

Procedures for Managing Electromagnetic Compatibility in Healthcare Facilities

Application The electromagnetic environment of a typical healthcare facility grows more complicated each year. The continual introduction of new, sophisticated biomedical, diagnostic, and therapeutic devices into the healthcare environment may, in some conditions, jeopardize the very medical procedures that such devices were intended to facilitate. To manage this complex environment, healthcare facilities should establish and follow procedures to prevent conditions leading to electromagnetic interference (EMI) and educate staff, patients, and visitors about EMI. The guidelines set forth to manage electromagnetic compatibility should be an integral part of a facility's clinical and administrative activities, thereby enhancing the overall performance of the staff, reducing the number of equipment malfunctions resulting from EMI, and improving the quality of patient care at the facility.

What To Look For Malfunctions of electronic medical equipment—including distortion of displayed medical information, incorrect diagnostic results, and interruptions of medical procedures—are possible symptoms of interference caused by radiated and conducted emissions. Most EMI symptoms are transitory, rarely resulting in a misdiagnosis, especially when the equipment user is aware of the equipment malfunction.

Measured in units of volts per meter (V/m), radiated emissions are primarily composed of electric fields, emitted from electrical and electronic equipment, that travel through the air. Among the common equipment found inside a healthcare facility that generate radiated emissions are high-frequency medical equipment such as electrosurgical units, magnetic resonance imaging (MRI) systems, and computed tomography (CT) scanners, as well as electronic fluorescent lighting. Wireless communication devices also produce radiated emissions. The cellular telephone is a prime example. As shown in Figure 1, medical equipment such as an EEG (electroencephalograph) may receive electric fields generated by the normal operation of a cellular telephone, thus

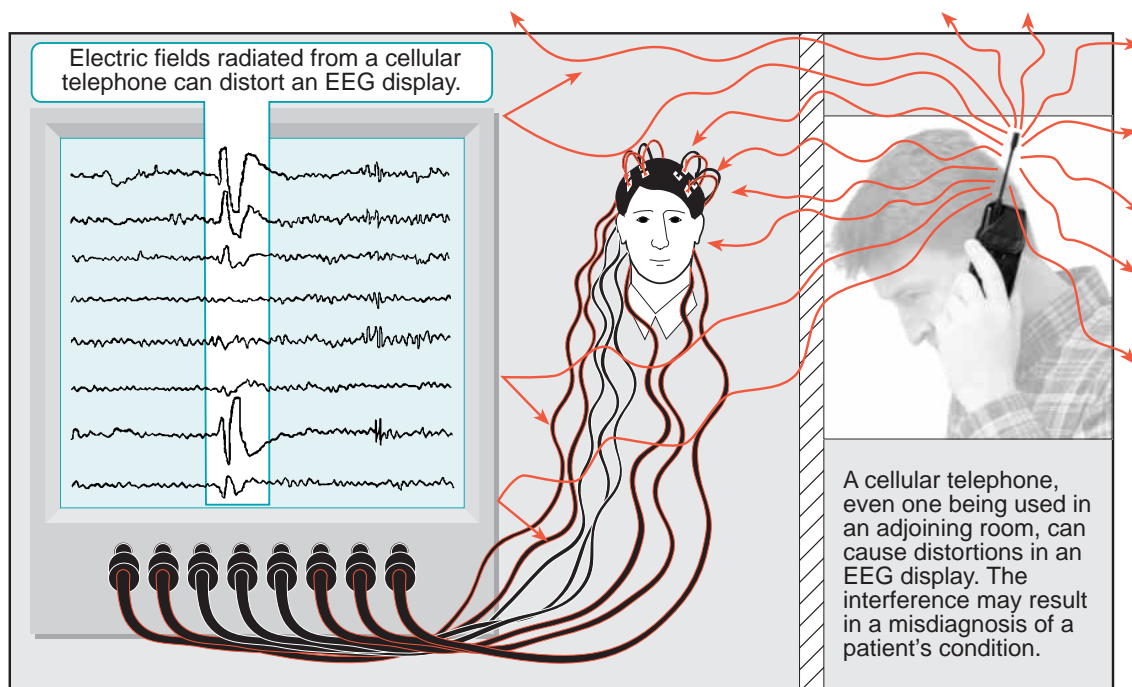


Figure 1. Electromagnetic Interference Caused by the Operation of a Nearby Cellular Telephone

distorting the data displayed by the device. In this case, leads from the equipment connected to the patient may act as antennas, picking up radiated emissions in the electromagnetic environment. Outside a healthcare facility, high-power transmission equipment, such as stationary broadcast transmission towers, are the most common sources of radiated emissions. The closer the source of radiated emissions to the equipment, the stronger the electric field. Depending on the frequency of the emissions and the immunity of the equipment, electric fields less than 3 V/m at the equipment are unlikely to cause it to malfunction (see IEC Standard 601-1-2/Ed.2 from the International Electrotechnical Commission for more information).

Measured in volts, conducted emissions are primarily composed of low-level, high-frequency electrical noise, also emitted from electrical and electronic equipment, that travels via electrical conductors. Among the common equipment found inside a healthcare facility that generate conducted emissions are electric hospital beds, heating-ventilation-and-air-conditioning (HVAC) equipment, electronic fluorescent lighting, and electric power tools such as electric drills and saws. Even different pieces of medical equipment can interfere with each other. One hospital reported that a urine-output monitor generated conducted emissions that interfered with an ECG (electrocardiograph), resulting in an artifact on the ECG printout that resembled arrhythmias (see Figure 2).

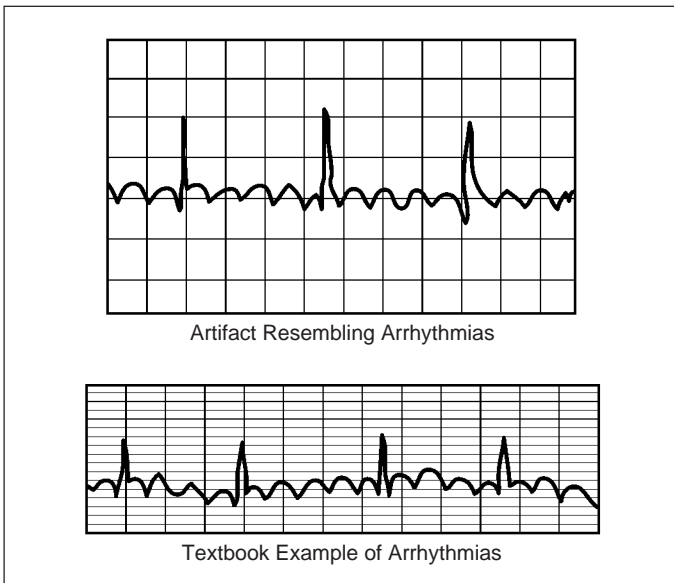


Figure 2. Artifact Resembling Arrhythmias on an ECG, Caused by Conducted EMI

Magnetic fields generated by power distribution equipment can be inductively coupled into electronic medical equipment. Measured in units of milligauss, these magnetic fields, often referred to as low-fre-

quency RFI (radio-frequency interference) or low-frequency EMFs (electromagnetic fields), propagate from a power conductor or equipment that carries an electric current. Among the common equipment that generate magnetic fields are power distribution transformers, appliances that contain electric motors and transformers, and some power-conditioning equipment. Additionally, power conductors within a building are a source of magnetic fields. However, because magnetic fields quickly decay as the distance from the source increases, interference occurs only when medical equipment is close to the source.

Even magnetic fields as low as one milligauss may interfere with electronic medical equipment that displays data on a cathode-ray tube (CRT) of a video monitor. If the magnetic field is strong enough at the CRT, it can affect the electron beams in the CRT, resulting in distortion of the video image. The probability of interference increases as the screen size increases, the distance between medical equipment and the source decreases, and the strength of the source increases.

If medical equipment is in the path of electromagnetic energy of sufficient power and is operating at the same frequency as that energy, then the normal operation of the equipment may be interrupted. Symptoms of EMI include unexplained changes in medical data, transient or persistent error messages on readouts, false readings from diagnostic equipment, and disabling or false triggering of alarms on monitors that have been set to go off during certain medical conditions of a patient.

PROCEDURES FOR MANAGING THE ELECTROMAGNETIC ENVIRONMENT

To help minimize the number of medical-equipment malfunctions caused by electromagnetic interference, each healthcare facility should review the following guidelines to help establish facility-specific EMC procedures. When forming coherent EMC procedures, consider the physical layout and electrical layout of a facility, its geographic location, its proximity to transmitters (radio, television, cellular, roof-top, and so on), and the locations of patient-care areas within a facility. For example, the emergency room, where sensitive monitoring equipment is used, may be close to medical equipment, such as imaging systems, that produce potentially disruptive emissions. Or, sensitive medical equipment may be placed next to vehicle-access areas, where two-way radios are in use. In either case, particular guidelines must be developed and followed to avoid EMI.

The biomedical engineering staff should work with the healthcare administration, safety committee, purchasing department, nursing, and other staff to craft EMC procedures that encompass many points of view. The procedures should then be approved by a governing

body, such as a board of directors. The approved EMC procedures should then be incorporated into the standard operating policies of a healthcare facility. At the time of hire, new-employee orientation should include training and reading material related to EMI in healthcare. Each employee should be required to sign a statement indicating that the facility's EMC procedures have been read and are understood.

Because medical equipment, the electrical environment, and staff continually change, EMC procedures should be reviewed regularly, particularly before new communication or medical equipment is put into service. Healthcare facilities should sponsor annual EMI updates and continuing EMI education.

Purchasing Procedures to Avoid EMI Problems

- Never assume that new communication equipment will not interfere with existing medical or security

equipment. The trend toward more sophisticated communication equipment has not been accompanied by a trend toward lower levels of emission.

- For areas such as intensive-care units and areas where a significant amount of patient-connected electronic medical equipment will be used, purchase electronic ballasts for fluorescent lighting approved by the FCC Part 18. Also, purchase lighting fixtures with RF-blocking prismatic lighting diffusers.
- Some medical equipment may be labeled *approved* and tested for compliance with the latest immunity standards by certain agencies such as the FCC (U.S. Federal Communications Commission), CSA (Canadian Standards Association), UL (Underwriters Laboratories), and the new CE mark, which signifies compliance with European guidelines for maximum radiated and conducted emissions. However, compliance testing does not ensure that the equipment is immune to EMI in all electromag-

Regulations, Rules, Codes, Standards, Recommended Practices, and Guides for Healthcare

Regulation or Rule (R), Code (C), Standard (S), Recommended Practice (RP), or Guide (G)	For Facilities				For Equipment			
	Emergency Power	Isolated Ground	Wiring	Environment	Immunity Limits	Immunity Tests	Emissions Limits	Emissions Tests
National Electrical Code (NFPA 70)	C	C	C					
Healthcare Facilities (NFPA 99)	S	S, RP	S, RP	RP				
Electric Systems in Health Care Facilities (IEEE 602, <i>White Book</i>)	RP	RP	RP	RP				
Emergency and Standby Power Systems (NFPA 110)	S	S						
Emergency and Standby Power Systems for Industrial and Commercial Applications (IEEE 446, <i>Orange Book</i>)	RP	RP						
Powering and Grounding Sensitive Electronic Equipment (IEEE 1100, <i>Emerald Book</i>)		RP	RP	RP	RP		RP	
Electromagnetic Compatibility (IEC 1000-3, -4)					S	S	S	S
Medical Electrical Equipment (IEC 601-01, Part 2: EMC Requirements and Tests)				S	S	S	S	S
Electromagnetic Compatibility (ANSI C 63.18 [19 and 21 to be published])				S		S, G		S, G
Industrial, Scientific and Medical Equipment Installed on User's Premises (ANSI/IEEE 139)								RP
Industrial, Scientific, and Medical Equipment (ISM) (FCC Part 18)							R	R
Radio Frequency, ISM Equipment (CISPR 11)							S, R	S, R
Guidance for Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers Part 1: Radiated Radio Frequency Electromagnetic Energy (AAMI TIR 18)				S				

Standards supporting the electrical design of healthcare facilities and equipment cover the areas of powering, grounding, equipment limits, and testing facilities and equipment. They are given legal status when adopted by state or local authorities.

netic environments. Precautions for installing and using medical equipment in an EMI-rich environment also apply to these “compliant” medical equipment.

- Before purchasing medical equipment, request from the vendor documentation about the equipment’s susceptibility to EMI and compliance with EMC-related standards.
- As manufacturers of medical equipment recognize and acknowledge the significance of EMI immunity, they will begin to develop equipment with higher levels of immunity. Look for equipment with technologically advanced designs, including filtering and shielding, that reduce the effects of EMI.

Procedures to Improve EMC

- Users of communication and medical equipment should always follow the installation, operation, and maintenance recommendations of the manufacturer to avoid or reduce medical equipment malfunctions.
- Unless the transmission from communication equipment can be turned off, do not try to modify it, such as by reducing its transmission power to eliminate an EMI problem. Such modifications may render the equipment inoperable or unreliable.
- Biomedical and facility engineers can apply the ANSI/IEEE Standard C63.18-1997, *Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of*

Tutorial: Predicting EMI Caused by RF Sources

EMC researchers at the McGill Biomedical Engineering Group have developed a method for predicting the strength of an electric field caused by a nearby external source of EMI (see the *FDA/AAMI Conference Report in To Read Further*). The method assumes that the radiated energy originates from an isotropic source, which radiates energy in all directions, and is propagated to the facility by line-of-sight. The frequency range of the method is between 30 MHz and 1 GHz, which is the range of most fixed transmitters such as FM radio, television, and land-mobile sources such as cellular telephones. Estimating the strength of an electric field caused by an isotropic EMI source requires only two pieces of information: 1) the distance between the transmitter (source) and the location in question and 2) the effective isotropic radiated power (EIRP) of the transmitter, which can be obtained from the FCC, local broadcast station, or from the transmitter itself (such as a cellular telephone).

The formula for estimating field strength is:

$$\text{Field (V/m)} = 5.48 \times \sqrt{\text{EIRP (W)}} \times \sqrt{2} / \text{Distance (m)}$$

If the EIRP is given in dB watts instead of watts, then convert the value into watts with the formula: $10^{(\text{dB W}/10)}$. For example, a 100 kilowatt transmitter antenna used by a local FM radio station located about one kilometer away would cause an electric field of about 2.5 volts per meter, whereas a 600 milliwatt cellular telephone one meter from medical equipment would cause an electric field of about six volts per meter. Generally, the threshold for an electric field causing EMI problems is about three volts per meter (3 V/m) at or near the equipment, assuming that the radiated electromagnetic energy in the background is about zero. Therefore, the formula for field strength can be used to determine the required separation distance to ensure that an electric field is

less than the threshold. The formula for estimating separation distance is:

$$\text{Distance (m)} = 5.48 \times \sqrt{\text{EIRP (W)}} \times \sqrt{2} / 3$$

In the example of the radio station above, the field strength is less than the threshold. However, the electric field caused by the cellular telephone exceeds the threshold. To estimate the separation distance for the cellular telephone, plug 0.6 (600 milliwatts) into the distance formula. The result, about two meters, suggest that a 600 milliwatt cellular telephone should be kept at least two meters from sensitive medical equipment.

You can automate estimations of field strength and separation distance by using a spreadsheet program such as Microsoft Excel or Lotus 1-2-3. The figures below show how to estimate the field strength and separation distance using an Excel spreadsheet.

	A	B	C	D	E	F
1	EIRP (Watts)	Separation Distance (Meters)	Field (V/m)			
2	0.01	10	0.0774989			
3						
4						
5						

	A	B	C	D	E	F
1	EIRP (Watts)	Separation Distance (Meters)				
2	1000	81.69101678				
3						
4						
5						

Medical Devices to Specific Radio-Frequency Transmitters, to estimate the immunity of in-house medical equipment to wireless in-house electronic equipment.

- Specialized shielding can absorb radiated emissions from antennas mounted inside the facility away from areas containing sensitive electronic medical equipment where these emissions must be reduced. However, some facilities may have in-house communication systems, such as a micro-cellular telephone system, that require broadcast signals to be accessible in all parts of the facility. Therefore, shielding may not be a viable EMC option.

- Before relocating communication or medical equipment, have the electromagnetic environment in the proposed area characterized and identify equipment used in nearby areas and possible EMI interactions that could take place.
- Institute and enforce regulations that ban or limit the use of all wireless communication devices in critical-care and other areas where an array of sensitive electronic medical equipment is used.
- As much as possible, increase the distance between the transmitter of a wireless communication system and medical equipment. Also, select communication equipment with the least amount of radiated power to do the job. These precautions are especially

Source	Frequency (MHz)	Output Power (W)	Estimated Field Strength (V/m)
Paging Transmitters	49	250	110*
Walkie-Talkies	27, 49, 145, 450	5	15*
State Police Radio	39	100	40
Biomedical Telemetry	174–216	0.8 μ W	0.006*
	460–470	0.002	0.3*
	512–566	0.1 μ W	0.002*
Mobile Radios	440–470	25	35*
Police/Ambulance	400–900	10–100	22–70*
Wireless LANs	912	0.1	2.2
Personal Digital Assistants	896–940	4	14
Radio Modems	896–901	10	22
Cellular Telephones	800–900	0.6–3	5.4–12
Personal Com. Service	1850–1950	0.2	3

*Distance is within the “near field,” which includes an electric field and magnetic field.
 Source: Association for the Advancement of Medical Instrumentation, *Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical*, Technical Information Report AAMI TIR No. 18—1997.

Source	Frequency (MHz)	Maximum Licensed Radiated Power (W)	Estimated Field Strength (V/m)
Amateur Radio	1.8 MHz–300 GHz	1,500	0.1*
AM Radio Broadcast	0.535–1.705	50,000	0.7*
FM Radio Broadcast	88–108	100,000	0.9
TV Channels 2–6	2, 3, 4: 54–72	100,000	0.9
	5 and 6: 76–88		
TV Channels 7–13	174–216	316,000	1.7
TV Channels 14–69	470–806	5,000,000	6.7

*Field strength may be greater if directional antennas are used.
 Source: Association for the Advancement of Medical Instrumentation, *Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical*, Technical Information Report AAMI TIR No. 18—1997.

important when a patient-care area lies in the path of transmitted signals.

- Some electronic medical equipment used to diagnose, treat, and create images produce useful electromagnetic energy essential to their operation. Such equipment should be separated from other communication or medical equipment that may be sensitive to radiated electromagnetic energy.
- Radiated emissions from wireless communication equipment such as cellular telephones may affect implanted medical devices such as pacemakers—even when the equipment is placed in the standby mode waiting for calls. Such wireless communication equipment should therefore be kept away from implanted medical devices.
- Facilities within sight of television, AM, and FM radio or other broadcast transmission towers may need more stringent EMI guidelines, including not allowing the location of diagnostic, treatment, and imaging equipment near windows or exterior walls adjacent to transmission towers. This precaution also applies to multi-story facilities next to buildings that have roof-top transmission antennas. It especially applies to floors within the medical facility that are at the same height as roof-top antennas.
- If the nearby roof-top antennas are operated by municipal agencies such as the local police and fire department, then negotiate with these agencies to lease space atop the healthcare facility. Relocating the antennas will enable the healthcare facility to control the direction of the radiated emissions to prevent them from passing through the facility. However, avoid placing such antennas next to sections of the same medical facility where sensitive electronic medical equipment may be used. Facility or maintenance engineering should keep records of all roof-top antennas, including EIRP (effective isotropic radiated power), frequencies, installation date, last maintenance data, contact person, owner, and purpose for antenna. Such records will enable better management of the facility's electromagnetic environment.
- The Emergency Care Research Institute (ECRI) recommends that “hospitals develop and implement a policy controlling the use of radio-frequency transmitting devices, not allowing the use of cellular phones and other transmitters in intensive and coronary care units and operating rooms, and prohibiting the use of cellular phones within a range of approximately one to three meters (about 3.3 to 9.8 feet) away from electronic medical devices.” The following communication equipment should therefore not be used in or installed near areas where patient monitors, treatment equipment, and patient-connected diagnostic equipment such as EEGs, ECGs, and EMGs (electromyographs) are being used:
 - cellular telephones
 - portable telephones

- hand-held walkie-talkies
- base station transmitters (table top and ceiling mounted)
- citizen's band radios
- amateur radios

- The electromagnetic spectrum within or near a facility continues to change. The FCC continually issues new frequency bands for wireless communication devices, and healthcare facilities install new wireless equipment. Therefore, the clinical engineering department should routinely monitor the electromagnetic spectrum within and near the outside of the facility and record changes.

Communicating EMC Procedures

- The best way to manage EMI problems is to increase the level of awareness among healthcare staff, visitors, and contractors who perform work in the facility. However, EMC procedures must be stated in moderate tones, neither too lenient nor too strict. For example, they should guide the facility in making intelligent decisions within a given physical and electrical environment instead of banning all emissions-producing equipment in all areas. On the other hand, they should always place patient safety first, instead of bending to the conveniences of visitors and staff.
- During the renovation and construction of facilities, facility engineers and maintenance staff should be responsible for issuing a special set of written guidelines to the construction manager as part of the official contract. The guidelines should regulate 1) the use of all hand-held wireless communication equipment and 2) the use of electrical construction equipment such as arc welders and reciprocating or rotary power tools within or near the outside of the facility.
- Before new or used medical equipment is placed into service, issue a statement to the users of the equipment describing the possible risks from EMI.
- Periodically issue an EMI newsletter among staff and other facilities within the same healthcare corporation. Or, make EMI a feature of an existing newsletter about safety in the healthcare facility.
- Inform companies who make regular deliveries to the facility not to operate vehicular or hand-held radio transmitters or cellular telephones when at the facility if the delivery area is adjacent to patient care areas and areas where imaging or radiology equipment is located.
- Operators of communication equipment may not be aware that medical equipment may be within signal range. Therefore, post signs throughout the facility to promote an awareness among end users of wireless communication equipment that communication signals may cause medical equipment to malfunction. Such signs should be posted at all entrances and exits to the facility, entrances and

exits to intermediate and critical-care areas, at the entrance to the cafeteria, communications, biomedical, and clinical engineering department, patient transport and maintenance elevators, loading docks, surgical suites, radiology and imaging areas, dialysis units, emergency rooms, and rooms adjacent to intermediate and critical care areas. In areas where the use of communication equipment is prohibited, post signs in conspicuous places and use a symbol meaning “not allowed,” as shown in Figure 3. Where wireless devices are permitted, a sign similar to Figure 4 should be posted. Additionally, devices that detect the use of cellular phones can be placed in critical areas or next to sensitive medical equipment. When a cellular phone is used next to such a device, it will sound an alert to inform the phone user and remotely inform hospital staff about the prohibited operation of the cellular phone. However, before installing and relying upon such a detection device, make sure it works in its intended electromagnetic environment.

Reporting EMI Problems

■ All malfunctions and discrepancies between clinical observation and readouts from medical equipment should be reported to the biomedical engineering department for evaluation, even if the malfunctions and discrepancies are only suspected. The biomedical department will then decide whether to report to U.S. Food and Drug Administration (FDA) through the MEDWATCH Program at 800-FDA-1088. Forms and instructions for reporting equipment malfunctions can be ordered from MEDWATCH or downloaded from the FDA Center for Devices and Radiological Health World Wide Web page at the following address:

<http://www.fda.gov/cdrh/manual/mdrman.html#appenda>

■ Malfunctions should also be reported to the manufacturer of the equipment, clearly identifying details of the malfunction that could help the manufacturer classify and better understand the problem. Finally, report equipment malfunctions to the AAMI (Association for the Advancement of Medical Instrumentation). Request that the AAMI discuss the malfunction in its next product-standard review meeting.

Getting Help

To increase the level of awareness about risks associated with EMI, establish procedures for exchanging information with other healthcare facilities, electric utilities, standards and professional organizations, and government agencies. Identify an EMC/EMI expert at the local utility who can conduct an electromagnetic energy site survey or troubleshoot an EMI problem. If the utility cannot do this, then have the utility recommend an EMC/EMI consultant. Facility, clinical, and biomedical engineers can help identify the source of



Figure 3. Sign Prohibiting the Use of Wireless Communication Devices

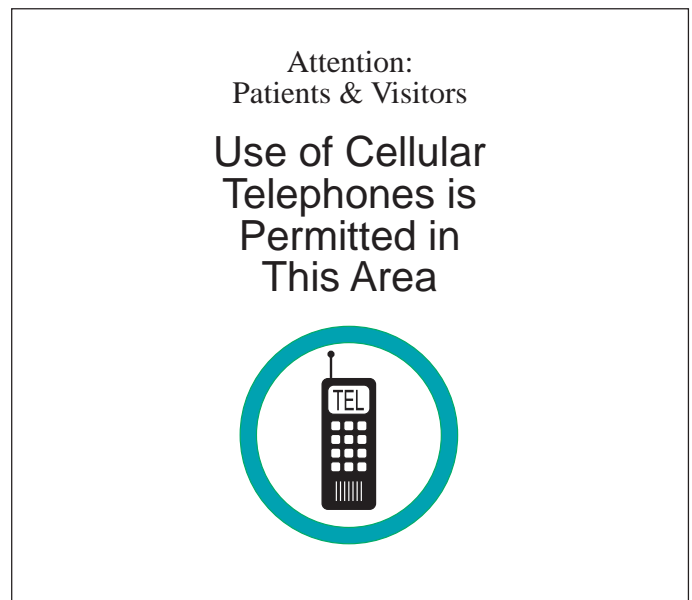


Figure 4. Sign Permitting the Use of Wireless Communication Devices

EMI causing medical equipment malfunctions. Finally, the FDA is a clearinghouse of information about EMI in healthcare facilities.

TO READ FURTHER

- *Power Quality for Healthcare*, BR-109172, White Plains, NY: EPRI Healthcare Initiative, 1997.
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- *IEEE Std 139-1988, Recommended Practice for the Measurement of Radio Frequency Emission from Industrial, Scientific, and Medical (ISM) Equipment Installed on User's Premises*, Institute of Electrical and Electronics Engineers, August 11, 1988.
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- Silberberg, Jeff, "Performance Degradation of Electronic Medical Devices Due to EMI," *Compliance Engineering* 10, pp. 25–39, 1993.
- *Technical Information Report: Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers, Part 1: Radiated Radio-Frequency Electromagnetic Energy*, AAMI TIR No. 18-1997, Association for the Advancement of Medical Instrumentation, Arlington, VA.

BENEFITS

- Reduce the number of medical equipment malfunctions by managing the use of equipment and devices that radiate emissions.
- Increase patient safety and equipment performance by identifying possible sources of emissions and mitigating their effects.

WHERE TO FIND HELP

- Your medical-equipment manufacturer or service company
- Your communication-equipment manufacturer or service company
- Your local electric utility
- The U.S. Food and Drug Administration
- Your biomedical engineering department

WHERE TO FIND HELP

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