge limited current injection with uniform trap distribution. Electrical breakdown of MnO2 capacitors initiated by the test started at about 25V25V – 35V (three times rated voltage). Conductive polymer dielectric breakdown occurred at lower voltage, about 10V10V – 20V (one to two times rated voltage). MnO2 parts were found to be more capable of self-healing during the electrical breakdown experiment than either of the conductive polymer technologies tested. Some additional work on conductive polymer materials may be required in order to understand their physical properties and potentials for future applications.
Voltage derating rules for solid tantalum and niobium capacitors, 2003 T. Zednicek AVX Czech Republic s.r.o., Dvorakova 328, 563 01 Lanskroun, Czech Republic Phone: +420 467 558 126 Fax: +420 467 558 128 email zednicekt@avx.cz J.Gill AVX Limited, Long Road, Paignton Devon TQ4 7ER, United Kingdom Phone: +44 1803697200 Fax: +44 1803697326	Conclusions: • Voltage derating is necessary for tantalum and niobium capacitors to prevent failure due to excess current availability. • Tantalum capacitors can be safely used at 80% of their rated voltage, but the MTBF will be lower and leakage current higher. • If a tantalum must be used across a low impedance source, consider incorporating a PFET integrator to reduce risk of failure. • A 20% derating is sufficient for OxiCapTM NbO capacitor in most applications. • Select–a–Cap software is available to help identify the correct part number including typical parameters in a given application.
Basic tantalum capacitor technology by John Gill AVX Ltd., Tantalum Division Paignton, England	This paper covers the general manufacturing techniques used to make a solid tantalum capacitor. The purpose of this paper is to give the layperson an understanding of current tantalum technology.

Reliability management of tantalum capacitors by Chris Reynolds AVX Tantalum Corporation 69 Landry Street Biddeford, ME 04005 207-282-5111	Tantalum capacitors can achieve high reliability in steady state applications. Tantalum capacitors have highly stable capacitance and frequency dependent characteristics. Short circuits are a low level, but not negligible, failure mode. Because of this, reliability management of tantalum chips means the effective control of the S/C failure mode, not least because this mode cannot be designed around by use of redundancy circuits, etc.
Surge in solid tantalum capacitors by John Gill AVX Ltd, Tantalum Division Paignton, England	A detailed look at factors that can cause surge failures in tantalum capacitors, how they can be diagnosed, and what can be done to prevent them occurring. Also an explanation of how surge affects the lifetime reliability of a tantalum capacitor.
Kemet Application notes for tantalum capacitors	General application class, storage conditions, polarity, operating environment, capacitance, dissipation factor, DC leakage, rated voltage, working voltage, surge voltage, reverse voltage, ESR, power dissipation, failure modes, reliability prediction, surge current, environmental considerations, mounting.
Quadtech Equivalent Series Resistance (ESR) of Capacitors	Questions continually arise concerning the correct definition of the ESR (Equivalent Series Resistance) of a capacitor and, more particularly, the difference between ESR and the actual physical series resistance (which we'll call Ras), the ohmic resistance of the leads and plates or foils. The definition and application of the term ESR has often been misconstrued. We hope this note will answer any questions and clarify any confusion that might exist. Very briefly, ESR is a measure of the total lossiness of a capacitor. It is larger than Ras because the actual series resistance is only one source of the total loss (usually a small part).
Vishay DC Leakage Failure Mode	This paper is submitted as an educational medium for use by anyone who has interest in solid tantalum chip capacitor performance. It represents technical phenomena that are generic to all solid tantalum chip capacitors. The intent is to provide a greater depth of understanding among users, purchasers and manufacturers of these capacitors. This paper provides a general description of tantalum capacitor construction, a discussion of DC leakage failure mechanisms, and some process controls relating to these failure mechanisms. Tantalum capacitors are classified as electrolytic capacitors and as such they are composed of four parts: anode, dielectric, electrolyte (solid or liquid), and cathode.
Vishay Solid Tantalum Capacitors: Frequently Asked Questions (FAQs)	Q. What is the difference between a fused and standard, non-fused tantalum capacitors? Q. What are the materials in a tantalum capacitor? Q. How are tantalum capacitors packaged? Q. What labeling information is present on reels and boxes of tantalum capacitors? Q. What are the recommended storage conditions for solid tantalum capacitors? Q. What is Vishay's selection of solid tantalum capacitors? Q. What is the termination coating on Vishay solid tantalum capacitors? Q. How can reliability of solid tantalum capacitors be calculated? Q. What is the moisture sensitivity of Vishay solid tantalum capacitors?

	Q. What is the shelf life of a solid tantalum capacitor? Q. What do the markings on Vishay leaded parts mean? Q. Are all Vishay solid tantalum capacitors RoHS compliant? Q. Why can't I use this 10 V rated capacitor using a 10 V power supply? Q. How long can you operate Vishay solid tantalums with the applied reverse voltage bias? Q. How long can you operate Vishay wet tantalums with the applied reverse voltage bias?
Characterization of Tantalum Polymer Capacitors NEPP Task 1.21.5, Phase 1, FY05 Erik K. Reed Jet Propulsion Laboratory	This document briefly describes the origin of MnO2-based solid tantalum capacitors, their methods of processing and construction, and their defining electrical characteristics versus the wet electrolytic capacitors they replace. The case for improved electrolyte conductivity is briefly presented and conductive polymer is identified as the candidate material of choice to replace MnO2 in the solid tantalum capacitor. The defining electrical characteristics of capacitors made with conductive-polymer solid electrolyte are described. Typical processing options and material issues related to conductive polymer electrolyte are identified. Details of the step by-step processing of typical tantalum polymer capacitors from tantalum powder to assembled and encapsulated devices are photographically presented. The electrical performance, dielectric robustness, reliability, and environmental stability of tantalum polymer capacitors are discussed in some detail.
Highly Accelerated Testing of Capacitors for Medical Applications Travis Ashburn, Dan Skamser KEMET Electronics Simpsonville, SC, USA travisashburn@kemet.com, danskamser@kemet.com	As the market for medical devices continues to grow and expand, it has become evident that product reliability must remain a top priority for medical device manufacturers. In order to guarantee reliability, device manufacturers must choose reliable medical-grade components for their high-reliability applications. Reliability testing for passive components, especially capacitors, is typically conducted through accelerated and highly accelerated life testing (HALT). Models are used to fit the distributions of insulation resistance to provide prediction capability for lifetime estimates. Risk is minimized by correctly rating the capability (temperature and voltage) of capacitors based on the models. In this paper, models and time-to-failure (TTF) predictions at application conditions for the widely used X7R and C0G ceramic capacitors are discussed.
Weibull Grading and Surge Current Testing for Tantalum Capacitors Alexander Teverovsky Parts, Packaging, and Assembly Technologies Office, Code 562, GSFC/ Dell Services Federal Government, Inc. Alexander.A.Teverovsky@nasa.gov	Failures in Ta capacitors occur typically either under steady-state operating conditions, or at the first power turn-on. • To reduce the probability of the first type of failures, capacitors are screened/qualified by WGT. • SCT is used to mitigate the risk of the second type of failures. What are these tests, how effective are they, and what can be done to improve the efficiency? • Scintillation break-down and self-healing in tantalum capacitors. • Failures as time dependent dielectric break-down (TDDB). • Weibull grading test (WGT). • Surge current test (SCT)

Reverse Bias Behavior of Surface Mount Solid Tantalum Capacitors Alexander Teverovsky, Ph.D. QSS Group, Inc./NASA	Solid tantalum capacitors are polarized devices designed to operate only under forward voltage bias conditions. Application of reverse voltage may produce high leakage currents with potentially destructive results. Such misapplications of these devices sometimes occur during bench testing, troubleshooting of engineering modules and/or during some malfunctions in operating systems. However, more serious consequences of reverse bias application are caused by incorrect installation of the capacitor on the board. In practice, the situation sometimes arises where assembled hardware is suspected of having one or more solid tantalum capacitors installed backwards. Verification of this problem is often complicated by the expense of disassembling hardware for close inspection. In these situations, program managers would benefit from a risk assessment that predicts possible consequences of reverse installation in the intended application and the probability of failures in the system within the mission operation time. Unfortunately, there is only limited published research regarding the ability of solid tantalum capacitors to survive such conditions. The manufacturers of solid tantalum capacitors provide very conservative guidelines regarding momentary reversals of polarity with no guarantee of performance under prolonged exposures to reverse voltages. This work explores the behavior of three lots (20 V, 35 V and 50 V rated) of solid tantalum chip capacitors from one manufacturer under various reverse bias conditions.
Reliability Characterization of Tantalum Capacitors with MnO2 Counter-Electrode Jonathan L. Paulsen KEMET Electronics Corp. PO Box 5928, Greenville, SC 29606 1-864-963-6300 (Phone) / 1-864-967-6876 (FAX) jonathanpaulsen@kemet.com	Reliability analysis of capacitors manufactured with manganese dioxide (MnO_2) solid electrolyte has traditionally been accomplished using Weibull failure rate grading. This method was developed decades ago using time-to-failure data from many tantalum capacitor samples with varying manufacturers and production specifications. Subsequent investigations have demonstrated that factors affecting reliability analysis can vary substantially for different MnO_2 capacitor designs. Since traditional Weibull characterization assumes similar performance for all parts regardless of process parameters, more refined reliability experiments may yield more useful information. The aim of this work is to develop a more flexible framework for reliability analysis of MnO_2 tantalums. To achieve this goal within a reasonable timeframe, accelerated life testing utilizing high electric field stress and temperature was performed on multiple test samples. The resulting time-to-failure data was fit to a failure model and then used to predict device reliability under less strenuous conditions.
High Capacitance Density Thin Film Integrated Tantalum Pentoxide Decoupling Capacitors Chris Thomason, Len Schaper, Julie Morgan, Susan Burkett, Richard Ulrich University of Arkansas	The process development and analysis of a multilayered thin film integrated capacitor is presented. Thin film integrated capacitors show great promise as IC power supply decoupling capacitors. Their low intrinsic inductance allows them to deliver fast switching high currents to the IC. However, current thin film capacitors are limited in capacitance

Fayetteville, AR clt03@uark.edu	due to the limitation of substrate area in boards or packages. Generally, there is not enough area available to produce the capacitance needed so that integrated capacitors can completely replace discretes. This paper discusses a multilayer thin film integrated capacitor design. The details of the multilayer process are described, as well as process challenges and preliminary results of the research. Currently, capacitance densities in the range of 0.4 µF/cm2 have been obtained with a two-layer process. In the future this value will be further increased with a three-layer process.
Failure Avoidance in Military Electronics / A Step-by-Step Guide to Best Practices, Tantalum Capacitors: Failure Modes & Mechanisms DfR Solutions	Discusses tantalum capacitor failure modes, mechanisms, and root causes
Reliability and Critical Applications of Tantalum Capacitors Yuri Freeman, Randy Hahn, Philip Lessner, and John Pryor KEMET Electronics Corporation 2835 Kemet Way Simpsonville, SC 29681 Phone: (864) 228-4068. Email: yurifreeman@kemet.com	High stability and reliability bring Ta capacitors into special applications, such as military, aerospace, and medical. At the same time, the key element of Ta capacitors, the Ta_20_5 dielectric, is inherently thermodynamically unstable. Stabilizing the dielectric and the Ta/Ta_20_5 interface can be accomplished by kinetic means. Extension of high stability and reliability to higher temperatures and voltages requires a deep understanding of these thermodynamic and kinetic factors and the manufacturing technology to affect the practical realization of this science.
Achieving the highest reliability level of tantalum capacitors Marc Beaulieu, AVX	Private presentation to the iNEMI project team.
Tantalum Chip Capacitor Reliability in High Surge and Ripple Current Applications Erik K. Reed KEMET Electronics Corporation QA&R Laboratory, Bldg. 1 P. 0. Box 5928 Greenville, SC 29606	Relentless miniaturization of electronic circuitry and the general movement from through-hole to surface-mount manufacturing have generated explosive growth in the use of surface mount tantalum chip capacitors. Many of these applications involve substantial exposure to surge and ripple currents. Such exposure invites questions regarding the impact of surge and ripple current on the long-term reliability of tantalum chip capacitors. To facilitate a better understanding of the impact of surge and ripple current on tantalum chip capacitor reliability, theoretical analyses of generic circuits are supported with discussion of experimental data. Simple circuits that highlight the fundamental theoretical principles behind transient surge and steady state ripple current applications are analyzed and pertinent reliability issues are discussed. The relationship of device ESR (equivalent series resistance) to surge and ripple current robustness and device temperature rise is established theoretically. Surge and ripple current test and measurement methods are briefly discussed and experimental test data are used to support many of the insights that are drawn from theory.
Screening and Qualification Testing of Chip Tantalum Capacitors for Space Applications Alexander Teverovsky Dell Perot Systems Code 562, NASA GSFC, Greenbelt,	In this work, the existing screening and qualification system for solid chip tantalum capacitors manufactured per MIL-PRF-55365 have been analyzed, and recommendations for improvements are discussed. A new test, break-down margin verification, is introduced, and a test flow for up-screening and quality verification of commercial tantalum capacitors for space

MD 20771 Alexander.A.Teverovsky@nasa.gov	applications is suggested.

Simplify selection and improve reliability of small form factor resistors, capacitors, and magnetics used in medical devices
Vishay Intertechnology, Inc
M. Olver, J. Adsero, J. Petheram, P. Gormally
	Discuss important passive components in medical devices and selection criteria:
	• Capacitors
	• Resistors
	• Magnetics
	• Provide fundamental concepts:
	  • Reducing valuable hybrid space
	  • Selecting passive components with proven reliability for medical device applications

Low De-rating Reliable and Efficient Ta/MnO_2 Capacitors Yuri Freeman, P. Lessner, and E. Jones KEMET Electronics Corporation 2835 Kemet Way Simpsonville, SC 29681 Phone: (864) 228-4068. Email: yurifreeman@kemet.com	Using Ta/MnO_2 capacitors with low (no) de-rating allows radical increase in the volumetric CV/cc and weight CV/g efficiency of these capacitors (smaller size and lighter weight), which are the major selling points of Ta capacitors. At the same time, smaller anodes result in higher equivalent series resistance (ESR), which is directly proportional to the external surface area and can mitigate this problem when low ESR is requested. Low (no) de-rating will also ensure sufficient supply of the Ta powder due to reduction in the anode weight for given rating of the Ta/MnO_2 capacitors.