Ansys

WHITE PAPER

When Failure Is Not an Option: Improving Medical Device Reliability

Medical electronics are expected to operate safely over extended periods of time to provide monitoring, therapeutic or life-sustaining functions for patients. Without built-in reliability, these devices could experience failures or malfunctions that greatly increase the possibility of infection or death. In the movie *Apollo 13*, NASA's Gene Kranz (played by actor Ed Harris) made the phrase "Failure is not an option" famous when discussing the Apollo 13 Moon landing mission. Similarly, failure is not an option when it comes to medical electronics devices.

Numerous reliability approaches exist in the medical electronics industry to prevent failures. Component and module reliability is typically determined by the parametric performance following a suite of stress tests. Stress tests are often derived from an industry standard and usually do not consider the capability of the device under specific use-conditions, such as implantables, defibrillators or other medical applications requiring safety measures. Extrapolation of these test results to failure rates is therefore not feasible or useful. Improving the effectiveness and efficiency of reliability assessment throughout the life cycle of implantable devices is essential, but it can also be a significant challenge.

With the continued consolidation of major electronics industries and the proliferation of materials and component changes, including smaller parts, reduced gate geometries, advanced packaging technologies and new materials, it is increasingly necessary to establish baselines and methodologies for reliability assessment. In this white paper, we will discuss the strategies and protocols to improve medical electronic device reliability and how these strategies will benefit both the patient and the manufacturer.

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/ 1. Common Reliability Approaches

Reliability is the characteristic expressed by the probability that the part will perform its intended function for a specific period of time under defined usage conditions. Rather than describing reliability as a probability, other common approaches include characterizing reliability performance in terms of reliability metrics such as mean-time-to-repair (MTTR), mean-time-between-failures (MTBF), defect rate per year (ppm/year) or failure-in-time (FIT).

Other approaches for reliability assessment involve a combination of stochastic and mechanistic methods to derive the bathtub curve shown in Figure 1. Typically, the failure rate is plotted as a function of time and is often characterized by three phases:

(a) An early life or infant mortality region where the failure rate decreases as a function of time.

(b) A constant failure rate region.

(c) A wear-out region where the failure rate increases as a function of time.

In phase 1, the early life failures are typically due to anomalous damage from manufacturing defects, such as solder joints, plated through hole issues and early component failures. For phase 2, failures in the constant failure rate region are attributable to a variety of stochastic variations in materials and processes. For phase 3, failures in the wear-out region are due to intrinsic time-dependent propagation of damage due to a variety of mechanisms such as corrosion, migration and fatigue.

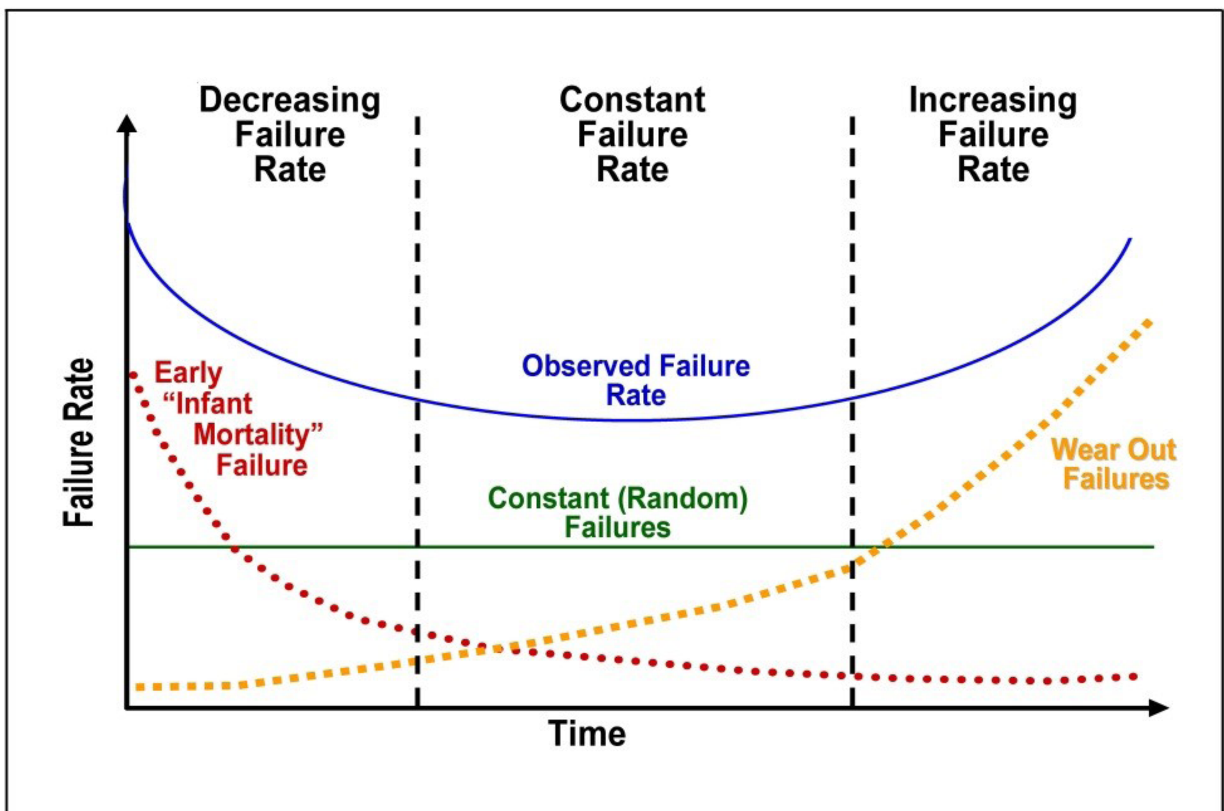

Figure 1. Bathtub curve

A common approach is to focus on eliminating the impact of wear-out mechanisms in the design phase and address the early life failures through a method like burn-in. However, the application of a mechanistic or a phenomenological approach for wear-out and burn-in requires optimization when used for high-reliability medical electronics. The reasons include:

1. Application conditions are benign, therefore, stresses do not result in wear-out mechanisms. Further, battery life limitation often precedes the wear-out of electronics, so it is rare that wear-out is a contributor to time-dependent failures.

2. Comprehensive product verification and validation during the design phase ensures substantial margins for wear-out mechanisms.

3. Data describing the infant mortality behavior and the bathtub curve are inadequate as a basis for reliability assessment and modeling.

2. Creating an Effective Reliability Program

A reliability program is typically categorized into three phases:

1) Development

2) Manufacturing

3) Monitoring (Use)

The development phase refers to the time period prior of the release of component, technology or product to production. This is when the bill-of-materials (BOM) is generated, the printed circuit board (PCB) layout is generated and the materials selection occurs. During the manufacturing phase, a released design is produced under controlled and qualified conditions. In this phase the manufacturing process flow is defined, solder paste reflow profiles are created, pick and place programs are generated, and post surface mount technology (SMT) processes are defined. The monitoring phase refers to the end use of the component, technology or product or the actual field application environments.

The focus during the development phase should be design margin improvement by eliminating failure modes, and therefore rendering these modes irrelevant for reliability analysis.

During the manufacturing phase, the focus is on anomalous behavior containment (i.e., detection and containment of extrinsic effects). This could encompass encountering materials that are incompatible with the manufacturing flow, or processes that are beyond the capabilities of certain components.

Given robust designs and contained anomalous behavior, the purpose of reliability programs during monitoring is to obtain a quantified basis for random failure modes (combinatorial extrinsic and intrinsic effects). This is accomplished by reliability monitoring.

The methods and tools used in each of these phases typically involve:

(1) A stress profile to precipitate latent defects.

(2) A characterized test methodology to detect a defect that has been precipitated.

(3) A sampling plan based on sensitivity of the expected change and the allowed error.

(4) Criteria for anomalous behavior.

(5) A closed-loop continuous improvement process.

A framework for the methodologies proposed for the development, manufacturing and monitoring phases is further described below. While this framework has been applied to a wide variety of components, materials and modules for high-reliability medical electronics applications, ceramic capacitors are used as an example to demonstrate the application of these methods.

3. Reliability Program Methodological Framework

3.1.1 Development: Design Performance and Process Capability Assessment

The complexity of a device, the multitude of component technologies and interactions of various failure mechanisms requires a holistic, phenomenological or mechanistic approach for design margins assessment. Conventional system decomposition or fault tree analysis methods are complex and often require a knowledge base unavailable during design and technology development. Development and change management schedules often impose time and resource constraints.

Being able to assess the design margins, the impact of testing and the real-world applications as early in the design cycle as possible is imperative. Ansys Sherlock software provides a more formalized and structured approach to root cause analysis that combines materials science, physics and chemistry to achieve product reliability early in the design stage.

Using Physics of Failure (PoF) provides a scientific basis for evaluating a medical product's usage life and hazard risks as a function of materials selected, e.g., PCB laminate, surface finish, thickness, copper thickness on PCB layers, solder and component mix (and their respective materials) under actual operating conditions.

The previously noted bathtub curve actually looks more like Figure 2 because real failure rate curves are irregular, dynamic and full of valuable information that can help understand the true product performance throughout the life cycle.

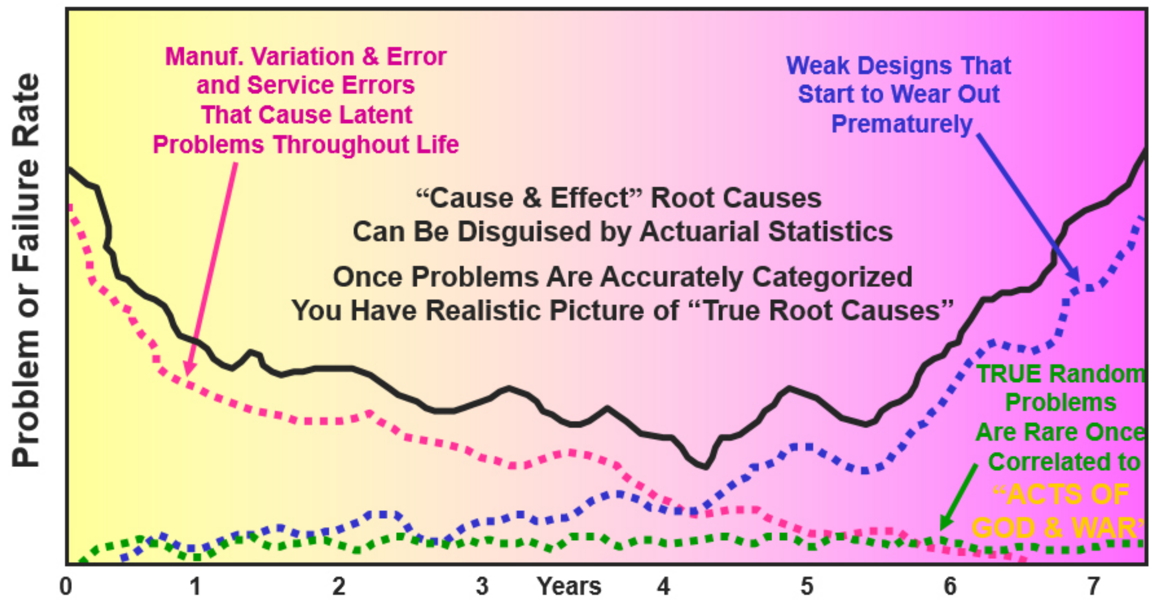

Figure 2. Realistic bathtub curve

A deep understanding of the failure modes and mechanisms in your medical electronic device at the earliest point in the design cycle is critical. In addition, understanding the environments the product may be used in is necessary, both during test and application. Failures can occur prematurely due to a variable fabrication or assembly defect, gradually due to wear out, or erratically due to an excessive stress that exceeds the capabilities/strength of a component or assembly. Being able to model these characteristics at the circuit card assembly level so that you can examine the product's responsiveness to changes in design, materials and suppliers is needed to ensure that failures do not occur. Sherlock allows users to input complex environments as shown in Figure 3 and obtain outputs that complete the life cycle curve.

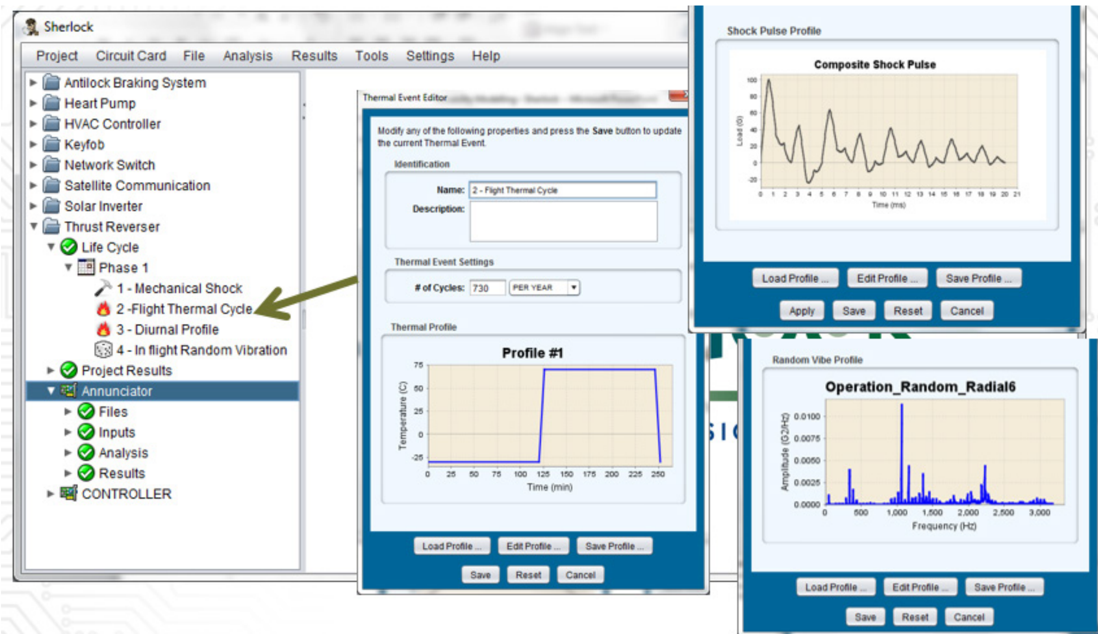

Figure 3. Thermal shock, mechanical shock and random vibration stresses in Sherlock

To perform the analysis the user must provide detailed inputs for the modeling software and calculation tools. This includes defining the reliability/durability objectives and expected environmental and usage conditions under which the product is required to operate. Once input is completed, automated calculations translate and distribute the environmental and operational loads across the circuit board to the individual parts. Sherlock then performs a specific design and application simulation to ascertain life expectancy and reliability distributions. It also prioritizes risks by applying PoF algorithms to the virtual PCB assembly model created.

In addition, Sherlock sets up design failure modes and effects analysis as shown in Figure 4, which greatly facilitates the process and reduces analysis time.

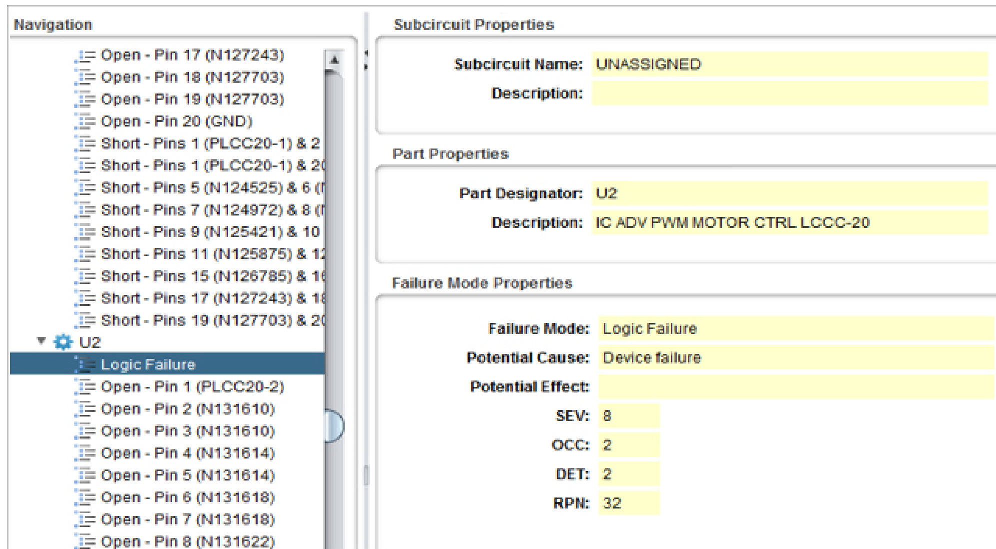

Figure 4. DFMEA structure

The output of the analysis provides insight into which components generate the most risk, how the entire assembly behaves with respect to the life expectancy and where the components with issues are located, as shown in Figure 5. The left image shows the parts list in descending order of risk (the red rows indicate a failure). The right image indicates which parts are at issue (again the red rows are failures) and the curve in the center illustrates how the assembly is behaving with respect to the required life expectancy.

Figure 5. Sherlock outputs identify components at risk.

This approach is the only method available for performing a comprehensive assessment of potential failure mechanisms from a variety of environments, e.g., elevated temperature, thermal cycling, vibration (random or sinusoidal) and mechanical shock. Doing this assessment in the design phase of product development assures a robust design with margin and mitigates risks from defects — all vital when failure is not an option. "What if" analyses can also be performed to see the impact of a change in material, a component's location, the solder formulation, etc., to immediately see the reliability change incurred. Design margin testing can then validate the models results.

In the example below, we show a capacitor performance (design) assessment. Design margin analysis requires that failure mechanisms be stimulated to failure and design "weaknesses" be eliminated. There are two elements of margin optimization: (1) Components must be selected having performance levels with margins with respect to application and process capabilities, and (2) components must be demonstrated for stable manufacturing.

EXAMPLE:

A 0603 2.2 uF capacitor is required to operate at 3 V continuous bias at 37 C for 12 years. Based on a risk assessment, the failure mode of interest is leakage due to dielectric breakdown. The 2.2 uF, 16 V capacitor has a dielectric thickness of about 1.2 um. The 2.2 uF, 25 V capacitor has a dielectric thickness of approximately 2 um. Two 0603 capacitors designs are tested to failure at twice the rated voltage of operation at 85 C. A sample size of 132 was selected based on the test capacity. The voltage acceleration exponent of 3 and temperature activation of 0.7 eV is assumed. Prior testing on capacitor failures has indicated a Weibull shape factor of 2.5 to 3. Using a 95% confidence level and a conservative Weibull shape parameter of 2.5, the fault-free time is required to be above 158 h at 32 V or 48 h at 50 V to demonstrate a 1 ppm quality level after 12 years at 95% confidence levels.

In Figure 6, the 2.2 uF, 16 V capacitor was tested at 32 V and the 2.2 uF, 25 V was tested at 50 V. The temperature of test was 85 C. Both capacitors indicate a Weibull slope of ~2.5–3, i.e., the failure modes are similar. However, the 25 V rated part shows greater design robustness margins and lower propensity for infant mortalities. With the selection of the 25 V designs, an intrinsic failure mode is made irrelevant.

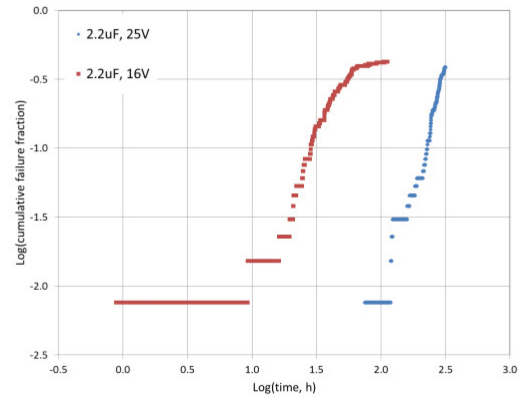

Figure 6. Results for capacitor testing

3.1.2 Manufacturing: Anomalous Behavior Containment

A Design for Manufacturability (DfM) assessment is a process of ensuring a design can be consistently manufactured by the designated supply chain with an absolute minimum number of defects. It requires an intrinsic understanding of best practices (what fails during manufacturing) and an understanding of the limitations of the supply chain. Ansys' Reliability Engineering Services (RES) approach to DfM is to optimize all the manufacturing functions, including supplier selection and management, procurement, receiving, fabrication, assembly, quality control, operator training, shipping, delivery, service and repair. It is also imperative that critical objectives of cost, quality, reliability, regulatory compliance, safety, time-to-market and customer satisfaction are known, balanced, monitored and achieved.

Ansys RES follows 10 DfM Guidelines to implement the design review process:

1. Know Your History
   - Develop and implement strategies to address and prevent recurrence of mistakes.
   - Know and understand problems and issues with current and past products (i.e., brainstorming sessions).
2. Standardize Methods
   - Standardize design, procurement, processes, assembly and equipment throughout your organization to reduce cycle time and repeated mistakes.
   - Don't redesign the wheel – limit unique components.
3. Simplify the Design by Parts Reduction
   - Parts reduction is one of the best ways to *reduce the cost of fabricating and assembling* a product and *increase quality and reliability*.
   - Develop an approved or preferred parts lists or a standardized BOM.
4. Design for Lean Processes
   - Lean supply, fabrication and assembly processes are essential design considerations.
   - Designs that are easy to assemble manually will be more easily automated.
5. Eliminate Waste – Seven Types of Waste
   - Overproduction, waiting, transportation, process inefficiencies, inventories/storage, unnecessary motion, defective products.
6. Design Parts for Handling
   - Minimize handling to correctly position, orient and place parts.
   - Use parts oriented in magazines, bands, tape, reels or strips when possible or use parts designed to consistently orient themselves when fed into a process.
7. Design for Joining and Fastening
   - Avoid threaded fasteners when possible, consider alternatives.
   - Where fasteners must be used, minimize variety.
8. Use Error Proofing Techniques
   - Make the correct assembly process visually obvious, well-defined and clear cut.
   - Minimize wording in instructions, use pictures, icons or photos instead.
   - Have written instructions in one location only – no competing documents!

9. Design for Process Capabilities
   - Know the process capabilities of the production equipment you expect to use.
   - Perform tolerance stack-up analyses on multiple, connected processes and parts.
   - Determine when new production process capabilities are needed.

10. Design for Test, Repair and Serviceability
   - Designing for ease of test and repair will make products more efficient, cost effective and reliable.
   - Use recommended component spacing.
   - Standardize approaches and methods of disassembly.

Ansys RES follows these guidelines in the performance of design reviews from a reliability perspective by assessing the schematic, circuit board layout, pads selected, signal routing, layer stack-up, materials chosen and derating utilized. It also points out component issues that present a long-term reliability risk.

The design assessment improves product design and process capability by eliminating failure modes. If design robustness is established, the focus during manufacturing is to ensure that the design margins are not compromised by anomalous reliability behavior. The root causes for anomalous behavior are extrinsic factors such as ambient environment excursions and workmanship deviations. Complexities due to the numerous sources of deviations can result in unpredictable symptoms. A failure mode and effects analysis is required to systematically identify potential stressors, effects of the stresses, defect precipitation, detection and mitigation strategies.

A prognostic and rapid containment of anomalies requires minimal handling intervention during assembly/test and real-time access to parametric quality data, traceability and transactional information.

However, when the number of unique components and electronic modules is large, a manual review of ongoing quality data is not practical. Automated analysis methods are required to flag anomalous behavior in real time. A simple approach is to establish intervention limits based on statistical limits and margins to specifications within a manufacturing lot or time period.

In multicomponent systems (e.g., in multichip modules), the identification of lots is more complex. An approach here is to transform the discrete censored data into a frequency domain and change the shape of mathematical functions to automate separation of the fast moving (e.g., within lot) and slow moving (e.g., lot to lot) responses.

Ongoing control of the process and component quality often provides an early warning of potential reliability risks. However, certain failure modes are not detectable under normal production process and test conditions. It is therefore necessary to complement the control strategy with a comprehensive reliability monitoring program.

3.1.3 Reliability Monitoring

Reliability monitoring focuses on providing a quantitative baseline for comparison of reliability performance between component families, process technologies or product families. Furthermore, reliability monitoring enables early detection of failures in time (reliability failure modes) and provides the ability to correct and prevent those failure modes.

Application of traditional reliability monitoring to medical electronics can be complex. A moderate-to-large sample size of a component or product is tested in the customer use environment without acceleration (voltage, temperature, etc.) Allowing the test to run long enough to generate failures allows the reliability bathtub curve for the product to be plotted. For high reliability medical electronics, this methodology can be time-consuming and expensive due to the inherent long life of the products and the battery life. In situations where adequate design margins are established and manufacturing controls are robust, it may be adequate to evaluate ongoing performance by lot- based screening methods at performance limits.

As an example, consider the highly accelerated life test (HALT) performed for design margins assessment in section 2.1.1. This method can also be deployed for ongoing assessment of capacitor lots. Figure 7 shows a summary of tests performed on multiple lots of a 100 nF ceramic capacitor. All the capacitors meet electrical specifications and known application requirements. However, differences are observed when certain lots are tested beyond their performance limits. Root cause analysis could not identify the failure mode and as such a risk-based decision may be required to establish the usability of these capacitors.

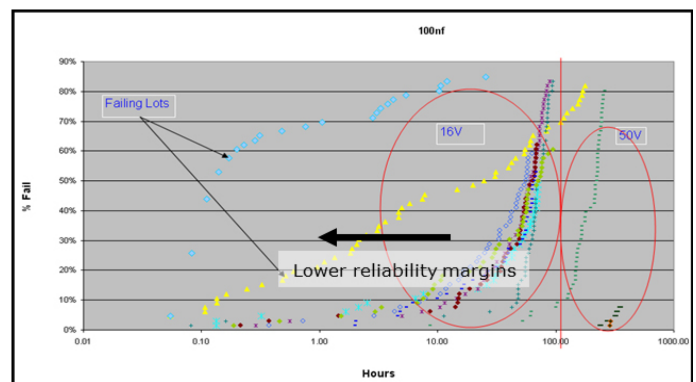

Figure 7. Ongoing sample-based, highly accelerated life test of MLCC

Burn-in is a methodology used to ascertain the quality of components and the manufacturing processes by applying operational or accelerated environmental stresses prior to shipment. It is assumed that the burn-in process catches the infant mortality failures in the population and that those that pass are better than those produced without burn-in.

The effectiveness of burn-in is dependent on several variables, e.g., product application success after burn-in, life expectancy, cost, warranty issues, cost of burn-in failures and cost of field failures.

Determining the best approach for burn-in usually starts by gathering data on time to failure, typically from prior tests. Then, graphical plotting of the data should provide insight into whether the failure rates are increasing, decreasing, constant or are a mix. Typically, Ansys utilizes Weibull plots for this purpose, as the beta parameter can identify the failure distribution. If the slope is greater than 1 then the failure rate is increasing; less than 1 means it is decreasing. Additional statistical analysis (histograms, probability plots) may be needed to more fully understand the failure behavior of the data. Ansys then uses the Weibull++ software and engineering judgment to fit the data to the best distribution from a statistical perspective.

Once the approach is defined, the determination of the duration of the burn-in can be ascertained as a function of the objective for the product being tested. Specifically, this could be the failure rate at the end of the burn-in, the post burn-in life expectancy, the cost, and the reduction or elimination of infant mortality.

The approach used is to utilize the two parameter Weibull calculation whose probability density function is:

$$f(t) = \frac{\beta}{\eta}\left(\frac{t}{\eta}\right)^{\beta-1} e^{-\left(\frac{t}{\eta}\right)^{\beta}}$$

The failure rate is then determined by:

$$\lambda(t) = \frac{\beta}{\eta}\left(\frac{t}{\eta}\right)^{\beta-1}$$

From this equation you can see that if β is less than 1 the failure rate will decrease with time and if it is greater than 1 it will increase.

From this, burn-in time to a specific failure rate goal can be accomplished using the following equations. Assuming that the failure rate objective is λ_G, then:

$$\lambda(t) = \frac{\beta}{\eta}\left(\frac{t}{\eta}\right)^{\beta-1} = \lambda_G$$

Solving for the burn-in time transitions the equation to:

$$t_b = \left(\lambda_G \frac{\eta}{\beta}\right)^{\frac{1}{\beta-1}} \eta$$

All this activity is inherent to Weibull++, where you can input the beta value and the sample size to be put in burn-in. The output is the duration of the burn-in to meet the initial objective.

/ 4. Summary/Conclusions

A reliability program for medical electronics is complex and requires significant interaction between manufacturing and the reliability engineering function. Understanding this process and utilizing the tools, like automated design analysis, can make the medical product meet the stated goal: "Failure is not an option."

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