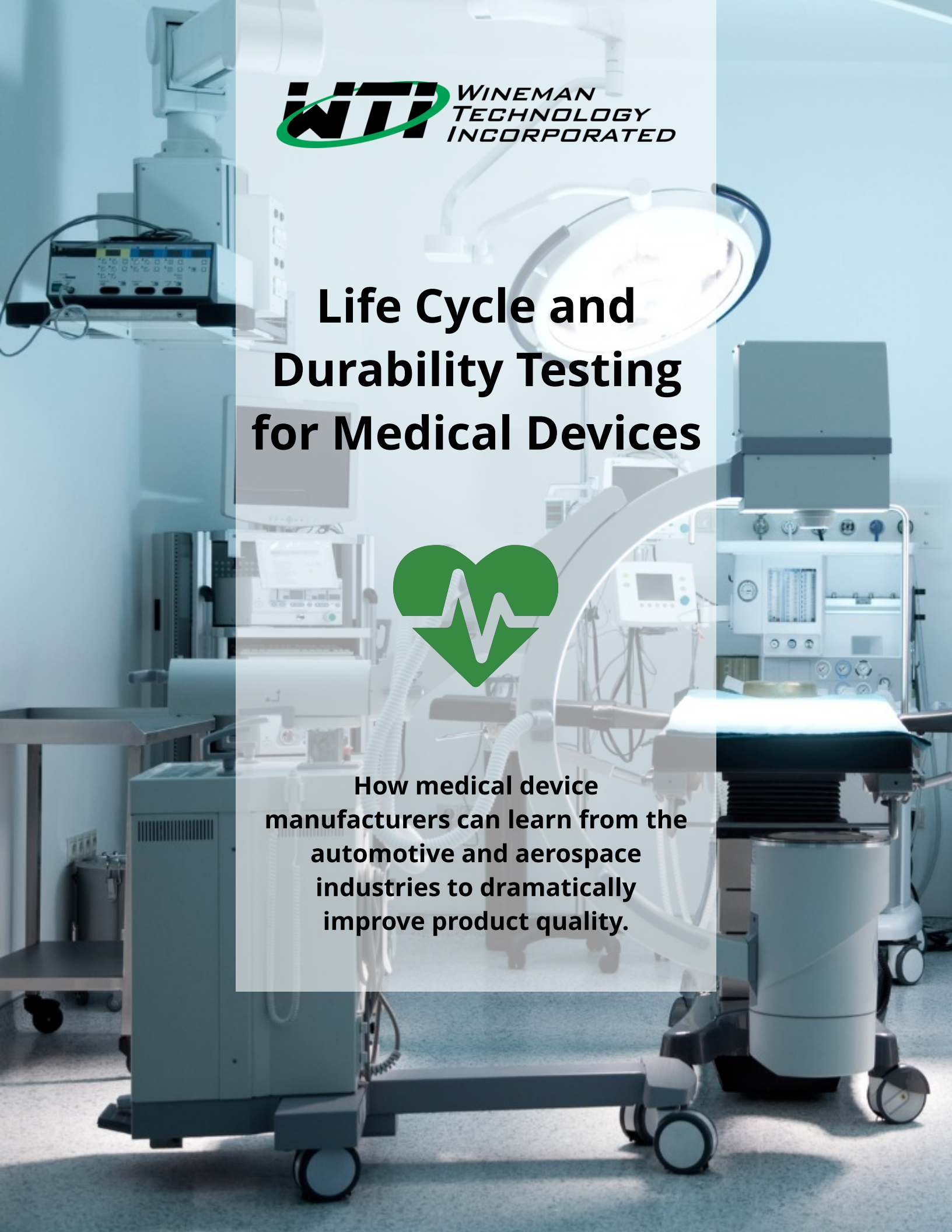

WINEMAN TECHNOLOGY INCORPORATED

Life Cycle and Durability Testing for Medical Devices

How medical device manufacturers can learn from the automotive and aerospace industries to dramatically improve product quality.

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An Interview with Wineman Technology Inc.

What can medical device manufacturers learn from the automotive and aerospace industries?

Improving medical device quality through life cycle and durability testing.

Life cycle and durability testing are crucial to ensuring quality in the aerospace and automotive industries, but are less often used in the medical device market. Many medical device companies build their products to ensure compliance, but not necessarily quality. Wineman Technology are specialists in military/aerospace and provide custom systems integration, automated test systems, machinery and controls modernization, and software development.They are bringing this experience to the medical device industry.

Wineman Technology is uniquely positioned to help life science domain experts with medical device testing, as well as building cutting-edge biomedical system test architectures and database solutions. With their strong background in systems integration, software development and turn-key test system design, they can deliver advanced equipment more effectively and on a tighter schedule than in-house design resources, or work with your team to augment your current capabilities.

By implementing life cycle and durability testing, medical device manufacturers can not only meet the threshold for compliance, but ensure true quality for their end customers.

What are some common challenges & mistakes in medical device testing?

What challenges do medical device developers face when it comes to testing?

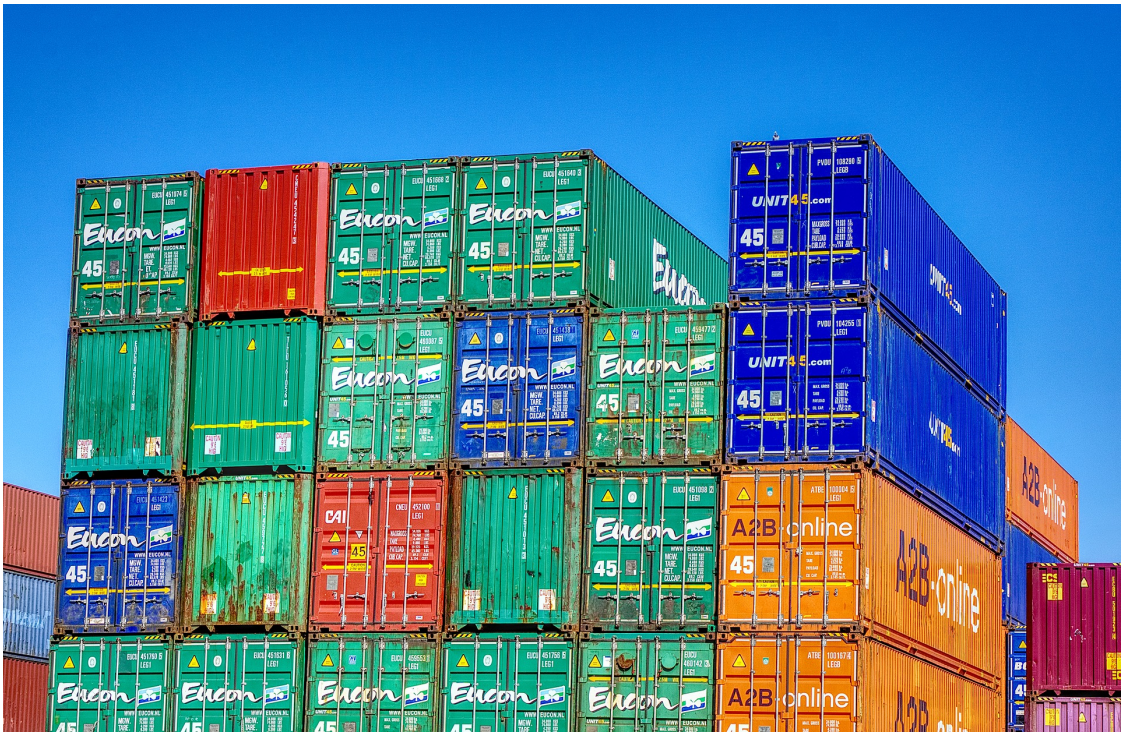
The medical device industry has enjoyed tremendous growth. However, serious adverse event reports related to medical devices have outpaced that growth. The need to get innovative products to market faster and simultaneously increase the quality of the devices are conflicting concepts. Couple that with the increased technical complexity and we have a true paradox. **The test system put in place must be more innovative than the products they are testing to ensure that a high-quality product can get to market quickly.**

What are some of the biggest testing mistakes you've seen?

Some of the more common testing mistakes we have seen relate to data collection. Often you find test systems on both ends of the spectrum – they either don't collect enough electro-mechanical test data or they lack the tools to analyze it. **If you don't have enough data, you can't make good engineering decisions.** If your data isn't organized, doesn't contain the appropriate metadata, or you don't have the tools to analyze it, you still can't make good engineering decisions.

How do you suggest medical device manufacturers implement device testing?

Utilize modular, open platforms from both a hardware and software perspective. Then, separate the user interface (UI) from the specific hardware control and data acquisition functions. That way additional hardware components can easily be integrated into the system later. This decoupling approach provides a more distributed, modular, and flexible software framework that requires less time and effort to develop specific test solutions and promotes reuse of existing code. **Instead of creating a test system for each project, create a platform for all projects.**



How can medical device manufacturers save time and lower costs when implementing testing?

How can developers ensure that their test strategies are approved in less time, speeding their time to market and speed to commercialization?

By leveraging the modular platform approach previously discussed, qualified hardware application components can be reused. Reuse allows testing to begin sooner in the development process when it is easier, faster and less expensive to fix anomalies that are discovered.

What are some key ways in which developers can lower their testing costs?

By generating a standardized UI and allowing hardware control software to be developed around a common communications architecture, the software development time can be cut in half.

Case Study: Stryker Instruments

Building a Universal Tester Platform for Life-Cycle and Durability Testing

The Challenge: Creating a flexible and scalable life-cycle and durability tester capable of handling a wide range of new medical products for design development and verification testing.

Stryker is one of the world's leading manufacturers of medical technology. It offers a diverse array of reconstructive, medical, surgical, and neurotechnology and spine products. As part of its research and development efforts, the company uses a series of test systems for life-cycle and durability testing during early product development. However, their existing platform was not architected to accommodate the company's new goals, and the hardware system design had limited channel count that limited the bandwidth of the test department. Stryker realized it was time to replace these test systems with a next-generation testing platform for both the development and verification phases of new products. The company wanted to realize its new goal, increase testing efficiency, by maximizing software reconfiguration without the need for programming, enhanced test automation, and hardware expandability. The system needed to be easily adaptable to a wide range of products and test requirements.

The Solution: Designing a high-channel-count, universal test-stand platform with a versatile software communications framework that allows additional hardware components to be easily added and controlled by the main operator interface.

Wineman Technology was contracted to design and build five "Totally Reconfigurable Universal System Tester" (TRUST) machines for Stryker Instruments Division's Test Lab. Built with LabVIEW system design software and the NICompactDAQ modular data acquisition platform, these Windows PC-based test stands provided general data acquisition of sensors as well as pneumatic and electromechanical control using scripts.

Case Study: Stryker Instruments

Building a Universal Tester Platform for Life-Cycle and Durability Testing

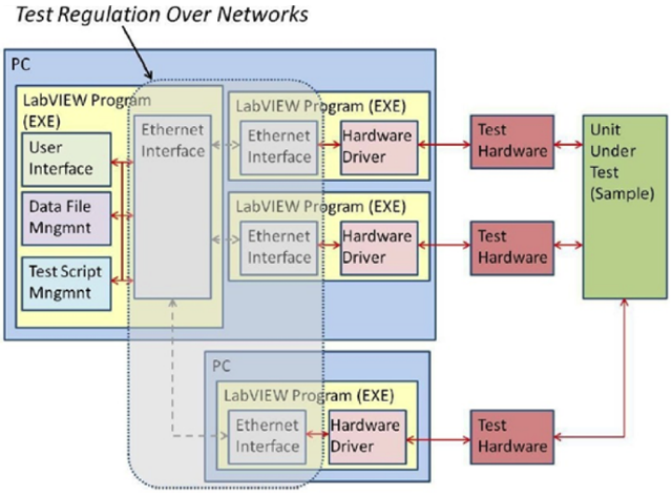
Key features included:

- 100 channels of analog and digital I/O, including thermocouple inputs, pneumatic actuators, and power relays
- Sample rates from 1 to 60,000 samples per minute or more, depending on how many channels were selected
- User-defined data recording with time stamp, using Technical Data Management Streaming (TDMS) file format or comma delimited text format
- Automated characterization of measurement equipment

The previous system was designed to run off detailed step sequences called scripts written using customized forms in Microsoft Excel, but it could run only five scripts at a time. Wineman Technology used object oriented programming (OOP) in LabVIEW capable of executing an unlimited number of scripts as long as the hardware could handle it. During a preliminary benchmarking test, the TRUST box easily handled 100 simple scripts running in parallel. This parallelism has provided Stryker the option to run two units under test (UUTs) from a single TRUST box, each independently, to provide a 100 percent throughput increase. An important design paradigm for the TRUST platform was to ensure that software did not limit performance. This way, the hardware could always be upgraded with more RAM and processing power if more scripts were needed.

Read the full case study here.

How does software infrastructure influence the efficacy of medical device testing?



Utilizing a proven and tested robust platform for automated testing helps ensure that when an anomaly is discovered the device is looked at first instead of the tester. When a one-off tester is developed to test a product, and an anomaly is discovered, often much time is spent ensuring that the tester is not the problem. The traceability included in a platform approach expedites the time it takes to analyze the data and make good engineering decisions.

What outcomes have you or your clients seen through the adoption of this methodology?

Wineman Technology's medical-focused test platform provides a more elegant and stable software solution that is scalable for incorporating new hardware components in the future. It utilizes a main software program to read scripts and dynamically sends commands to secondary software applications that control the system’s hardware functions via a standardized Ethernet protocol. This methodology has been used to reduce current test system expenditures by 50 percent while increasing effectiveness of the system with added functionality. Furthermore, the technicians and engineers that create the tests utilize the same environment for script creation, eliminating the need for additional training.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