



Medical Devices in a Wireless World

What You Need to Know About Medical Device Manufacturing, Wireless Technologies and Compliance

BY IVAYLO TANKOV

While wireless technology is now an integral component of a wide variety of manufactured products, factors unique to the medical device market have kept wireless from making inroads there. However, the tide is turning to the point where manufacturers can now offer wireless benefits to North American practitioners, patients and payers, as long as the medical device manufacturers can meet the standards established by different and unrelated regulatory bodies.

This article will define the regulatory bodies involved, the criteria important to each of them, and the steps a medical device manufacturer needs to take to sell wireless medical devices in North America.

THE POWERS THAT BE

There are basically two regulatory bodies that impact compliance for wireless medical devices in the United States: the Food & Drug

Administration (FDA) and the Federal Communications Commission (FCC).

All medical device manufacturers are familiar with the FDA regulations for placing a medical device on the US market. Although the agency was not known by its present name until 1930, its roots go back to 1848, and its modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act.

The FCC is no stranger to those of us who live here in the world of compliance. Since its formation by the Communications Act of 1934 "...for the purpose of promoting safety of life and property through the use of wire and radio communications" among other things, the FCC has established a broad base of rules and standards that have impacted virtually every American in one way or another.

Every medical device using wireless technology must comply with both the FDA and FCC requirements. As

the primary function of the device is medical, the FDA requirements are considered primary with the FCC requirements considered supplementary. Both, however, are mandatory. The FDA expects a wireless product to comply with FCC requirements before its compliance with the FDA regulations is demonstrated.

Further, the FDA just recently updated its recommendations for medical devices using/integrating wireless technologies. While full compliance with the new regulations is not yet mandated, the agency has made it quite clear that it expects to see its recommendations addressed.

FCC RULES OF COMMUNICATION

As most *In Compliance* readers already know, typically a wireless medical device must follow the FCC rules particular to the type of wireless

technology it employs. The rules consider various frequencies, power and other radio features. The FCC's main requirements for this product type are presented in Title 47 of the Code of Federal Regulations, which contains more than 100 parts; each part regulating a specific technology or combination of technologies using the same radio spectrum.

The type and scope of testing will also depend on the type of radio used in a given device. Manufacturers can use the FCC pre-certified radio modules, which still require limited testing on the system level to show compliance of the finished device. Using them saves time and money. Alternatively, companies can design and manufacture their own radios to incorporate into a product, which will require a full scope of wireless testing to certify the radio and the product.

THE FDA'S EXPECTATIONS

Every medical device is considered unique in its functionality and as such, needs to be evaluated individually to determine the best regulatory approach to take it to market. The FDA's generic requirements apply to all devices, but the manufacturer and testing laboratory need to choose the most applicable technical standards to which the product will be tested. Each technology performs differently, and the choice of technology automatically impacts a product's performance and also has bearing on the device's security and susceptibility to interference from other electronic devices. Generally, the FDA mandates that a medical device be tested to satisfy the FDA's and international minimal requirements for safety and electromagnetic compatibility (EMC).

"Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" is the main document governing the use of wireless

technology in medical devices. The document was originally published in 2007, and the most recent revision, published in August 2013, outlined several new recommendations for medical device manufacturers to follow. While at this point the recommendations are only suggestions, the FDA is on file as having urged manufacturers to demonstrate that they have considered the recommendations in their application for approvals. The specific recommendations suggest the medical device manufacturer:

1. Explain clearly why and how it selected a specific wireless technology.
2. Prove that the quality of the wireless service has been considered.
3. Show that its product can co-exist with other radio equipment in the vicinity without generating any problems; the intent being to minimize the possibility of a technology error where decisions about people's well-being are made in an environment full of wireless cell phones, tablets and laptops.
4. Illustrate how the security of wireless signals and data has been addressed to protect confidential patient information.
5. Demonstrate how other electronic devices might interfere with the radio portion of the medical device; i.e. EMC performance of the wireless technology.
6. Provide clear operations instructions in the user documentation for both the medical staff and patients.
7. Offer detailed maintenance and care instructions for the medical device.

The FDA also wants medical device manufacturers to perform risk management as part of their quality system under Title 21 CFR Part 820. When preparing pre-

market submissions for the FDA, manufacturers should know that in the risk-based approach to verification and validation section, the agency will expect to be given information about:

1. Quality of wireless service: With wireless technology, a medical device might experience a delay in administering or terminating therapy. This depends on how fast data is transferred back and forth between a medical device in question and other medical or IT infrastructure equipment.
2. Wireless coexistence: A device's radio channel might interfere with other wireless devices nearby. Multiple devices in a hospital use various wireless technologies and might interfere with each other on the radio portion of the spectrum.
3. Security of wireless signals and data: When patient information is transferred over the air and is not properly encrypted, it can be intercepted. Unauthorized access or harmful interference (such as maliciously altering data) will compromise patient's private records and might impact healthcare delivery.
4. EMC of the wireless technology: Yet another consideration is how susceptible a medical device's interface is to the electromagnetic interference (EMI) from nearby devices that do not use radio transmission, such as computers. For example, a pacemaker worn by a patient might be affected by a PC of the nurse who is checking him in.

INTERNATIONAL COMPLIANCE

From an international perspective, medical devices are covered by the International Electrotechnical Commission's (IEC) 60601 standard. IEC 60601-1 addresses basic safety and essential performance (BS&EP)

criteria. The BS&EP criteria describe the product's intended use and operation and any of its features or functions that might cause harm or injury to the users, patients and surroundings. Degradation of features and functions is allowed, provided it does not affect essential performance and safety of the product.

In order to demonstrate compliance, the medical device manufacturer must develop a list of the product's key functions and associated risks, and this list would be used to determine if the product is in a pass or fail status during and after the test. From this, the manufacturer will develop an essential performance document. During immunity testing, degradation of performance that affects essential performance would not be acceptable. Some examples of these situations include:

- Changes in programmable parameters,
- Distortion of image/data,
- Change/interruption of intended operating mode,
- Unintended operation/movement,
- Component failures, and
- False alarms.

EMC TESTING ACCORDING TO IEC 60601-1-2

EMC testing according to IEC 60601-1-2 can be broken into two parts: emissions and immunity. The emissions

test evaluates the RF energy the product emits, while immunity testing determines product performance according to its EP & BS criteria under the electromagnetic effects. All operational modes should be considered for testing in full or partially to determine compliance for the overall system. The summary of the EMC tests to be performed is listed below:

EMISSIONS (Class AB, Group 1/2)

- Conducted
- Radiated
- Harmonics
- Flicker

IMMUNITY (EP & BS, Life-Supporting/Non-Life Supporting)

- ESD
- Radiated Immunity
- Conducted Immunity
- Surge
- EFT/Burst
- Voltage Dips/Interrupts
- Magnetic Fields

Group 1: All equipment that does not fall into Group 2.

Group 2: All equipment that intentionally generates and uses, or only uses, radio-frequency energy in the range of 9 kHz to 400 GHz in the form of electromagnetic radiation, inductive and/or capacitive coupling,

for the treatment of material or inspection /analysis purposes.

Class A: Equipment suitable for use in all establishments except domestic and establishments directly connected to a low voltage power network supplying residential buildings.

Class B: Equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which services residential buildings.

Life Supporting or Non-Life Supporting:

Based on this classification, some immunity test strengths would be higher for Life-Supporting equipment due to the inherent risks associated with the use of this equipment.

Determining the correct product class and group is essential in that the limits for various classes and groups are defined differently in the standard. For example, conducted emissions limit (the main terminal disturbance voltage limit) between 5-30 MHz for Class A, Group 1 product is 73 dB(µV)- Quasi Peak & 60 dB(µV)-Average. If the product is a Class B, Group 1 type, the limit between 5-30 MHz is 60 dB(µV)-Quasi Peak and 50 dB(µV)-Average, regardless of the rated input power. The summary matrix of tests mandated by the IEC60601-1-2 standard is featured in Figure 1.

60601-1-2	Magnetic Immunity	Radiated Immunity	ESD	Conducted Immunity	SURGE	EFT/B	DIPS & INT	Radiated Emissions	Conducted Emissions
Non Life Supporting	3 A/m	3 V/m	6/8 kV	3V	1 kV/2 kV DM, CM	1 kV/2 kV I/O, AC	0%V 0.5 cycle & 5 sec	Class A/B, Group 1/2	Class A/B, Group 1/2
Life Supporting	3 A/m 50 & 60 Hz	10 V/m		3V 10V for ISM			40%V 5 cycle		
							70%V 25 cycle		

Figure 1

WHAT ELSE IS INVOLVED IN THE STANDARD?

The medical device manufacturer's responsibility for EMC is not limited to testing. Per 60601-1-2, the product-related risks and warnings are to be clearly indicated and explained to the user, patient and others so they can take necessary actions to limit any interruption. Some warnings must be placed in an obvious location on the product itself and in related files and documentation. A summary is listed below:

Warnings & Markings:

- Non-ionizing radiation use for diagnosis or treatment
- ESD sensitive port
- Interference warning
- Minimum amplitude of the

patient's physiological signals and consequence of use below specified standard limits

- If tested in-situ, the list of frequencies tested and a warning that some frequencies specified by the standard were omitted due to the specifics of the in-situ testing

Environment Use:

- Shielded location,
- Domestic, hospital, etc. use,
- Potential electromagnetic site survey at the installation location, and
- An EMC site survey might be needed for EMC sensitive products; if EMC noise level is too high, preventive actions need to be taken.

Limitation of Use:

- Use by healthcare professionals only

- Interaction with adjacent equipment
- Distance to RF communication equipment (tables)
- Floor specification
- Mains power quality
- UPS use for respiratory devices

Safety Instructions for Accessories:

- Cable types and lengths
- Specifications for replacement parts of the manufacturer-provided cables, accessories and components

Justification for Lower Immunity Levels:

- Due to physical, technological or physiological limits of the device; for example, Radiated Immunity tested at 1V/m between 150-160MHz.



OTHER GLOBAL ACCESS CONSIDERATIONS

Above and beyond the above-mentioned considerations, medical devices also face the same hurdles as most every other product intended for sale in foreign markets. For example, the product will need to be designed to meet all mandatory base certifications and safety deviations peculiar to each individual country, which may be different from those in the US, Canada and EU. In addition, certain countries require the applicant to be a legal entity in that country, while some require the actual testing to be done in-country, meaning manufacturers need to assure samples are available in sufficient quantities and timeliness. Translation of user documentation can also pose problems.

Further, some countries have specific EMC regulations that may have more stringent limits than the US, Canada or the EU, while other countries may not allow the use of certain radio frequencies.

The bottom line is that garnering international approvals can be difficult enough for any type of product; getting approvals for a medical device is only more difficult. However, choosing the right testing partner can help a medical device manufacturer lower its level of difficulty. The right testing laboratory will help a medical device manufacturer identify legal requirements and harmonized standards, make sure properly configured product samples are available, coordinate shipping, assure appropriate documentation and language, and execute pre-tests to assure compliance.

BRAVING THE NEW WIRELESS WORLD

While wireless technologies have opened up a seemingly unlimited world of potential, many medical device manufacturers face a delayed

introduction for their products utilizing wireless technologies due to the additional compliance requirements. Unfortunately for those manufacturers, a delayed product launch in a hotly contested market such as that for medical devices can have severe downstream ramifications in terms of market adoption and acceptance, resulting in lower share-of-market opportunities and lost revenues.

The easiest way for medical device manufacturers to mitigate the likelihood of compliance-caused launch delays is to involve the testing laboratory as early in the product development cycle as possible. While the product is still in the concept stage a testing laboratory can advise the manufacturer about the general regulatory requirements and suggest wireless technology options suitable from the point of view of technical

certification. When the manufacturer has a clear idea of what the product looks like, the test lab can determine exact requirements based on technical specifications. This approach introduces a significant degree of confidence into the regulatory compliance process, increasing the odds that the product passes the tests and gets to market on time and on budget. 

(the author)

IVAYLO TANKOV
is Director of Competence Center, Information and Communication Technologies (ICT) and Wireless Products at TÜV Rheinland. Tankov's focus is on ICT and use of licensed and unlicensed wireless technologies in manufacturing, commercial products, consumer electronics and healthcare sectors.



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TÜV Rheinland earned the award based on the following achievements:

- **Exceptional Customer Service**
- **Expertise in Wireless Technology & Testing** (ZigBee and Medical Devices)
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