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Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations

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Introduction

The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration has been active in the area of medical device electromagnetic compatibility (EMC) for many years, including radiation measurement, test-method development, immunity testing, and participation in national and international voluntary standards committees. This report includes a discussion of the issues that have caused the agency to intensify its efforts in medical device EMC, summaries of several electromagnetic interference (EMI) problem reports, a brief description of standards and guidelines for medical device EMC, and recommendations for actions that could be taken to improve the EMC of medical devices and to prevent EMI problems.

EMC Issues for Electronic Medical Devices

Several factors have motivated CDRH to intensify its efforts in the area of medical device electromagnetic compatibility, including increased awareness of EMI problems, recent trends in healthcare delivery, and rapid growth in telecommunications technology.

EMC is particularly important for medical devices because EMI has been alleged to cause malfunction of medical devices that, according to the reports (many of which are unconfirmed), resulted in death, serious injury, misdiagnosis, or delivery of inappropriate therapy. Fortunately, the large majority of reported EMI incidents appear to have been "near misses", in which EMI problems were discovered under conditions in which patients were not adversely affected.

Contributing to the problem is the fact that much medical equipment presently in use was not designed or tested for EMC, and the immunity of some devices to radiated electromagnetic fields can be on the order of 0.1 V/m. Some of the techniques used to control emissions can improve the immunity of a device; thus, this equipment might have had higher immunity, had they been regulated for radiated electromagnetic emissions. However, in the U.S., most medical devices are exempt from the Federal Communications Commission (FCC) emissions requirements that computers and other electronic equipment must meet.

Attributing medical device malfunction to EMI is very difficult for several reasons. When troubleshooting a particular malfunction, medical device users and hospital engineers may not realize that EMI could be the cause. Also, without continuous monitoring using sophisticated and expensive equipment, they have no way of knowing the characteristics of their electromagnetic environment, including when or where intense radiofrequency (RF) fields might be present. This is compounded by the fact that many RF

transmissions, particularly from hand-held and mobile sources, are transient, and thus even more difficult to trace or identify. Many medical device service calls result in "no problem found." One industry quality assurance manager estimated this to be 25 percent of all service calls. This may be due to the standard practice of removing a malfunctioning device to the controlled environment of an electronics shop or laboratory, rather than checking its performance in its use environment, or even investigating the use environment itself.

Patient-coupled devices, those which intentionally or unintentionally couple RF energy conductively, capacitively, or inductively to or from the patient, are of particular concern. These devices often incorporate high-gain amplifiers in order to measure low-level signals. In addition to cables and lead wires acting as antennas, the human body can act as an antenna as well. Rectification of RF signals can occur at electrode-skin interfaces. When multiple patient-coupled devices are used on the same patient, the signals can couple in unexpected ways.[1] The additional uncertainties introduced by patient coupling were considered in the development of International Electrotechnical Commission (IEC) 601-1-2, the international EMC standard for medical electrical equipment. As a result, IEC 601-1-2 allows manufacturers of patient-coupled equipment to specify test levels and test methods; that is, it sets no minimum standard for patient-coupled devices. This is particularly troubling because much of the equipment used in patient care is patient-coupled.

In addition to interference from communications devices, reported problems have involved electromagnetic interference from one medical device to another.[2] For this reason, electromagnetic emissions from medical devices must be controlled as well as their immunity, even though medical device emissions have generally not caused problems with radio reception.

The trend toward home-use, ambulatory, and mobile medical devices is likely to result in the use of devices in more uncontrolled electromagnetic environments. Furthermore, if the device malfunctions in these environments, trained health-care professionals may not be present to intervene, and a replacement device may not be readily available.

Another trend is the increasing proximity of medical devices to relatively intense sources of RF energy. Medical devices with insufficient immunity can be affected by local, high-power AM, FM, and TV transmitters. Devices with insufficient immunity that are used in hospitals can also be affected by transmitters that are located on the roof, such as paging systems, cellular phone base stations, and repeaters for land-mobile services. Two-way radios used in transport and emergency situations are potentially problematic because their power output is moderate and they are often used very close to medical devices. Devices used in the home can be affected by nearby amateur or citizens band (CB) radio. In addition, wireless communications devices are proliferating. Interference to medical devices has, in fact, been reported to have been caused by: fixed sources such as radio and TV transmitters; mobile sources such as two-way radios and cellular phones; and hand-held sources such as two-way radios, cellular phones, and wireless computer equipment.

Cellular phones and wireless computer equipment are of particular concern because, in the absence of proper precautions, they could come extremely close to medical devices. In general, the immunity of an electronic device is finite, yet the field strength can be very high when the distance between a medical device and a transmitter approaches zero. Many users of cellular phones do not realize that the phones continue to transmit while in the standby mode (waiting to receive calls). A visitor could cause interference by setting a cellular phone on top of a medical device. A health-care provider with a cellular phone in their pocket could cause interference by standing too close to a medical device. Users of wireless computer equipment also may not know precisely when a particular computer device is transmitting. Both cellular phones and wireless computer equipment can cause interference to sensitive medical devices, including devices that may be in a different room or on a different floor of the building. The visual barriers between the source and "victim" equipment make such problems more difficult to identify and prevent.

Digital cellular phones and personal communication services (PCS) equipment may be cause for even more concern because of the pulse modulation used in signal transmission. Some communications equipment (e.g. some U.S. digital cellular phones) use pulse modulation rates that are within the physiologic passband of parameters (e.g. the electrocardiogram) measured from the patient. Other communications equipment (e.g. the European GSM cellular phones) use pulse modulation rates that are in the audio band and are expected to interfere with devices such as hearing aids.[3] The effect on medical devices of spread-spectrum transmitters requires further study, but it will most likely vary from device to device, depending on the susceptibility bandwidth of the device at PCS frequencies. The effect on a device with wide susceptibility bandwidth could be as if it were caused by continuous interference, while the effect on a device with narrow susceptibility bandwidth could be as if it were caused by transient interference.

Furthermore, since the peak power of a cellular phone is controlled by the base station, the actual transmitted power is difficult to predict. The reproducibility of "ad-hoc" or "informal" EMC testing, where hospital engineers evaluate the performance of in-house medical devices in close proximity to portable, in-house transmitters, will be difficult to achieve unless the output power is measured or, with the assistance of the transmitter manufacturer, fixed.

Problem reports

Numerous incidents of electromagnetic interference with medical device performance have been reported to the FDA from 1979 to the present, over 100 of which were cited in reference 2. Incidents which have been reported since the publication of reference 2 include the following:

Cellular phones have been found to be capable of interfering with patient monitors, pulse oximeters, infusion pumps, ventilators, and pacemakers. Table I lists some of the results of "ad-hoc" or "informal" electromagnetic compatibility testing that was performed by hospital engineers, using analog, 0.6-W cellular phones.[4]

Table I. Test Results: Interference from 0.6-W Analog Cellular Phones

Device	Effect	Proximity
Infusion pump	Flow sensor triggered - causes pump to stop	0.2 m of the flow sensor
Incubator	Temperature settings fluctuate, causing the heating element to turn on	0.1 m of the LED display
ECG/Apnea	False apnea alarm	0.1 m of monitor
Ventilator	Change in delivered gas volume	0.3 m of right side
Oxygen monitor	Oxygen saturation reading increases	0.13 m of monitor

Wireless computer equipment has been reported to interfere with patient monitors, pulse oximeters, and infusion pumps. Problems caused by wireless computer equipment were alluded to in a phone call received by the author in November 1993 from an attorney representing the computer equipment manufacturer. He stressed that no patient injury had occurred, and that the problems were solved by separating the wireless computer equipment and the affected medical devices. He said that the equipment that caused the interference operated in the 900-MHz band at very low power. When I asked for further information, he said that he would have to discuss the matter with his client. Seven months and two attorneys later, the author received a letter containing the minimum information agreed upon: the medical equipment that was affected, and what was done to correct the problems. The letter described the wireless computer equipment as "either a UHF-frequency mobile radio communications device or the accompanying base station," and reported four cases as follows:

- I.V. pump monitors and drip sensors rebooted and lost memory after the design of the drip sensor was changed. After investigation, it was discovered that the redesigned sensors did not have sufficiently shielded cables and, as a result, were pulling in RF emissions from the mobile radio communications devices. The hospital stopped using the redesigned equipment and has asked the manufacturer to upgrade the cables.

- Several oximeters located near a mobile radio communications device rebooted and lost parameters. One oximeter manufacturer resolved the problem by providing copper shielding to upgrade the base of its equipment. When other vendors declined to do so, a procedure was put in place that prevents using the mobile radio communications device within six feet of an oximeter.

- Several cardiac monitors experienced otherwise impossible "spike" readings when the print stylus was within three feet of a mobile radio communications device. A

procedure has been adopted that does not transmit such readings when a mobile communications device is near the monitors.

- A fetal heart monitor located in a nursery experienced incorrect readings. The problem was resolved when a base station, which had been placed on a wall outside the nursery, was moved 25 feet from the monitor. The base station ultimately was relocated 50 feet from the monitor.

Additional reports received by the FDA since the publication of reference 2 in which problems were alleged to have been caused by electromagnetic interference include those listed below. Reference numbers beginning with M and V are access numbers into FDA medical device databases for the mandatory Medical Device Reporting (MDR) program and the voluntary Product Reporting Program (PRP), respectively.

- A heated wire humidifier respiratory circuit/controller caused interference with ECG monitoring that varied with the heater cycle, resulting in apparent arrhythmia and pacemaker spikes (M420310, M434529, M443474, M443960, M445216, M445740, M447012, and M447013).

- Powered wheelchairs moved unintentionally, possibly due to electromagnetic interference (V59371, V59693, and V59914).

- Ventilators alarmed, ceased operation, and displayed error codes due to EMI or power line disturbances. In one case, the altitude setting of a ventilator was found to have been changed to 9900 m. The altitude-setting change could not be duplicated. (M447940 and M447942)

- A ventilator "spontaneously shut down" due to excessive RFI. All units at one hospital were modified with additional shielding (M458056).

- An external pacemaker/defibrillator ceased pacing during EMT radio transmissions, causing "excruciating pain" to the patient (M458375).

- A defibrillator monitor flatlined and went into defibrillation mode spontaneously. The manufacturer changed the RF shield, and the unit then functioned properly (M482677).

EMC standards and guidelines for medical devices

EMC standards and guidelines applicable to medical device include MDS-201-0004, Electromagnetic Compatibility Standard for Medical Devices, October 1, 1979; IEC 601-1-2, Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, April 1993; ~~and~~ Reviewer Guidance for Premarket Notification Submissions, November 1993. Each has advantages and disadvantages.

MDS-201-0004

MDS-201-0004 was developed by McDonnell Douglas under a contract with the FDA and published in 1979. It contains requirements and test methods for both emissions and immunity. While it was never made mandatory, it has been used by some manufacturers of medical devices as a voluntary guideline. However, its limits and test methods are not harmonized with international standards, magnetic field immunity testing is only required at the power frequency, and the radiated RF immunity test methods may be inadequate because testing in a (non-anechoic) shielded room is permitted and interconnecting cables are decoupled from the field by placing them close to the ground plane. For these reasons, it is recommended that more up-to-date standards be used, rather than MDS-201-0004.

IEC 601-1-2

IEC 601-1-2 is a collateral standard to IEC 601-1, the general safety standard for medical electrical equipment. IEC 601-1-2 is a good step in the right direction for medical device EMC. It is a general, product-family standard, and contains requirements for both emissions and immunity. It has some very good labeling requirements. For example, the manufacturer is required to provide guidelines for avoiding or identifying and resolving electromagnetic interference. In addition, it requires that the front panel of intentional emitters of electromagnetic energy (e.g. electrosurgery units (ESUs)) be labeled with the IEC symbol for non-ionizing radiation (see Figure 1). IEC 601-1-2 also requires that radiated electromagnetic immunity testing be performed using amplitude modulation at a frequency within each significant signal-processing passband of the device.

Figure 1. IEC Non-Ionizing Radiation Symbol

However, IEC 601-1-2 has several disadvantages, foremost of which is that the immunity performance (pass/fail) criteria (the equipment "continues to perform as intended by the manufacturer or fails in a manner that does not create a safety hazard") are unclear, and have been misinterpreted by reputable testing laboratories. A "safety hazard" is defined by IEC 601-1 as a "potentially detrimental effect on the patient, other persons, animals, or the surroundings, arising directly from equipment." Thus, a device can fail safely and still create a safety hazard by its unavailability; e.g. when diagnosis or treatment is interrupted or cannot begin. Furthermore, even if a manufacturer uses the "fail" option appropriately, there is no requirement to disclose to the user or purchaser that the "fail" option was chosen, nor is there a requirement to disclose the failure modes that were observed during the test.

Examples of "safe failures" that were considered by the manufacturer and/or test lab to "pass" IEC 601-1-2, yet that could create safety hazards, were described in an EMC test report that was submitted to the FDA for a cardiac ablation device. The footswitch became non-operational following electrostatic discharges to the footswitch connector. The manufacturer considered this to be a "pass" because the footswitch is an optional component and the device could still be operated from the front panel. During common-mode surge testing, a component in the RF generator failed, disabling the device. The manufacturer considered this to be a "pass" because no energy would then be applied

to the patient. These failures, had they occurred in actual use, could have resulted in rescheduling of an invasive procedure, yet the device specifications would need only to state (erroneously in this case) that the device "passed" IEC 601-1-2.

In addition, IEC 601-1-2 permits radiated electromagnetic immunity testing of non-life-supporting equipment at the frequencies within the range 26 MHz to 1 GHz that were set aside for industrial, scientific, and medical (ISM) equipment by the International Telecommunications Union (ITU). There are exactly four such frequencies: 27.12, 40.68, and 915 MHz, with 433.92 MHz under consideration. This testing skips over wide frequency bands where susceptibility could occur, including most frequencies used by FM and TV transmitters, as well as cellular phones. IEC 601-1-2 also states that test methods and immunity test levels for patient-coupled devices, those for which RF energy could be coupled conductively, capacitively, or inductively to or from the patient, are specified by the manufacturer. Thus, while many devices under the scope of IEC 601-1 are patient-coupled, it sets no minimum standard for these devices. Several requirements are also currently missing from IEC 601-1-2 ("under consideration"), including those for low-frequency emissions; magnetic field emissions and immunity; voltage dips, interruptions, and variations; and conducted RF immunity.

A New Work Item Proposal (NWIP) has been approved by the IEC so that the working group that wrote IEC 601-1-2 can begin drafting the first amendment. Changes to the pass/fail criteria and the test frequencies for non-life-supporting equipment will be considered, an attempt will be made to complete clauses presently listed as "under consideration", and the applicability of additional IEC EMC standards will be discussed.

Reviewer Guidance for Premarket Notification Submissions

The FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, is a general guidance document for submission of "510(k)" applications for respiratory and anesthesiology devices. It contains, as an appendix, recommendations for labeling and for electrical, mechanical, and environmental performance testing. This document had previously been adapted to home-use respiratory devices in March 1992, based on an unreleased draft of a mandatory FDA performance standard for infant apnea monitors. At that time, IEC 601-1-2 had not yet been published. To the extent possible, the reviewer guidance was harmonized with IEC 601-1-2 by referencing the same ratified basic EMC standards and paraphrasing portions of the same draft basic EMC standards referenced by IEC 601-1-2.

The Reviewer Guidance references the radiated and conducted electromagnetic emissions requirements of CISPR 11 and magnetic field emissions requirements and test methods RE101, which covers the frequency range 30 Hz to 100 kHz, of military standards MIL-STD-461D and -462D. The immunity performance criteria of the Reviewer Guidance state that under the test conditions, the device should perform within specifications and exhibit no equipment alarms, no degradation or loss of function requiring operator intervention (except for up to 5 seconds after electrostatic discharge), and no loss or corruption of stored data. It recommends that ESD testing be performed

up to 8 kV for air discharge and up to 6 kV for contact discharge to the device and to both horizontal and vertical coupling planes.

Radiated electromagnetic field immunity testing is recommended at 3 V/m, using either pulse modulation or 80 percent sine-wave modulation at 0.5 Hz, over the frequency range 26 MHz to 1 GHz. As in recent drafts of IEC 801-3, establishment of a planar area of uniform field is recommended. The document recommends that all six sides of the device be exposed, where practical, using horizontal and vertical E-field polarizations. Limitations on frequency sweep rate, or step size and dwell time, are recommended, so that susceptibilities of slowly-responding medical equipment, such as respiratory devices, are not missed. In addition, recommendations are made regarding standardized placement of cables, with emphasis on the importance of exposing interconnecting cables to the plane of uniform field.

The Reviewer Guidance recommends AC voltage fluctuation tests, including steady-state voltage from 95 to 132 Vrms, dropout for up to 10 ms, and sags to 90 Vrms and surges to 150 Vrms for up to 500 ms. It also recommends the following:

- Transient burst testing according to IEC 801-4: signal leads up to 1 kV, using a capacitive clamp, and power leads up to 2 kV;

- Surge testing according to a draft of IEC 801-5: up to 1 kV line-to-line and 2 kV line to ground;

- Conducted electromagnetic immunity testing according to the requirements and test methods of CS114, which covers the frequency range 10 kHz to 10 MHz, of military standards MIL-STD-461D and -462D.

- Magnetic field immunity testing according to the requirements and test methods of RS101, which covers the frequency range 30 Hz to 100 kHz, of military standards MIL-STD-461D and -462D.

In addition, the Reviewer Guidance recommends that respiratory devices be tested using quasi-static electric fields up to 2000 V/m at 0.5 Hz. This simulates the movement of electrostatically-charged objects and people in the vicinity of the device: conditions that were found to cause apnea monitors to malfunction in the laboratory and that are not simulated by ESD testing.

The Reviewer Guidance is harmonized with, and a superset of IEC EMC standards. It features unambiguous degradation criteria, and makes no special allowances for patient-coupled devices. However, its disadvantages include that the default modulation frequency is tailored to respiratory devices, it references military standards for requirements and test methods that were not readily available in the form of voluntary standards, and the radiated immunity test level can be exceeded by hand-held, mobile, and fixed transmitters at close range.

In future drafts of this reviewer guidance, it is planned to reference IEC 601-1-2, with modifications and additions.

Recommendations

Much additional work is needed by voluntary standards organizations; medical device manufacturers, users, and regulators; test laboratories; and researchers in order to assure electromagnetic compatibility of medical devices. In the opinion of the author, adherence to the following recommendations could improve medical device EMC; however, these are not to be construed as official FDA policy.

Needs in the voluntary standards area include: emissions and immunity test methods for patient-coupled devices, special requirements (e.g. higher test levels) for devices used in environments where field strengths can be particularly high, and further development of device-specific standards, including specific pass/fail criteria, test methods, and test levels that are based on the criticality of the function of the device and the field strengths likely to be found in the use environment.

Manufacturers should consider EMC in the design stage of electrical and electronic medical devices, and they should test their products to EMC standards. Above and beyond this, if the device is often used in environments where field strengths exceed the test levels of EMC standards, it should be tested to higher levels. In addition, manufacturers should use pass/fail criteria that assure effectiveness as well as safety of the device in its intended use environment. Because testing to standards cannot fully duplicate all conditions that the device will experience in use, manufacturers should correct significant design-related EMC problems that are discovered during use, and report EMC problems to the appropriate regulatory authorities. Manufacturers should provide clear guidance to the user in avoiding or identifying and resolving EMI problems. Adequate labeling is particularly important if the device is often used in high field-strength environments but cannot be made to function as intended in these environments.

EMC test laboratories should be sure to understand the pass/fail criteria of the standards to which the device is tested. EMC testing of medical devices can be very different from EMC testing of computers or communications equipment. It is essential that test engineers use device-specific modulation frequencies, as well as sweep rates and dwell times that are sufficiently slow to allow the device to respond.

Device users and health-care facility engineers, administrators, architects, and planners can also help prevent EMI problems. The first step is to promote awareness of the potential effects of EMI on medical devices throughout the facility. Equipment purchased should conform to appropriate EMC standards. Hospital engineers should examine the EMC test report to determine the pass/fail criteria used and how the device performed during the test. Medical device users should follow the manufacturer's recommendations for avoiding EMI problems. Problems that occur should be reported to the appropriate regulatory authorities.

Health-care facility engineers should become aware of RF sources on the roof of the building and in the vicinity. Roof-top sources found to disrupt the performance of medical devices within the facility should be removed, if possible, and the use of portable RF sources such as walkie-talkies and cellular phones in close proximity to electronic medical devices should be restricted. Before hospitals were air conditioned, there were signs posted in the neighborhood: "quiet - hospital zone". To this day there are signs posted near construction sites warning that the use of two-way radios can set off explosives unintentionally. Perhaps it may be necessary, until all medical equipment in use meets minimum electromagnetic immunity standards, to post signs in the neighborhood of health-care facilities warning against the use of two-way radios, particularly mobile radios of moderate to high power such as those used by EMS, police and fire services, delivery services, shuttle busses, and taxis.

Whether or not a medical device meets minimum electromagnetic immunity standards, assuring that the device is not exposed to ambient RF fields that exceed its radiated immunity can help prevent interference problems. This can often be accomplished by maintaining physical separation between the device and RF sources. While the field strength to which a medical device is exposed can only be determined accurately by precise RF measurements, if the radiated immunity of a medical device and the peak effective radiated power of a transmitter are known, the distance to be maintained between them to help prevent interference, referred to as the "protection distance",[5] can be estimated within approximately an order of magnitude.

In free space, in the far field (distance greater than the wavelength of the transmitter), and for typical antennas, the field strength from a transmitter varies proportional to the inverse of the distance from the transmitter. If the effective radiated power of a transmitter is known, the dipole equation can be used to calculate an estimate of the field strength in the far field as a function of distance.[5] If the radiated RF immunity of a medical device is known, substituting the immunity for the field strength and solving the dipole equation for distance yields the following:

$$d = 7\frac{\sqrt{P}}{E}$$

where P is the peak effective radiated power of the transmitter in watts (W), E is the immunity of the medical device in volts per meter (V/m), and d is the protection distance in meters (m). This approximation does not apply at distances less than the wavelength of the transmitter (near field). Therefore, for low-power sources that are normally hand-held, an appropriate minimum separation distance is on the order of 1 m.

The limitations ~~of this~~ estimate are described below. The following is assumed:

- A single transmitter is present, radiating at its maximum rated power; and
- The worst-case susceptibility of the medical device occurs at the frequency of the transmitter.

In addition, if multiple sources (e.g. cellular phones) are in use, the actual distance could be greater than that determined from the equation. If a single source is radiating less than its maximum power rating or the worst-case susceptibility of the medical device occurs at a frequency other than that of the transmitter of interest, the actual distance could be less than that determined from the equation.

The actual distance is also affected by antenna efficiency and pattern; multipath reflections; and absorption of buildings, objects, and people. The equation above is an approximate worst case for commonly-used antennas and is based on the antenna efficiency of cellular phones.[5] Multipath reflections could result in an actual distance that is greater than that determined from the equation, and absorption could result in an actual distance that is less than that determined from the equation.

Table II presents some example estimates, based on the assumptions above.

Table II. Example Protection Distance Estimates*

Peak Power of Transmitter	Immunity of Medical Device		
	0.1 V/m	3 V/m	10 V/m
10 mW	7 m	1 m	1 m
100 mW	22 m	1 m	1 m
600 mW	54 m	1.8 m	1 m
2 W	99 m	3.3 m	1 m
100 W	700 m	23 m	7 m

* See discussion in the text of the limitations of this estimation.

EMC should also be considered in the design, site analysis, floorplanning, and construction of health-care facilities. Architectural EMC techniques should be used in the design and construction of the facilities. Power distribution should be designed to minimize conducted interference from high-power equipment. Potential sites under consideration for new facilities should be examined for proximity to high-power transmitting antennas, and an electromagnetic site survey should be made. Floorplanning is important for both new and existing facilities, and units in which particularly sensitive devices are used, such as fetal heart monitors, EEG, EMG, and older apnea monitors, should not be located near imaging systems, elevator shafts, or electrosurgery suites. Attention should also be paid to equipment located on the floor above and below sensitive medical devices, as well as proximity to outside walls or drive-throughs that might be exposed to mobile two-way radios at close range. Some existing rooms may need to be shielded, in order to assure proper operation of these devices.

Areas in which further research is needed include development of standardized radiated emissions and immunity test methods for patient-coupled devices and, for all devices, ways of performing radiated immunity testing that is faster, less expensive, and more thorough than existing test methods. If radiated immunity test methods were developed that were sufficiently thorough, fast, and inexpensive, it could be feasible to achieve greater assurance of EMC by sampling the EMC of production units, rather than only testing one sample of each model, as is current practice.

The effects of aging and service on the EMC of medical devices also needs to be studied. The hypothesis has been made that the immunity of many devices degrade with age,[6] and further research is needed to determine the validity of the hypothesis and the causes of such degradation, if any. It has been reported that some EMC measures have been defeated during servicing of equipment. Causes for this need to be investigated, and possible prevention measures need to be developed.

Finally, better methods of specifying the immunity of medical devices are needed. As can be seen from the susceptibility curve for an apnea monitor shown in Figure 2, a single immunity number for a device is usually representative of the worst case, and it does not convey a sufficient amount of information. The actual immunity of the device will often be considerably higher in particular portions of the frequency range. However, most devices do not have a response as linear as that of the apnea monitor characterized in Figure 2. For example, the powered wheelchair characterized in Figure 3 exhibits susceptibility that is complex not only with respect to frequency, but also with respect to field strength. As a result, a simple immunity-vs.-frequency curve similar to that in Figure 2 cannot easily be developed for this powered wheelchair.

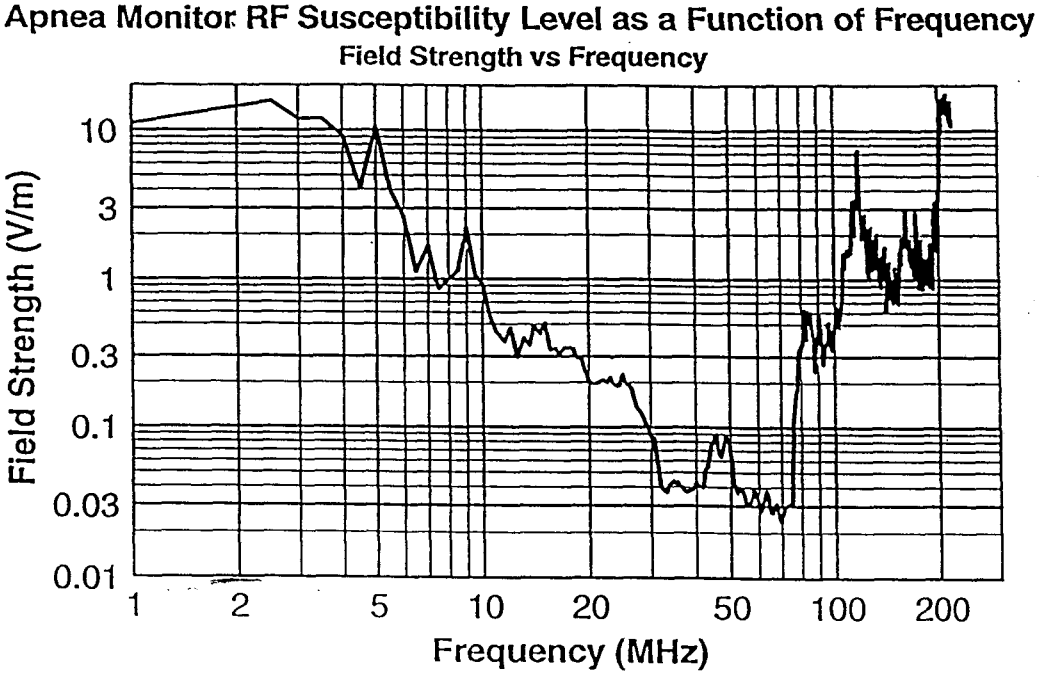

Figure 2. Susceptibility spectrum of an apnea monitor

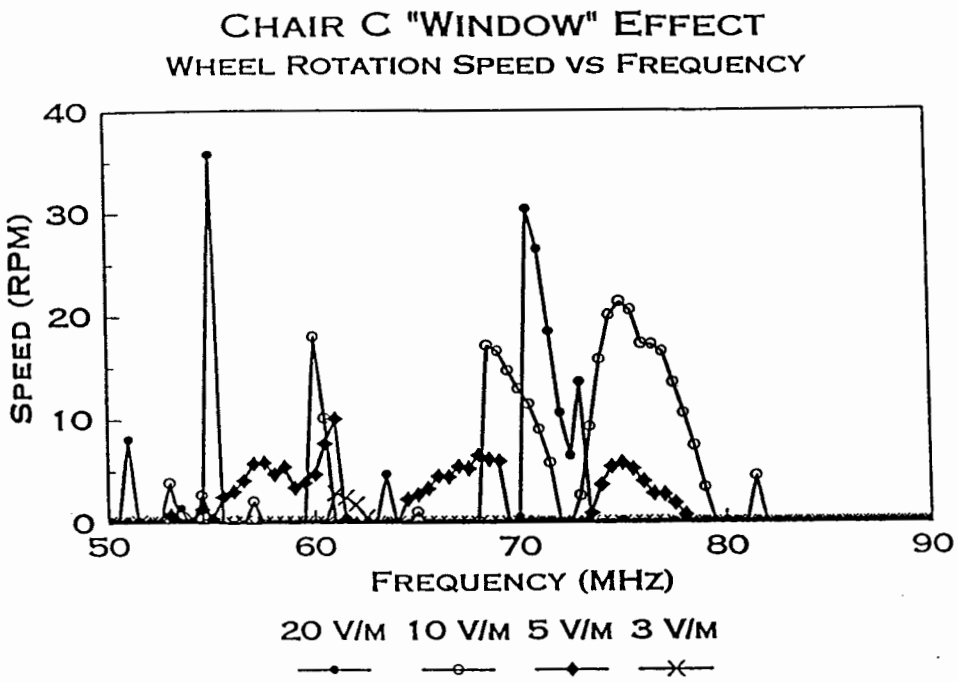

Figure 3. Susceptibility spectra, at various field strengths, of a powered wheelchair

Conclusions

The challenge is ahead. Assurance of electromagnetic compatibility of electronic medical devices cannot be achieved by any one group alone. It will require the continued efforts and cooperation of voluntary standards organizations; manufacturers of both medical and communications devices; test laboratories; researchers; regulators; device users; hospital engineers; and planners, designers, and administrators of health-care facilities.

Acknowledgements

Figures 2 and 3 are courtesy of Paul S. Ruggera and Donald M. Witters, Office of Science and Technology, CDRH, FDA.

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