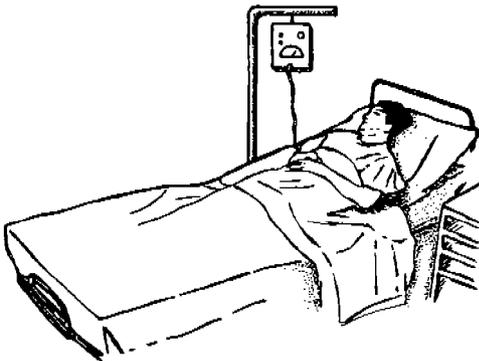




Just the Facts

24-004-0595

Electromagnetic Interference and Medical Equipment



- ◆ EMI
- ◆ Medical Devices
- ◆ Cellular Phones

Recent reports of deleterious effects on electronic medical devices, by electromagnetic energy, have caused concern among health care providers. One such report in Compliance Engineering (Reference 1) enumerates various problems with medical devices allegedly caused by conducted and radiated electromagnetic energy-as well as electrostatic discharge and static-magnetic fields. Electronic medical device problems attributed to electromagnetic interference (**EMI**) include device failure, loss of control, and erratic operation-any of which could circumstantially threaten someone's life.

Electronic medical devices are increasingly subjected to electromagnetic emissions from sources brought into the hospital environment such as cellular telephones, radios, and some paging systems. Both hospital staff and visitors have inadvertently caused **EMI** problems while using these sources within several meters of susceptible devices. For example, in Scandinavia a cellular telephone caused an infusion pump to switch to the maximum infusion rate while a potent drug was being administered [Reference 21].

Manufacturers of artificial pacemakers have long identified **EMI** susceptibility problems. They subject pacemakers to susceptibility tests to ensure that the device is adequately shielded against electromagnetic energy levels one would expect individuals to normally

encounter. These efforts have resulted in lifting all restrictions regarding proximity of pacemaker users to microwave ovens. Still, these individuals are restricted from certain areas of hospitals where electromagnetic fields could interfere with pacemaker operation-such as physical therapy clinics where radiofrequency (RF) diathermy is used, and **MRI** facilities.

Susceptibility testing of medical devices is not regulated in the United States, and manufacturers of medical devices are specifically exempted from compliance with the Federal Communications Commission (FCC) emission standards. Therefore, manufacturers have not been compelled to perform susceptibility tests-although many have voluntarily done so. Yet without standard test methods, medical device manufacturers may use minimal test criteria and reduce their production costs at the expense of susceptibility.

The majority of medical equipment now in use in hospitals throughout the United States has not been reviewed by the FDA for susceptibility. Consequently, much of the electronic medical equipment presently in use may either cause **EMI** or be susceptible to **EMI**. Recently, the Food and Drug Administration (FDA) has expanded their efforts to require susceptibility test data from manufacturers applying for FDA approval of certain medical devices.

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The American Society for Hospital Engineering has published several suggestions for reducing the risk of EM1 problems associated with electronic medical equipment (Reference 3). These suggestions are provided below:

- ◆ Verify that the FDA has examined the EMC test **data** from the manufacturer prior to acquiring new equipment.
- ◆ Keep potential sources of EM1 away from susceptible devices. Some hospitals have already restricted the use of cellular telephones and radio transmitters in rooms containing life-sustaining equipment (e.g., Intensive Care, Cardiology, Surgery, and Dialysis).
- ◆ If induced RF currents from unshielded cables are causing **EMI**, then rerouting the cables or substituting shielded cables may eliminate the problem.
- ◆ Analyze the building's electric wiring and grounding systems for conducted RF currents. Isolating susceptible devices from these systems is a potential solution to conducted interference problems.

We encourage all health care practitioners to report incidents of **suspected EMI** to their facility engineers. The FDA regulations require users of electronic medical equipment to report incidents of equipment failure that may have caused or contributed to a death or serious injury. The Radiofrequency Program of the U.S. Army Center for Health Promotion and Preventive Medicine is available to assist in identifying and solving possible EM1 problems.

References:

1. Silberberg, J.; Compliance Engineering, Vol. 10, No. 5. Fall 1993; 'Performance Degradation of Electronic Medical Devices Due to Electromagnetic Interference. "
2. Bostrum, U.; Clinical Engineering Update, No. 10, November 1991; "Interference from Mobile Telephones-a Challenge for Clinical Engineers. "
3. American Society for Hospital Engineering of the American Hospital Association. (August 1994). Healthcare Facilities Management Series. Electromagnetic Interference: Causes and Concerns in the Health Care Environment. Chicago, IL: **AHA**.