



Connected Medical Devices: 10 Insights to Improve Efficacy, Safety, and Time to Market

eBook

 **KEYSIGHT**

Contents



INTRODUCTION

[GO TO INTRODUCTION](#)



INSIGHT 1

Pass Radio Certification on the First Try

[GO TO INSIGHT 1](#)



INSIGHT 2

Pick the Right Battery

[GO TO INSIGHT 2](#)



INSIGHT 3

Event-Based Power Analysis Optimizes Battery Life

[GO TO INSIGHT 3](#)



INSIGHT 4

Avoid Power Integrity Issues with Low Voltage Components

[GO TO INSIGHT 4](#)



INSIGHT 5

Signal Integrity Remains within Reach Even with Increased Data Processing

[GO TO INSIGHT 5](#)



INSIGHT 6

Reduce Uncertainty Due to Advanced and Shrinking Component Packages

[GO TO INSIGHT 6](#)



INSIGHT 7

Take Control of Device Security by Finding Hidden Vulnerabilities

[GO TO INSIGHT 7](#)



INSIGHT 8

Ensure a Positive User Experience

[GO TO INSIGHT 8](#)



INSIGHT 9

Commit to Coexistence Testing to Resolve Interference

[GO TO INSIGHT 9](#)



INSIGHT 10

Reduce Measurement Errors to Make Better Decisions

[GO TO INSIGHT 10](#)



CONCLUSION

[GO TO CONCLUSION](#)

INTRODUCTION

Your work is important. Patients and medical staff worldwide benefit from the life-changing and life-saving connected medical devices that you are developing. Yet these devices are more complex than ever as is their path to the marketplace. Engineers are rethinking their workflows to confront these issues and ensure the devices they produce are safe and efficacious while avoiding costly rework and delays.

This eBook outlines some of the common challenges facing engineers who develop connected devices and provides insights that will help achieve critical safety, efficacy, and time-to-market goals.



INSIGHT 1

Pass Radio Certification on the First Try

TIME TO MARKET

Failing radio certification can set you back weeks, if not months. Here are two steps that will help you avoid this potential obstacle.

Step one: Implement pre-compliance testing. Before sending a device out for radio certification, test and document the performance of the radio and antenna. Your internal measurements will determine whether your device has plenty of room to pass or is close to the margins.

Step two: Develop a database of radio certification measurements. For each device, you will have both the internal measurements and certification results. Over time and after multiple projects, you will gain insights that tell you exactly how pre-compliance measurements map to the specific compliance tests you administer. This process will instill confidence in how the next device will perform in certification.

Pre-compliance testing will help you avoid delays that result from failing radio certification. In fact, implementing a database of pre-compliance testing results can help you release connected medical devices ahead of schedule.



Learn more

Discover how Keysight [Regulatory Compliance Test Solutions](#) can accelerate the certification of connected medical devices operating in unlicensed bands.



INSIGHT 2

Pick the Right Battery

EFFICACY

SAFETY

TIME TO MARKET

Not all batteries are the same even though their specifications say so. So how do you pick the right battery?

Start with battery emulation. Advanced battery test and emulation software creates battery profiles of actual batteries. You can then import the battery profiles and use them repeatedly in tests without having to use the actual batteries. As you measure and record a real battery as it loses charge, take snapshots of various battery conditions — from new to old and recharged. These snapshots provide consistent profiles of battery performance. It is important to use the same battery behavior to gain a deep understanding of device performance so you can make changes and updates.

It is also essential to understand how a connected medical device consumes charge over time. The best way to conduct a battery drain analysis is with seamless ranging. Connected medical devices, by design, often have current levels that vary by several orders of magnitude. While this condition is difficult to measure without glitching or inaccurate measurements, seamless ranging takes care of it properly.

Seamless ranging enables accurate measurements of the upper and the lower ends of current. You will see the complete current waveform from nano amps to amps, in one pass.

Now you better understand battery behavior from new to end of life. This helps you make the right design decisions so that you deliver a device that operates to spec and avoid costly rework and schedule delays.



Learn more

This white paper shows how you can use battery emulation software to accurately predict and extend battery life of connected medical devices: [4 Ways to Enhance IoT Battery Performance Using Emulation Software.](#)



INSIGHT 3

Event-Based Power Analysis Optimizes Battery Life

EFFICACY

TIME TO MARKET

What levers can you pull to improve the battery run-time of a connected medical device? With event-based power analysis, you can simultaneously probe multiple functions such as sleep mode, radio, and processors to determine how much charge each function is using. By using intelligent data gained through event-based power analysis to write software and configure hardware, you can improve efficacy and shorten your go-to-market timeline.

Using event-based power analysis, you can observe device behavior at different voltage levels to simulate device behavior as the battery ages. One application analyzes battery end-of-life. With better data on the amount of charge various functions consume, you can make informed decisions on what device behaviors to turn on and off as the battery reaches end-of-life. This capability is valuable to patients because it extends the run-time of the device and delays complete failure.



Learn more

Discover how event-based power analysis can help you optimize the battery life of connected medical devices: [X8712A IoT Device Battery Life Optimization Solution](#).



Pass Radio Certification with Ease

Pick the Right Battery

Optimize Medical Device's Battery Life

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Manage Signal Integrity Challenges

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Perform Device Coexistence Test

Boost Medical Device Testing Capabilities

INSIGHT 4

Avoid Power Integrity Issues with Low Voltage Components

EFFICACY

SAFETY

TIME TO MARKET

Low voltage components make connected medical device design more challenging because tolerances on voltage are much smaller. Coupled with higher data rates, longer traces, and more components on-board, it is hard to maintain consistent voltage levels across the printed circuit board assembly (PCBA). Power integrity simulation is critical to ensure you are getting the right voltage to the right place consistently.

Simulating power integrity prior to board fabrication avoids delays that result from having to troubleshoot a failing board. Removing power integrity risks early in the product development cycle helps ensure that connected medical devices will run properly when they reach the market. Power integrity simulation software is available on a subscription basis with flexible licensing to preserve capital.



Learn more

For more information on how to get the best visibility into power integrity issues, take a moment to review the [Keysight Power Integrity Analyzer Reference Solution](#).



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INSIGHT 5

Signal Integrity Remains within Reach Even with Increased Data Processing

EFFICACY

SAFETY

TIME TO MARKET

Increased data processing in connected medical devices presents new obstacles to signal integrity. Crosstalk from adjacent traces, boards running at lower voltage levels, and more on-board processing all present challenges to the quality of electrical signals. Poor signal integrity poses risks for device failure and potential delays in release to the market. The efficacy of connected medical devices depends greatly upon signal integrity.

Here are three steps to effectively manage signal integrity challenges in connected medical devices.

- 1 Use software simulation tools to find and eliminate many signal integrity issues before you fabricate your board. This will save both time and money.
- 2 Use purpose-built signal integrity software on network analyzers and oscilloscopes to verify performance of the PCBA after you build it.
- 3 Document learnings in the quality management system (QMS) and use them to reduce risk and get to market faster with future designs.



Learn more

The white paper [Signal Integrity Fundamentals](#) outlines signal integrity fundamentals from simulation to measurement to help you design connected medical devices with higher reliability and lower cost.



INSIGHT 6

Reduce Uncertainty Due to Advanced and Shrinking Component Packages

EFFICACY

SAFETY

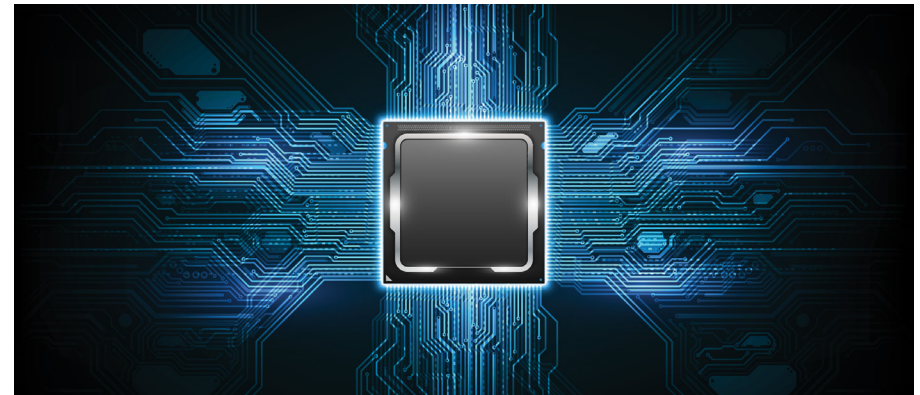
TIME TO MARKET

Traditional manufacturing test access relies upon physical access to nodes on boards. Yet higher node counts and high-speed differential signaling make it impossible to test at every node using traditional in-circuit test (ICT) bed-of-nails solutions.

Boundary scan-based test methods help you regain manufacturing test coverage. The Institute of Electrical and Electronics Engineers (IEEE) 1149.1 and IEEE1149.6 boundary scan offer a limited test access solution for both ICT and stand-alone test systems. Boundary scan is a method for testing semiconductor device-to-device interconnects on PCBAs after the manufacturing process.

The boundary scan test enables control of device pins independent of the device's actual function, and makes it possible to test for faults manufacturing issues cause. Boundary scan offers a mechanism to verify placement of the correct device type, and it tests non-boundary scan devices that connect to a boundary scan device. The boundary scan also increases test coverage and minimizes the number of physical test points that boards require.

Boundary scan implementation on boards begins in design where semiconductor devices with boundary scan capability are selected with proper design for test (DFT) to maximize boundary scan test coverage.



Learn more

Read the application note: [Boundary Scan DFT Guidelines for Good Test Coverage](#).



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INSIGHT 7

Take Control of Device Security by Finding Hidden Vulnerabilities

EFFICACY

SAFETY

TIME TO MARKET



Cyberattacks pose significant risks to connected medical devices. An attack against a medical device's radio interface may impede essential performance and potentially cause harm to a patient.

One of the most overlooked risks to connected devices is upstream supply chain vulnerabilities. These vulnerabilities hide deep inside the protocol stacks on embedded system on chip (SoC) sets that come from third-party manufacturers. Notoriously hard to find, these vulnerabilities often go undetected in security scans and frequently make their way onto devices in production. Left unchecked, vulnerabilities enable attackers to bypass on-board security controls, making it easier to crash, deadlock, or freeze a device.

Device manufacturers are the last line of defense and since they bear ultimate responsibility for the products they ship, it is critical to rigorously validate the security of all onboard components. Identifying protocol-level vulnerabilities requires a comprehensive testing mechanism called protocol fuzzing. Essentially, the testing mechanism injects various errors into a communication exchange to confuse the entity at the other end of a connection. Using this form of testing, a simple chipset may take a matter of minutes to test, while a more

complex system could take days or weeks of continuous testing and require automation to complete.

As connected medical devices grow more complex and valuable, cybercriminals will develop new methods to exploit them — device manufacturers must fight back. One way to do that is to integrate protocol fuzzing into a larger cybersecurity validation strategy. Then quality control teams can play an active role in preventing device hacks to reduce risk and maintain patient trust and safety. Fortunately, new tools are getting smarter, including some from Keysight, and will now automate intelligence across the workflow. These tools use the power of digital twins to minimize test cycles, identify issues faster, and empower test teams that have little to no cybersecurity experience.

Learn more

Check out our webcast to acquire strategies to protect your company and ensure patient safety without causing lengthy production delays and budget overruns: [Simplify FDA Cyber Validation](#).



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INSIGHT 8

Ensure a Positive User Experience

EFFICACY

SAFETY

TIME TO MARKET

The growing complexity of connected medical devices makes user experience testing critically important. One approach is to hire an army of testers to manually test the performance of numerous features, interfaces, and communications protocols on dozens of hardware and software platforms. However, bear in mind that trained medical professionals do not necessarily run medical devices. In fact, in many cases, patients operate the devices. Clearly, hiring lots of manual testers is expensive, slow, and may yield limited intelligence.

A more efficient and realistic approach is to use artificial intelligence and test automation to evaluate the user experience. Software-based solutions will find more paths through your complex application. Software-based solutions work faster than human testers because they use test automation. Software-based user experience testing will focus more time on testing areas of device software where defects are more prevalent using artificial intelligence. Plus, automated software-based user experience testing ensures that your development and test teams stay in sync.

The automated approach identifies more defects faster, and tests more scenarios across the entire workflow to help you deliver an effective, safe, and efficacious device to patients and medical professionals on time.



Learn more

Read our case study to learn how software engineers used Keysight's Automating Intelligence software model to automate testing of embedded software for medical devices and improve quality and efficiency: [FUJIFILM Software Company](#).



Commit to Coexistence Testing to Resolve Interference

EFFICACY

SAFETY

TIME TO MARKET

Since most connected medical devices operate in unlicensed spectrum, coexistence presents a challenge. The Association for Advancement in Medical Instrumentation (AAMI) technical information report (TIR) 69, the American National Standards Institute (ANSI), and IEEE C63.27-2017 standards are clear — when it comes to radio frequency (RF) communications, you must play nice or face the scrutiny of government regulatory bodies.

First, you must conduct testing that is repeatable and controlled, and broadcast over-the-air or using cables. However, this essential testing does not reflect the environment in which your device will operate. That is why you must also conduct coexistence testing in the field, and monitor the electromagnetic environment using a portable spectrum analyzer with real-time spectrum analysis (RTSA) capabilities.

RTSA detects small signals that stronger signals often mask. Measure signals as narrow as 5.52 μ s with one hundred percent probability of intercept. You can document RF traffic in a hospital lobby, nurses' station, or a patient room. Field testing is critical because you must know how your device works in the real world. Regulatory bodies value data demonstrating that you conducted coexistence testing to mitigate risk in actual medical environments.



Learn more

For more details on how coexistence testing works, read: [RF Coexistence Testing for IoT Medical Devices](#).

Repeatable and controlled existence testing is essential. You are taking a risk if you skip going into the field to conduct coexistence testing.

Reduce Measurement Errors to Make Better Decisions

EFFICACY

SAFETY

TIME TO MARKET

Over time, instrument performance will drift. Left unchecked, your ability to make consistent, accurate, and repeatable measurements will decline. Drift conditions have a direct impact on the decisions you make and ultimately affect the efficacy, safety, and delivery schedules of connected medical devices. As a medical systems or medical devices manufacturer, you must prove that your quality management systems comply with the International Organization for Standardization (ISO) 13485 standard. If your measurements drift too far, you may fail an audit by government regulators, face additional regulatory scrutiny, or even lawsuits. Regular and proper calibration will ensure your instruments are accurate, operate within specifications, and have traceability backed by calibration certificates.

Thorough instrument testing will give you confidence measurement results. A comprehensive, high-quality calibration process includes extensive testing of all specifications in compliance with current standards, complete and actionable data, superior measurement accuracy, and potentially, custom adjustments to re-center instrument performance. The confidence you gain in your measurements outweighs the costs associated with a high-quality calibration that minimizes measurement uncertainty. Regular calibration will also enable you to formulate more accurate insights to inform your decisions. The goal is to reduce rework, avoid delays, and ensure maximum value to patients from your connected medical devices.



Learn more

Want better test results? Learn more about Keysight [Calibration Services](#).



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CONCLUSION

Efficacy and safety start with Keysight. We are with you every step of the way as you work to deliver safe, compliant, high-quality connected medical devices on schedule. Trust Keysight to help you gain accurate insights and get measurements right earlier so you can turn a visionary idea into a life-changing reality faster.

Connected Medical Device Testing Starts with Keysight.

For more information on Keysight's test and measurement solutions for connected medical devices, visit our [website](#) today.



Keysight enables innovators to push the boundaries of engineering by quickly solving design, test, and validation challenges to create the best product experiences. Whether you're looking to improve your development process, optimize and secure your network, or get a head start on technologies like 5G, 6G, electronic or autonomous vehicles, IoT, or quantum — Keysight accelerates innovation with intelligent insights built on the most accurate measurements to reduce risk and speed time-to-market. Our fusion of technology knowledge, measurement science expertise, and tailored solutions help you forge ahead with confidence in our connected and dynamic world. What's next starts here, with Keysight.



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