

Medical Devices and EMI: The FDA Perspective

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THE EMI PROBLEM

An electric powered wheelchair suddenly veers off course; an apnea monitor fails to alarm; a ventilator suddenly changes its breath rate.^{1,2,3} These are just a few examples of the problems that might occur when radiated electromagnetic (EM) energy interacts with the sensitive electronics incorporated into many medical devices. Over the years, many incidents of suspected electromagnetic interference (EMI) with medical devices have been documented.⁴ In addition, recent congressional hearings⁵ and

media attention^{6,7} have heightened concern for the safe and effective use of devices in the presence of EMI. For medical devices the environment has become crowded with potential sources of EMI (Figure 1).

Because of its concern for the public health and safety, the Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), has been in the vanguard of examining medical device EMI and providing solutions. Extensive laboratory testing by CDRH^{8,9,10} and others^{11,12,13,14} has revealed that many devices can be susceptible to problems caused by EMI. Indeed, the CDRH has been investigating incidents of device EMI and working on solutions (e.g., the 1979 draft EMC standard for medical devices¹⁵), since the late 1960s, when there was concern for EMI with cardiac pacemakers.¹⁶

The key to addressing EMI in medical devices is the recognition that it involves not only the device itself but also the environment in which it is used, and anything that may come into that environment. More than anything else, the concern with EMI must be viewed as a systems problem requiring a systems approach. In this case the solution requires the involvement of the device industry, the EM source industry (e.g., the power and telecommunications industries), and the clinical user and patient. The public must also play a part in the overall approach to recognizing and dealing with EMI.

This article briefly outlines the concerns of the Center for Devices and Radiological Health, FDA, for EMI in all medical devices with electrical or electronic systems, and focuses on the strategy developed to minimize these problems.

THE COMPLEXITY OF DEVICE EMI

As our society seeks new technology, medical devices can usually be found in the forefront. There is an ever-increasing use of electronics and microprocessors in devices of all kinds from relatively simple devices like electrical nerve stimulators to the more recent advances in imaging such as magnetic resonance imaging (MRI). In the medical industry there is a tendency toward more automation in devices to monitor patients and help perform diagnoses. Microminiaturization has revolutionized the medical device industry; smaller devices require less power and can perform more functions.

At the same time, there is a proliferation of new communications technology, personal communications systems (PCS), cellular telephones, and wireless computer links, to name a few. With these advances are coming some unforeseen problems: the interactions between the products emitting the EM energy and sensitive medical devices. Even the devices themselves can emit EM energy which can react with other devices or products.

Electromagnetic compatibility, or EMC, is essentially the opposite of EMI. EMC means that the device is



Figure 1. Typical Electromagnetic Environment for Medical Devices.

compatible with (i.e., no interference caused by) its EM environment, and it does not emit levels of EM energy that cause EMI in other devices in the vicinity. The wide variation of medical devices and use environments makes them vulnerable to different forms of EM energy which can cause EMI: conducted, radiated, and electrostatic discharge (ESD). Further, EMI problems with medical devices can be very complex¹⁷, not only from the technical standpoint but also from the view of public health issues and solutions.

A brief overview of radio frequency interference (RFI) can help to illustrate some of the variables that make device EMI so complex and difficult to address effectively. In general, the strength of the EM field at any given distance from the source of the radiated signal (transmitter) is directly proportional to the radiated power of the transmitter and inversely proportional to the distance. The role of distance from the EM energy source is highlighted by Figure 2. The relatively low power cellular telephone

creates a 3 V/m field strength at 1 m, while a more powerful hand-held CB transceiver creates the same field strength at 5 m. Further, the high power TV transmitter creates this same field strength at a distance of 1000 m. It is easy to see then, at small distances from the radiator where EM field strength can be very high, even the best-protected devices (i.e., with a high level of immunity) may be susceptible to EMI. However, the device may be susceptible to only some of the variations (e.g., frequency or modulation) in the EM energy. This is why some devices may be affected by a nearby transmitter of a certain frequency, and other devices at the same location may not be affected. Add to RFI the other forms of EMI and it quickly becomes apparent that devices can face a fairly hostile environment which can ultimately affect the patient or device user.

FDA CONCERN WITH EMI

The consequence of EMI with medical devices may be only a transient "blip" on a monitor, or it could be as serious as preventing an alarm from sounding or causing inappropriate device movement leading to patient injury or death. With the increasing use of sensitive electronics in devices, and the proliferation of sources of EM energy, there is heightened concern about EMI in many devices. While the numbers of reports with possible links to EMI have been steady, these numbers are generally not indicative of the actual occurrence of incidents. Indeed, in investigating possible EMI-related problems it is usually the case that the EM energy which caused the event has dissipated (e.g., the EM energy source was shut off or removed from the area). Only through careful measurement and testing can the true nature of EMI susceptibility be determined. The complexity of the testing and the vast range of devices involved make it a very difficult task indeed to address EMI.

The CDRH has regulatory authority over several thousand different kinds of medical devices, with thousands of manufacturers and variations of devices. The very nature of this range of devices does not lend itself to "generic" approaches. For example, an apnea monitor is very different from a powered wheelchair, in form, function, and configuration.

The EM environment that envelops the devices can vary widely, from the rural setting to the commercial setting, to the urban setting, and of course, the hospital setting. The International Electrotechnical Commission (IEC) has classified the EM environment into eight areas and defined the typical EM environment in each area.¹⁸ Within each area there are conditions for the location and power of local EM energy sources (e.g., transmitters), which, if exceeded, would result in higher EM field strengths. Table 1 indicates the general classifications and the upper range of radiated EM field strength specified for each environment.

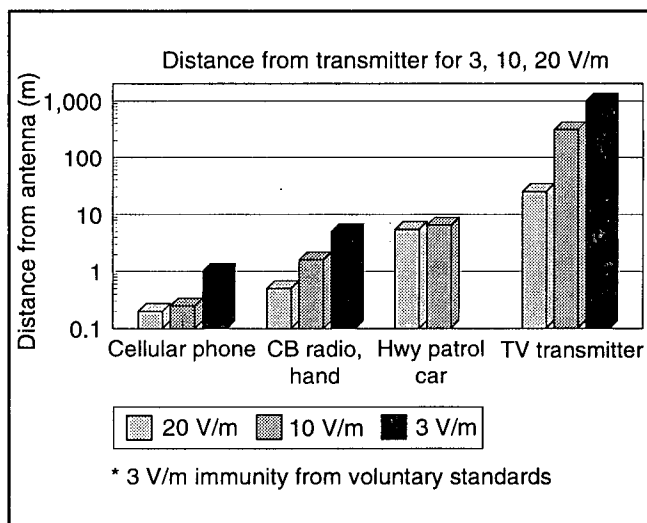


Figure 2. Radiated Field Strengths for Common Transmitters.

CLASSIFICATION	SIGNAL STRENGTH*
Residential	
Rural	up to 3 V/m
Urban	up to 10 V/m
Commercial	up to 10 V/m
Light Industrial	up to 3 V/m
Heavy Industrial	up to 30 V/m
Traffic	up to 30 V/m
Dedicated Communications Center	up to 1 V/m
Hospital	up to 3 V/m

*Frequency and source dependent, with conditions for the proximity of local radio transmitters. If transmitters exceed conditions (power, distance), then field strengths could be higher.

Table 1. IEC TC-77 Classifications of Electromagnetic Environments for Radiated Signals.

FORMATION OF THE CDRH EMC WORKING GROUP

Concern in the CDRH has led to the formation of an EMC Working Group. This group was charged by the Deputy Center Director, Dr. Elizabeth Jacobson, to:

- assess all device areas to identify EMC concerns;
- coordinate the development of a strategy to assure EMC in all appropriate devices;
- provide a focal point for actions;
- keep the Center Director and staff informed of activities involving EMI/EMC.

This initiative involves virtually all of the CDRH offices and functions. The formation and subsequent accomplishments of the group have already had an impact on the regulatory approach, research, and interactions with the device industry.¹⁹

A comprehensive plan for addressing medical device EMC needs to focus on the primary aspects of device safety and effectiveness.

The EMC Working Group has developed a draft strategy to address EMC concerns across all appropriate device areas. This involves awareness (and education), regulation, research, cooperation with other agencies and organizations, and coordination and cooperation with manufacturers and users.

PLANS FOR DEVICE EMC

A comprehensive plan for addressing medical device EMC needs to focus on the primary aspects of device safety and effectiveness. Although many manufacturers in certain device areas, such as cardiac pacemakers, have been addressing EMC for some time, discussions with users, manufacturers, and EMC test facilities personnel indicate that there still appears to be a general lack of awareness of the EMI problem. Thus, one key element in our plan includes raising this awareness and educating users, manufacturers, and regulators about EMC.

AWARENESS

The CDRH has always placed a high priority on providing information to the public. For example, when the CDRH developed information that some apnea monitors could fail to alarm due to EMI, an FDA safety alert was sent out to large numbers of clinicians and users of these devices, warning of the problem and providing tips for the safe use of the devices.²⁰ Following the extensive investigations into EMI with powered wheelchairs and motorized scooters, the FDA published an article in its Medical Bulletin, which goes to over 1 million clinicians, provid-

ing information about device EMI.²¹ In addition, a question-and-answer document was developed for the users of powered wheelchairs and motorized scooters.²²

PRE-MARKET

The pre-market approach to device regulation was charged to the former Bureau of Medical Devices by the 1976 Amendments to the Food, Drug, and Cosmetics Act. In the early 1980s, this bureau was merged with the Bureau of Radiological Health to form the Center for Devices and Radiological Health. Under the 1976 Amendments, and the more recent Safe Medical Device Act of 1990,²³ CDRH has authority to require device manufacturers to submit information about the safety and effectiveness of their devices. EMI has implications in both the safe and effective use of devices. Thus, a central part of the strategy for dealing with EMC concerns is to address these concerns in pre-market submissions.

In some device areas, notably the respiratory and anesthesia areas, concern with EMI has evolved over a period of years because of problems with such devices as the apnea monitor. Indeed, there is a draft FDA standard for apnea monitors with EMC requirements that grew out of our investigations of EMI problems. This draft standard is presently undergoing public comment.²⁴

Because of the vast range of devices, and the time and resources it takes to develop mandatory standards, a more general approach is being planned to address EMC in all appropriate device areas with respect to the pre-market concerns. This approach includes the development of priorities and guidelines for pre- and post-market and research activities.

Development of the guidelines for the regulators and manufacturers have been proposed in phases, including:

- a general guideline to address EMC across a broad range of devices which would be harmonized with prevailing national and international standards; and
- ultimately, specific guidelines tailored to concerns in each device area and developed in accordance with pre-market priorities for EMC.

POST-MARKET

For devices already in use, the post-market domain, plans are being formulated to address EMC utilizing the Good Manufacturing Practice requirements (Title 21 Code of Federal Regulations 820) and inspection guidance (FDA, CDRH Compliance Policy Guidance Manual 7382.830, 5/94). There are also plans to gather information from the manufacturers of radiation emitting products, such as electronic article surveillance systems, to examine the implications for device EMI.

In addition, the collection of incident reports, mandatory in the cases of patient death or injury,²⁵ is another major tool to assess the post-market use of devices. With the large number of devices being used today, and the

steady number of incident reports, plans are underway to better distinguish EMI incidents from other types of device incidents. The plans involve building a separate database of carefully scrutinized incident reports, which would form the foundation that would grow with later reports. A system to separate and analyze EMI reports will serve as a resource in making decisions and setting priorities.

RESEARCH AND STANDARDS

Research and work with voluntary standards organizations have been ongoing in CDRH for several years. Present investigations include examinations of reported EMI to cardiac pacemakers from digital cellular telephones, EMI to ventilator devices, and follow-up on powered wheelchair EMC. The CDRH laboratory is equipped to perform these kinds of investigations and has the experienced staff to develop test protocols. Indeed, the CDRH work with powered wheelchair EMC has contributed greatly to draft test requirements and procedures for a national (ANSI/RESNA) and an international (ISO) standard.^{25,26}

National and international standards activities play an important role in medical device EMC, which is why CDRH has promoted and supported the development of voluntary EMC product family standards for medical devices and EMC requirements for device-specific standards. In addition to ANSI/RESNA and ISO, CDRH has worked with AAMI, the ANSI-Accredited Standards Committee C63, and the International Electrotechnical Commission (IEC). In many cases, the Center's EMC laboratory findings and environmental measurements are utilized in proposals and recommendations to these voluntary standards organizations. The Center has been particularly interested and active in the development of IEC 601-1-2,²⁷ and has attempted to harmonize our recommendations with this document to the extent possible, given the FDA mandate to assure safety and effectiveness. The European equivalent of this standard will become especially important as of January 1996, when the European Community EMC Directive becomes effective.¹⁷ IEC 601-1-2 is an important step towards assuring EMC of medical devices; however, CDRH has some critical concerns about this document, and is participating in the development of the first amendment to this document.

WORK WITH OTHER AGENCIES

There are additional plans to work with other federal agencies and professional organizations to promote medical device EMC. Present activities include participation in the EMC Risk Assessment project ongoing at the Walter Reed Army Medical Center. Engineers at Walter Reed have begun an ambitious program to document the incidents of EMI in devices and to address solutions. CDRH scientists have brought laboratory data and a rich history of experience to the meetings with Walter Reed staff. In addition, CDRH is continuing its dialog with the

Federal Communications Commission (FCC) to promote medical device EMC.

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SOME ACCOMPLISHMENTS TO DATE

The CDRH EMC Working Group and others have accomplished much in a short time. Chief among the accomplishments is the formulation of strategies to address EMC in all appropriate device areas. By taking a more comprehensive approach, the CDRH has been proactive in raising awareness and concern for EMC/EMI in devices. The EMC Working Group cooperated with AAMI to present a one and one-half day forum on medical device EMC. The objective of the forum was simple: make known the concern for device EMC, and provide a forum for interaction by the users, clinicians, manufacturers, EM source industries, the public, and CDRH to address the concern.

The EMC Working Group has also been busy assessing the various device areas in the pre-market domain to help in devising priorities for guidance development and laboratory testing. In addition, the Group has provided training for the CDRH staff about EMC, developed strategies, and made recommendations for CDRH/FDA policy toward EMC. Various members of the EMC Working Group have been taking the lead in activities outside the CDRH to address EMC in medical devices.

The laboratory investigation of powered wheelchair EMI, and subsequent standards efforts, illustrates that device EMC can be achieved through cooperation among CDRH, manufacturers and users. Below is a brief overview of this work.

EXPERIENCE WITH POWERED WHEELCHAIR EMC

CDRH became aware of suspected EMI in powered wheelchairs and motorized scooters in mid-1992. By late 1993 CDRH laboratory investigations and testing had revealed serious EMI reactions by these devices over a wide range of radio frequencies (1 MHz to 1000 MHz).

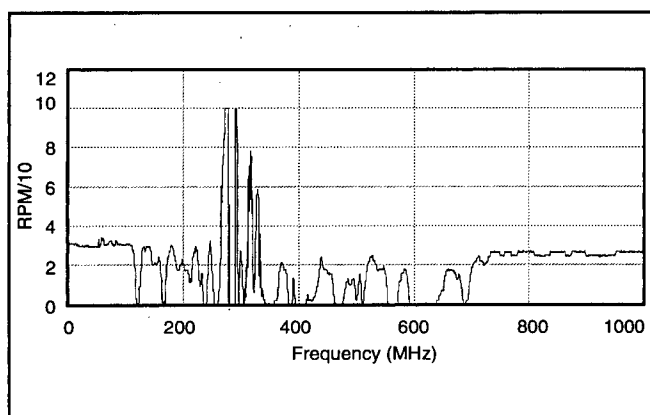


Figure 3. Test results, before EMC modifications, for sample powered wheelchair tested with the wheels in motion during exposure.

The evidence indicated that these devices could experience incidents of uncontrolled movement or electromechanical brake release in the presence of moderate radiated EM fields (as low as 3 to 10 V/m). This was sufficient to warrant notifying powered wheelchair users, through user organizations,²⁸ of the potential for EMI, and to solicit information concerning actual incidents. Further testing revealed that the EMI seemed to affect the control system of the powered wheelchairs resulting in electromechanical brake release and unintended wheel movement.

In many cases, motorized scooters utilize the same type of control systems as the powered wheelchairs. Thus, there was concern that the scooter devices could also suffer from EMI. EMC tests were performed on samples of motorized scooters. The results revealed that these devices could also exhibit EMI problems.

Experience from EMC testing of other devices led CDRH researchers to develop testing procedures which fully challenged the devices. These procedures became the basis for the 1993 CDRH proposals to the RESNA and the ISO for EMC tests and requirements in their respective standards. The proposals were made to harmonize as much as possible with the IEC 801-3 standard (recently renumbered to IEC 1000-4-3)²⁹ for radiated immunity testing. However, in the process of performing the laboratory tests, CDRH created unique procedures which take into account the relatively slow response time of powered wheelchairs. Through careful scrutiny of submissions of EMC test data by the device manufacturers, and verification testing by CDRH, it became clear that the procedures devised by CDRH were more accurate in determining EMI problems than the existing standard procedures.

Additional testing procedures were developed to examine the device response as the wheels were kept at a constant speed to simulate normal movement of the wheelchair. Figure 3 represents the results of testing on one device (before modifications were made by the manufacturer). In this case, the wheels were fixed at a constant speed of 30 RPM during the exposure of the device. Note that there are several places where the

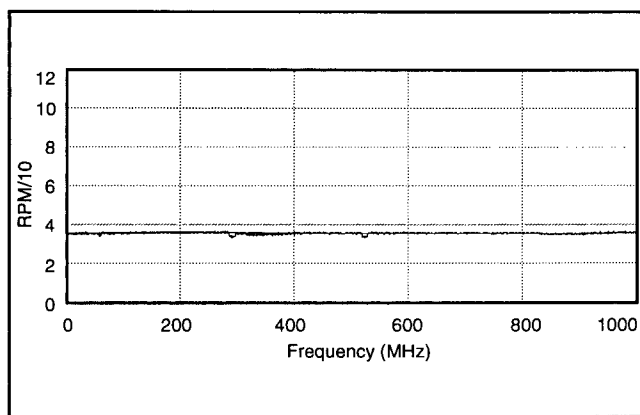


Figure 4. Test results, after modifications, for the same sample device (from Figure 3) tested with the wheels in motion during exposure.

motion of the wheels deviated from the 30 RPM baseline, indicating EMI to the wheelchair. These tests were performed at the EM field strength of 20 V/m. This level was chosen because the device manufacturers had stated they could build devices immune to this level, which is approximately the field strength from a hand-held transceiver at 0.6 m (2 ft). Many powered wheelchair users utilize radio transceivers and cellular telephones for communications, any of which could be placed within this distance of the device's control system.

Following careful EMC modifications to the powered wheelchair by the manufacturer, with the appropriate shielding and circuit modifications, the same powered wheelchair was retested and found to be immune (no EMI reactions) across the entire frequency range (Figure 4). This demonstrated that these devices could indeed be made immune to 20 V/m. With such findings in hand, CDRH notified powered wheelchair and scooter manufacturers in May 1994³⁰ that future submissions for these type devices should address EMC in labeling and testing. Additional work with the RESNA subcommittee for EMC refined the original CDRH EMC test proposal and reduced the number of test points, to make the procedure more affordable to perform, without compromising the test reliability.

The experience with powered wheelchair EMI demonstrates the ability of CDRH to work with the device manufacturers to recognize and address an EMI problem. Many of these device manufacturers were helpful in sharing information, providing samples, bringing together interested parties, and working towards a solution of the problem. CDRH was able to develop a new and more accurate test procedure in a relatively short time frame, building upon its years of experience in the laboratory and in EMC testing of devices.

SUMMARY

There is still much work to be done to reach the goal of assuring device EMC across the broad range of devices. The CDRH EMC Working Group has been charged by

the Deputy Center Director to continue this effort, which will likely last some time into the future and impact all electrical and electronic medical devices. Given the nature of the EMI problem, and the quick pace of technology, plans for this program must be dynamic and flexible. The very nature of EMI is complex, with large uncertainties in nearly every aspect. The CDRH approach will reflect these constraints and rely in large measure on the cooperation of all parties.

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