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Common Reasons Why Medical Devices Fail at Each Stage of the Product Development Process

What your process is missing and how testing can help you succeed

White Paper

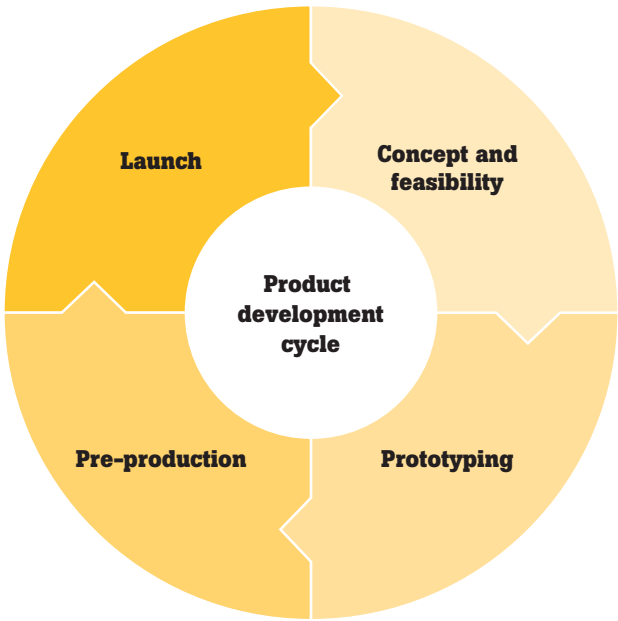
A medical device design engineer faces many challenges from medical device conception through product launch. One must effectively navigate clinical problems, negotiate and finalize specs, specify features, understand physical and software interfaces, build and test prototypes, and comply with regulatory standards – all while delivering on schedule and on budget with the upmost quality and reliability. No small order!

As a result of these challenges, many original equipment manufacturers often resort to building their own testing solutions, or test racks, for validation and verification throughout the development process. This method can be very expensive and time consuming (and not to mention, quite messy!). The good news is there are a variety of testers, analyzer and simulators available to simplify testing and make the product development process easier. Using any combination of these tools can help development and test teams make cost-saving decisions, solve problems before they arise, reduce time to market, and gain confidence a device will advance to the next stage of the development process.

While most organizations use some form of stage gate process, each process and stage might be different company to company. In this white paper, we'll outline a very generic stage process, identify common reasons why medical devices fail in that stage and explain how Fluke Biomedical analyzers and simulators help.

We'll also cover:

- How testing with a reliable, known signal output can help in the design process
- How Fluke Biomedical testers, analyzers, and simulators help you test devices and prototypes to troubleshoot and find bugs
- How test automation can help you test more efficiently, and allow for customization and standardization
- How Fluke Biomedical testers, analyzers, and simulators can help you meet regulatory standards and assist with testing supporting regulatory submissions.



Concept/Feasibility

During concept or feasibility stage, an engineer typically seeks to answer the question, "Do I think this will work?" In this stage, system architectures are drafted, key technologies are explored, and bread board prototypes and tool kits are strung together across the bench. After part of a system is brought up, a patient simulator can be used to insert clinical data where a patient cannot be used. An engineer can use a patient simulator to test variability in his or her concepts and start to look at limits. Using a known ECG input will more reliably test signal chains and algorithms than a signal generator. Patient simulators such as the ProSim 8 Vital Signs Simulator enable engineers to test many physiological parameters including: ECG, non-invasive blood pressure (NIBP), invasive blood pressure (IBP) temperature, cardiac output, respiration, pulse oximetry and more.

As different systems are tested, the same simulator can be used to test and compare results between team members. This ensures more consistency between tests.

Top reasons devices fail at this stage:

1. Real data isn't always used for testing, and doesn't exercise the design under real circumstances
2. Prototypes aren't tested the same way with known inputs
3. Insufficient technical risk assessment

Imagine this:
The design team is working on a new monitoring device that has a new embedded architecture including discreet electronic components such as an FPGA to complete data acquisition and passes the data to an ARM processor that runs diagnostic algorithms and user interface. To test the new processors and features, the team builds a few prototype systems from vendor supplied design kits, including evaluating two different FPGAs. While bringing up the systems, the technician observes they have different behaviors. After eliminating obvious causes (cables, interfaces, etc.), the team can use a known input from a patient simulator to characterize the behavior of the two FPGA's and exercise the features using identical inputs. This helps reduce the risk of error associated with testing using independent methods.

Prototyping

After a system architecture is agreed upon and the concept has been validated, prototypes are built to further development and continue verification activities toward regulatory submission. Questions engineers seek to answer in this stage usually center around, "Does the device work like I intend it to? Will it meet specifications and pass verification and validation?"

At this stage, different parts of the product development are coming together for integration. Software and firmware is moving from running on developer kits to running on target embedded hardware. This migration is typically challenging. At this stage, testing with clinically relevant inputs helps isolate issues. Testing also helps during radiated emissions/conductive emissions (EMI).

A vital signs simulator, such as the ProSim 8, can input not only different physiological parameters, but gives the engineer the ability to manipulate them, sometimes independently in steps. This allows the engineer to see what signal chains are emitting if there are issues. Using both a patient simulator and an electrical safety analyzer to test late stage prototypes will help prepare for safety and type testing. An electrical safety analyzer, such as the ESA 615 can be used to test to global safety standards such as IEC 60601/80601, NFPA 99, and IEC 62353. Conducting electrical safety testing ahead of submitting the product for external type approvals can speed up the submission and time to market.

Utilizing clinical inputs from the ProSim 8 can also be useful for evaluating user interface design. During UI reviews, clinical parameters can be varied to demonstrate alarm limits, arrhythmia detection, and others. This will allow designers and users to see how the system will respond and what inputs are required by the user. These activities will help meet the FDA's human factors guidance and ANSI/AAMI HE75 Human Factors Engineering in design of medical devices.

Top reasons devices fail at this stage:

1. Devices aren't all tested according to known inputs
2. Testing isn't performed with each iteration or version
3. Tight launch timeline doesn't allow for complete testing
4. Usability testing is insufficient or incomplete
5. Edge or boundary testing isn't complete

Imagine this:
The design team is working on developing a new infusion device using pneumatic pumps. While building and testing prototypes, the team wants to evaluate how different pumps work over time. Using an IDA-5 Infusion Device analyzer, the team can set up four prototypes and record the results over several hours and compare pump rates and flow behaviors.

Pre-Production

This phase is usually marked by last-minute preparations for product launch. Teams are doing last minute validation and verification to ensure a product is ready to go to market. At this stage, there is a lot of activity, including: manufacturing preparation, regulatory approvals, and internal training.

Pre-production activities involve a lot of testing. The automation capability of many Fluke Biomedical testers lend well to this type of testing. Automation can be built via Ansur Test Automation Software or by using remote commands and writing automation in another tool such as Matlab© or Labview©.

Preparing and setting up the manufacturing environment and process is a large part of pre-launch activities. Assemblers, operators, and technicians need to be trained on how to build and test the new product. Supply chains need to be set up. Assembly and test instructions need to be written and validated. Quality plans are drafted. Similar to automating testing earlier while conducting test passes, test automation can be implemented for factory testing. This ensures consistent testing and documentation that is compliant to standards.

The Impulse 7000 Defibrillator Tester can be automated using Ansur Test Automation software or using commands from a script such as Matlab or Labview. This level of customization allows you to adapt the test sequences and parameters to your process. Having a known, repeatable process helps reduce errors and the risk of quality defects. The Impulse 7000 can test both mono and biphasic defibrillators and AED's, and has 12 Lead ECG output to trigger events.

Demonstrating the new medical device to other team members is easier with a clinical input to the system to simulate the complete patient condition. You can show off features, such as setting alarm limits, arrhythmia detection, while varying clinical inputs.

Service preparation includes training of service personnel and preparing service manuals. FDA and other global agencies encourage the OEM to specify recommended preventive maintenance frequency and inspection of the medical device. This includes periodic inspection and testing of the device. Specifying a particular test device in the service manual will allow for more consistent results between customer and company field and bench service.

Top reasons devices fail at this stage:

1. Insufficient scope of testing for verification and validation
2. Testing not aligned to regulatory or market needs
3. Insufficient number of devices tested
4. Regulatory standards aren't well understood
5. Manufacturing testing development and validation delayed or rushed

Imagine this:
The manufacturing and test engineering teams need to set up test stations and train operators to build a new defibrillator system. The team integrates an Impulse 7000 Defibrillator Analyzer to test each system after assembly. The use of the Impulse 7010 external load box allows the defibrillator system to be tested for a wider range of chest impedances and more closely follow international standards. They are able to write test automation for the analyzer allowing for more efficient testing. The use of the defibrillator analyzer and automation makes operator training very easy and safe.

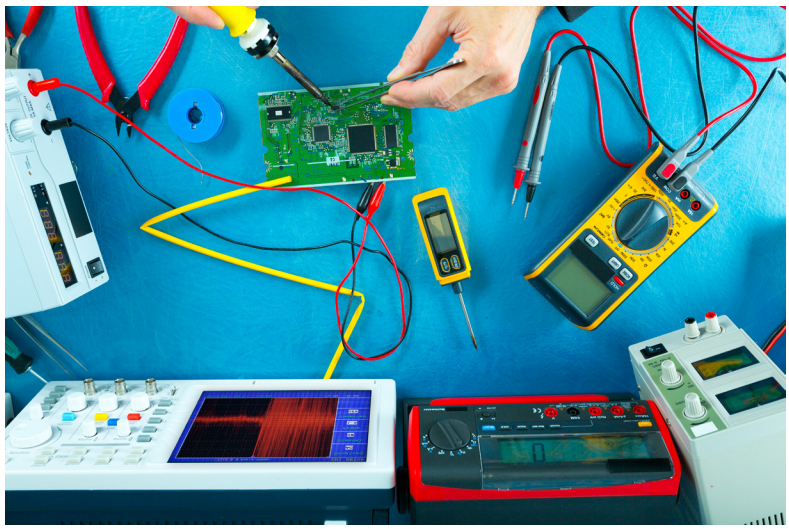
Product Launch and ongoing PLCM

Product launch occurs when the company has completed development, applicable regulatory activities, trained internal (and external where appropriate) staff, and prepared operations, service, marketing, and sales to begin presenting to customers and accepting orders. Key questions arise such as, "Are we ready to launch" and "How do we show this off?".

Sometimes the product is launched at a conference or industry trade show. An IDA-5 Infusion Device Analyzer can be used to help demonstrate an infusion device by showing occlusions, flow rates, and other parameters.

After product launch when a product is serviced, in-house or in the field, the product is usually tested prior to return to service. The VT305 Gas Flow Analyzer can be used to test and troubleshoot a ventilator by a field service engineer. The VT305 can then be used to test for proper function and output prior the ventilator being placed back into service.

Customers may have questions after installation and in-servicing or new clinicians might join the staff after these activities. Customers may call into technical support with simple or



complex questions. Technical support personnel might have similar equipment to try and replicate observed issues or to familiarize themselves with the customer's issue. The ProSim 8 can help technical support test the device and advise the customer on expected outcomes. If the customer also has a patient simulator, results can be compared.

Top reasons devices fail at this stage:

1. Not able to properly demonstrate product to customer or for training
2. Not prepared to service product, different set ups in different locations
3. Field staff not trained, or not trained well
4. Insufficient validation to customer use, not enough customer use case data collected for design.

Imagine this:

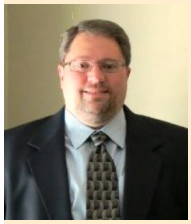
A clinical trainer is preparing for an in-house service for a new patient monitor system installed in a hospital. He or she needs to train the nursing staff on the use and features of the new monitors. Using a patient simulator, the trainer is able to show how all the features work including alarms and setting alarm thresholds. During hands-on training, the nursing team is able to change the inputs to show different cases and is able to see the interaction between bedside and central stations.

Conclusion

Introducing a new medical device is a massive effort that requires coordination among many teams. Using testers, analyzers, and simulators can help at each stage of product development and commercialization. These testers, analyzers, and simulators aid the user by building confidence in their design, testing different prototype solutions, helping to find bugs faster, allow for more efficient testing, and allow for customization, automation and standardization of testing. These devices may be more cost effective and efficient than building in house test solutions. Fluke Biomedical offers a wide range of devices to test a variety of medical devices and applications.

Fluke Biomedical testers, analyzers, and simulators are great for use in bench testing, pre-production verification and validation activities, manufacturing testing, and for in house or field service applications.

About the author



Andrew Clay, Product Marketing Manager for Fluke Biomedical

Andrew Clay has spent the bulk of his 20 year career working in many medical device capacities including R&D, product development and commercialization. Since joining the Fluke Biomedical team in 2013, Andrew has been instrumental in the advancement of the industry-leading ProSim Patient Simulator portfolio.

About Fluke Biomedical

Trusted for the measurements that matter.

Fluke Biomedical is the premier, global provider of test and measurement equipment and services to the healthcare industry. We serve biomedical engineers, quality-assurance technicians, medical physicists, oncologists, radiation-safety professionals and are continually expanding our range of solutions to a broader range of health and safety professionals. For more information on Fluke Biomedical, visit www.flukebiomedical.com.

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www.flukebiomedical.com/TestForSuccess

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