EMC Compliance for Medical Devices

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Precisely Right.

The effect of electromagnetic interference becomes more and more important in the use and application of the electrical /electronic products as technology advances. In general, the product's operational status is evaluated taking into consideration its electromagnetic compatibility (EMC). Because medical devices deal with a treatment of the human body and life, it is not surprising to expand the evaluation concerns to safety matters. Within this article, we will summarize the current requirements and the upcoming changes.

Author:
Ozgur Ozturk
TUV Rheinland of
North America, Inc.

TÜV Rheinland
www.tuv.com | info@tuv.com | 1-TUVRHEINLAND

Most of the time, a medical product gets tested and evaluated according to a version of IEC 60601-1-2 based on the country it will be marketed for. Before we look closely at the standard, let us understand what EMC means specifically for medical devices.

What Does EMC Compliance Mean for Medical Devices?

EMC compliance for most devices in the market could be defined as ensuring that:

- electromagnetic disturbances produced do not affect the correct functioning of other equipment;
- a product has an adequate level of immunity to electromagnetic disturbances to operate as intended in the environment where it is used (residential, industrial and commercial).

For medical devices, however, EMC compliance is ensuring that:

- electromagnetic disturbances produced do not affect Essential Performance and Safety of medical devices
- electromagnetic disturbances produced do not affect the correct functioning of other equipment

Therefore, the very first stage of planning would be to define the medical product's Essential Performance and Basic Safety criteria (EP&BS) and design the EMC compliance plan around these criteria.

Essential Performance (EP) & Basic Safety (BS) Criteria:

The EP & BS criteria describes 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.

The manufacturer needs to come up with 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 are:

- 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 6060-1-2 can be divided in two parts: emissions and immunity. The emissions test evaluates the RF energy the product puts out, and the immunity test determines the product's performance according to its EP & BS criteria under the electromagnetic effects. Please keep in mind that a product's all operational modes should be considered for testing in full or partially to determine compliance for 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 right product class and group is essential because the limits for various classes and groups are defined differently in the standard. For example, conducted emissions limit (the mains terminal disturbance voltage limit) between 5-30 MHz for Class A, Group 1 product are 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.

60601-1-2 Summary	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		3V			0%V 0.5 cycle & 5 sec		
			6/8 kV		1kV/2kV DM,CM	1kV/2kV I/O, AC	40%V 5 cycle	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			70%V 25 cycle		

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 any other people so that 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,
- 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.

How to Handle Radios?

Wireless communication is currently at the forefront of the digital age. It has become a significant part of our everyday lives and can be found almost in every environment, including medical, industrial, commercial and finance.

Wireless devices have many advantages due to the following characteristics:

- great convenience (easy and clean setup/access)
- continuous access to information
- low power and cost
- short frequency range

These advantages make wireless technology invaluable in healthcare environments, even though its use brings along many associated risks. Extreme caution and care must be used when employing wireless technology in a setting where we deal with human life.

Before delving into the risks of the wireless technology, let us see what 60601-1-2 currently states about radios and radio equipment.

Section 6.1.1.1 e – Emission Requirements

*ME EQUIPMENT and ME SYSTEMS that include radio equipment

ME EQUIPMENT and ME SYSTEMS that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this collateral standard in the dedicated transmission band of transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this collateral standard shall apply.

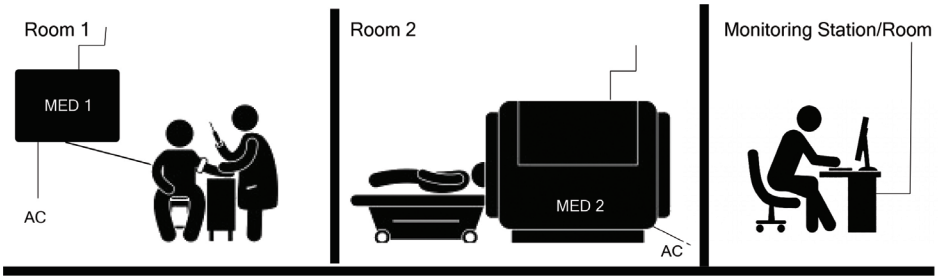
Section 6.2.1.11 – Immunity Requirements

For ME EQUIPMENT and ME SYSTEMS that include radio equipment and in which the IMMUNITY of the radio communication FUNCTION had been tested and found to comply with applicable national radio regulations, the radio equipment is exempt from testing to the IMMUNITY requirements of this collateral standard, provided the IMMUNITY requirements of the applicable national radio regulations for the exempted immunity test are grater than or equal to those determined in accordance wit 6.2.1.1. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the IMMUNITY requirements of this collateral standard shall apply.

In summary, the above two excerpts state that as long as the radio has been tested and found compliant with the relevant radio standard, and the limits of the radio standard are equivalent or more stringent than the 60601-1-2 specifications, no additional testing necessary.

While this concept makes sense, the wireless communication aspect of a device is often regarded as an important part of the product's EP & BS criteria. If so, testing the entire system with a wireless communication device on becomes critical in evaluating the system's performance (including the wireless communication part) for both emissions and immunity tests. In the end, any malfunctioning could result in data interruption, distortion and/or delay, which could all affect the patient outcome or even cause a wrong dosage of medication. Therefore, the manufacturer should address the wireless communication concept of a device during the product's safety risk assessment to determine any risks of wireless malfunctioning.

Now, we will look into other risks associated with the use of wireless devices in healthcare environment. Below is an example of a small medical care facility where both patients are connected to medical devices using wireless technology, and the data is transferred to a monitoring station.



Risks?

1. Potential Interference between devices and ambient noise
2. Immunity of the devices to wireless RF
3. Wireless Coexistance
4. Cyber/Software/Protocol Security

Can Cause

Interference to Practice of Medicine

Device Breakdown

Data Signal Distortion/Interruption

Transmission Delay

Transmission or Critical Data/ Patient Outcome

Loss of personal info/security

Current EMC testing according to 6060-1-2, as discussed above, intends to cover risk item 1, so let us assume we are compliant

Let us consider risk item 2. Although some of the 60601-1-2 immunity test frequencies might correspond to the existent frequencies of RF communication technologies, we cannot easily state that a device has been tested because no current requirements mandate such testing. Even though some companies might have thought of this type of interference and done some preliminary testing of their own, it would have been very difficult to determine the test strength since it would depend on proximity of the devices. This is why the IEC is introducing a new EMC standard for medical devices to add the RF proximity testing and provide coverage for this type of interference.

Wireless Coexistence is defined in FDA's "Draft Guidance for RF Wireless Technology in Medical Devices" as follows: "ability of one wireless system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules."

Given that most wireless devices operate at unlicensed ISM band, when they are located close to each other, interference is likely to occur in their transmission. To ensure interoperability between devices, the manufacturer of the medical product needs to do some verification tests and analysis. Unfortunately, there is no specific standard or requirement explaining in detail how to conduct testing, at what level, and what to consider as pass/fail criteria. IEEE 802.15.2 & IEEE1900:2, along with FDA's "Radio-Frequency Wireless Technology in Medical Devices," could be used to understand the concept and build a plan for a specific device. Of course, any associated risks should be included within the device's safety risk assessment process and documentation.

As in every telecommunication application, cyber security in healthcare is an important concept because information, including personnel, financial and patient-related, could be transmitted during the process. Manufacturers are advised to consider preventive actions to help secure sensitive data.

New & Upcoming

The main goal of the above-mentioned new version of 60601-1-2 being developed for the EMC compliance is to ensure that the practice of medicine and healthcare is not disturbed by common EMC phenomena. The standard will introduce new product categories and test levels as well as a new test. It will also incorporate the EMC concept into the risk management process.

Let us have a look at some of the changes the new standard will introduce. Please note that there might be some updates by the time the standard gets published and/or becomes mandatory.

Test Level Comparison	Current		Upcoming Edition			
	NLS	LS	Hospital	Clinic	Home	Transport
Magnetic Immunity (A/m)	3	3	30	30	30	30
Radiated Immunity (V/m)	3	10	3	3	10	20
ESD (kV)	6/8	6/8	8/15	8/15	8/15	8/15
Wireless Communication Equipment Immunity* (V/m)	None	None	30	30	30	30

* The new standard recognizes that the RF wireless equipment is no longer prohibited/limited in most patient environments.

The new standard will introduce:

- New product categories depending on the environment (hospital, small clinic, home and transport)
- Test levels per new product categories
- New safety and performance requirements for the equipment
- Safety engineering into medical EMC / Risk Management
- Increased immunity test levels to minimize the risk of electromagnetic interference

Additionally, the new standard will

- Restrict the use of lower immunity levels for compliance
- Require test plan/risk analysis preparation from the manufacturers upfront prior to testing

The new standard will require almost all devices within its scope to be re-tested partially or in full depending on the product's category and safety and performance criteria. The new requirements might complicate compliance matters for many manufacturers; therefore, preliminary planning and pre-compliance check and testing will be a key action to avoid any delay when the standard becomes mandatory. In any compliance effort, advance preparation is crucial for successful execution. TUV Rheinland of North America is working on a preliminary program to assist medical device manufacturers to transition to the new compliance requirements.

To Sum It Up

EMC compliance for medical devices carries additional responsibilities due to associated eminent risk. Upfront planning and preparation is essential for a successful testing campaign. It is recommended that the manufacturers factor in the EMC phenomena into the EP&BS criteria during a product's design phase. Along with the current version of 60601-1-2, the upcoming new standard should be taken in consideration by the manufacturers to achieve compliance so that any potential delay can be avoided when the new standard becomes mandatory. The new standard will introduce new product categories, more stringent test levels and some new concepts, such as immunity test for RF proximity wireless communication equipment and EMC risk assessment.

It is understandable that whenever a new standard requirement comes into play, it can cause discomfort. It should be kept in mind that the new version of 60601-1-2 addresses some of the potential hazards to minimize the risk of electromagnetic interference, which can disrupt the practice of science, medicine and saving lives.

With any inquires and for more information, contact Ozgur Ozturk, Senior Business Manager, TUV Rheinland of North America, Inc., EMC and Telecommunication Services:

Tel: +1 (919) 649-3906
Fax: +1 (919) 554-3542
Email: oozturk@us.tuv.com
http://www.tuv.com