

An Unlikely Marriage Keeps Quality Flourishing

Chris Rehl

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Integrating product testing with design helps companies balance consumer demands with rapid production and the need for high quality.

By: Chris Rehl

TESTING

The design and development of medical electronics products is under increased scrutiny today. Whether it's pacemakers, electrostimulation devices, electrocardiograms, x-ray machines, patient monitors, or next-wave biosensor implants, each serves as a lifeline for improving patient healthcare for millions across the globe. Unlike other industries, all medical devices carry strict requirements for high reliability and flawless operation.

Reliability and operational excellence are more imperative than ever before, especially as device use is expected to propel forward with the aging baby boomer generation. Increased consumer demand puts designers and manufacturers in a tricky spot, as product life cycles shrink, and the need for high quality remains nonnegotiable. Balancing these is a tall order and one that is getting help from an unlikely method—integrating testing with product design.



Test systems provide production line data to monitor required product behavior.

A Call for Reliability: Loud and Clear

Although some industries maintain that there is an 80/20 rule (trading off quality for lower costs or faster time to market), there's no room for error in the device industry.

Properly performed reliability analysis covers the entire life cycle of medical electronics devices, including early defects, random events, and wear out. The tools and methods that are used to perform reliability analysis include predictive modeling, operational translation, empirical modeling and analysis of testing, and operational data. Without putting these methods into place, product quality can suffer and create disastrous results.

For example, in 2004, a ventilator manufacturer recalled about 10,000 respirators when it was discovered that the backup batteries were failing. In 2008, a teenager passed away when a similar device, and its backup battery, failed to work during a two-hour power outage.

Besides carrying possibly deadly results, these incidents are damaging to the reputation of the OEMs that build the products. Any shortcoming can result in massive product recalls, millions of dollars in losses, potential lawsuits, and a drastic drop in brand loyalty. Recent high-profile defibrillator recalls provide further proof of the need to improve reliability and quality of devices. Here is a sampling of those recalls:

- A March 2007 voluntary recall of 42,000 Defibtech LLC semiautomatic external defibrillators, in which a potential low-battery problem would result in the inability to deliver a defibrillation shock.
- A 2005 Class I recall of 672 automatic external defibrillators from HeartSine Technologies after several device shutdowns resulted in fear that the devices would be unable to deliver shock or would cause delays in treatment or death.
- A 2005 recall of a subset of Medtronic implantable cardioverter-defibrillators due to potential battery shorting.
- A 2005 recall of at least nine models of pacemakers from Guidant Corp. after product failures from a seal leakage.

As these instances illustrate, the highest level of long-term quality and reliability starts in the design phase. Many electronics products include software that controls the operation of the device, which means that rigorous automated software validation and testing methods must be implemented to ensure reliable, real-world operation.

This software testing includes not only testing for pass results but also negative testing. Negative testing simulates improbable real-life situations that may occur, during which the product must be able to function or recover without behaving improperly. Automated testing not only shortens testing time and increases product reliability, but also helps satisfy FDA requirements and documentation. This is carried out through the programmatic collection and archival of all pertinent product test and manufacturing process data, which can be easily maintained and searched.

A Double Take: Testing Matters

Potential quality issues must be flagged immediately through test and measurement strategies. Tests must be performed and the results incorporated as feedback directly to the initial phases of design. This strategy provides better insight and visibility, and ensures that improvements are made throughout all phases, including concept, design, prototype production, and postsales support. These strategies must include rigorous software quality assurance testing as well as hardware testing as it is assembled. Functional or final assembly testing ensures that the product will work as designed, from the combined hardware and software perspective.

It is critical for medical electronics devices to undergo failure modes and effects analysis and failure mode effects and criticality analysis. Such analyses help further reduce or eliminate failure modes with high severity and probability.

Test and design generally aren't discussed together. In the past, product designers came up with new ideas and concepts and took them through to prototyping. After that, prototypes were passed on to manufacturing, and designers were free to concentrate on next-generation products.

How and when these steps take place are changing. New products drive competitive advantage, and when they fail in the field, manufacturers are stuck. They have to get the next new product out faster to recover lost revenue, and that's when problems arise. If OEMs don't take the time to understand why an initial product failed, designers are doomed to repeat mistakes.

To curtail this vicious cycle, testing needs to be driven internally and must play a role in design strategies. It should be a more comprehensive strategy in which data and information flow, opening the doors for continual process and quality improvements, now and down the road.

In the design improvement process, three key areas require extra attention:

- Test systems, within the manufacturing process, to monitor how designs are brought to reality.
- Data collection of the end-to-end process—from design specification to component quality to the manufacturing process to postsales repair actions.
- Documented test strategy and planning, involving the design and new-product introduction teams within the OEM and the electronic manufacturing services (EMS) companies.

Test Systems

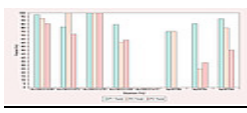
Test systems give designers assurance that manufacturing process steps have preserved their concepts and prototypes. It is typically divided into front-end and back-end testing.

Front-end testing includes various forms of tests that validate whether printed circuit boards are assembled properly and whether any mechanical problems exist early in the assembly process. Examples include flying probe, in-circuit, optical, and x-ray testing. These testers can typically be used for a variety of different product types and can be programmed to properly test the various products. A specific understanding of the product is not required.

Back-end testing is performed to validate functional integrity of subassemblies and final assemblies. Functional testers are typically unique for each product type and include specific stimulus and reading interfaces to verify functionality. Unlike front-end testing, these devices require programming and specific knowledge of the product being tested, including operational

parameters and specifications.

Data Collection



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Figure 1. ([click to enlarge](#) [3])

Access to real-time data provides critical visibility into process and product quality performance.

Ensuring that original design concepts become a reality and that products are assembled as envisioned in the production phase is being driven by the myriad test and process data. This information identifies controllable sources of variance that eliminate waste, improve yields, and ensure that production remains on track (see Figure 1).

Testing and data collection should be done with key industry regulations in mind. Design controls guidance for medical device manufacturers is outlined by FDA 21 *CFR* 820.30 and subclause 4.4 of ISO 9001. In addition, ISO 13485 specifies the regulatory requirements for a quality management system.

The basic principles of these frameworks suggest a series of steps—planning, input (product requirements), output (the actual design), verification, validation, transfer (turning the design into reality on the production floor), change tracking, and history management. A large amount of traditionally disparate data must be gathered, analyzed, and archived. These data will come from a variety of production-related sources and can include the following:

- Quality data from component manufacturers. These ensure that key performance and margin specifications are verified before the production process begins.
- Information from assembly test steps, including automated optical inspection, x-ray, and in-circuit testing. This information helps identify process and mechanical design issues early.
- Functional test data from the assembly stage that ensure proper operation of subassemblies before moving to subsequent assembly steps.
- Repair actions that occur on the manufacturing floor. These can point out design issues when the data are analyzed.
- Final system testing data to verify that products are built as designed.
- Postsales support and repair center operations data taken from the field. Such data enhance customer interactions, and repair operations, and also provide a complete product genealogy linked back to the initial design phase.

Test Strategy and Planning

Defining a test strategy and planning accordingly is essential. The new product process involves four basic phases—analysis, concept, implementation, and sustainability.

Successful product launches require a close collaborative working environment both internally and with EMS partners. Designers must play an important role in the new product introduction process and should not be relegated simply to developing prototypes.

Once a product has moved through the process steps and is launched into volume production, it is important to continually monitor test data to improve the overall manufacturing. A well-defined strategy removes costs from the supply chain. It enables the company to think greener and improve yields and reduce waste. It also helps designers detect component quality issues before major issues arise.

Conclusion

Developing the right data collection and analysis strategies is the best way to keep up to date on today's industry requirements and ensure adequate product performance without losing sight of quality. Using test data and turning them into actionable insights tears down the walls between design and the implementation of devices. It creates a collaborative working environment in which process improvements, innovation, and more intelligent answers to today's biggest product design challenges are brought to front and center focus.

Chris Rehl is director of marketing at Cimtek (Needham, MA).

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