

# Medical Product EMC

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**Abstract—** With the advent of the second edition of IEC 60601-1-2 and the FDA's acceptance of consensus standards such as the IEC 61000-4-x series, the EMC landscape for medical electrical equipment is undergoing a significant change. The EMC test requirements for medical products are very similar to those applied to other types of products such as radio equipment, networking equipment, and information technology equipment. However, IEC 60601-1-2 incorporates many specific test application guidance notes that require special consideration. In addition, there are several dozen additional standards that address unique characteristics for particular products. In many cases, the EMC test levels or methods are modified from those given in IEC 60601-1-2 for these products. IEC 60601-1-2 sets out a list of compliance criteria associated with essential performance of the product. Correctly specifying these criteria is key to meeting the essential requirement for safety specified by the medical device directive. The standard also sets out requirements for information that must be provided to the user in the form of warnings and markings, the environment for which the product was designed, including limitations of use, and list of accessories that may safely be used with the product. This paper will discuss the assessment methods that are required by IEC 60601-1-2 that could affect product design

*Keywords-EMC; essential performance; risk analysis; user instructions; medical devices*

## I. INTRODUCTION

With the publication of the second edition of IEC 60601-1-2 [1] and its European equivalent, EN 60601-1-2 [2] being listed in the Official Journal, the EMC requirements for medical electronic devices will forever change. Products that will remain in production after the mandatory effective date of November 1, 2004 may require redesign to comply with the requirements of the second edition. Changes in design will also affect the FDA approval. Even if no changes are required, testing will need to be performed to assess the product's performance in light of the expanded scope of testing and compliance criteria of this new edition. There is no grandfathering of equipment that was assessed using the first edition of the standard. A presumption of conformity with the essential requirements of the medical device directive may only be assumed if the new edition is employed. For the sake of brevity, whenever I refer to the standard, I am talking about the second edition of EN 60601-1-2.

## II. TEST REQUIREMENTS - EMISSIONS

On the emissions side of the EMC requirements in EN 60601-1-2, most products that currently are sold would only need testing to address the additional requirements specified in EN 61000-3-2 and EN 61000-3-3. All other requirements remain unchanged from edition 1.

## III. TEST REQUIREMENTS - IMMUNITY

### A. Performance Requirements

As you read EN 60601-1-2, you eventually get to the section on compliance criteria (36.202.1 j), which delineate degradations to performance that are not allowed during immunity tests. A degradation is, for example, a deviation from the manufacturer's specifications. The degradations listed are:

- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- false alarms;
- cessation or interruption of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise is indistinguishable from physiologically produced signals or the noise interferes with interpretation of physiologically-produced signals;
- artifact or distortion in an image in which the artifact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm.

At first glance, you decide that these degradations of performance are not allowed during the tests and that your product will not be able to meet these criteria without a significant redesign. However, as stated, the intent of this section is to describe these degradations in light of the Essential Performance and safety of the product being tested. The product is allowed to exhibit degradations that do not affect Essential Performance and safety during the tests.

### B. Essential Performance

What is Essential Performance? This is a defined term in the standard. It is “performance characteristics necessary to maintain the Residual Risk within acceptable limits.” According to the standard, the Essential Performance “shall be identified by a risk analysis.” However, if a risk analysis is not performed, then all functions shall be considered essential and need to be evaluated during the immunity tests. A Function is a clinically significant feature that the product provides. ISO 14971 provides the methodology for performing the risk analysis and determining the Residual Risk.

The implication here is that you should perform a risk analysis prior to establishing the compliance criteria to avoid the need to perform more tests against more stringent criteria. Depending on the class of device as determined from Annex I of the medical device directive, a notified body will likely need to be consulted in determining the performance criteria to apply based on the risk analysis. The establishing of the performance criteria is crucial to evaluating the observations made of product operation during immunity tests and in determining the methods used to monitor the product. The risk analysis must account for all manners of use of the product. After assessing all the risks and determining the residual risk level, you enumerate the compliance criteria.

### C. Tests

Now that you have established the compliance criteria you will use during the immunity tests, you are ready to test. The standard includes the basic set of immunity tests that are applied. These are identical to the tests that are applied for other products such as radio equipment, networking equipment and information technology equipment except that the standard incorporates many specific test application guidance notes that require special consideration. Table 1 lists the immunity tests applicable to medical devices and the basic levels for non-life supporting products.

The list may include additional tests and the test specification column may change based on the type of equipment to be evaluated. It is beyond the scope of this paper to present the appropriate specifications for all medical devices. However, some examples can serve to illustrate the point. EN 60601-2-24, particular to infusion pumps, modifies the test specifications: ESD test levels are extended to include 8 kV contact discharges and 15 kV air discharges; radiated immunity test level changes to 10 V/m; magnetic immunity test level increases to 400 A/m. EN 60601-2-10, particular to nerve stimulators, adds a conducted immunity test at 27.12 MHz using a custom setup described in the standard. EN 60601-2-2,

particular to HF surgical equipment, modifies the compliance criteria and the emissions test configuration.

TABLE I. IMMUNITY TESTS

Environmental Phenomena	Test specification	Test setup
Electrostatic Discharge	±2, 4, 6kV (Contact) ±2, 4, 8kV (Air)	EN 61000-4-2
RF fields	80 - 2500 MHz 3V/m 80% AM, 1 kHz or 2Hz	EN 61000-4-3
Fast transients Power Signal	5/50ns ±2.0 kV ±1.0 kV	EN 61000-4-4
Surges Line to PE Line to Line	1.2/50µs ±0.5, 1.0 & 2.0kV ±0.5 & 1.0 kV	EN 61000-4-5
RF Voltage (Conducted Immunity)	0.15 – 80 MHz 3V 80% AM, 1 kHz	EN 61000-4-6
Magnetic Fields	50 Hz 3A/M	EN 61000-4-8
Voltage Dips	> 95%, 10 ms 60%, 100 ms 30%, 500 ms	EN 61000-4-11
Voltage Interruptions*	> 95%, 5 s	EN 61000-4-11

\* Note: The compliance criterion may be relaxed for this test.

### D. Basic Immunity Test Modifiers

For most of the immunity tests, the standard specifies modifications to the methods of the basic standards listed in table 1. For example:

1. During ESD testing, discharges shall begin at 1 per second and the time may need to be increased to distinguish between a response caused by single discharges and a response caused by multiple discharges.
2. The dwell time at each frequency step for conducted and radiated immunity must be set to allow the product to be fully evaluated at each step. Dwell times exceeding 15 seconds are not uncommon.
3. Electrical fast transient tests are not performed on patient cables.
4. During electrical fast transient and conducted immunity tests, patient connections shall be terminated with artificial hands.
5. CDNs shall not be used for conducted immunity tests on patient leads.
6. The potential equalization conductor shall be tested for conducted immunity.
7. Electrical fast transient, surge and voltage dips and short interruption tests shall be performed at the minimum and maximum rated voltages if the product has multiple voltage ratings or auto ranging capability.
8. Magnetic field immunity tests shall be performed at both 50 and 60 Hz test frequencies unless rated for only one power frequency.
9. Products that control, monitor or measure physiological parameters shall be tested for radiated immunity using a 2 Hz modulation frequency.

#### IV. PRODUCT INFORMATION

Assuming that you have performed all of the appropriate emissions and immunity tests using the agreed upon compliance criteria with acceptable results, the requirements of the standard are still not yet fulfilled. The standard requires several tables be included in the instructions furnished to the user along with other statements about the EMC characteristics of the product. Examples of the tables that shall appear in the user documentation are shown in Figures 1, 2, 3 and 4. Preceding the tables, the instructions shall include a statement that the product needs special precautions regarding EMC and needs to be installed and operated according to the information in the tables and that portable and mobile RF communications equipment can affect the operation of the product.

Now that you have added all the information about the EMC characteristics of the product to the instructions, you are done, correct? Not quite. The standard specifies additional statements concerning use. These include:

1. For a product that has a connector for which an exemption from the ESD test is used, an ESD warning symbol and warnings about proper use of the product that is sensitive to ESD shall be included along with procedures to be followed to prevent ESD to the connector in use.
2. The minimum amplitude for patient physiological signals if specified and a warning that operation below these levels may cause inaccurate results.
3. A list of the cables, maximum lengths of cables, transducers and other accessories that have been evaluated for use with the product against the requirements of the standard and a warning that the use of different accessories etc. may result in increased emissions or reduced immunity of the product.

Guidance and manufacturer's declaration - electromagnetic emissions		
The model 003 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the model 003 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The model 003 pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11 Harmonic Emissions	Class A	The model 003 pump is suitable for use in all establishments other than domestic and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Voltage Fluctuations/flicker emissions	Complies	
IEC 61000-3-3		

Figure 1. Emissions Guidance for Users

Guidance and manufacturer's declaration - electromagnetic immunity			
The model 003 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the model 003 should assure that it is used in such an environment.			
Immunity Test	Test Level	Compliance Level	Electromagnetic environment guidance
Electrostatic Discharge IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%..
Electrical Fast Transient / Burst IEC 61000-4-4	± 2 kV for mains ± 1 kV for signal leads	± 2 kV for mains ± 1 kV for signal leads	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV common mode, AC mains ± 1 kV differential mode, AC mains	± 2 kV common mode, AC mains ± 1 kV differential mode, AC mains	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Field IEC 61000-4-8	400 A/m	400 A/m	Power frequency magnetic fields above those typically found in commercial or hospital environments are acceptable.
Voltage dips, short interruptions and voltage variations on AC mains IEC 61000-4-11	> 95% of nominal voltage for 1/2 cycle 60% of nominal voltage for 5 cycles 30% of nominal voltage for 25 cycles > 95% of nominal voltage for 5 seconds	> 95% of nominal voltage for 1/2 cycle 60% of nominal voltage for 5 cycles 30% of nominal voltage for 25 cycles > 95% of nominal voltage for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the respirator requires continued operation during mains interruptions, it is recommended that the respirator be operated from an uninterruptible power supply or battery.

Figure 2. Immunity Guidance for Users

4. A warning that the product should not be used next to, or stacked with, other equipment, but if this type of operation is deemed necessary that the product should be observed to verify normal operation when used in this manner.
5. If the product must be used in a shielded location, then additional information about the type of shielded location and emissions characteristics of other equipment that can be used inside the shielded location with the product. *Note: this is only a partial list of the information and additional guidance is provided in the standard for products that will be installed in shielded locations.*

6. Guidelines for resolving issues that may arise from the use of products that apply RF energy for diagnosis or treatment. A radio is not considered as applying RF energy.
7. For products that receive RF energy during operation, information about the frequency or band of reception, the bandwidth of the receiver and a warning that operation of the product may be interfered with by other equipment.
8. For radio enabled products, the frequency band of operation, modulation characteristics and effective radiated power of the radio.
9. If an exemption for large permanently installed equipment has been used, then the instructions shall state that this exemption was used and that RF immunity was not performed over the entire frequency range from 80 MHz to 2.5 GHz, that RF immunity was performed only at selected frequencies and a list of the transmitters that were used for the EMC tests and their frequencies and modulation characteristics.

For products that have no Essential Performance as determined by the risk analysis and were not tested for immunity or were allowed any of the degradations listed previously, then the requirements for EMC information in the instructions is considerably less. It is not necessary to include the tables of figures 2, 3 or 4, some of the statements about products used in shielded locations and the statements required above for large permanently installed products.

If a product cannot meet the specified immunity test levels of the standard for some technological or physiological reason, then lower levels may be used. The justification for using the lower level(s) shall be provided in the instructions and the EMC compliance information shall be presented accordingly. The table in figure 2 must provide guidance to the user to take precautions to keep the EMC environment in which the product will be used within the reduced compliance levels stated.

#### V. RADIO FUNCTIONS IN MEDICAL DEVICES

In line with current trends, many medical device manufacturers are incorporating wireless functions in their products. The standard anticipates this situation in two additional ways.

1. If a radio is provided with the product either internally or as a separate unit, the radio part of the device or system may only need approval against the applicable radio standards. However, if the function of the radio affects the essential performance of the system, then the radio and medical device both must be evaluated for immunity using the medical equipment standard.

The emissions of the radio part must comply with the medical equipment standard except in the dedicated transmission band. This means that spurious emissions of the radio must meet the CISPR 11 limits, which in most cases are

more restrictive than the spurious emissions limits for the radio device.

Recommended separation distances between portable and mobile RF communications equipment and the model 003				
<b>The model 003 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model 003 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model 003as recommended below, according to the maximum output power of the communications equipment.</b>				
Rated maximum output power of transmitter <i>W</i>	Separation distance according to frequency of transmitter <i>m</i>			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 0.35\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Figure 3. Separation Distance Guidelines

#### SUMMARY

The new edition of EN 60601-1-2 presents many challenges to manufacturers. From the beginning of the design process, manufacturers are encouraged to seek assistance from test labs and certification agencies to understand the provisions of EN 60601-1-2 as they apply to their specific product.

#### REFERENCES

- [1] IEC 60601-1-2:2001, International Standard for Medical electric equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirement s and tests.
- [2] EN 60601-1-2:2001, European Standard for Medical electric equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirement s and tests.


Guidance and manufacturer's declaration - electromagnetic immunity			
<i>The model 003 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the model 003 should assure that it is used in such an environment.</i>			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	10 Vrms	10 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the model 003, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 0.35\sqrt{P}$
	150 kHz to 80 MHz outside ISM bands <sup>a</sup>		
Radiated RF IEC 61000-4-3	10 Vrms	10 Vrms	$d = 1.2\sqrt{P}$
	150 kHz to 80 MHz in ISM bands <sup>a</sup>		
	10 V/m	10 V/m	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 Ghz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). <sup>b</sup> Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range. <sup>d</sup> Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: right;">  </div>
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.			
<sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.			
<sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM].			
<sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Figure 4. Conducted And Radiated Immunity Guidance

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Based in the heart of Silicon Valley, Elliott Laboratories is a world-class Regulatory Compliance Laboratory. With over 25 years of experience servicing the needs of product manufacturers, Elliott's clients save time and money by achieving their regulatory compliance requirements quickly and efficiently, enabling them to bring their products to market without costly delays. Elliott continues to pursue a course of partnering with best-in-class service providers to offer a full-service compliance solution designed to meet the needs of even the most demanding product manufacturers.