

# Current and Proposed EMC Tests for Medical Devices

GARY FENICAL

Instrument Specialties Co., Inc., Delaware Water Gap, PA

*The need to use existing documents such as IEC 601-1-2 as a basis for creating product specific standards cannot be overemphasized.*

## INTRODUCTION

As the electromagnetic spectrum becomes more congested, the need for electromagnetic compatibility (EMC) among electrical and electronic equipment becomes more and more important. Also, because of the proliferation of electronic devices, these devices must work in close proximity to, and with each other.

By virtue of its usage, electrical and electronic medical equipment must perform as intended and not emit levels of electromagnetic energy that interfere with other equipment. Yet, the incidence of interference in MRI imaging systems, malfunctions in patient connected medical equipment, and even problems with electric wheelchairs and scooters are becoming more prevalent.

The need to establish specific electromagnetic compatibility requirements for medical equipment is well-recognized. Although there are several EMC specifications, this article will concentrate on the IEC 601-1-2 requirements because they are among the most recent and they contain newer EMC testing technology. Also, they are becoming recognized throughout the world and will be instrumental in the European Medical Devices Directive. Organizations such as ANSI/RESNA are using the IEC 601-1-2 standard as a basis for their customized requirements.

Electromagnetic emission standards are essential for the protection of the public radio and telecommunication services. Emissions standards are also required to provide some assurance

that other electrical and electronic equipment will operate as intended if they are built with reasonable levels of immunity. The IEC (International Electrotechnical Commission) is a worldwide body which promotes international cooperation on all questions concerning standardization in the electrical and electronic industries. The IEC publishes standards whose content is entrusted to various technical committees. The IEC collaborates closely with the ISO (International Organization of Standards). Hence, the IEC has published a document, IEC 601-1-2<sup>1</sup>, upon which this article is based.

It must be realized however, that IEC 601-1-2 gives certain levels for immunity and refers to other documents for emissions that may or may not be sufficient for assuring that equipment continues to operate as intended. Tailoring of the requirements outlined in IEC 601-1-2 is essentially mandatory for most medical equipment. The specification should only be used as a guideline for producing product specific standards.

As of the writing of this article, the committee draft version of IEC 601-1-2 Second Edition had been distributed for public review. The bulk of this article is written around the requirements of the existing first edition with comments on what may be expected in the second edition.

## EMISSIONS

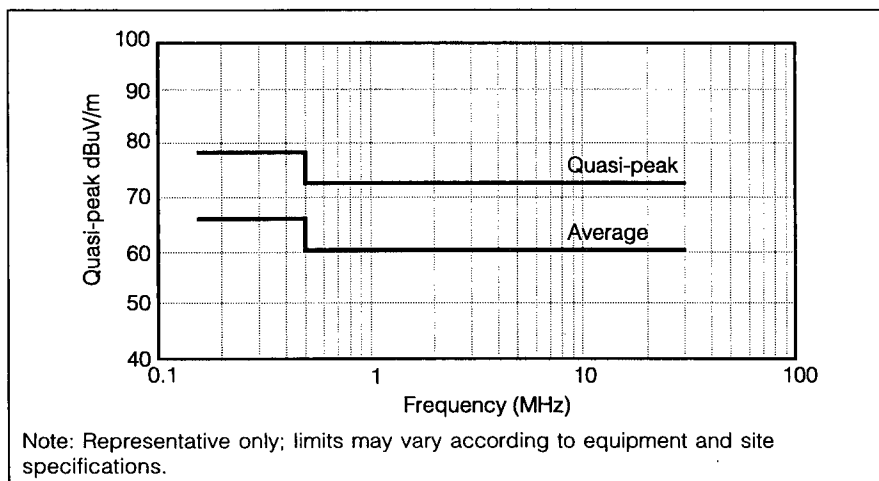
Equipment shall comply with the conducted and radiated emissions require-

ments of CISPR (International Special Committee On Radio Interference). Equipment classification is determined by the manufacturer, and is based upon intended use. Equipment may be tested at a standard test site, which includes a turntable and ground plane, and which has known attenuation curves. Equipment may also be tested after it has been installed on the users' premises.

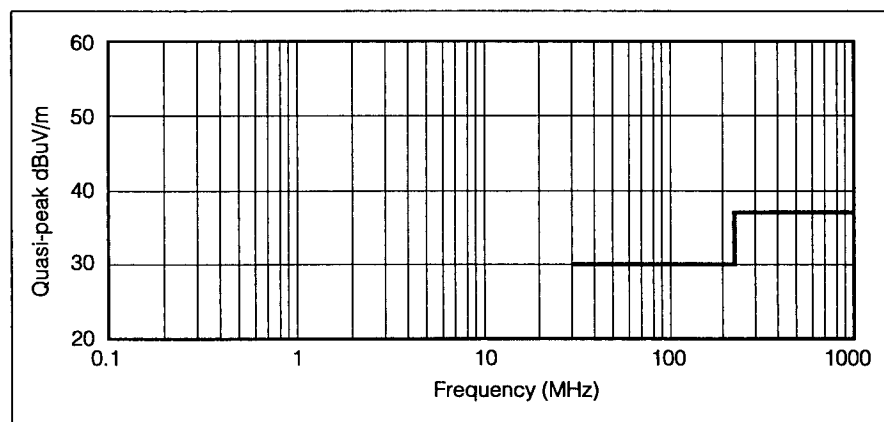
Of course, medical equipment may be in one-of-a-kind installations and type-testing of the installation is the only practical solution to demonstrate compliance to the requirements. It would be impractical to list all iterations of the emission limits in this article; a general overview of the frequency ranges is given. The reader is advised to refer to CISPR 11<sup>2</sup> for the appropriate requirements and amplitude levels once the class of equipment and test location are determined.

Much of the medical equipment tested falls into Group 1, Class A of CISPR 11. Currently, there are no requirements for low frequency emissions, harmonic distortion, and/or voltage fluctuations but some equipment that operates in an intermittent mode must meet variations of the CISPR 14<sup>3</sup> CLICK requirements. The frequency range covered by CISPR 11 is from 150 kHz to 18 GHz. Conducted emissions for low and medium voltage power mains (100 V to 415 V) are specified from 150 kHz to 30 MHz.

The frequency range for radiated emissions is 150 kHz to 18 GHz (Figure 1). Depending upon the class and use of the equipment, various fre-



**Figure 1.** CISPR 11 Conducted Emissions.



**Figure 2.** CISPR 11 Radiated Emissions - Group a Class A @ 30 Meters. Limits from 150 kHz to 30 MHz are under consideration.

quency ranges may be defined. Only the magnetic component of the radiated field is measured from 150 kHz to 30 MHz but the limits are still under consideration (Figure 2).

Above 30 MHz, both the vertical and horizontal components of the electric field must be measured. General amplitude limits are established to protect the public broadcast services. Therefore, when the limits are plotted versus frequency, one will notice the change of amplitude, especially in the TV bands. The amplitude limits do not consider that the equipment may have to operate in close proximity to sensitive medical equipment. The specification also refers to certain frequencies designated by the International Telecommunication Union (ITU), which establishes limits for frequencies for in-

dustrial, scientific, and medical equipment at 2450 MHz, 5800 MHz, and 24125 MHz.

In the second edition, CISPR 15 is referenced for lighting in stand-alone devices, CISPR 13 is referenced for audio and video equipment and CISPR 22 will be allowed for certain information technology equipment (ITE) devices. Harmonic distortion and voltage fluctuations will come under IEC 1000-3-2 and IEC 1000-3.

## IMMUNITY

General immunity requirements are specified in IEC 601-1-2. Test methods and levels are based upon the IEC 801 series of immunity requirements. If lower limits are justified, accompanying documents shall contain the level,

its justification, and any action which shall, as a consequence, be taken by the installer or user. Accompanying documents shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects.

If the use of the equipment is restricted because of its electromagnetic characteristics, relevant restrictions shall be described in the accompanying documents. Compliance with the requirements shall be checked by verifying that the equipment continues to perform its intended functions, as specified by the manufacturer, or fails without creating a safety hazard.

## ELECTROSTATIC DISCHARGE (ESD)

Equipment shall comply with the current edition of IEC 801-2.<sup>4</sup> A level of 3 kV shall apply for direct contact discharge to all conductive accessible parts and coupling planes. A level of 8 kV shall apply for air discharge to nonconductive accessible parts.

In the second edition, performance criteria is changed from safety based to continued utility of the equipment. The level for contact discharge may change to 6 kV.

## RADIATED RF ELECTROMAGNETIC FIELDS

Equipment shall comply with the future IEC 801-3<sup>5</sup> (second edition) requirements. A level of 3 V/m shall be used from 26 MHz to 1 GHz. Other levels apply to equipment installed and/or normally used in shielded locations such as X-ray and MRI facilities. In general, the 3 V/m requirement shall be decreased in proportion to the shielding effectiveness of the location.

There are provisions for amplitude modulation of the signal depending upon the passband of the equipment under test (EUT). If the EUT has no specific passband, the signal shall be amplitude modulated at 1 kHz.

The second edition will require swept frequency test procedures for all equipment opposed to the current situation,

in which swept frequency test procedures are only required for life support equipment. The lower frequency will be raised to 80 MHz while the upper frequency will be extended to 3 GHz. Life support equipment is redefined and a 10 V/m limit is required for such equipment above 800 MHz.

## CONDUCTED BURSTS OR ELECTRICAL FAST TRANSIENTS

Test methods and instruments specified in IEC 801-4<sup>6</sup> shall apply. A 1-kV level shall apply for equipment connected to the power line with a plug. For permanently installed equipment, a level of 2 kV shall apply. Interconnecting lines longer than 3 meters should be able to withstand a 0.5-kV surge.

The second edition removes the distinction between plugged and permanently installed equipment. The levels are raised to 2 kV for the mains and 1 kV for interconnecting lines.

## CONDUCTED SURGES

Test methods and instruments specified in IEC 801-5<sup>7</sup> (which is currently under consideration) shall apply. The power lines of the equipment shall meet levels of 1 kV for differential mode and 2 kV for common mode. Signal lines are not tested. Telecom lines are covered by other standards. Ring wave and damped sinusoid tests are not applicable.

The second edition states that *clinical utility* must be maintained at test levels of  $\pm 0.5$ ; 1 and 2 kV for ac power lines to ground and  $\pm 0.5$  and 1 kV for AC line(s) to line(s). Again, the distinction between plugged and permanently installed equipment is eliminated.

## POWER LINE DISTURBANCES

The second edition contains additional requirements. With respect to voltage dips, short interruptions and voltage variations on power lines, equipment

Voltage Test Level (% $U_{\text{nominal}}$ )	Duration (Periods)
0	0.5
40	5
70	25

**Table 1.** Permitted Voltage Variations on Power Lines.

Voltage Test Level (% $U_{\text{nominal}}$ )	Duration (Periods)
0	5

**Table 2.** Permitted Loss of Clinical Utility.

with a rated input power of 1 kW or less shall maintain clinical utility, and equipment with a rated input power over 1 kW may experience a temporary loss of clinical utility when tested to specified levels (Table 1).

Temporary loss of clinical utility is allowed provided the equipment and/or system remains safe, experiences no component failures, and is restorable to the pre-test state with operator intervention when tested to specified levels (Table 2).

## CONDUCTED IMMUNITY ABOVE 9 KHz

The test methods and equipment are described in IEC 1000-4-6 but there are thirteen modifications. Equipment shall maintain clinical utility when tested to a level of 3 volts up to 80 MHz. The lower or starting frequency is also defined within the 13 modifications, which are quite extensive. Interested parties are advised to review the modifications.

## POWER FREQUENCY MAGNETIC FIELD IMMUNITY

Equipment shall maintain clinical utility when subjected to a level of 10 A/m. The methods and equipment of IEC 1000-4-8 shall apply but with four modifications. Again, the reader is advised to check the specification for the modifications.

## CONCLUSION

In conclusion, manufacturers of electrical and electronic equipment for use in all industries are recognizing the need for specifications that insure compatibility among equipment and systems. Also recognized is the fact that "generic" standards are not necessarily appropriate; they may be too severe or, even worse, may not be severe enough. The need to use existing documents such as IEC 601-1-2 as a basis for creating product specific standards rather than all-inclusive rigid test standards cannot be overemphasized; the practice should be universal.

There is no disputing the importance of electrical and electronic medical equipment in today's society. Therefore, it is well-recognized that this equipment must operate as intended and also not interfere with the operation of other equipment.

This article only gives an overview of the EMC requirements for medical devices as described in IEC 601-1-2, First Edition and draft second edition. The reader is advised to become intimately familiar with the documents for the manufacturing of electro-medical products.

## REFERENCES

1. International Electrotechnical Commission, "Medical Electrical Equipment - Part 1: General Requirements for Safety - Part 2: Collateral Standard: Electromagnetic Compatibility - Requirements and tests," First Edition 1993-04.
2. International Electrotechnical Commission - International Special Committee on Radio Interference, C.I.S.P.R. Publication 11, "Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment (excluding surgical diathermy apparatus)," Second Edition 1990.
3. International Electrotechnical Commission - International Special Committee on Radio Interference, C.I.S.P.R. Publication 14, "Limits and Methods of Measurements of Radio Interference Characteristics of Household Electrical Appliances, Portable Tools and Similar Electrical Apparatus," Second Edition, 1985.
4. International Electrotechnical Commission, IEC 801-2, "Electromagnetic Compatibility for Industrial-process Measurement and Control Equipment," Part 2: Electrostatic

*Continued on page 246*