

ENGINEERING, FACILITIES, EQUIPMENT, AND PROCUREMENT

Biomedical Equipment Maintenance

Food and Drug Administration (FDA) Concerns on Electromagnetic Interference (EMI) with Medical Devices

The following article appeared in the Winter 1996 edition of *User Facility Reporting Bulletin* published by the Food and Drug Administration (FDA). The *Bulletin* can be accessed in .pdf format through the internet at:

<http://www.fda.gov/cdrh/fusenews.html>

Although this article is focused toward equipment users, it does contain some good information regarding background, FDA's EMI strategy, reporting requirements, and information sources.

FDA Concerned About Interference With Medical Devices

by Judith Kalson and Don Witters

Recent media reports have highlighted the possibility that cellular phones and other radio transmitters may interfere with the operation of cardiac pacemakers. FDA's Center for Devices and Radiological Health (CDRH) has been assessing this type of interference phenomenon (known as electromagnetic interference or EMI) for many years. Laboratory tests and reported incidents have shown that many different types of medical devices can be susceptible to EMI. In fact,

nearly any device or product that is electrically powered can be affected by some form of EMI.

The problem occurs when EMI disrupts the normal function of a medical device. Incident reports suggest that patient safety could be compromised if a critical device (such as a cardiac pacemaker) or device function is disturbed by radio signals (e.g., from radio or TV broadcasts or two-way radios), by AC power-conducted interference (e.g., surges or "brown outs"), or by electrostatic discharge (such as occurs when walking across carpet in a room with low humidity).

With the accelerating pace of technology, especially in communications and computers, there are now many sources of radio transmission in common use. At the same time, medical devices are becoming more sophisticated and performing more functions. Unfortunately, when a radio transmitter – such as a cellular phone or wireless computer link – gets too close to a sensitive medical device, there is a potential risk that EMI will cause serious consequences for patient safety and effective treatment.

When a device is immune to reactions with the types of signals in its use environment, it is said to be electromagnetically compatible (EMC). Even if devices are designed and tested for EMC, some interference problems might still occur. Unfortunately, EMC can be affected by many things, such as the frequency, power output, or distance from the radio transmitter. For example, as the distance from a radio transmitter decreases, the power intensity increases, and the likelihood of EMI increases. Further, since devices are themselves sources of signals, one device may affect another.

FDA scientists have many years of experience involving EMI with medical devices. They have developed a comprehensive strategy to focus attention and devise solutions for this problem. Much of the effort is directed toward raising awareness and understanding of the EMI phenomenon, since EMI is a complex problem that

involves both the medical device and the environment in which it is used. FDA's primary goal in the area of EMI is to minimize the risk of interactions by encouraging manufacturers to design protection into the devices; by raising awareness of EMI among all concerned (including the manufacturers of radios and other EMI sources such as AC-power utilities); and by working with industry toward assuring compatibility.

Patient and clinician problems associated with EMI can be minimized by considering the following points:

- Be aware that EMI can cause steady, momentary, or intermittent disruption of the performance of medical devices.
- Follow the recommendations of device manufacturers for avoiding EMI.
- Purchase equipment that conforms to EMC standards.
- Take steps to prevent known sources of interference (e.g., cellular phones, hand-held transceivers) from coming too close to patient monitors and other sensitive electronic medical devices.
- When an EMI problem is suspected, contact the device manufacturer for assistance. Local clinical engineers may also be able to assist in identifying and correcting the problem.
- Make a note for the record if you believe a problem is linked to interference from a recognizable source of EMI in the vicinity.¹

In recent months, FDA scientists have completed EMI testing of such devices as cardiac pacemakers, hearing aids, ventilators, and powered wheelchairs. We will continue to test medical devices and work with standards organizations and device manufacturers. However, we need your help in identifying medical devices that may have been

affected by EMI, leading to serious injury or death. Under the Medical Device Reporting regulation, instances of serious injury must be reported by the user facility to the manufacturer of the device, or to FDA if the manufacturer is not known. Instances of death must be reported to the device manufacturer, if known, and to FDA. EMI incidents that do not involve a death or serious injury may be voluntarily reported to FDA through the MedWatch program. For more information about EMI problems, contact the Division of Small Manufacturers Assistance at 1-800-638-2041, or consult the CDRH/EMC web page at:

<http://www.fda.gov/cdrh/emc/index.html>

Reference:

¹ Food and Drug Administration (1994). Electromagnetic Interference May Cause Problems with Some Medical Devices. FDA Medical Bulletin, 24, 2. Rockville, MD: Food and Drug Administration.

Judith Kalson is a nurse consultant and Don Witters is a biomedical engineer. Both are in CDRH's Office of Science and Technology and are members of the CDRH EMC Work Group that Mr. Witters chairs.

(AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

Quality Assurance

Safety Alert--Ventilators, Intensive Care, Neonatal/Pediatric, MDC 14361, Bear Cub 750vs Ventilators, Allied Healthcare Products, Inc.

Reference ECRI *Health Devices Alerts* Number 1997-A19, 9 May 1997, Accession No. A3250. ECRI reports the control and alarm setting potentiometers in these ventilators may experience instability. Allied Healthcare has received reports of control instability while setting the rate, inspiratory time, and low positive end-expiratory pressure/continuous positive airway pressure alarm. However, the firm believes all eight potentiometers in the above units are susceptible to this condition. Allied Healthcare states the performance of the affected ventilators will vary depending on the level of instability and the control being set. The manufacturer states that in all reported cases the instability manifested itself during control adjustment only and was apparent immediately. Allied Healthcare notified customers of this problem by an Urgent Medical Device Alert dated 10 March 1997. Using activities should verify receipt of the 10 March 1997 letter from Allied Healthcare. Identify any affected units in your inventory. Ensure all personnel at your facility who use these ventilators are aware of this problem. If any of the units in your inventory show signs of instability, contact Allied Healthcare at (800) 232-7633 in the US to arrange for repairs; customers outside the US should contact David Bernat, Product Manager, Allied Healthcare, at (909) 351-4809. The firm states that the ventilator will support the patient in accordance with the displayed settings. Allied Healthcare states that if your facility's ventilators are operating normally, no further action is required. For further information, contact Allied Healthcare at the above numbers. (AFMLO/FOM-E, Capt David Zemkosky, DSN 343-4028)

Medical Equipment Management

Shared Procurement Equipment Items Currently Available

AFMLL 04-97, Attachment 1, pages 1 and 2, contains a list of all current Shared Procurement contracts and optional contracts available through the Defense Personnel Support Center (DPSC). If you plan to order any of these items for your facility, use the specific ordering instructions and overall program guidance contained in AFMLL 04-96, pages CE-4 and CE-5. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

“Piggyback” Contracts Currently Available

AFMLL 16-96, Attachment 1, pages 4 and 5, contains a list of all current “piggyback” contracts currently available through DPSC. These contracts will allow facilities to “piggyback” requirements onto existing orders placed for specific quantities. Many of these contracts are designed to buy large quantities at reduced prices, and are written with the option of buying additional quantities at the same price. The list includes available quantities and “Order By” dates. To order, send your MILSTRIP requisitions to DPSC, and reference the contract number (from the listing) in the notes section. (AFMLO/FOM-P, Capt David Zemkosky, DSN 343-4028)

WILLIAM H. HILL
Deputy Chief, Air Force Medical Logistics Office