APPLICATION NOTE

Why Multi-Interference Testing Matters for Modern Medical Devices

Ensuring Wireless Reliability in RF-Congested Healthcare Environments

KEYSIGHT

The Growing Wireless Challenge in Modern Healthcare

Modern medical devices increasingly rely on RF wireless technology to enable seamless data exchange and coordinated responses through machines (M2M) communication and cloud connectivity. These wireless capabilities are essential for a variety of advanced and smart healthcare applications such as telesurgery, Remote Patient Monitoring (RPM), connected emergency response and wearable diagnostics. As healthcare systems evolve toward more connected and intelligent infrastructures, the demand for reliable wireless communication continues to grow.

However, these devices often operate in RF-congested environments like hospitals, where multiple wireless systems (Wi-Fi, *Bluetooth®*, LTE, etc) compete for the limited spectrum. This congestion significantly increases the risk of RF interference, which can degrade device performance, disrupt communication, and pose serious risks to patient safety.

Importance of Multi-Interference Testing

Multi-interference testing is critical for ensuring safe, reliable wireless performance in medical environments, and for helping device manufacturers build robust, compliant systems, particularly for high-risk and critical use cases.

Ensuring Safe and Reliable Performance in Medical Environment

- **Real-world complexity**: Medical devices rarely operate in isolation. They must function reliably in shared and congested RF environments. Hospitals are among the most challenging, with dense infrastructure and overlapping wireless protocols competing for limited bandwidth.

- **Complex interference effects**: Multiple sources of interference can interact in unpredictable ways, leading to intermodulation distortion, receiver desensitization, and a degraded signal-to-noise ratio, all of which may disrupt or delay wireless communication.

- **Patient safety:** Delays or failures in wireless communication can result in missed alarms, delayed clinical response or incorrect therapy delivery, posing serious risks to patient outcomes. For example, implantable or life-support devices with Wireless Telemetry. Failure could result in delayed detection of life-threatening arrhythmia.

Strengthening Device Integrity in Real World Conditions

- **Design optimization**: Multi-interference testing provides valuable insights that guide key design decisions such as antenna placement, shielding strategies, and protocol selection, to maximize overall device performance.

- **System resilience**: Validating performance under realistic and high-stress conditions ensures devices remain dependable across diverse environments, from crowded hospital wards to fast-paced emergency scenarios.

- **Risk management**: Identifying interference-related failure modes allows manufacturers to justify acceptable risk levels and enhance design robustness. This helps prevent costly failures and maintain brand trust, especially vital for mission-critical medical devices where reliability is paramount and cannot be compromised.

What is Wireless Coexistence Testing?

Wireless coexistence testing evaluates a wireless device's ability to maintain its functional wireless performance when exposed to interferences from multiple RF systems operating within the shared spectrum bands, whether on co-channel or adjacent channel frequencies.

In contrast, traditional Electromagnetic Compatibility (EMC) testing, which primarily focuses on one-directional interference, is inadequate for addressing the challenges of shared RF environments. Therefore, it is complemented by wireless coexistence testing to ensure safety, reliability and robustness of the device operating in increasingly crowded RF environment.

The U.S. Food and Drug Administration (FDA) has designated ANSI C63.27 as a recognized consensus standard for wireless coexistence assessment to help manufacturers ensure device reliability and support consistent regulatory review. Manufacturers are strongly encouraged to adopt the standard for all wireless medical devices, making it as part of regulatory approval submission (e.g., 510(k), PMA).

Wireless Coexistence Evaluation Overview Based on ANSI C63.27 Standard

The ANSI C63.27 standard provides a structured guidance on test procedures and performance metrics to ensure comprehensive assessment of wireless coexistence capabilities of an Equipment Under Test (EUT), with particular focus on technologies operating in unlicensed frequency bands such as *Bluetooth*, Wi-Fi, ZigBee, and LTE-LAA, which are susceptible to interference.

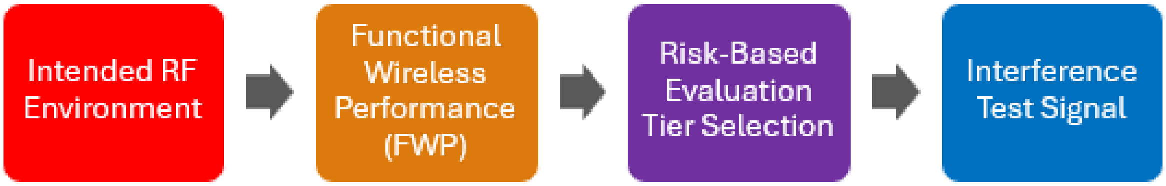


Figure 1. Critical factors in wireless coexistence evaluation process outlined in C63.27 standard

Intended RF Environment

Manufacturers must define the characteristics of the intended operational environment of the device. This includes identifying potential sources of interference, their signal type, frequencies, and power level. This characterization is essential for defining realistic test scenarios that accurately reflect the conditions under which the device will be deployed.

Functional Wireless Performance (FWP)

FWP refers to the subset of wireless functions that are essential to device's operation. If these functions are degraded, they could lead to unacceptable risk. Manufacturers must define appropriate measurable Key Performance Indicators (KPIs) to measure FWP under interference. Common KPIs include, but are not limited to:

- Throughput: Data transfer rate.
- Latency: Communication delay.
- Packet Error/Loss Rate: Percentage of failed data transmissions.
- Retransmission Attempts: Frequency of repeated sends.

These KPIs help distinguish between acceptable and unacceptable performance during testing.

Risk-Based Evaluation Tier Selection

ANSI C63.27 outlines a 3-tiered evaluation approach based on the potential risk associated with wireless performance failure, as summarized in the table below.

This tiered approach ensures that higher-risk devices undergo more comprehensive testing.

Evaluation	Risk Level	Definition	Testing Scope
Tier 1	High	FWP failure could result in serious harm and injury	Most rigorous testing with most concurrent multi-interference scenarios
Tier 2	Moderate	FWP failure may cause degraded performance or delayed operation, but not immediate harm	Intermediate testing with broader interference scenarios
Tier 3	Low	FWP failure has minimal impact. e.g. inconvenience or delay	Minimal testing with a limited set of interferers

Table 1. Risk-Based Evaluation

Interference Test Signals

The interference signals and their characteristics used to evaluate the EUT's performance are defined by the manufacturer based on the device's Radio Access Technology (RAT), operating frequency, and intended use RF environment. During testing, one or more concurrent interferers are introduced on co-channel and/or adjacent channels to replicate realistic scenarios.

EUT RAT	Operating Band	Interferers	Key Performance Indicators	# of Concurrent Interferers
Bluetooth / BLE	2.4 GHz ISM	2.4 GHz Wi-Fi, *Bluetooth*, LTE	Data Throughput, Packet Error Rate Connection Drops	1-3
2.4 GHz Wi-Fi	2.4 GHz ISM	2.4 GHz Wi-Fi, *Bluetooth*, LTE	Data Throughput, Latency, Retransmission Rate	1-3
5 GHz Wi-Fi	5 GHZ UNII	5 GHz Wi-Fi, LTE-LAA, CV2X	Data Throughput, Packet Error Rate, Receiver modulation quality (EVM)	1-5
LTE LAA	5 GHZ UNII	5 GHz Wi-Fi, LTE-LAA, CV2X	Downlink throughput, block error rate	1-5
ZigBee	2.4 GHz ISM	2.4 GHz Wi-Fi, *Bluetooth*, LTE	Packet Delivery Rate, Latency	1-3

Table 2. An example of typical test configurations based on common practices guided by ANSI C63.27.

Actual test setups may vary depending on the device's intended use and the criticality of its wireless functions.

How Keysight Wireless Coexistence Test Solution Enables Multi-Interference Testing

The Keysight Wireless Coexistence Test Solution provides a pre-verification platform to assess the coexistence capability of an EUT under realistic RF interference conditions. It evaluates both physical-layer behavior and application-level mitigation strategies to ensure robust wireless performance.

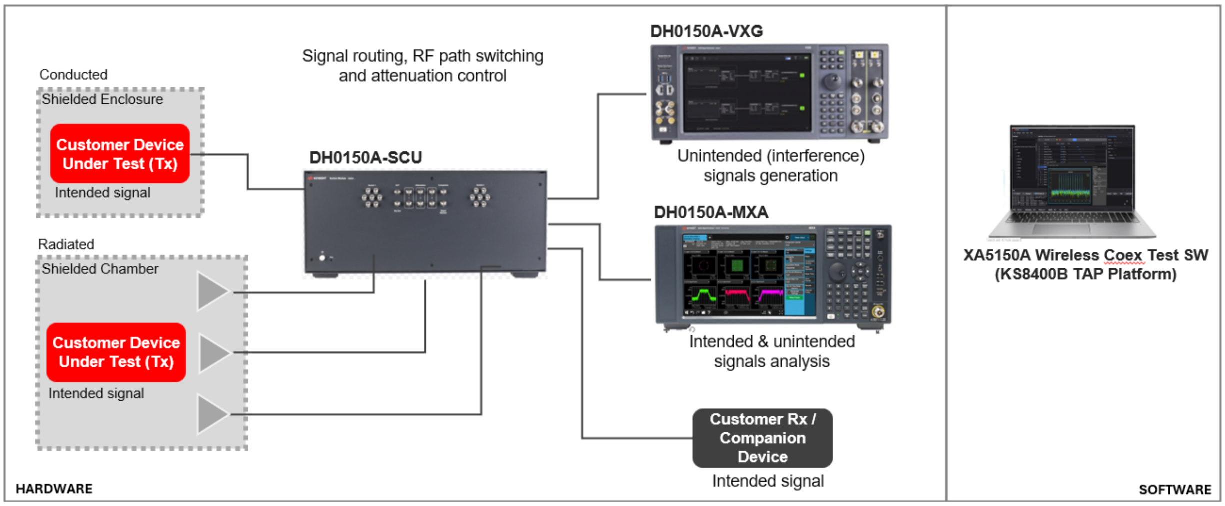


Figure 2. Keysight Wireless Coexistence Test Solution, seamless transition between conducted and radiated test configurations within a single setup

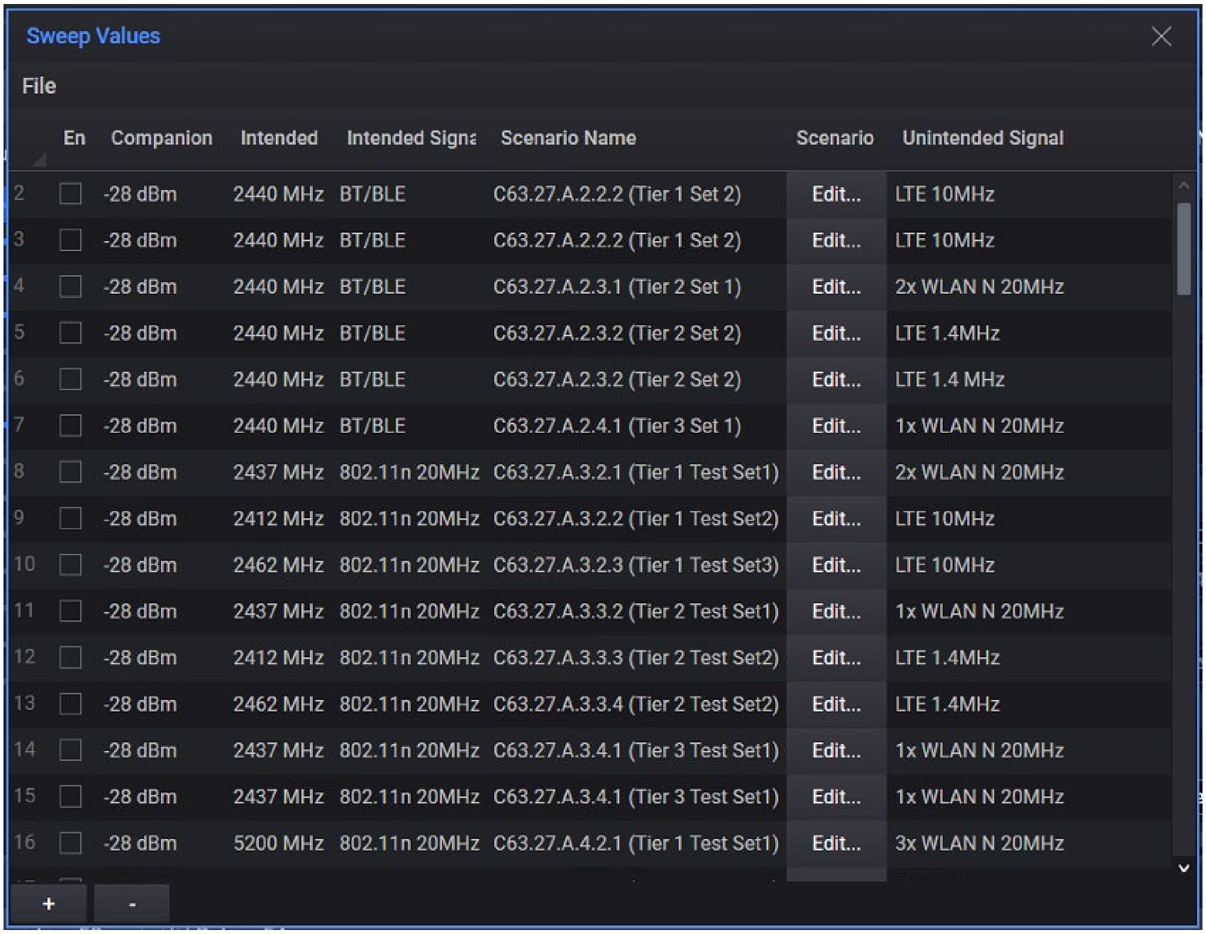
Multi-Interference Signal Generation

The solution is capable of simulating the desired congested RF environments by generating band-specific single or up to 8 multiple concurrent interference waveforms with configurable protocols, frequencies and amplitude level for each waveform, which is ideal for most Tier-1 and Tier-2 testing scenarios. The solution is also scalable, allowing the number of concurrent signals to be expanded in the future for more rigorous testing requirements when needed.

Automated Test Execution

XA5150A Wireless Coexistence Test Software includes a waveform library comprising standardized interference profiles in accordance with ANSI C63.27 across multiple wireless protocols, automates test execution, delivers quantitative measurements (throughput, packet error rate, etc), and generates comprehensive result file.

Additionally, the software is customizable to create user defined test cases such as, user specific KPI for FWP, EUT/Companion device control that further enhance the testing automation.



Sweep Values

File

	En	Companion	Intended	Intended Signa	Scenario Name	Scenario	Unintended Signal
2		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.2.2 (Tier 1 Set 2)	Edit...	LTE 10MHz
3		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.2.2 (Tier 1 Set 2)	Edit...	LTE 10MHz
4		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.3.1 (Tier 2 Set 1)	Edit...	2x WLAN N 20MHz
5		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.3.2 (Tier 2 Set 2)	Edit...	LTE 1.4MHz
6		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.3.2 (Tier 2 Set 2)	Edit...	LTE 1.4 MHz
7		-28 dBm	2440 MHz	BT/BLE	C63.27.A.2.4.1 (Tier 3 Set 1)	Edit...	1x WLAN N 20MHz
8		-28 dBm	2437 MHz	802.11n 20MHz	C63.27.A.3.2.1 (Tier 1 Test Set1)	Edit...	2x WLAN N 20MHz
9		-28 dBm	2412 MHz	802.11n 20MHz	C63.27.A.3.2.2 (Tier 1 Test Set2)	Edit...	LTE 10MHz
10		-28 dBm	2462 MHz	802.11n 20MHz	C63.27.A.3.2.3 (Tier 1 Test Set3)	Edit...	LTE 10MHz
11		-28 dBm	2437 MHz	802.11n 20MHz	C63.27.A.3.3.2 (Tier 2 Test Set1)	Edit...	1x WLAN N 20MHz
12		-28 dBm	2412 MHz	802.11n 20MHz	C63.27.A.3.3.3 (Tier 2 Test Set2)	Edit...	LTE 1.4MHz
13		-28 dBm	2462 MHz	802.11n 20MHz	C63.27.A.3.3.4 (Tier 2 Test Set2)	Edit...	LTE 1.4MHz
14		-28 dBm	2437 MHz	802.11n 20MHz	C63.27.A.3.4.1 (Tier 3 Test Set1)	Edit...	1x WLAN N 20MHz
15		-28 dBm	2437 MHz	802.11n 20MHz	C63.27.A.3.4.1 (Tier 3 Test Set1)	Edit...	1x WLAN N 20MHz
16		-28 dBm	5200 MHz	802.11n 20MHz	C63.27.A.4.2.1 (Tier 1 Test Set1)	Edit...	3x WLAN N 20MHz

Figure 3. Interference Waveform Library comprising standardized profiles in accordance with ANSI C63.27

Spectrum Monitoring and Analysis

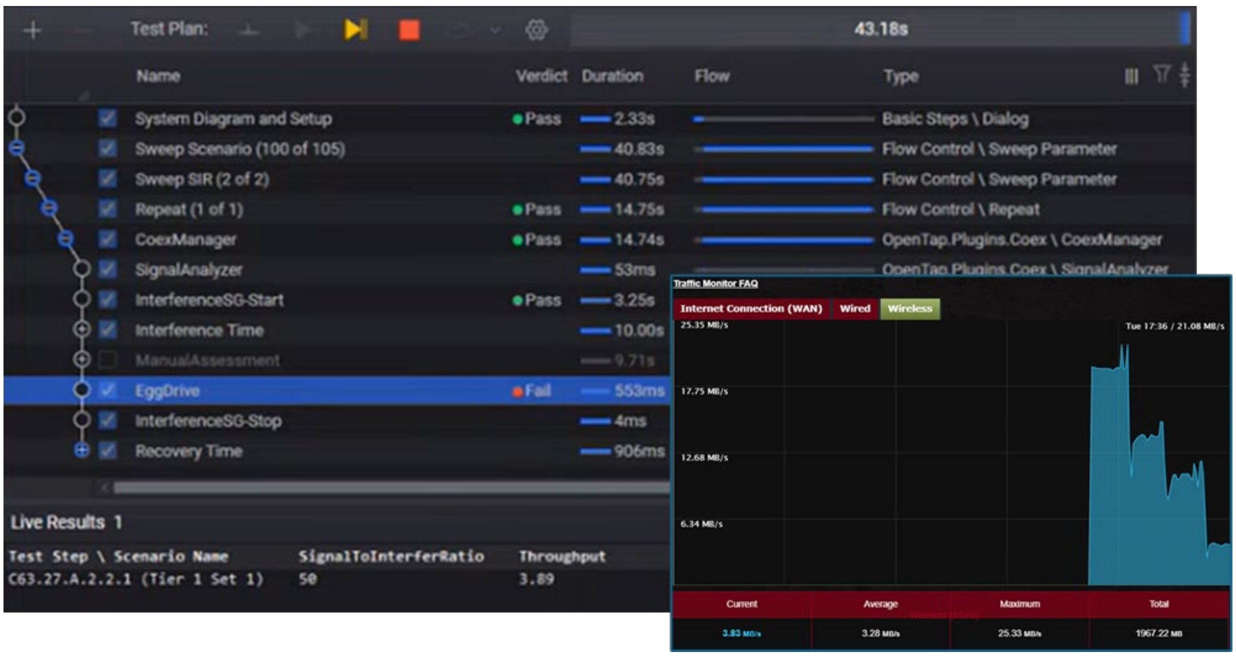
The MXA signal analyzer's Real-Time Spectrogram (RTSA) capability provides a comprehensive view of the spectral environment over time, enabling continuous monitoring and validation of the EUT's FWP under interference conditions. Its color-coded density display highlights signal presence and frequency occupancy, making it easy to distinguish intended transmission from interfering signal and ensuring accurate characterization of coexistence behavior.

Streamless Setup for Conductive and Radiated Test

The Keysight Signal Conditioning Unit (SCU) provides fully automated signal routing, RF path switching, and attenuation control for flexible test configurations. This unit enables seamless transition between conducted and radiated test configurations within a single setup, reducing complexity and improving test efficiency.

Identifying FWP Failures Using the Solution

A hospital-grade wireless infusion pump using 5 GHz Wi-Fi with a 40 MHz channel bandwidth, was evaluated for coexistence performance in a simulated RF-congested environment. The test setup included three concurrent interferers: 64QAM 802.11n with 40 MHz bandwidth, at maximum channel utilization on co-channel and 2 adjacent channels, with amplitude step from -50 dBm to -20 dBm.



Using Keysight Wireless Coexistence Test Solution, EUT was subjected to a throughput test while transmitting data to a companion device.

EUT exhibited a significant drop in data throughput (from 20 Mbps to 3.9 Mbps) during telemetry transmission. These results failed the predefined FWP KPIs, which required a minimum throughput of 8 Mbps. The performance degradation indicated that the EUT could not reliably maintain real-time data transmission in a congested RF environment, potentially delaying critical infusion updates. This insight prompted design revisions to improve channel agility and interference mitigation.

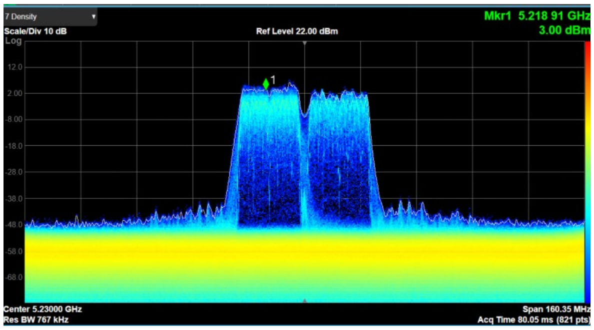


Figure 4. EUT transmitting telemetry data to a companion device under normal operating conditions prior to introducing interference, serving as a reference for evaluating FWP

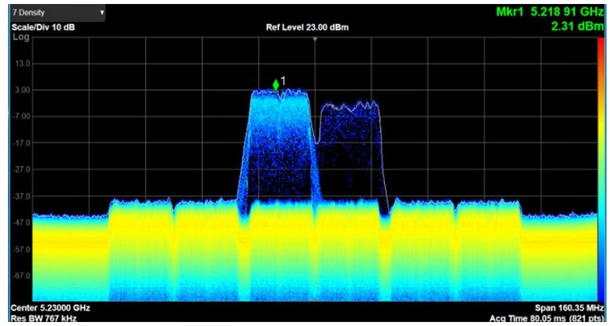


Figure 5. EUT experienced drop in throughput when exposed to co-channel and adjacent-channel interference.

Conclusion

As wireless connectivity becomes increasingly vital to medical device functionality, ensuring reliable performance in RF-congested environments is critical. Keysight Wireless Coexistence Test Solution plays a pivotal role in this process by simulating complex RF environments with multiple concurrent interferers. Its scalable architecture and automated test capabilities support rigorous evaluation across all risk tiers, helping manufacturers optimize design, validate performance, and meet regulatory expectations, ultimately enhancing patient safety and device reliability in connected healthcare settings.