

EMC STANDARD FOR MEDICAL DEVICES

The primary purpose of this standard was to establish a reasonable level of assurance that medical devices will operate safely and effectively in the electromagnetic environments expected in use. However, hardening medical devices against EMI is a losing strategy unless some attempt is made to limit the steadily growing ambient. Therefore, emission limits were established, the desired effect being to halt the growing ambient at present levels. Since this standard is explicitly intended for medical devices, it is obvious that many of the major contributors to the electromagnetic environment will remain uncontrolled. However, it was hoped that this standard would serve notice to users that electromagnetic compatibility should be considered when purchasing nonmedical equipment. Any such equipment which emits electromagnetic energy at levels in excess of the limits presented in this standard is a potential source of interference for medical devices, even if those medical devices conform to the susceptibility requirements of the standard.

Degradation Criteria

One of the most troublesome problems encountered in the development of this standard concerned degradation criteria or pass/fail criteria during susceptibility testing. Without a specific device and application in mind, it is not possible to generalize as to what kinds of performance degradation should be considered unacceptable. For example, if a patient monitoring console incorporates a digital clock (time-of-day) for the convenience of the nurses, it might be unfair to say that the patient monitor has failed the susceptibility requirements if the clock malfunctions. On the other hand, if that clock is depended upon to automatically transmit patient status at regular intervals, one might say that a malfunctioning clock is reason for failing the patient monitor.

During the public reviews of early drafts, comments were made to the effect that this standard should specify degradation criteria for every medical device on the market. This suggestion is clearly not within the scope of a baseline standard. Therefore, it was decided to adopt a labeling approach which allows manufacturers to determine those malfunctions they deem insignificant and which requires manufacturers to list those insignificant malfunctions in their device literature, thereby allowing users to judge the insignificance (or significance) of those malfunctions in the users' particular applications.

Within the meaning of "insignificant malfunction" are included those primary device characteristics, the performance of which may degrade beyond the manufacturer's specification but not to the extent that it represents a hazard. For example, if the manufacturer's normal specification for noise on an electrocardiograph is $50\mu\text{V}$, the manufacturer may feel that $100\mu\text{V}$ noise is an acceptable degradation of performance when exposed to susceptibility testing. Therefore, that manufacturer would be required by this standard to state in the labeling that the noise specification is degraded to $100\mu\text{V}$ under susceptibility conditions and that this is considered an insignificant malfunction. If this labeling approach is found inadequate for specific devices, detailed susceptibility degradation criteria may be included in the individual medical device performance standards.

In early drafts of this standard, a distinction was made between critical and noncritical parameters. Critical parameters of a device were those that could result in immediate

jeopardy to the patient. When performing susceptibility tests, the test levels were significantly higher for critical parameters. This distinction was eliminated for several reasons. First, the critical/noncritical distinction was being confused with insignificant malfunctions, even after several lengthy discussions at two public review meetings. Second, it was difficult to identify device parameters that were, and always would be, noncritical independent of application. With the advent of computer-aided diagnosis, many parameters that ordinarily could be considered noncritical (such as patient temperature) assume a more significant role. Third, since the susceptibility levels for noncritical parameters reflected the environment in 99% of all medical facilities, the higher susceptibility levels for critical parameters reflected levels that would be found in less than 1% of medical facilities.

An FDA Medical Device Standards Publication, *MDS-201-0004*, dated October 1, 1979, is not a mandatory requirement of any government agency. Although the standard was published by the FDA, it has since been submitted to the American National Standards Institute, Inc., for consideration and possible adoption.

The requirements contained in the standard are based upon data taken during a hospital and emergency vehicle survey program, a review of the data gathered during previous hospital measurements, EMC tests on medical devices, established EMC test methods, and discussions in public review meetings. During the eight-month survey program, tests were performed in ten hospitals and two emergency vehicles. EMC tests were performed on selected medical devices as a means of determining the practicability of the requirements and test methods contained in the standard. The EMC test methods specified in this standard are based upon established test procedures. Whenever possible, the test methods developed for military EMC standards were selected. The established test methods were selected in an attempt to minimize the impact of this standard upon the medical device manufacturers and the EMC test community. Most military-oriented EMC test facilities should be capable of performing the tests outlined in this standard without having to purchase or rent additional test equipment.

The following is a list of EMI control requirements contained in the standard:

1. Conducted Emissions, broadband, 1 kHz to 30 MHz.
2. Conducted Emissions, narrowband, 500 Hz to 30 MHz.
3. Radiated Emissions, broadband, 10 kHz to 1 GHz.
4. Radiated Emissions, narrowband, 10 kHz to 1 GHz.
5. Conducted Susceptibility, 100 Hz to 30 MHz.
6. Radiated Susceptibility, Electric Field, 10 kHz to 1 GHz.
7. Radiated Susceptibility, Magnetic Field, 60 Hz.
8. Transient Susceptibility, Conducted, Time domain.

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