Assuring Component Reliability in Medical Electronic Devices

A smart, end-to-end solution for capacitor reliability yields better, more dependable medical electronic devices.

AUTOR Ravi Subrahmanyan

SUMMARY

Rapid technology advances in medical microelectronics, driven by increased service life, miniaturization, lack of redundancy and functional integration, requires a rigorous development, manufacturing and monitoring methodology to assure reliability. Such an approach must be relevant throughout the product lifecycle and, for every component in a system hierarchy. It must also be effective and efficient.

Innovative solutions for managing medical microelectronics device reliability can be accomplished using end-to-end advanced reliability methodology (e2ARM). This solution can be applied to any component or system. This article demonstrates how to assure reliability of a specific component — the capacitor. Effective reliability assurance is demonstrated using rigorous design principles and data rich manufacturing. Efficient monitoring is realized using custom physical and digital factory automation. In this example, multiple decades of e2ARM experience translates into fail-safe designs with robust margins and fast response manufacturing with rapid quality containment.

MICRO SYSTEMS ENGINEERING
an MST company

MST
Micro Systems Technologies

Assuring Component Reliability in Medical Electronic Devices

A smart, end-to-end solution for capacitor reliability yields better, more dependable medical electronic devices.

While reliability is critical for medical electronic devices -- not only those used for life-sustaining purposes, but for monitoring and therapeutic applications as well -- it's just as critical for the components comprising those devices. A perfect case in point is the capacitor, a commonly used component in modern medical electronic devices. Conventional approaches to capacitor reliability often lack the rigor required to ensure these components work right, every time.
Micro Systems Engineering, Inc. (MSEI), a subsidiary of Micro Systems Technologies (MST), has deployed an end-to-end solution for accurately assessing and assuring capacitor reliability. The solution builds on MSEI's comprehensive, systematic, end-to-end advanced reliability methodology (e2ARM), which focuses on the application of reliability technologies throughout a device's lifecycle - from development and manufacture to monitoring. The result is a unique and innovative solution for rigorous capacitor design, development and monitoring.

1 The Capacitor's Role in Medical Electronic Devices

Capacitors have many uses in the medical electronics device field. In power conditioning applications, for example, reservoir capacitors are used in power supplies to smooth current fluctuations for signal or control circuits. They can also be employed in charge pump circuits as the energy storage element for generating higher voltages. In capacitive coupling applications, capacitors are commonly used to separate the alternative current (AC) and direct current (DC) components of a signal because they can pass AC signals while blocking DC signals. And, in decoupling applications, capacitors are used to decouple one part of a circuit from another. Noise caused by other circuit elements is shunted through the capacitor, effectively reducing its impact on the rest of the circuit.

Like all components, capacitors are subject to failure. The capacitor's main failure mode is high leakage current caused by internal flaws or defects that occur during manufacturing (e.g. voids or cracks). During the assembly of a medical electronic device and through device usage, thermo-mechanical stress can cause these defects to grow, leading to a high leakage current failure. For example, the failure can drain the device's battery and, in turn, cause the medical electronic device utilizing the capacitor to fail prematurely. Replacing these devices once failure occurs is not always an option. Instead, their reliability must be assured from the outset.

2 Redefining Capacitor Reliability Assessment and Assurance

The MSEI e2ARM solution succeeds in assessing and assuring reliability in medical electronic devices where other conventional approaches fail. Now, MSEI has expanded the e2ARM solution to target capacitor reliability.

The MSEI capacitor reliability solution has three prime components. The first is a rigorous new component introduction (NCI) process that targets capacitor design, manufacturing process and technical verification for each chosen supplier. The second component is a risk-based enhanced incoming capacitor test that enables screening for any anomalous capacitor lots. The final component is a comprehensive production test suite and monitoring system that ensures any anomalous capacitor in the completed device is screened out.

Custom platforms for handling automation, data collection and data analysis developed at MSEI over the last 15 years allows comprehensive and complete coverage. Whether in development or in serial production, the same platforms are leveraged for 24/7 utilization and efficiency.

3 A Rigorous Approach to Capacitor Design, Development and Monitoring

MSEI's new component development process for capacitors begins with capacitor selection (Figure 1). The focus here is on selecting a capacitor capable of meeting the system requirements of the medical electronic design in which it will be used, with sufficient margin. To aid in the selection, numerous mechanical, electrical and reliability parameters of candidate capacitors are identified and evaluated for risks.

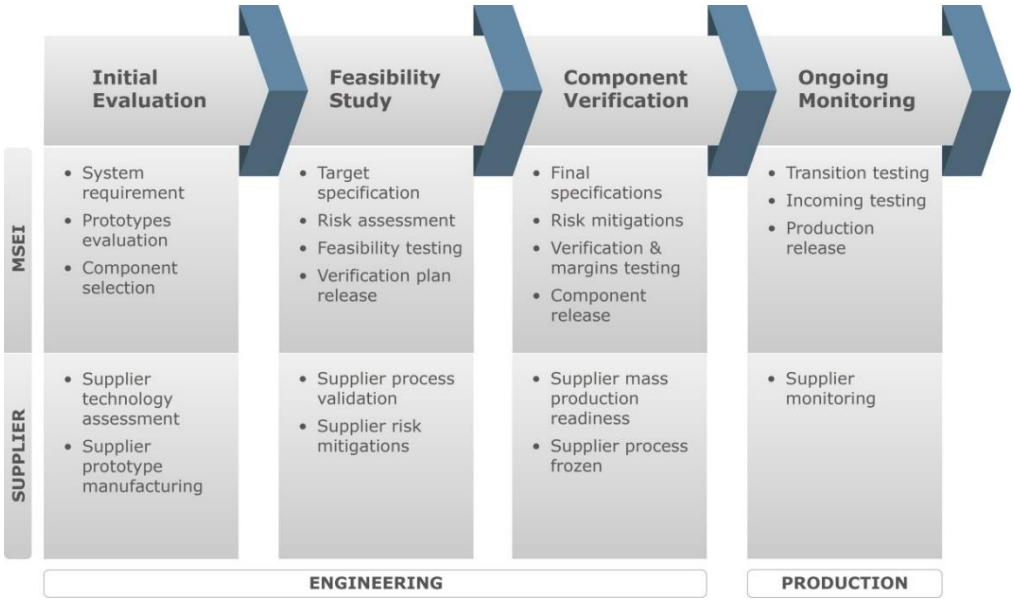

Figure 1. MSEI component development process

Next, a supplier and technology capable of meeting the previously created requirements and manufacturing a capacitor with consistent quality is selected. This is accomplished through a rigorous supplier technical evaluation process. For capacitor verification, a technical feasibility study and risk assessments are performed. Following completion of all assessments, a verification plan is created to finalize the verification process. Transition testing is then performed to ensure the capacitor consistently meets requirements across multiple supplier manufacturing lots.

4 The New Component Development Process in Action

While MSEI's component development process is applicable to any component utilized in a medical electronic device, for illustrative purposes, consider the example of a ceramic capacitor. In this particular example, capacitor lots from four different suppliers were considered.
During a capacitor's development, roughly 20 initial and post-stress electrical and structural parameters are evaluated and monitored. Parameters such as voltage breakdown (VBD) are used for margins assessment or monitoring, while others, such as destructive analysis and leakage after accelerated conditions, are used to obtain a holistic view of the design and its performance. Ongoing visual inspection or measurement of capacitance, dissipation factor and insulation resistance are generally used to detect anomalies. High volume capacitor handling, data collection and data analysis are fully automated by custom handling and software platforms.

The VBD test has been shown to have correlation with the capacitor's quality and reliability margins. Capacitor lots with tight VBD distribution are an indication of good manufacturing process controls, while similar distributions between lots show good lot-to-lot consistency. Because of this, the VBD test was one metric for development of the example ceramic capacitor, in particular, to evaluate the quality and reliability performance of multiple capacitor lots from four different suppliers.

As shown in Figure 2, VBD test results clearly demonstrate that the ceramic capacitor lots from supplier E have the best performance, with the highest average VBD value and lot-to-lot manufacturing consistency. Supplier G's manufacturing processes results in early failures (Supplier G L2 in Figure 2) and large lot-to-lot (Supplier G L1 versus Supplier G L2 in Figure 2) variations. Components from supplier D and F show lower design margins. As a result, the capacitors from supplier E were selected to undergo further testing.

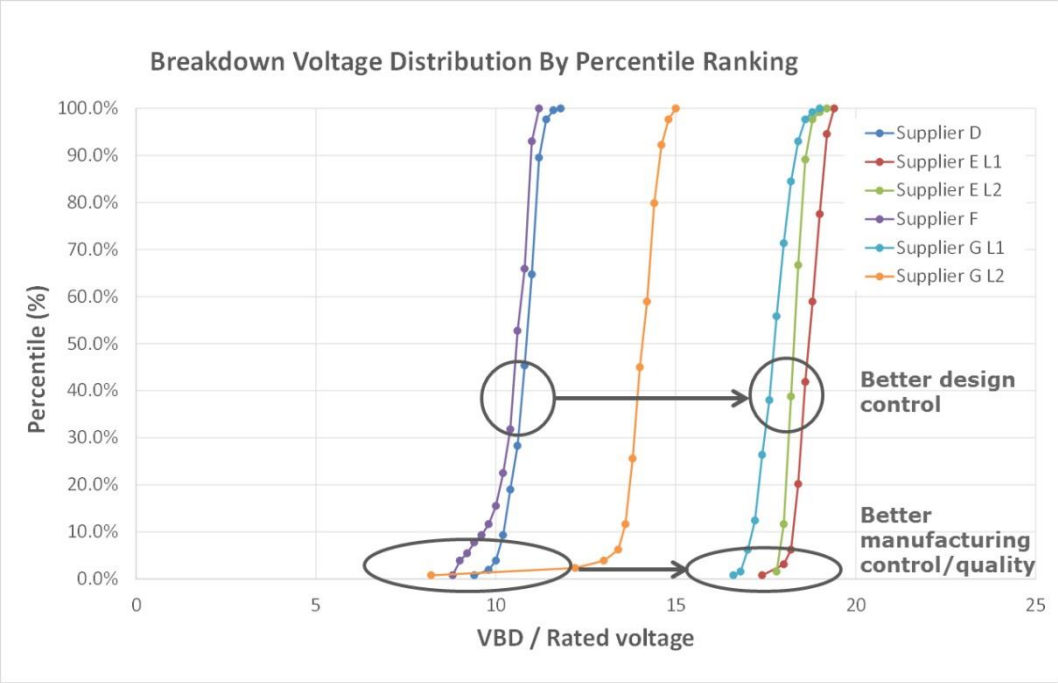

Figure 2. VBD results on various lots of ceramic capacitors from four different suppliers

Next, the multiple ceramic capacitor lots from supplier E underwent verification testing, which included numerous mechanical, electrical, and reliability parameters. Sample selection and accelerated test conditions used for the testing were based on physics-of-failure models and sound statistical sampling methods.

To develop good monitoring criteria, a baseline performance data set must be developed over an extended period of time that includes multiple supplier lots and tens of thousands of parts. In this case, a transition test plan was established to develop this baseline data set.

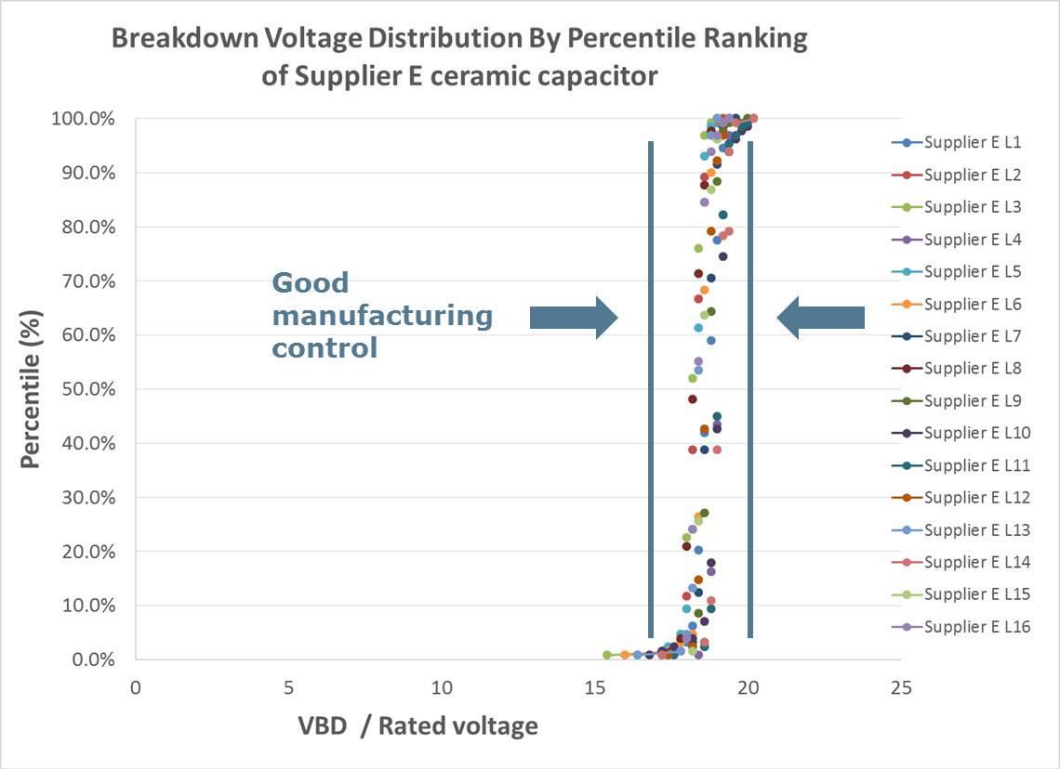

Figure 3. VBD test results of 16 capacitor lots from supplier E

As an illustration of this step, Figure 3 shows very tight distribution of VBD test results from two verification lots, and additional 14 distinct manufacturing lots of ceramic capacitors from supplier E. These transition test results were used to establish a baseline performance for the ceramic capacitor from supplier E, and in turn, this baseline data can be used for ongoing incoming test to detect anomalous lots in the future.

5 Monitoring for Anomalies at Incoming

When capacitor lots are received from a supplier, they are screened for any anomalous behavior using incoming capacitor tests done with custom built automated test equipment and data analysis tools. MSEI's risk-based enhanced incoming capacitor tests provide 100 percent automated visual inspection and capacitance measurement for selected capacitor values, as well as sample-based anomalous lot detection testing for all capacitors.

6 Visual Inspection (AOI) and Capacitance Measurement

To mitigate the supplier's outgoing quality risks for certain capacitor values after electrical testing had been performed, MSEI has developed a capability (Figures 4 and 5) wherein 100 percent of the incoming reels are de-reeled, visually inspected on six sides, electrically tested, and reeled again. These capabilities undergo a stringent and enhanced process validation for compliance to medical electronics standards.

Figure 4. MSEI's AOI System capacitor handling and an AOI image example.

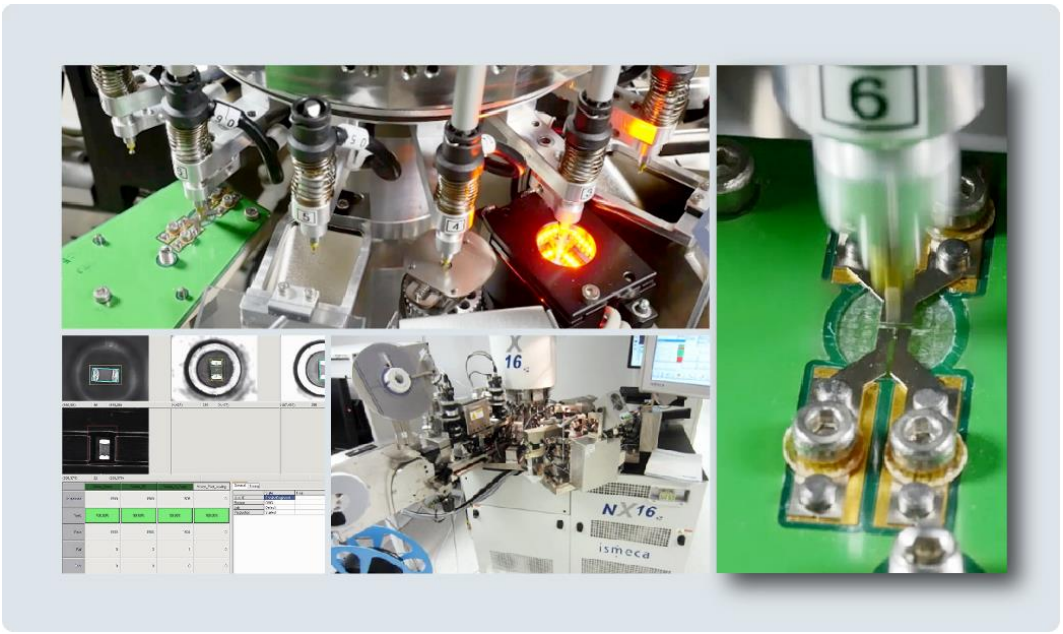

Figure 5. MSEI's automated capacitor test, handling, and tape and reel machine

7 Anomalous Lot Detection Testing

Sample-based electrical testing and reliability assessment is performed using capacitors assembled on coupons that simulate actual process use conditions. Specific capacitor tests performed include temperature coefficient of capacitance (TCC) test and automated high-speed parametric test (see Figure 6). Reliability testing is also conducted and includes a VBD test, Highly Accelerated Life Test (HALT), and Air-to-Air Thermal Cycling Test (AATC). In addition, cross section analysis is used to verify construction anomalies. The coupons and other destructively analyzed samples are typically archived in controlled conditions for future problem solving.

Figure 6. MSEI's custom-built automated test and an example of data output

Over the past 15 years, MSEI has collected over 10 million data points covering over 200 different capacitor part numbers. Leveraging this robust performance baseline, the large volume of parametric and reliability data generated by the incoming component testing mandates automation of data analysis. To address this information challenge, MSEI developed an automated early detection and warning software suite. The suite provides customizable and traceable alarms that automatically highlight anomalous capacitor lots. It also generates alerts for production and engineering staff when an anomaly is found. A sample screen shot from this analysis tool is shown in Figure 7.

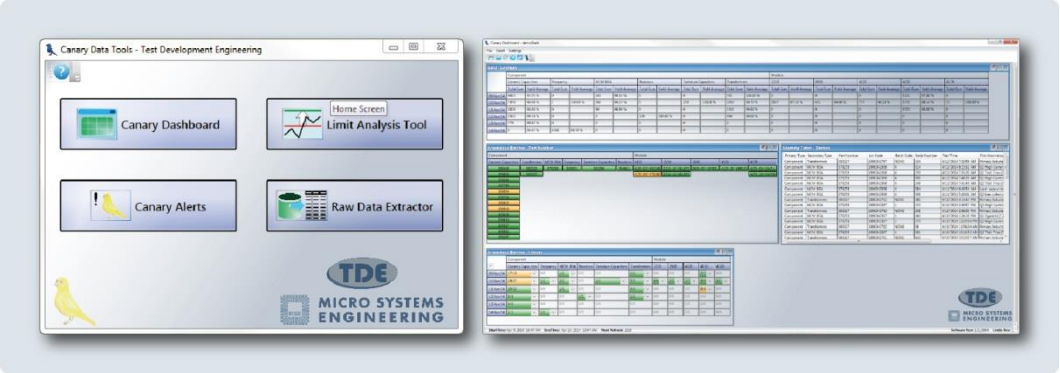

Figure 7. MSEI's software suite provides simultaneous background analysis and alert generation of multiple components types, parts and lots. The lots highlighted in yellow on the right indicate observations that require further investigation prior to acceptance

An example of MSEI's anomaly detection process is shown in Figure 8.

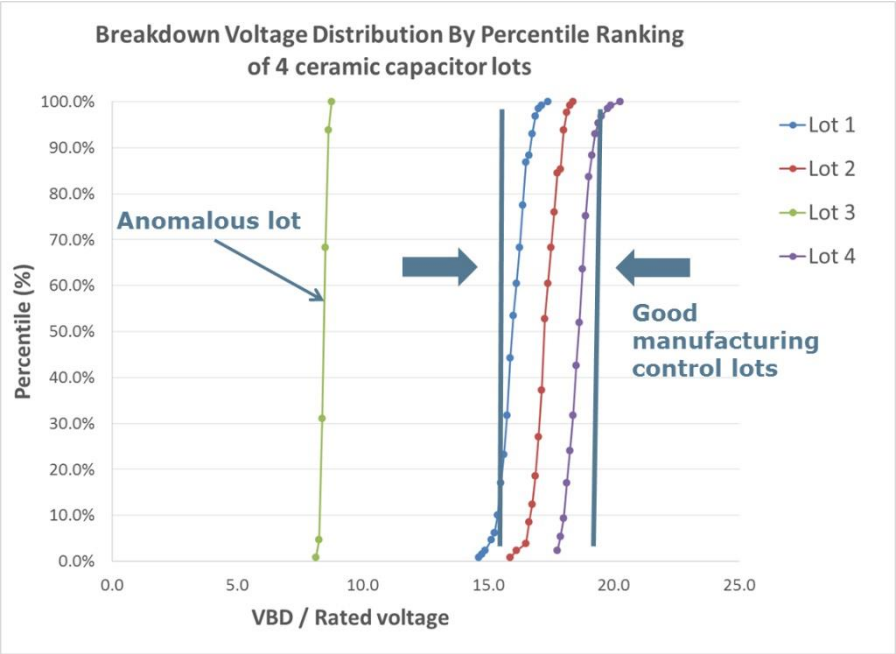

Figure 8. This example VBD test result shows an anomalous capacitor lot and alert. The three nominal lots (1,2 & 4) are representative of typical behavior

During the testing, the software suite detected an anomalous capacitor lot with a lower VBD to rated voltage ratio of approximately 8, as compared to the other nominal lots with a typical VBD to rated voltage ratio between 16 and 18 and generated an alert. Investigative construction analysis was then performed on the anomalous lot using cross sectioning and optical microscopy techniques. The analysis demonstrated that it had thinner dielectric layers, thicker metal layers, and smaller top/bottom cover layers, as compared to the layers of the other three nominal lots.

8 Monitoring Performance during Production

As part of ongoing production, MSEI utilizes a comprehensive automated production test suite and monitoring systems, which consists of Flying Probe Testers (FPT), functional testers with Automated Functional Test Systems (AFTS), and a Manufacturing Execution System (MES) for storage, retrieval, and analysis of test results (Figures 9 and 10). Serialized data collected through the MES is used to correlate changes in capacitor performance and reliability.

Figure 9. The MSEI production test suite and monitoring system uses electrical testers like the FPT shown on the left. The right-most image depicts the tester probing a capacitor.

Figure 10. The AFTS handles all module functional tests during production

The FPT detects anomalous capacitors in the module and rejects anomalous units. The FPT is capable of probing directly on components eliminating the need for board space for test points. The functional testers with AFTS allows highly precise multiaxis probing and functional, RF and motion tests at 37°C. The data from the FPT and AFTS are automatically stored in the MES system along with the capacitor traceability information. This allows automated detection of anomalous capacitor behaviors during production.

9 Uniquely Suited to Address Capacitor Reliability

Assuring capacitor reliability is a concern in the medical electronics industry today, especially given the industry's many and varied uses of the components and the possibility for premature device failure that exists when those components don't operate as expected. MSEI's end-to-end solution for capacitor reliability, based on its innovative e2ARM reliability methodology, addresses this challenge head on. The solution provides the methodology, process and tools for the rigorous design, development and monitoring needed to assure capacitor reliability. With over 35 years' experience in the industry and a proven track record for about half a billion capacitors, MSEI's solutions and customer involvement continue to translate into better, more reliable capacitor components and, in turn, medical electronic devices that can be counted on to work right, every time.

10 About the Author

Dr. Ravi Subrahmanyan is the executive director, Advanced Technologies, Micro Systems Engineering, Inc. (Lake Oswego, OR). He leads a team for selection and deployment of design and manufacturing technologies for use in high reliability microelectronics applications.

Responsible :

Micro Systems Engineering, Inc.
6024 SW Jean Road
Lake Oswego, OR 97035 / USA

info.msei@mst.com
www.mst.com
Tel. +1 (503) 744-8500

Micro Systems Technologies Management GmbH
Sieversufer 7-9
12359 Berlin / Germany

info@mst.com
www.mst.com
Tel. +41 (30) 68905-4001