



"How to Confirm Compliance of Medical Devices with EMC Regulations and Secure WLAN Performance?"

Medical Equipment Digitalization and Wireless Usage

A digital transformation (DX) is underway at medical organizations, which treat inpatients by collecting test data, monitoring physical condition, and storing and managing medical data. Recently, medical care is beginning to use AI-based diagnostic systems. To transfer medical data, wireless communications such as WLAN are used increasingly for the following reasons.

- Smooth inspection and fast transmission because of easy equipment handling.
- Flexible use locations due to easy connection to core systems.
- Lower costs and shorter installation due to easy system installation.

Although wireless communications are convenient, some issues are listed below.

- Signal cannot reach remote access point (AP) and obstructions in communications path.
- Communications interrupted by external radio interference.

Assuring stable wireless communications in diverse medical settings requires design, development, verification, and operation of wireless medical devices based on several assumptions.



- ◆ **Enterprises:**
Medical device manufacturers
- ◆ **Major Issues:**
Compatibility of medical devices with EMC regulations and assurance of wireless communication performance
- ◆ **Solution:**
Network-mode wireless performance measurements to evaluate product easily before commercialization
- ◆ **Results:**
 1. Support quantitative understanding of wireless performance during EMC countermeasures
 2. Enable easy fast verification to cut development period

Major Issues

To assure patient safety, wireless medical devices must operate properly in the presence of various electromagnetic interference. Medical electrical equipment and systems must comply with the IEC 60601-1-2 EMC standard specifying a strict immunity test level of ± 15 kV for air discharge. Complying with EMC standards may require adding radio-wave absorbers and shielding materials. Unfortunately, such measures may degrade the wireless communication performance of medical devices. As a result, the stable wireless communication performance of a product to be commercialized in conformance with the EMC standards must be checked for every possible usage environment.

Solutions to Issues

Although the communication status of WLAN medical devices can be checked simply using a commercially available AP, this method does not quantify the transmit power and receiver sensitivity. As a result, any transient change in the operating environment may prevent stable communications if the device true communication performance is lower than believed. Consequently, the wireless communication performance must be quantified to assure stable communications in every possible usage environment.

The basic evaluation methods are:

- Transmit power test to measure strength of radio waves transmitted from medical device to AP.
- Receiver sensitivity test to calculate the packet error rate (PER) found by counting acknowledge (ACK) frames returned by medical device in response to test packets sent from AP.

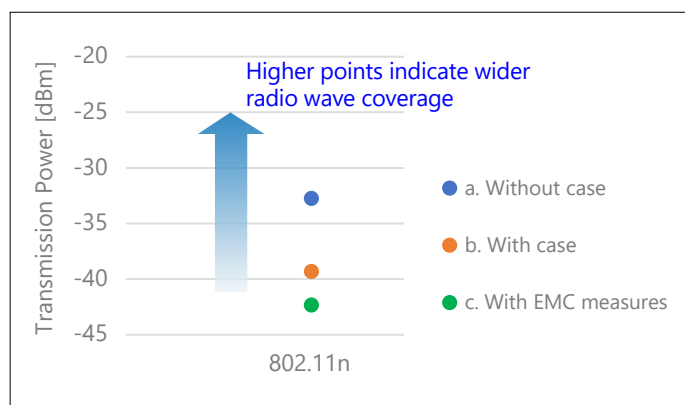
Whether the product meets its target wireless communication performance or not is checked by evaluating whether EMC countermeasures degrade performance.

Effects of EMC Measures on Transmit Power and Receiver Sensitivity

An example of how to evaluate wireless performance using a WLAN tester (MT8862A) at development of a WLAN product is described below. Performance before and after taking EMC countermeasures is compared using over-the-air (OTA) testing. The transmit power test estimates received power based on increasing attenuation with distance caused by increasing the separation between the device under test (DUT) and the test antenna.

Figure 1 shows the measured transmission power test results and Figure 2 shows the receiver sensitivity results for IEEE 802.11n WLAN communications under three different DUT conditions.

- Without case: Electrical unit without main case installed (exposed wireless module) and no EMC measures.
- With case: With main case installed and no EMC measures.
- With EMC measures: With main case installed and EMC measures.



Standard	a. Without case	b. With case	c. With EMC measures
11n	-32.74	-39.32	-42.32

Figure 1 Transmission.

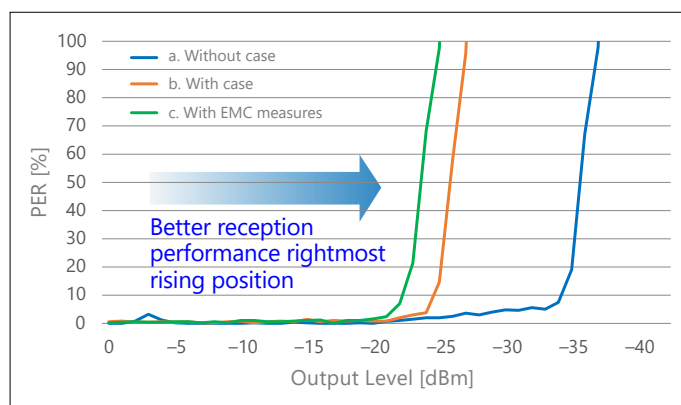


Figure 2 Receiver Sensitivity.

PER plotted as tester transmission power decreasing by 1 dB from 0 dBm with WLAN tester transmission output level on x-axis

From Figure 1, the transmit power of b is lower (by about 7 dB) than that of a, and EMC countermeasures in c further reduce transmit power (by about 3 dB). From Figure 2, the receiver performance of b is lower (by about 9 dB) than that of a, and the EMC countermeasures in c further reduce performance (by about 3 dB). Quantifying wireless performance using a WLAN tester confirms whether the target performance is achieved.

The MT8862A network mode uses standard WLAN protocol messaging (WLAN signaling) to evaluate transmission power and reception performance when the DUT is connected. It measures RF transmit/receive characteristics, such as transmit power, modulation accuracy (EVM), and receive sensitivity (PER) of WLAN-equipped devices under actual operating conditions without requiring special tools, controls, or measurement environment.

For the detailed evaluation method, visit [“Wireless Connectivity Test Set \(WLAN Tester\) MT8862A”](#).