THE IMPORTANCE OF WIRELESS COEXISTENCE TESTING FOR CONNECTED MEDICAL DEVICES

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ABOUT THE AUTHOR

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WIRELESS TECHNOLOGY AND FREQUENCY BAND SATURATION

Communication has advanced unbelievably quickly in the 150 years between the Pony Express and the advent of the internet. The shelf life of information has drastically decreased - from weeks to seconds, and the distance we are willing to travel for information has shrunk to virtually nothing. We demand instantaneous access to a massive range of data, no matter where we may be in the world. Companies are spending billions of dollars for faster access to information, and consumers spend more each year on faster devices. Cellular carriers, aware of this trend, have shifted from voice-only networks to data-centric services, and are relying more heavily on spectrum sharing.

The first recognizable iteration of Wi-Fi launched in 1999, and for Bluetooth about 2 billion Bluetooth devices were sold prior to 2008. In 2022, however, 4.9 billion Bluetooth were shipped in the span of a single year. There are now Wi-Fi access points in planes, dog collars with GPS, and toothbrushes with Bluetooth connectivity. Radio devices are everywhere: there are more users, more devices, and greater saturation of frequency bands.

Beyond the proliferation of the devices themselves, multiple radio technologies are also being combined into single devices. Many cell phones now have seven different radios: Bluetooth, Wi-Fi, GNSS (global navigation satellite system), wireless power transfer, nearfield communication, as well as ultra-wideband for location sensing, and, of course, 4G or 5G cellular radio.

The radio spectrum is a valuable and finite resource that needs to be shared across all applications, so efficient spectrum utilization is critical as well as a growing concern of regulators. New technologies such as smart antenna systems and orthogonal frequency-division multiplexing (OFDM) are being developed to try to optimize use of the frequency spectrum. Optimizations such as cognitive radio, which is programmed to select the least congested nearby channels to try to minimize interference, are mandated by trade groups such as the Wi-Fi Alliance and regulatory bodies including the FCC and European Council are following suit.

WIRELESS COEXISTENCE RISKS AND CHALLENGES FOR MEDICAL DEVICES

Connected medical devices monitor patient health, make crucial health information accessible when it is needed, and are often instrumental in saving lives but they rely on proper operation in their electromagnetic environment. Unfortunately, thousands of incidents of electromagnetic interference (EMI) occur in healthcare every year. The US Food and Drug Administration (FDA) has a database called MAUDE (Manufacturer and User Facility Device Experience) that tracks medical device malfunctions. It currently contains more than 250,000 reports of issues related to electromagnetic compatibility (EMC), and between 2010 and 2019, there were reports of more than 170 deaths attributable to EMC, electrostatic discharge, or wireless malfunctions. Because of the way the reports are compiled and recorded, it is not possible to determine how many of these incidents are specifically related to wireless coexistence, but these figures obviously raise concerns about the adequacy of wireless device testing and how such risks can be reduced or eliminated.

HOW MEDICAL TECHNOLOGIES USE RADIO BANDS

Manufacturers are increasingly using wireless technologies for functions that are critical to patient well-being, using a variety of radio technologies and frequency bands. Some of these are exclusive to medical devices, but many are shared with other applications or entities. Examples include:

- Inductive radio, which is typically below 200 kHz
- Medical Device Radiocommunication Service (MedRadio) 401-406 MHz, including medical micropower network (MMN) devices
- Medical Implant Communication Service (MICS) 401-406 MHz
- Industrial, Scientific, and Medical (ISM) bands are various specific bands shared by medical devices, industrial devices, and various scientific devices
- Medical Body Area Networks (MBANs) are adjacent to the 2.4 gigahertz ISM band and allows multiple sensors on a patient's body to communicate with a control unit
- Wireless Medical Telemetry Service (WMTS) is a safe, proprietary band also used for sensors, like the MBANs, but typically limited to critical care in healthcare facilities

Medical micropower networks (MMNs) are a subset of MedRadio specifically for implanted nerve stimulators. Thanks to extensive negotiations with the military and the FCC, MMN bands can only be used for these implantable nerve stimulators.

Some bands used by medical technology are not limited at all. Wi-Fi is essentially ubiquitous in medical facilities. Most facilities use a secure network used to transmit patient data both within the facility and to other medical facilities. MRI, X-Ray, and other screening or diagnostic devices may transmit images or data through the secure Wi-Fi network, and it can also be used for tracking patient or staff movements through the facility. Off-the-shelf technologies like Wi-Fi have pros and cons: widespread use of Wi-Fi makes interoperability easier and using a tried and tested technology like Wi-Fi in a new medical device reduces development time. However, Wi-Fi technologies have generally poor product support, become obsolete relatively quickly due to consumer technology churn, and operate on very crowded bands (2.4 and 5 GHz).

Bluetooth is also becoming more widespread in healthcare; there is a new use case called the Bluetooth Health Device Profile that has been specifically developed for use in transferring medical data. Common current uses for Bluetooth include inventory tracking, sensors, and glucose monitoring. An emerging application uses 2.4 GHz Bluetooth to send a wake-up signal to an implant, and the implant then uses inductive or MedRadio to transfer data. Additionally, ZigBee, a mesh networking protocol, is used for real-time monitoring systems, similar to MBANs.

RFID is also widespread in medical facilities. It covers multiple unlicensed bands and is primarily used for tracking: everything from million-dollar pieces of equipment to single doses of drugs can be tracked with RFID.

Cellular technology in medical applications faces similar hurdles to Wi-Fi. It is used for data transfer, step counters, and even some diagnostic imaging. The high-bandwidth capabilities of 5G are also prompting more explorations of cellular technology in medicine, such as remote robotic surgery or ambulances connected directly and continuously with a hospital.

A critical advantage for all these technologies, and a large part of the reason they are now so in demand, is wireless mobility. Healthcare providers and patients need to be able to move freely, whether across the world or from one room to another, without losing access to their data. This application for radio technology is not only convenient but can lead to better health outcomes due to faster communication and fewer geographic barriers to accessing the best care.

Radios also pose a special challenge as medical device manufacturers must use wireless communication in a crowded spectrum.

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REDUCING THE RISK OF INTERFERENCE WITH COEXISTENCE TESTING

The more users there are on a single band the greater the risk of interference becomes. There are now billions of Wi-Fi, Bluetooth, and cellular devices in use, with still more added every day. Device manufacturers must manage risks and work proactively to prevent interference in their products as interference may be inconvenient for consumer products, but have much more serious consequences for medical devices.

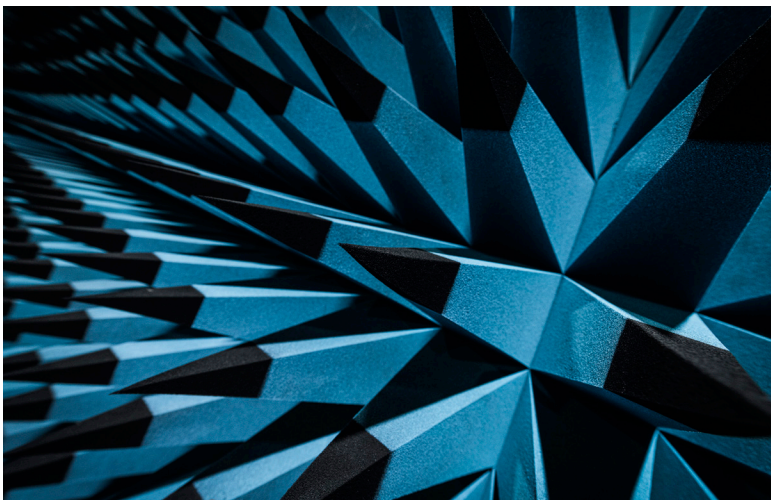
Unfortunately, while risks to the proper operation of safety-critical devices have been acknowledged methods for quantifying those risks have been varied and not comprehensive. This lack of information highlights the importance of widespread wireless coexistence testing for medical devices. To take a step back – how is coexistence different than normal EMC testing?

Electromagnetic compatibility (EMC) is the ability of electronic systems to function acceptably in their electromagnetic environment. Essentially – does a product work in the field despite potential interference. Coexistence can thought of as a subset of EMC specifically for radio products that demonstrates wireless communication in the presence of in band or out of band radios without affecting functional wireless performance, basic safety, and essential performance.

It is a common misconception that standard EMC tests developed by IEC are sufficient to mitigate the risk of interference from nearby wireless sources. However, the specific exclusion bands that are part of most standards eliminate the assessment of in-band interference, and with standard EMC testing there is no way to quantify the risk of interference from other users of the same frequency band like other nearby wireless medical devices. As such, EMC testing to familiar standards will not directly address coexistence for the radio.

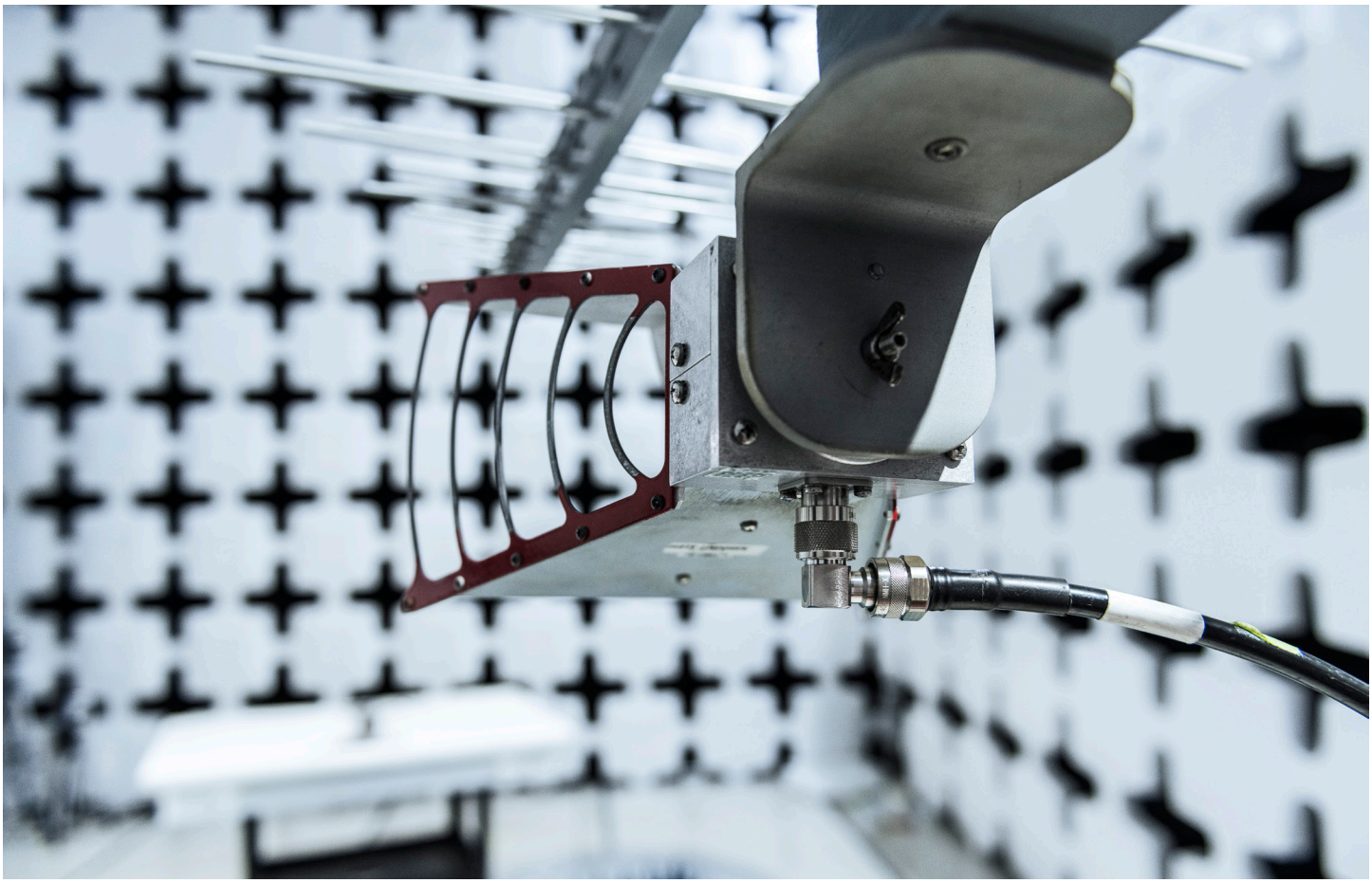
In the European Union, the Radio Equipment Directive has some standards in the official journal with requirements similar to coexistence testing but they are not comprehensive. Tests such as receiver blocking, adjacent channel selectivity, and adaptivity are similar to coexistence tests, but they use CW or Additive White Gaussian Noise instead of a representative real-world signal. Additionally, these tests focus only on radio performance, not host performance. When a radio is incorporated into a host, like a medical device, it may change the radio performance in a way not addressed by these tests.

Another factor to consider is that in-band interference is more likely to emerge as a problem for devices that operate in the same band over a long period. Wireless products in a healthcare environment, like a hospital, are likely to be operating simultaneously for very long periods of time.



In 2007, the FDA issued a guidance document that included consideration of coexistence for wireless devices. This FDA guidance document recommended a risk analysis, which is a key part of any medical device evaluation for compliance. Although this document was a recommendation when first published, the FDA now requires an evaluation of coexistence for nearly every product that implements wireless technology. Today, it is a growing area of interest for the FDA and medical device manufacturers are facing questions during the product approval process of whether it has been adequately addressed by risk analysis or testing.

HOW COEXISTENCE TESTING IS PERFORMED



Historically, some labs performed coexistence testing by purchasing off-the-shelf radios and operating them in a shielded room in proximity to the specific device that was the subject of the test. This type of testing has limitations, however. Some devices, like cell phones, will jump between multiple bands while in use, and there was no way for the technicians conducting these tests to control what band or bands these off-the-shelf devices were using during the test. This meant that repeatability was, in some cases, impossible. Furthermore, the results of the tests could only be reliably applied to the exact off-the-shelf devices used in testing, and were not necessarily applicable to other types of devices that used similar radio technology. This also presents an unknown level of risk whenever new radio devices enter the market.

Currently, the recommended testing approach is to thoroughly test and ensure device compatibility in the intended electromagnetic environment using the following steps:

- Perform a risk analysis to determine failure modes and thresholds for wireless communications that occur due to interference, using medical device standards relevant to application and geography
- Satisfy ANSI C63.27 for co-channel interference, adjacent channel interference, and adjacent band interference
- Supplement with additional testing as new technologies enter the market and new threats emerge

WHAT IS ANSI C63.27?

ANSI is the American National Standards Institute, a US-based standards development organization and C63 is a standards development committee focused on EMC and radio testing, The standard C63.27 American National Standard for Evaluation of Wireless Coexistence was first published in 2017 and provides a method for evaluating device coexistence, with a focus on mitigating risk. The second edition was released in 2021, with a few significant changes.

C63.27 provides the methods for evaluating devices, specifies test plan requirements, and provides guidance on how risk analysis and the results can be used to estimate the likelihood of coexistence. It is a generalized test method for any wireless product it, but the focus for implementation has been on medical devices.

The standard does not provide pass/fail parameters because they will be specific to each radio and application. It instead provides testing guidance and indicates how to evaluate the risk presented by interference from other radios. This will be based on key performance indicators (KPIs) for the functional wireless performance (FWP) – essentially, a combination of monitoring radio performance and how it relates to overall device performance. For example, a KPI might be bit error rate, while the FWP is a function of the EUT that depends on a wireless link, and will be affected if the bit error rate drops. The 2021 edition requires a determination of whether the EUT passed or failed based on its FWP while the 2017 only required reporting of results.

The overall methods in the standard apply to any type of radio, but the standard is intended to test the performance of the end device as a whole, not just the radio modules within the device. The same radio module can be used in both a medical device and an entertainment device, but the functionality, failure thresholds, and potential errors will be extremely different in these different applications.

While C63.27 provides generalized methods for testing coexistence, it currently only contains guidance for a limited number of technologies and frequency bands (Bluetooth, WiFi, and DECT). The methods described can be used for any radio, and with the FDA's increased scrutiny of wireless in medical devices medical device manufacturers should investigate testing to C63.27 for any radio in their product.

The standard contains three potential levels for evaluating a device. Level three is the least rigorous, testing the fewest signals and providing only very general insight for devices where performance errors are undesirable but will not cause serious consequences. Level one is the most rigorous and is used for devices where a lack of coexistence can cause unacceptable consequences.

Setup for testing contains three items – the EUT, a companion device communicating with the EUT, and an interference source. Four test methods are described in C63.27. The choice of the test method is up to the user of the standard and should be chosen in partnership with your chosen test laboratory. The four methods are:

- Conducted (Wired) Method – performed by using a mixer to combine the intended and unintended signals and connecting to the antenna port or the EUT. This excludes the antenna itself from testing and is the most repeatable but least realistic test method.
- Chamber/Hybrid Method – the equipment under test and the equipment generating signals are each placed in a separate chamber to control how the equipment under test is exposed to the signals.
- Radiated-anechoic Method – places the equipment under test in a chamber with both intended and unintended signal emitters. This creates an environment that does not necessarily replicate the deployed environment but removes environmental variables that would decrease repeatability.
- Radiated Open Lab Method – this method involves no chambers or shields and usually attempts to replicate the deployed environment. This testing may be affected by ambient signals, and limits the interfering signal to those legally allowed by spectrum regulators.

Not all medical products containing a radio necessarily need testing per C63.27, but a risk analysis does need to be conducted to evaluate potential effects and failure modes. AAMI TIR69:2017 is a technical information report that offers a process to assess and categorize the risks associated with the wireless functions of a medical device. If the risk assessment shows that the device's wireless technology presents no significant risk, the manufacturer can choose not to test for wireless coexistence, however, many manufacturers choose to do so anyway. C63.27 provides a more comprehensive risk assessment and specifies tests for both basic safety and essential performance.

CREATING A WIRELESS COEXISTENCE TEST PLAN

C63.27 specifies that, prior to testing, the manufacturer must create a test plan that includes key performance indicators, the intended functional wireless performance, and how they will be monitored. The manufacturer will need to provide information that includes the test methods to be used, the intended signals for the device, and the interfering signals to be tested. A common misconception is that the test lab will make these decisions. Test labs can help discuss test needs and provide guidance, but manufacturers are ultimately responsible for the development of the risk analysis and for identifying what needs to be monitored during testing.

To determine appropriate coexistence parameters, manufacturers must have a good understanding of what radiofrequency signals may interfere with their device, based on when, where, and how it will be used. Because there are a finite number of frequencies, different methods have been devised so that the same frequencies can be used in multiple ways:

- FDMA stands for frequency-division multiple access. An example of this is FM radio. The FM band is split into multiple channels that can be used simultaneously, but one channel cannot be used by two stations at the same time and in the same location.
- TDMA stands for time-division multiple access. This means that different radios use the same frequency band, but at different times to avoid interference – essentially, taking turns.
- CDMA stands for code-division multiple access. CDMA uses transmitter coding and spread spectrum techniques to allow multiple transmitters to share channels and bands.

The goal of coexistence testing is to determine if a given device, considering its output power, can reliably operate in its intended frequency band without interference, either from within the same band or from adjacent bands. There are three primary values that testing will focus on:

- Maximum separation distance between interference and EUT
- Maximum duty cycle of interfering signals
- Maximum frequency separation of signals in the adjacent channel/band

Interference can come in multiple forms:

- Adjacent interference: when two channels are close each other there can be overlap between them, decreasing the overall signal quality in both bands
- Co-channel interference: when two different transmitters using the same channel can be picked up by the same device, creating crosstalk
- Harmonic interference: out-of-band transmitters can sometimes cause a harmonic signal to show up in a different band

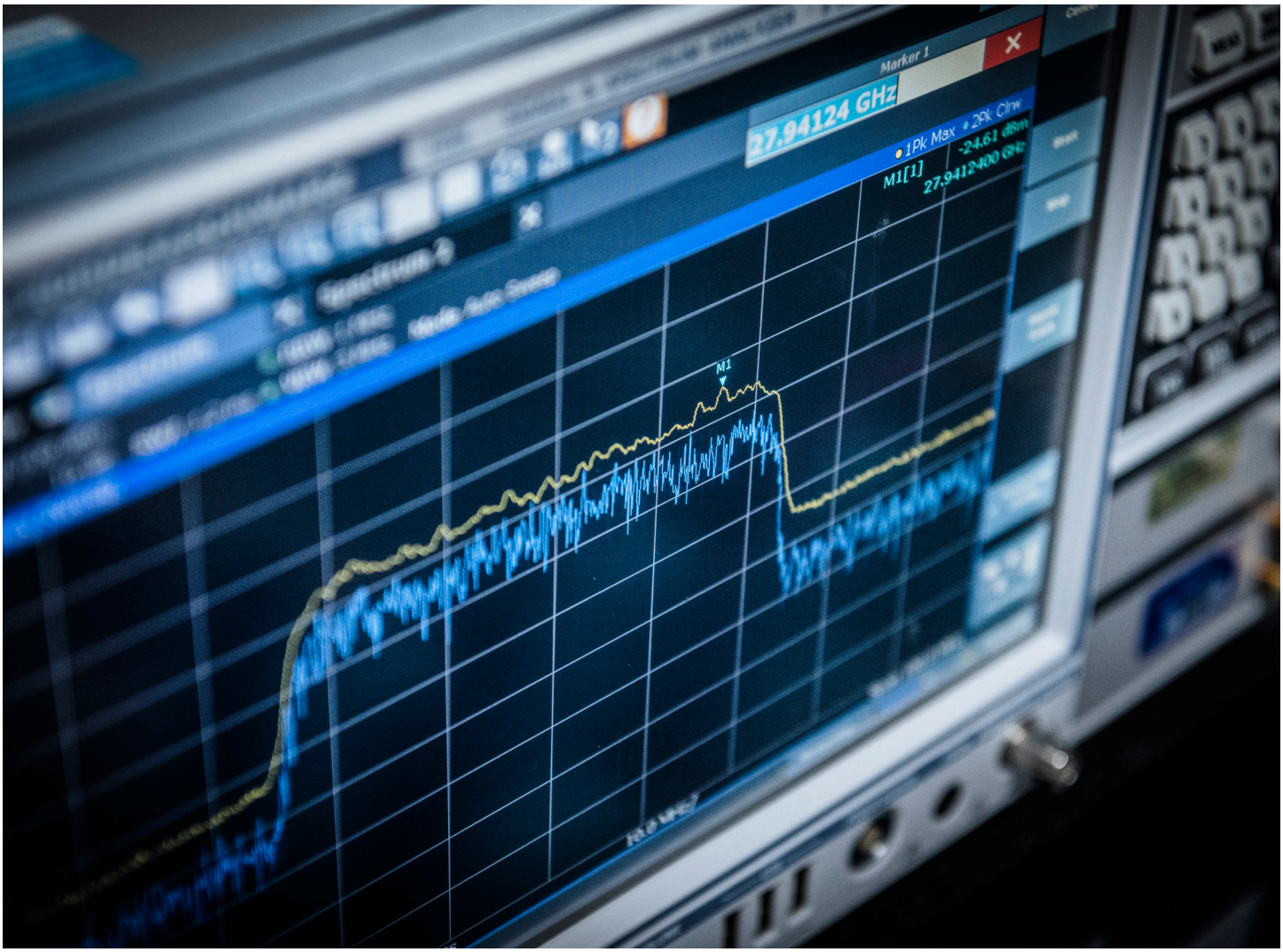
With a well-designed test plan, test data will help determine crucial coexistence parameters for the device and form the basis for proper risk analysis. Manufacturers will be able to evaluate both the point at which the equipment's key performance indicators begin to degrade and at what point the equipment becomes nonfunctional. These values can be used to calculate minimum signal strength, the minimum separation distance from other transmitters, and other technical and safety parameters.

EXPERT OBSERVATIONS FROM THE TESTING LAB

Many medical devices use off-the-shelf Bluetooth, cellular, and Wi-Fi technologies, and fortunately, these well-established technologies already have certain protections against interference, like cognitive radio, built in. This reduces some risks that need to be tested for custom-built radios. Manufacturers can make some modifications to off-the-shelf radio modules or systems to improve their performance in medical devices, such as changing frequency bands, adjusting radio sensitivity, or improving antenna performance, but off-the-shelf technology typically can't be significantly modified. Even so, any results from testing can be used to benchmark future module purchases, as well as adjust the radio parameters.

Cellular technology has the added advantage of higher transmit power, more frequency bands, and frequency division duplexing – where transmitting and receiving are on separate channels. These features can help prevent unintended signals from affecting the intended signal.

For purpose-built radios, manufacturers must include some sort of collision avoidance programming. Manufacturers must also be mindful of the firmware or software controlling the radio. In testing, we have found firmware in Bluetooth or Wi-Fi devices that unintentionally negates the cognitive radio functions or the collision avoidance functions, reducing the device's resistance to interference.

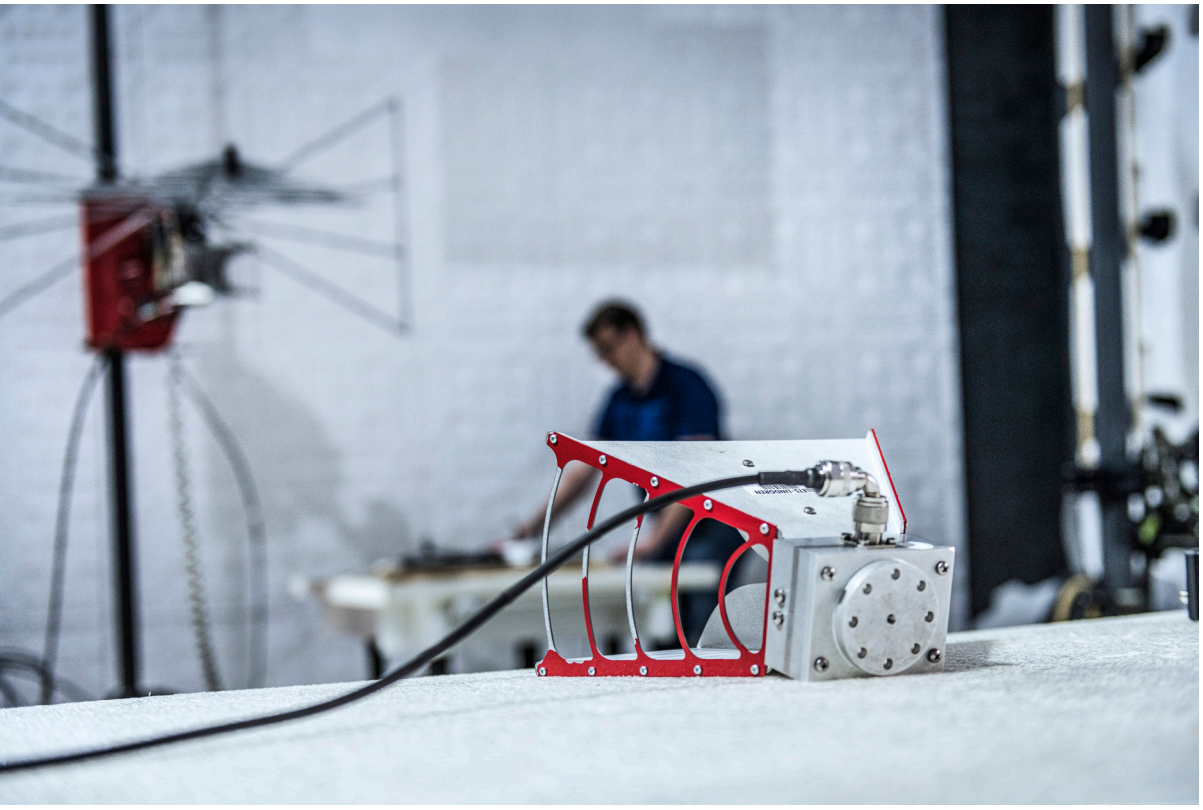


THE FUTURE OF WIRELESS COEXISTENCE

The second edition of ANSI was published in 2021. The primary changes include further clarification on the interfering signal parameters and additional testing for LTE-LAA equipment. The requirements for tier one testing have also been updated with additional tests now required for that category. The new version of the standard also includes a new Annex F, which lays out parameters for estimating the likelihood of coexistence. This is an important component of risk management. It's important that manufacturers and their testing partners be familiar with the updated version of this standard when creating their test plans. A working group is being formed to release a corrigendum covering some minor fixes to the 2021 edition.

Future editions of the standard will likely address some limitations in the current edition. For example, the output power of the interfering signal or intended signals could be varied over time to simulate movement around a facility, reflections, or channel utilization. The duty cycle of these signals could also be increased or decreased during testing.

As new technologies develop and the use of radio bands change, the devices that rely on these technologies will also need to undergo coexistence testing. The FCC has opened the 6 GHz band for unlicensed use, and there are now many 5G bands in use. Other new bands are being opened for different applications and use of radios in medical facilities continues to grow.



With the rapid pace of technological development, the ever-changing regulations surrounding radio devices, and the high stakes associated with medical technologies, manufacturers must fully understand the requirements and best practices associated with their products and must have a reliable, well-informed, and communicative testing partner to guide them through the testing process.

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