

Keysight Technologies

Design and Test Solutions for Medical Devices

Technical Overview

Greater insight. Greater confidence.
Accelerate design and development
of next-generation medical devices.



Introduction

In developed and developing nations alike, the demand for medical services is growing. As the need for care grows, technology continues to play a larger role in patient care.

Patient monitoring is a key example. Although a wired connection is considered the most reliable approach, robust wireless connections are becoming more widely used for emergency, in-patient and out-patient scenarios. For example, wearable and implantable wireless sensors allow medical staff to continuously monitor the condition of ambulatory patients.

In addition to wireless monitoring, technology is also enabling new capabilities in diagnostics, therapeutics, imaging and surgical robotics. Present and future advanced RF, wireless, digital, component and material technologies will continue to enable improvements in the quality of care delivered around the world.

Keysight Technologies, Inc. is ready to help you design and develop these new medical devices. Our expertise—and product portfolio—spans the radio frequency (RF), microwave, wireless and digital technologies that are the building blocks of today's medical technology. Essential Keysight products include design and test solutions that address areas of concern related to the use of wireless technology in and around medical devices: RF interference, electromagnetic interference (EMI), electromagnetic compatibility (EMC), interoperability, and digital interface. In addition, our solutions can help you address needs such as component characterization, power management and battery life.

We can help you all across the product life cycle: early R&D, device integration, design validation, manufacturing and pre-conformance testing. Get greater insight and greater confidence with Keysight—and accelerate the design and development of next-generation medical devices.

Medical Device Design and Test Challenges

Keysight, the world's premier measurement company, provides design and test solutions that solve your medical device challenges through products lifecycle.

RF Interference

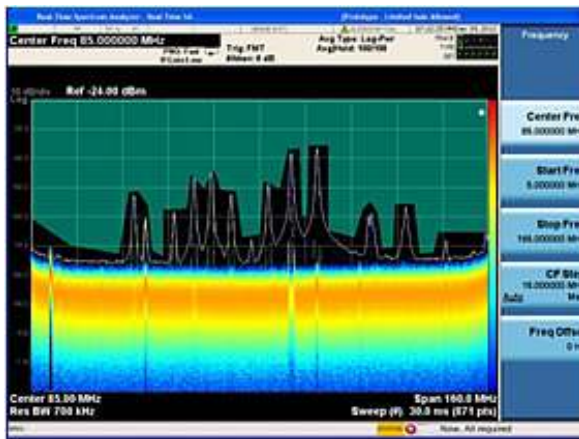
Most current advanced medical devices leverage the benefits of electronic engineering, but this adapting of electronic engineering also brings RF interference issues among medical devices. Increasingly more and more portable, wearable, and implantable medical devices are now being used in the environments which have more factors of RF interferences. Therefore, RF interference is one of the most critical challenges for medical device developers.



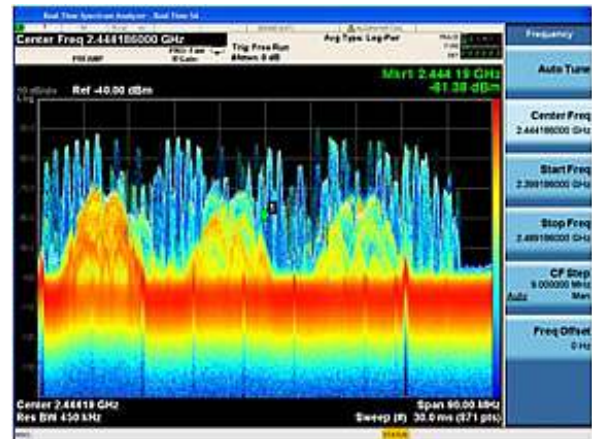
N9030A PXA Signal Analyzer with real-time spectrum analysis capability

N9030A PXA signal analyzer with real-time spectrum analysis capability is an ideal tool to help you develop the components and subsystems used in medical devices or if you are managing the increasingly complex signal environment including RF interference in healthcare facilities. For your medical component/subsystem design and verification, the PXA offers the most advanced analysis for those "must-have" measurements such as phase noise, noise figure, and analog/digital

modulation. In addition, covering up to 50 GHz of frequency, the real-time PXA with up to 160-MHz bandwidth effectively characterizes time-domain factors such as settling time, frequency drift, and transient processes. For management of your signal environment, the real-time PXA helps you to see, capture, and analyze the most elusive interference signals, known or unknown, with durations as short as 3.57 μ s with 100% probability of intercept and full amplitude accuracy.



PXA signal analyzer's frequency mask triggering in the real-time capability along with the lower noise floor (-157 dBm/Hz at 10 GHz), lets medical device developers see and capture elusive low level signals.



PXA signal analyzer with real-time capability identifies transient spurious emissions for tightly integrated communication systems or burst/hopping waveforms.

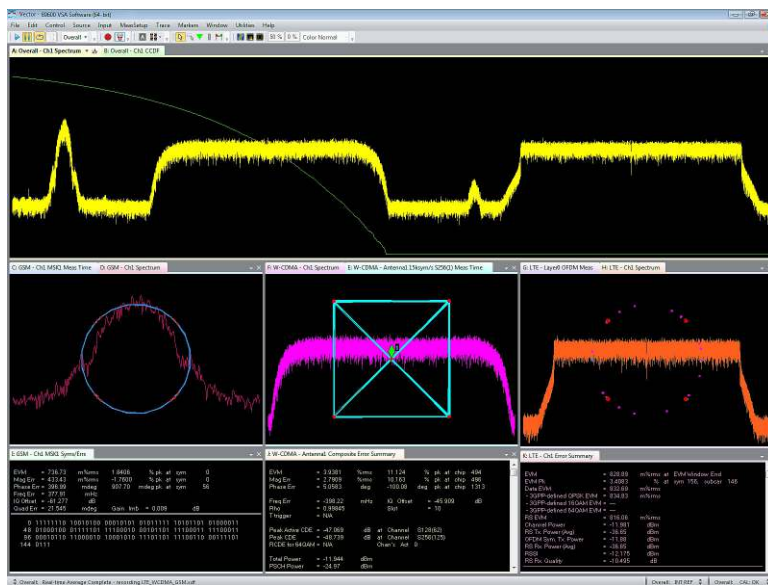
Medical Device Design and Test Challenges

FieldFox handheld RF and microwave analyzers enable users to carry the precision of a benchtop analyzer in the palm of their hands, making it easier to install and maintain wireless medical devices and systems in hospitals and clinics. FieldFox's measurement precision enables installers to be assured that telemetry characterization will correlate with performance data from the manufacturer. The interference analysis tools enable the biomedical and clinical engineering teams to quickly pinpoint and mitigate electromagnetic interference.



FieldFox handheld RF and microwave analyzers

89600 VSA software Traditional testing and trouble shooting look at one signal in one place at a time which can impede progress and overlook problems related to signal interactions. Faster testing under real-world operating conditions is critical in product categories that depend on rapid introductions of new or modified medical device designs. Today, the 89600 VSA software offers an alternative: make multiple measurements simultaneously using one or multiple front-ends. Multi-measurements extend all the capability of the 89600 VSA software to multiple simultaneous measurements in the time, frequency and modulation domains for all supported signal formats. It can do all of this using digitized waveforms from more than 40 supported instruments, and the software can coordinate measurements from multiple instruments at the same time.



Multiple simultaneous measurements are derived from shared or independent acquisitions

Medical Device Design and Test Challenges

Electro-Magnetic Interference (EMI)

EMI presents a risk of patient safety because more and more medical devices on or in patients are frequently used in environments which include broad EMI sources such as mobile phones, tablets, and both consumer and industrial electronic products.



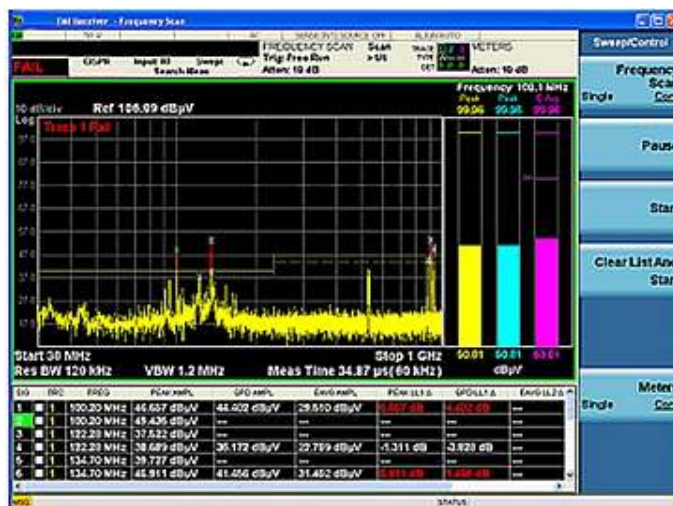
N9038A MXE EMI receiver

N9038A MXE EMI receiver is ideally suited for high-performance commercial, medical and military electromagnetic interference (EMI) and electromagnetic compliance (EMC) testing. In addition to CISPR and MIL STD compliant specifications, Keysight MXE offers a range of build-in features that enhance EMI/EMC measurements. MXE also includes X-Series signal analysis and graphical measurement tools that make it easy to examine signal details. With these diagnostic capabilities, the MXE complements your knowledge of developing safety medical device.



EMI test chamber with N9038A MXE EMI receiver

N9020A MXA signal analyzer with N6141A embedded EMI measurement application performs pre-compliance conducted and radiated emissions tests. The sensitivity of the MXA signal analyzer enables users to see device emissions hidden in the noise floor. It also gives them the ability to continuously monitor signals over time, so they can catch intermittent signals. Bar graphs and report-generation tools support your documentation needs.

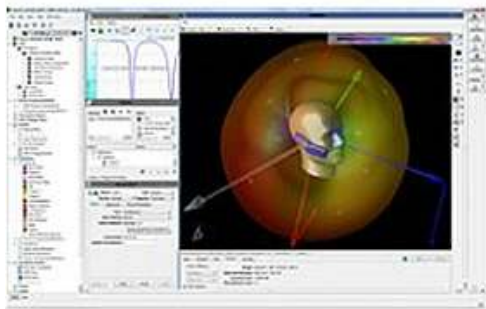


N9020A MXA signal analyzer with N6141A embedded EMI screen capture

Medical Device Design and Test Challenges

Electromagnetic Professional (EMPro) is a 3D modeling and simulation environment for analyzing various 3-dimensional EM problems. EMPro features a modern design, simulation and analysis environment, high capacity time- and frequency - domain simulation technologies (FDTD and FEM) and integration with ADS (Advanced Design System), the industry's leading RF/microwave and high-speed design environment. The

application of EMPro is not only for typical high frequency, high speed, and antenna applications, but also expands to EMI, medical, and bio applications, for example, MRI and pacemaker designs. By using EMPro, designers can also ensure the design passes regulatory and operator compliances, such as Over-The-Air performance, Specific Absorption Ratio (SAR), and Hearing Aid Compatibility (HAC), before going into expensive physical design testing.



Birdcage



B-field plot



SAR plot



SAM head for mobile phones

EMPro software and 3D simulation examples



Materials	
skin	
tendon, other	
fat, yellow marrow	
cortical bone	
cancellous bone	
blood	
muscle	
grey matter	
white matter	
CSF	
sclera/cornea	
vitreous humor	
nerve	
cartilage	
tongue, thyroid	
cerebellum	
esophagus	

Material Definitions

EMPro human body models for medical applications

Medical Device Design and Test Challenges

Wireless Technologies in Medical Device

Applying wireless technologies into medical device brings various benefits including always-on patient monitoring, seamless communications among person to person and machine to machine, wireless sensing, and more. In addition to medical dedicated wireless technologies, medical industry is widely adapting off-the-shelf wireless connectivity technologies such as WLAN, Bluetooth® 4.0 Low Energy, Zigbee, Near Field Communication (NFC) and cellular technologies including HSPA and LTE for better wireless connections among medical devices and whole systems. Keysight provides broad and powerful wireless design and test solutions for all product life cycles.

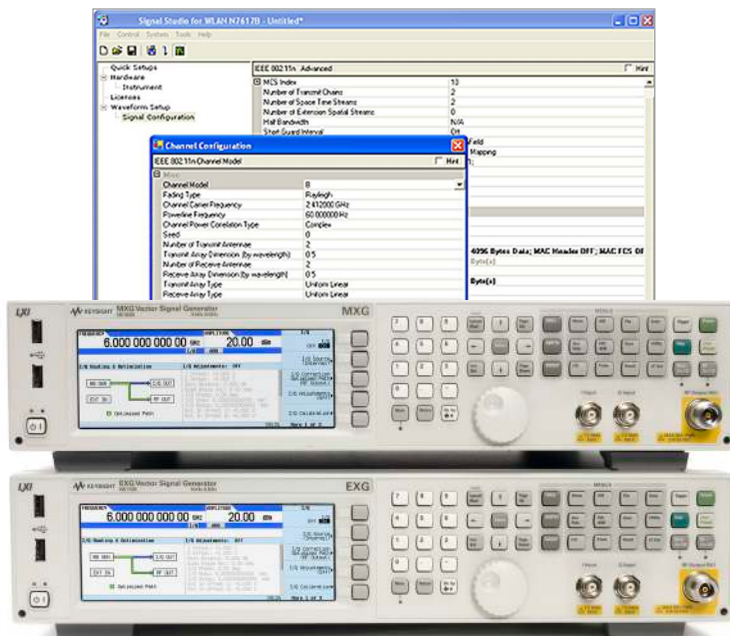
X-series signal analyzers and 89600 VSA software provides accurately measure frequency, amplitude and modulation including distortion, spurious, phase noise, and 2G to 4G cellular communication signals as well as various wireless connectivity signals

such as WLAN, Bluetooth, Mobile WiMAX®, and more. They also offers flexible modulation analysis software or measurement applications so you can demodulate a broad range of standard-based and general-purpose digital signals and formats.



N9020A MXA signal analyzer

X-series vector signal generators with Signal Studio signal creation software enable you to create high performance signals covering a frequency range of 9 kHz up to 6 GHz with up to 160 MHz modulation bandwidth, quickly and easily verify the performance of devices and receivers that use broad wireless standards, verify interference testing, and troubleshoot a device's operation in the presence of common wireless signals.



X-series vector signal generators with Signal Studio software

Medical Device Design and Test Challenges

N4010A wireless connectivity test set helps wireless medical device developers and manufacturers to test multiple wireless connectivity technologies including WLAN 802.11 a/b/g/n, Bluetooth and Zigbee with one test platform, and increase manufacturing throughput with fast, accurate measurements. Using with N4011A MIMO/Multi-port Adapter, wireless medical device developers

can test WLAN MIMO (up to 4x4) devices and modules. Also, N4010A provides a broad range of measurements for evaluating wireless formats in the 2.4 GHz or 5 GHz bands using with the Keysight 89600 Vector Signal Analysis software or N4018C/19C Bluetooth®/WLAN Wireless Test Manager software.



N4010A wireless connectivity test set with N4011A MIMO/multi-port adapter

Near Field Communication (NFC) a fusion technology that provides new valuable service to the users by integrating RFID Technology with Mobile Communication devices & Wireless Internet infrastructure, provides various benefits to wireless medical devices including pedometer, thermometer, BPM, weight scale, etc. NFC communication and option to communicate data to hub that can later connect to remote health services over the network.

- Validated tool for NFC forum certification program
- RF and protocol testing in one single instrument
- One -box test solution no need for external instrumentation
- Robots supported

T3111SNFC
Conformance
Test System

- NFC & RFID devices emulator
- Users can build their own test cases
- Automated test cases execution



T3121SNFC
R&D Test System

NFC R&D and conformance test solutions

Medical Device Design and Test Challenges

Battery Life and Current Drain Measurements

The importance of battery life is critical for portable battery powered medical device developers. The convergence of wireless connectivity, high speed digital processing, and real time monitoring abilities requires understanding and accurately measuring battery current drain. Long periods of sleep/idle, wakeup/active, and short RF bursts creates a tough demand on the battery. Today's test tools fall short when trying to measure dynamic current from sub-microamps to amps.



N6705B DC power analyzer

Keysight current drain analysis solution consists of the N6705B DC Power Analyzer, N6781A 2-Quadrant Source/Measure Unit and 14585 Control and Analysis Software. This integrated solution includes a patented innovative measurement called "Seamless Measurement Ranging." This capability provides you with the ability to measure dynamic current drain from sub-microamperes to amperes in a single measurement acquisition. Extremely wide dynamic range 1,000,000:1, over 7 decades of measurement, and with close to 28 bit vertical resolution.

The N6781A SMU module in the N6705B DC Power Analyzer is optimized for determining run-time of the whole portable medical device, making this the best choice for DC measurement with the highest sensitivity and widest dynamic range for battery drain analysis.

Perform battery run down tests using the actual medical device battery. The N6781A SMU module is configured as a virtual logging ammeter to digitize the current drain. The N6781A Aux DVM input is connected across the battery

to record the battery voltage. Average current, charge (mAh), energy, (Wh), and run time, are calculated based on 14585A software markers at the start and shutdown points.



N6781A 2-quadrant source/measure unit

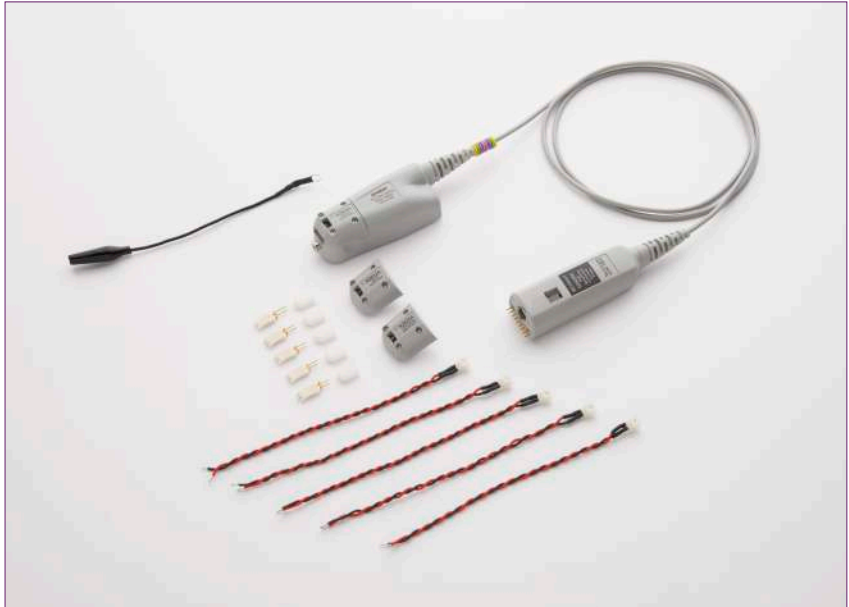


14585A control and analysis software

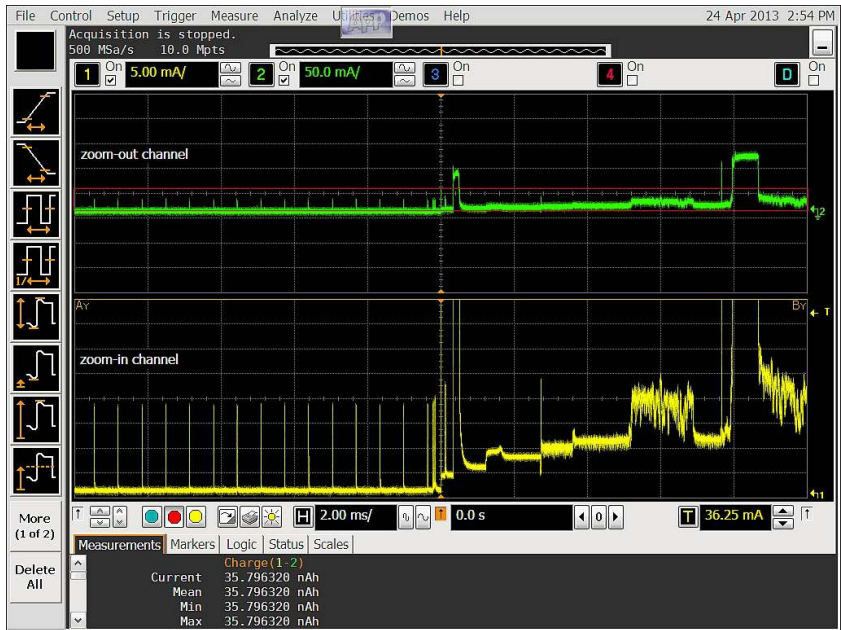
Medical Device Design and Test Challenges

N2820A series high sensitivity current probes

For many engineers designing or testing medical devices, oscilloscope is a major tool of choice when it comes to measuring low level AC/DC current signals as well as voltage signals. The N2820A Series High Sensitivity Current Probes address the need for high-sensitivity current measurements with a wide dynamic range. These probes also offer the advantage of physically small connections to the device under test (DUT), since today's application environments require an extremely small form factor. The new N2820A/21A AC/DC current probes offer the industry's highest sensitivity among oscilloscope current probes, going all the way down to 50 μ A, with a maximum current range of 5 A. The new probes are optimized for measuring the current flow within the DUT to characterize sub-circuits, allowing the user to see both large signals and details on fast and wide dynamic current waveforms.



N2820A/21A AC/DC current probes offer the industry's highest sensitivity among oscilloscope current probes



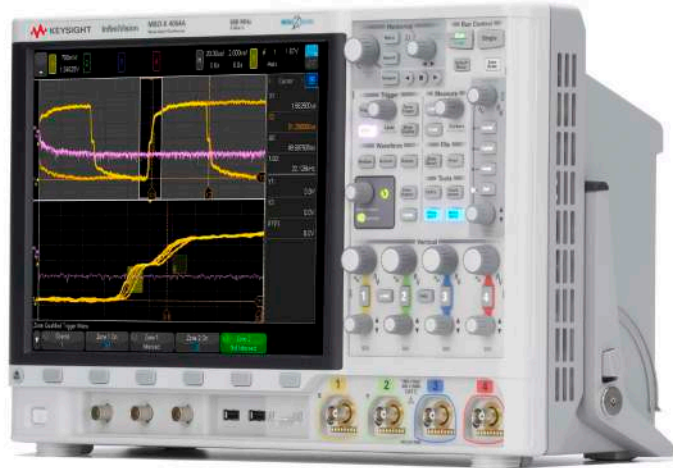
N2820A 2-channel high sensitivity current probe with "zoom out" view of the waveform and "zoom in" view to observe extremely small current fluctuations

Medical Device Design and Test Challenges

Digital Interface

Medical device developers should verify various digital signals and interface protocols over a wide range of speeds, including CAN, I²C, USB, and PCI Express, as well as, digital video interfaces like HDMI.

InfiniiVision 4000 X-series oscilloscopes help find the most elusive problems in your design with the industry's fastest update rate (1,000,000 waveforms/sec) to display the most signal detail. The InfiniiVision 4000 X-Series also helps you quickly debug your medical device design with industry exclusive InfiniiScan Zone touch triggering on the industry's largest capacitive touch screen display in this class. Plus get the capabilities of five instruments in one, with complete upgradability including bandwidth, MSO, dual-channel WaveGen DVM, and serial protocol analysis (CAN, I²C, SPI, USB 2.0, and more).



InfiniiVision 4000 X-series oscilloscope

Infiniium series oscilloscopes
Infiniium 9000 Series oscilloscopes offer the world's first scope-based protocol viewer with multi-tab viewing, allowing you to quickly move between correlated protocol and

physical layers. Infiniium 9000 H-Series high-resolution oscilloscopes provides precision viewing of small and high dynamic range signals with more resolution and less noise than traditional oscilloscopes.

Infiniium 90000 Series oscilloscopes are engineered for unmatched real-time bandwidth and measurement accuracy in addition to the industry's most comprehensive application-specific measurement software for testing today's medical devices.



Family of Infiniium oscilloscopes

Medical Device Design and Test Challenges

Power Measurement

Accurate power measurements are critical for medical device designs to provide precise, safe medical analysis, as well as, fast rise time, bandwidth and reading speeds.

E4416A power meter with E9321A power sensor and a directional coupler provide accuracy and intuitive measurements because they display measured power in the preferred kW or dBm units. With one single sensor, this solutions can cover wide dynamic range from 316 W to 35,500 W (55 dB to 75.5 dB) which have more than 20 dB usable dynamic range to supports multiple type of RF platform. E4416A-E22 can quickly and accurately measure the average and peak power of an excitation signal in the form of a pulse (i.e., rectangular, trapezoidal, complex sine). Measurement speeds of more than 40 readings per second and accuracies better than 5% over the operating frequency range of 10 MHz to 300 MHz.



EPM and EMP-P series power meters and sensors

Medical Device Design and Test Challenges

Component Characteristics

RF device and component testing requires an innovative mix of time, coverage and cost-per-DUT. Finding your balance starts with the right combination of speed and performance in your test system.



M9381A PXIe vector signal generator combines Keysight quality and performance in the PXI form factor. It accelerates throughput by delivering new levels of speed in signal generation—fastest analog tuning, **fasttune** digital baseband tuning, versatile list mode, and more—to accelerate the characterization, validation and production of RF components and devices.

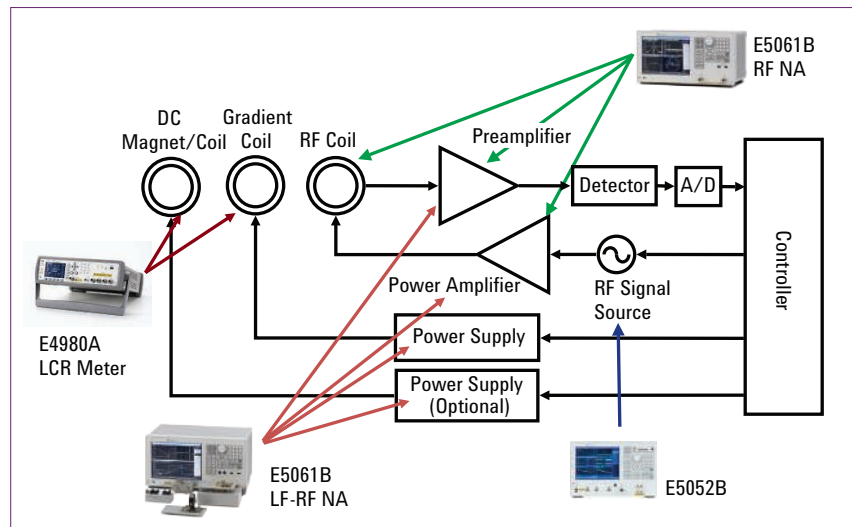
M9381A PXIe vector signal generator requires 5 slots and can be combined with other PXI modules in a PXIe 18-slot chassis to build a complete test solution in a small form factor.

The M9381A PXIe Vector signal generator provides frequency coverage from 1 MHz to 3.0 or 6.0 GHz, and up to 160 MHz of RF modulation bandwidth to support emerging wireless standards. It accelerates test throughput with less than 10 μ s digital baseband tuning and less than 225 μ s full RF range tuning, linearity and accuracy, reducing overall test time.

- Signal Studio signal creation software for WLAN, Bluetooth, and frequency coverage for WMTS, ZigBee, RFID, MBAN, MICS, ISM and custom formats
- Measurement integrity for critical wireless transmissions
- Speed for high throughput RF wireless medical device test without compromise on signal quality

Component test solution plays critical roles to help component developers and manufacturers for medical devices including MRI, RFID, and various material and impedance measurements in biomedical industry. Keysight provides various component test solutions including E5061B RF/LF-RF Network Analyzers, LCR Meters, E5052B Signal Source Analyzer. With an example of MRI components test case, E5061B LF-RF Network Analyzer is the best choice for R&D engineers and circuit designers to verify the amplifiers and power supply, E5061B RF Network Analyzer, a direct successor of HP/Keysight 8712, helps MRI production engineers test RF coils, amplifiers and filters with its fast, accurate and cost-performance balanced test capabilities, and E5052B Signal Source Analyzer measures MRI oscillators phase noise with

exceptionally fast and accurate test capabilities along with its easy operation and one-box simple configuration.



MRI component test diagram

Medical Device Design and Test Challenges

Service and Maintenance

Whether inside a hospital or an outside clinic, it is critical for medical device developers and medical service providers to have the most accurate test and measurement capabilities at their finger tips, allowing them to quickly and accurately install and maintain wireless medical devices and systems continuously addressing the safety of patients.

Handheld digital multimeters

From electronics troubleshooting to installation and maintenance of machinery, Keysight U1200 series handheld digital multimeters are designed to withstand harsh working conditions and to improve safety. Each DMM is compatible with the U1177A Infrared (IR)-to-Bluetooth® adapter which offers wireless remote connectivity to Android smartphones or tablets and PCs. Our range of handheld DMMs are also equipped with smart features to help you quickly detect problems and obtain accurate measurements.

Clamp meters

Our clamp meters are designed to address the toughest electrical challenges without compromising on safety. Certified with safety ratings and equipped with a wealth of features – you are now ready to make measurements with more confidence. The U1210 series clamps also support wireless remote connectivity.

Handheld oscilloscopes

Our U1600 series handheld scopes are designed to be used across a wide range of applications and troubleshooting tasks, most commonly in servicing X-ray machines. Each model comes with different specifications to tailor to your needs, and is safety certified for safer measurements. We are the technology leader in the handheld scope market with both our high resolution VGA TFT display and the 2 M points memory, found in our U1620A 200 MHz scope.



View and data log measurements wirelessly on an Android smartphone or tablet with the U1177A adapter



Handheld Tools including Digital multimeters, Digital oscilloscopes, LCR meters, Capacitance meters, Clamp meters, Multifunction calibrator meter

Get greater insight and greater confidence with Keysight—
and accelerate the design and development of next-generation
medical devices.

Design & Development

Keysight design and development tools help you verify your medical devices even before having prototypes. We are determined never to let test equipment needs stand in your way of developing innovative products for evolving medical device design and development.

Design Verification & Conformance

Keysight offers pre-conformance and design-validation test systems built around our test tools. Keysight's test solutions let you check your new products against requirements so you can determine if your medical product will be allowed to operate in the defined geographic region.

Integration & Interoperability

Keysight provides test equipment help ensure your medical devices will conform to integrate and interoperate with other devices. Keysight also provides tools and services to streamline the way you prepare for certification, helping you evaluate module performance, characterize interoperability, and make sure your integration effort results in certified products.

Service & Maintenance

Keysight's tools allow you to do more in the field in less time and increase your ability to detect and eliminate interfering signals among medical devices used in or out of hospital environments.

Manufacturing

Keysight extends its expertise to offer stand-alone products and system solutions to help get your medical device designs to market faster and more efficiently.

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A personalized view into the information most relevant to you.



www.axiestandard.org

AdvancedTCA® Extensions for Instrumentation and Test (AXIe) is an open standard that extends the AdvancedTCA for general purpose and semiconductor test. Keysight is a founding member of the AXIe consortium.



www.lxistandard.org

LAN eXtensions for Instruments puts the power of Ethernet and the Web inside your test systems. Keysight is a founding member of the LXI consortium.



www.pxisa.org

PCI eXtensions for Instrumentation (PXI) modular instrumentation delivers a rugged, PC-based high-performance measurement and automation system.



Three-Year Warranty

www.keysight.com/find/ThreeYearWarranty

Keysight's commitment to superior product quality and lower total cost of ownership. The only test and measurement company with three-year warranty standard on all instruments, worldwide.



Keysight Assurance Plans

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Up to five years of protection and no budgetary surprises to ensure your instruments are operating to specification so you can rely on accurate measurements.



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Keysight Electronic Measurement Group
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Get the best of both worlds: Keysight's measurement expertise and product breadth, combined with channel partner convenience.

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