

EMC TEST REQUIREMENTS FOR MEDICAL DEVICES

Existing and proposed requirements to achieve EMC of medical devices are addressed.

Daniel D. Hoolihan and Paul L. Cook, Amador Corporation, Taylors Falls, MN

INTRODUCTION

In the United States, medical devices historically have been exempt from regulatory limitations in the technical area of electromagnetic compatibility (EMC). However, the requirements of the international market have begun to force American manufacturers to reconsider the design and testing of medical devices for compliance with their intended electromagnetic environment.

The environment in which medical devices must function can range in severity from the operating room to the benign atmosphere of a patient's hospital room or a doctor's office. As a result, a medical device should meet some minimum EMC requirements for susceptibility and emission. Whether these requirements are forced on equipment designers by national or international legislation or by their customers in the medical community appears to be the only major issue.

DOMESTIC REQUIREMENTS MDS-201-0004

In the United States, a voluntary EMC Standard on medical devices has existed since 1979; the standard is entitled "EMC Standard for Medical Devices, MDS-201-0004." This standard was developed and distributed by the Department of Health, Education, and Welfare (now known as the Department of Health and Human Services).

The standard contains both emission and susceptibility requirements.

The conducted emission test on the power lines covers the frequency range from 500 Hz to 30 MHz, and has limits for broadband as well as narrowband emissions. Battery operated devices also are subject to this test if they can operate while the batteries are charging. Emission measurements are made using a current probe while the line impedance is controlled by using 10 μ F feedthrough capacitors.

Radiated emission requirements cover the frequency range from 10 kHz to 1 GHz, and include both narrowband and broadband limits on electric field emissions. This testing is performed in a shielded room, with the antenna located 1 meter away from the equipment under test (EUT). The test sample is normally mounted on a copper ground plane for all of the tests, including radiated emissions.

There are four susceptibility tests in the standard: two conducted and two radiated.

Conducted RF susceptibility on the power leads covers the frequency range from 100 Hz to 30 MHz. The test level ranges from 1.5 to 4.5 volts RMS, depending upon the test frequency. Figure 1 illustrates the limits.

The second conducted susceptibility test is a transient spike test on the

power leads. The transient pulses are 10 μ sec in duration and have an amplitude of 150 volts peak when measured onto a matching 5-ohm load impedance.

The first radiated susceptibility test is a magnetic field susceptibility test at 60 Hz. This testing is done in a Helmholtz coil and the limit is 1 microtesla.

Radiated electric field susceptibility testing is done over the frequency range from 10 kHz to 1 GHz for the U.S. standard. As illustrated in Figure 2, the test levels range from 0.5 V/m to 7.1 V/m depending upon the frequency under test. Most electronic products, with the exception of physiological monitoring devices, are able to pass this test relatively easily. Monitoring devices have difficulties primarily because of the low-level signals they are trying to measure and the fact that the government requires that the RF test frequency be modulated within the passband of the monitoring system.

AAMI

A second United States voluntary standard in the medical device area is a pacemaker standard. This standard, released in August of 1975 under the sponsorship of the Department of HEW, is supported by The Association for the Advancement of Medical Instrumentation (AAMI).

The standard has a radiated susceptibility EMC requirement which

*See advertisement on page 327.

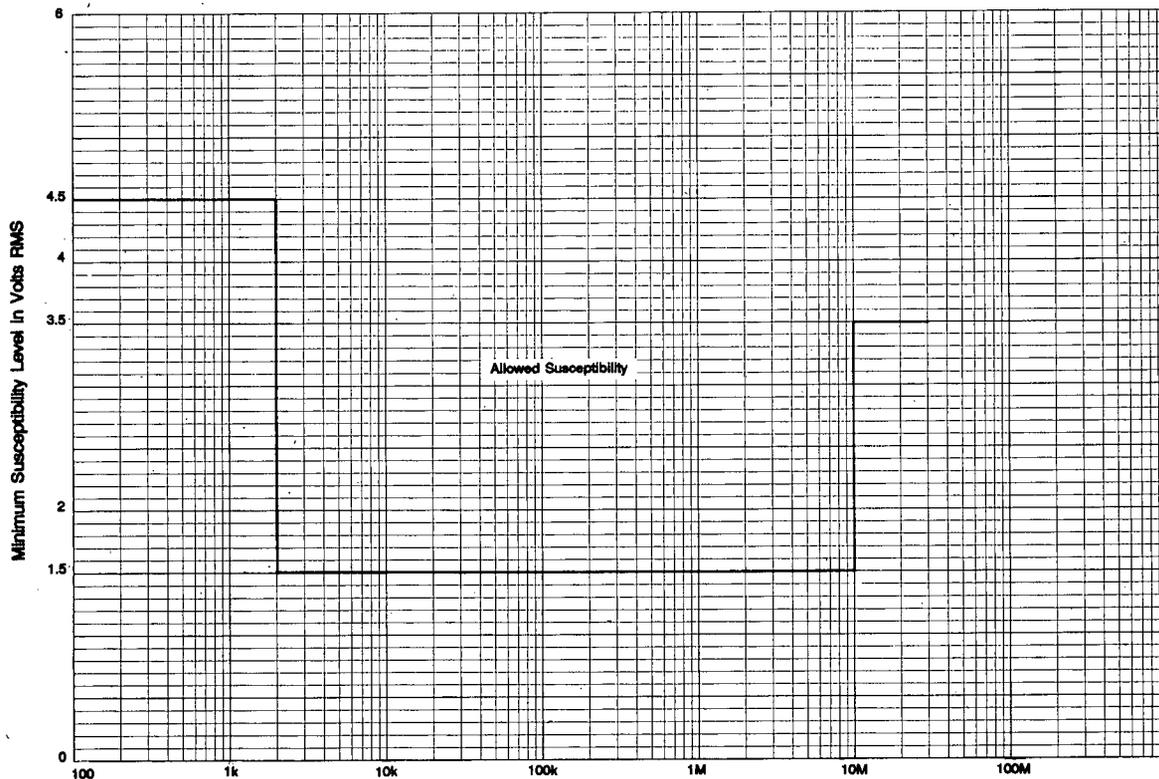


Figure 1. Minimum Conducted Susceptibility Level, 100 Hz to 30 MHz.

requires exposure to 450 MHz electric fields, at 200 V/m (peak pulse amplitude). AAMI also requires conducted susceptibility testing at 50, 60 and 400 Hz, using a 100 mV (rms) continuous wave (CW) signal.

INFANT APNEA MONITORS

The FDA is presently working on a mandatory standard for infant apnea monitors. These devices are used when physicians suspect that an infant may have breathing disorders which may cause the infant to stop breathing while asleep. This standard is in its second draft, and it includes the following types of EMC tests:

- **AC power line variation and transients.** The power variations include line voltages from 95 volts to 132 volts, dropouts for 10 milliseconds, slow sags and surges with durations of 500 milliseconds, 6 kV ring wave transients,

and 150 volt 10 μ sec pulse transients.

- **Conducted susceptibility.** 3 volts rms between 100 Hz to 40 MHz. Tests both CW and 100 percent modulation at 1 Hz sine wave.
- **Radiated electric fields.** Between 10 kHz and 1 GHz. Tests both CW and 100-percent modulation with 1 Hz square wave.
- **Electric field testing.** At 1 Hz at a field strength of 2,000 V/m, utilizing a parallel plate apparatus.
- **Magnetic fields.** Between 60 Hz and 5 MHz. Field strength is up to and including 1 microtesla, and testing is done in both CW and modulated modes (100-percent, 1 Hz square wave).
- **Conducted emissions.** Tested per the requirements given in MDS-201-0004.

- **Radiated emissions.** Electric field emissions tested per the requirements given in MDS-201-0004.

- **Radiated emissions.** Magnetic field emissions are tested per the requirements of MIL-STD-461C and 462 (Notice 3).

- **Electrostatic discharge (ESD).** 6 kV, per IEC 801-2.

This new standard is scheduled to become effective in the summer of 1990.

INTERNATIONAL STANDARDS IEC 601-1

A third voluntary standard is an International Standard, IEC 601-1. This document is published by the International Electrotechnical Commission; its title is "Medical Electrical Equipment - Part 1: General Requirements for Safety."

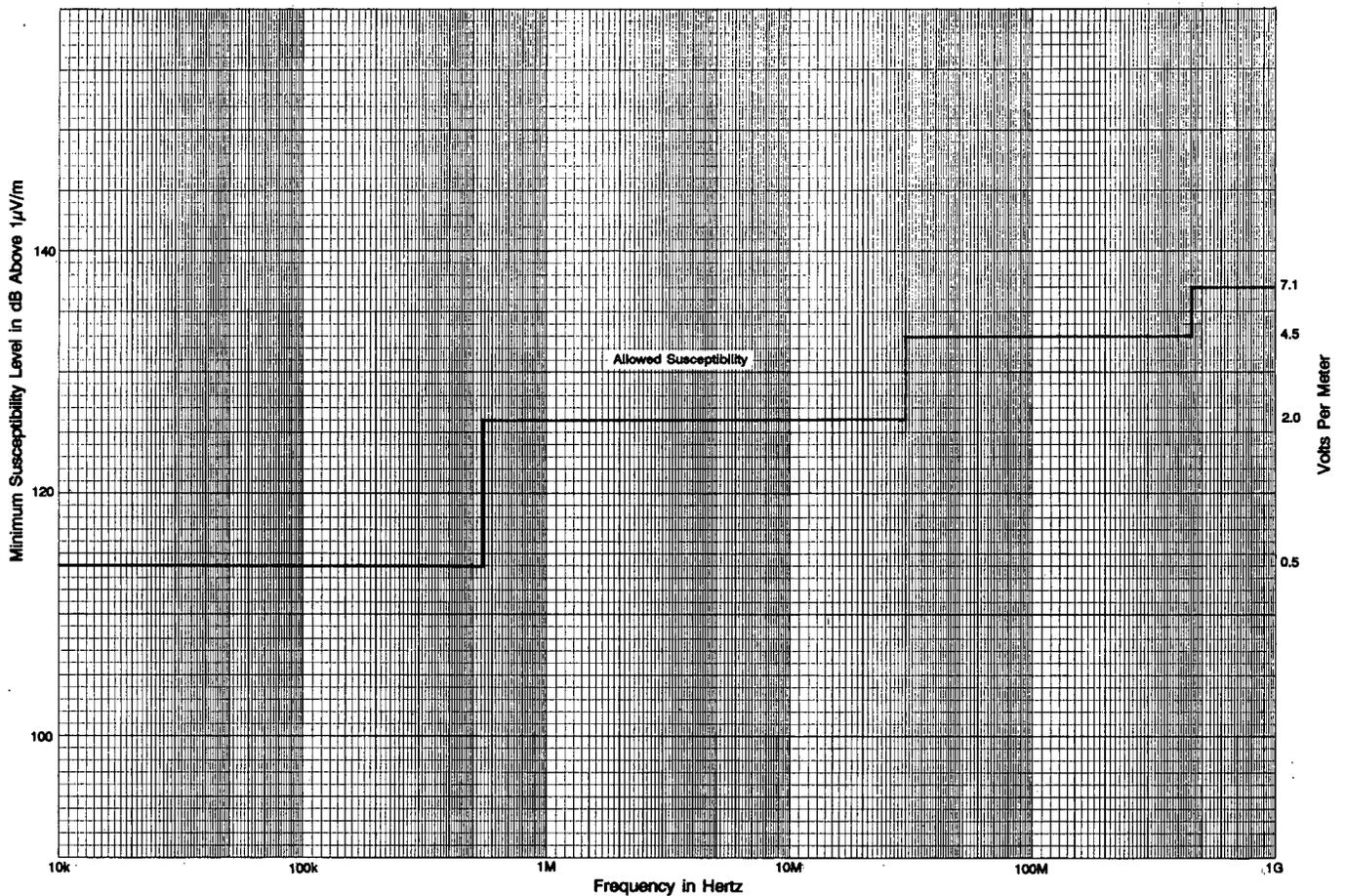


Figure 2. Minimum Radiated Electric Field Susceptibility Level, 10 kHz to 1 GHz.

Section Five of this standard is entitled "Protection Against Hazards From Unwanted or Excessive Radiation." This Section has 8 subsections:

- X-Radiation
- Alpha, Beta, Gamma, Neutron Radiation and Other Particle Radiation
- Microwave Radiation
- Light Radiation (including lasers)
- Infra-red Radiation
- Ultraviolet Radiation
- Acoustical Energy (including ultrasonics)
- Electromagnetic Compatibility

Out of these 8 categories, only one (X-Ray) has any specific requirements at this time; all other categories list requirements as "Under Consideration."

FUTURE REQUIREMENTS

The sole function of the C63 Committee of the American National Standards Institute (ANSI) is electromagnetic compatibility. This committee has a Working Group examining medical device testing, in general, and specifically preparing to respond to international concerns for the electromagnetic environment of the medical devices.

The Working Group will be responsible for formulating the U.S. position statements on EMC testing of medical devices and communicating those positions to the appropriate international technical organizations.

The International Electrotechnical Commission (IEC) includes a Technical Committee No. 62: Electrical Equipment in Medical

Practice. Within this TC62 a Subcommittee 62A addresses common aspects of electrical equipment used in medical practice. Finally, Working Group 13 on Electromagnetic Compatibility serves as an expert advisory group to TC62 within SC62A. It advises on the nature and frequency of EMC problems with electrical equipment in medical practice. It also evaluates the need for EMC standards for electromedical devices and will propose EMC requirements for IEC 601-1.

Future coordination between ANSI and the international world will be through a relationship with WG 13 of SC62A. ■