POTENTIAL INTERFERENCE WITH MEDICAL ELECTRONIC DEVICES*

RICHARD REIS, M.S., P.E.

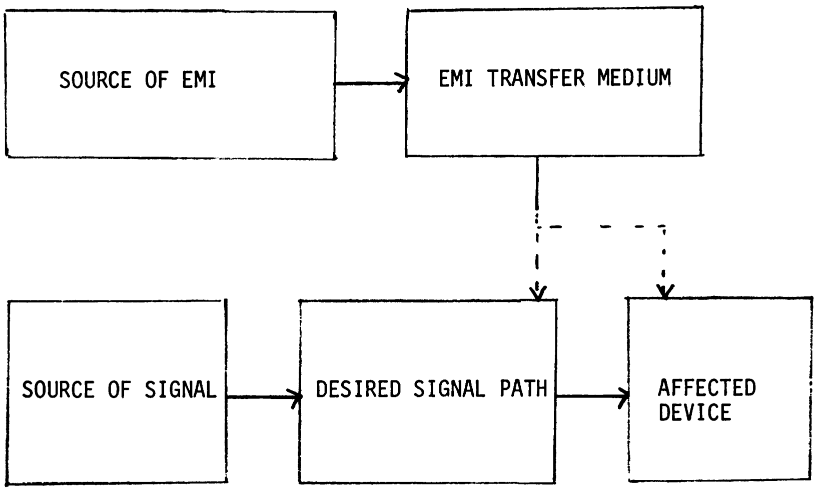
Biomedical Engineer
Bureau of Medical Devices
Food and Drug Administration
Silver Spring, Maryland

NONIONIZING electromagnetic radiation can adversely affect diagnostic and therapeutic medical devices that process bioelectric signals, transducer electrical signals, or radio telemetered signals. Frequencies of interfering radiation range from below 50 Hz. to beyond one gigahertz. This electronic "smog" may be sensed directly by the affected device; it may be demodulated and sensed. These effects are mitigated by limiting the level of emissions where medical devices are likely to be used and by decreasing the susceptibility of devices. An implantable artificial cardiac pacemaker is a well-known example of a device that can be sensitive to interference because of its widespread use and the publicly perceived dependence of pacemaker patients.

The bad news about the potential electromagnetic interference with medical electronic devices is that these devices appear to be more sensitive to electromagnetic waves than organisms. The good news is that the effects of electromagnetic interference are more easily detected and it is possible to make devices less sensitive to it.

Let us consider the mechanism of interference. The accompanying figure shows the general mechanism for interference entering a medical electronic device. The most susceptible types of devices are those that utilize low level electrical signals to gather diagnostic information or to perform a therapeutic function. Bioelectric sources, transducers, telemetry signals, and low level recordings are four areas where electromagnetic interference can distort essential device function. Examples of various devices and their effects are shown in Table I. With any type of medical device, the primary mechanism encountered is noise, distortion, and loss

*Presented as part of a *Symposium on Health Aspects of Nonionizing Radiation* sponsored by the Subcommittee on Public Health Aspects of Energy of Committee on Public Health of the New York Academy of Medicine and held at the Academy April 9 and 10, 1979.



General mechanism for interference entering a medical electronic device

of signal. In therapeutic devices function is lost because the signal is used to make therapeutic decisions. Based upon many reports of effects on medical devices, I would rank sources in decreasing order of importance as shown in Table II. The interference can be transferred through the subject, power lines, space, or other instruments.

Electrosurgical units use radiofrequency energy to cut and to control bleeding. The large amounts of energy they emit effectively prevent simultaneous electrocardiography. Ruggera and Segerson[1] measured electromagnetic fields as high as 1,000 v. per centimeter at 16 cm. from the operating probe. These signals diminish greatly with distance. Bochenko[2] investigated energy flow and found that power is drawn from an outlet to produce cutting and coagulation within the patient's tissues. Unfortunately, some of the radiofrequency energy reaches other medical devices through the patient, by power lines, and by radiation. Careful design can reduce the level of radiated and conducted energy.

Diathermy provides therapeutic heat to subcutaneous tissues,[3] but has been associated with dangerous interference and heating of cardiac pacemakers.[4] In a reported incident, an external pacemaker was inhibited by a fluoroscope.[5] Much of the interference is near field. In one case the magnetic field from an audible alarm speaker on a blood-pressure monitor activated a magnetic reed switch on a ventilator, and disrupted the normal ventilation cycle.[6]

TABLE I. SOURCES OF ELECTROMAGNETIC INTERFERENCE

Rank	*Description*	*Example(s)*
Decreasing importance		
1	Other medical devices	Electrosurgical units diathermy
2	Power lines	Device cords, etc.
3	General electric equipment	Motors, fluorescent lights
4	Communications	TV, FM, CB
5	Natural	Lightning, solar flares

Power lines interference is quite common. Huhta et al.[7] discuss how line frequency noise can enter an electrocardiograph and how to mitigate these effects. Kostinsky[8] reported that certain external pacemakers are sensitive to power-line interference conducted to the device by touching its front panel. Powered limb prostheses can be commanded by low level electromyographic signals. These signals can be easily overwhelmed by external interference.[9,10] It is also suspected that high tension power lines can disrupt normal operation of implanted cardiac pacemakers.[11]

Interference from electric equipment can take many forms. Electric motor brushes, antitheft devices, automotive ignition systems, and microwave ovens are potential offenders. Even an electric watch can interfere with a medical device.[12]

Communications can also interfere with medical device operation. Emergency mobile communication systems can require placement of transmitters close to sensitive electromedical equipment. An indirect mechanism was reported in which the sweep coil of a television set distorted an electrocardiogram.[13] The Environmental Protection Agency has investigated a case where an electronic thermometer was sensitive to a nearby FM station.[14] Vreeland et al.[15] studied the effects of broadcast stations upon cardiac pacemakers and recommended a susceptibility limit of 1 v./m. average and 1.5 v./m. peak.

Lightning is the significant source of natural interference. Because it is intermittent and intense, lightning is more of a problem from damage it can cause through power-line surges than for occasional interference.

Because of the problems of electromagnetic interference, the Bureau of Medical Devices is developing guidelines for medical device susceptibility. To define the problem, Jenkins et al.[16] surveyed radiation levels

TABLE II. TYPES AND EXAMPLES OF EMI SUSCEPTIBLE SIGNALS USED IN MEDICAL EQUIPMENT

Signal type	Examples of susceptible devices (effect) Diagnostic	Therapeutic
Electro-physiologic	Electrocardiograph (noise, distortion)	R-Wave inhibitable Pacemaker (inhibition, competitive pacing)
Transducer	Blood pressure (noise, distortion)	Respirator (loss of control)
Telemetered	ECG ward monitor	Programmable pacemaker (''phantom'' programming)
Recorder	Heart rhythm monitor (noise, distortion, and loss of signal)	

present in various medical facilities, and Hoff[17] took this study one step further by suggesting standards and explaining their rationale. The Food and Drug Administration expects to publish the standard as a formal guideline.

Pacemakers are the devices most frequently associated with dangers from electromagnetic interference. Actual or potential pacemaker interference has been reported from antitheft devices, microwave ovens, microwave search radars, CB radios, electric motors, ignition systems, and arc welders. Concern about the health hazards from electromagnetic interference with pacemakers is only partially justified because few pacemaker patients are totally dependent upon their pacemakers.

Pacemakers work by providing an electrical stimulating pulse directly to the heart about 70 times per minute. Pacemakers are generally installed just below the skin with a lead directed to the heart through a vein. In a minority of cases the lead may be sutured to the epicardium or may be screwed into the epicardium using a corkscrew electrode.

Interference can enter directly into a pacemaker circuit, but interference is more likely to enter by way of the pacemaker lead which can act as an antenna. In terms of interference susceptibility, there are two principal types of pacemaker electrode leads. The bipolar lead places both the stimulating electrode and the electrical return electrodes on or in the heart. These are less susceptible because the spacing of the electrodes and, thus, the effective antenna length are shorter, and the electrodes are better shielded by the body.

In the case of the unipolar lead, the pacemaker case acts as the return electrode. Here the spacing between the leads is much greater, the effective antenna length is longer, and therefore the susceptibility is greater. Because unipolar systems possess some medical advantages, they are used frequently.

Several different types of pacemakers are in use. About 90% of pacers are of the demand type, capable of sensing the R-wave portion of the individual's interior electrocardiogram through the pacing lead. When the pacemaker senses the R-wave which coincides with each heartbeat, it withholds or inhibits the output pulse. Unfortunately, some types of electromagnetic interference can appear to the pacemaker as a series of R-waves and thus falsely inhibit the pacemaker. Because these pacemakers are usually implanted in people who have some sort of underlying bradyarrhythmia, inhibition of the pacemaker would probably cause the patient's slower underlying rhythm to take over. If this happens, the symptoms the patient had before pacemaker implantation would return: dizziness, fainting, and nausea. If inhibition occurs in a totally dependent patient, death could ensue.

Because radiofrequency interference with cardiac pacemakers has been identified as a potential hazard for many years, pacemakers now incorporate metallic enclosures, radiofrequency blocking filters, and band-pass filters to mitigate against this hazard. In addition, since many potential sources of electromagnetic interference lie within the band pass limits (about 6 to 80 Hz.), the pacemaker incorporates a feature that converts the pacemaker to a fixed rate mode when continuous interference is present. In this mode the pacemaker emits pulses regardless of cardiac activity. This, in turn, results in less efficient competitive pacing if natural pacing is also present. This is generally considered less dangerous than inhibition because the patient receives continuous cardiac support.

To investigate a reported incident concerning a pacemaker and a CB radio, the Federal Communications Commission and the Food and Drug Administration's Bureau of Medical Devices recently conducted tests at the Commission's laboratory in Laurel, Md. We placed the pacemaker in a saline solution in a foam tank and irradiated it at 27 MHz. at 3 v. per meter. Three modulation schemes were used. Forty millisecond bursts were transmitted at a rate of two pulses per second to attempt to inhibit the pacemaker. Voice-modulated single side-band was also used to attempt inhibition. In other test runs continuous wave modulation was applied to attempt to revert the pacemaker to fixed-rate operation. Although we did not cause any discrete effects, we did note a shift in pacemaker threshold. This may indicate that the pacemaker would be inhibited at much higher field intensities.

Finally, work done at the Georgia Institute of Technology since 1973 shows that while great variability exists in the level of susceptibility from pacemaker to pacemaker, it does appear that more recent pacemakers are less susceptible to interference.[18]

REFERENCES

1. Ruggera, P. S. and Segerson, D. A.: Quantitative radiation measurements near electrosurgical units. *AAMI 12th Annual Meeting,* March 13-17, 1977.
2. Bochenko, W. J.: A prospective review of electrosurgical units in the operating room. *AAMI 12th Annual Meeting,* March 13-17, 1977.
3. Guy, A. W., Lehmann, J. F., and Stonebridge, J. B.: Therapeutic application of electromagnetic power. *Proc. I.E.E.E. 62:*55-75.
4. McRee, D. I.: Potential microwave injuries in clinical medicine. *Ann. Rev. Med. 27:*109-15, 1976.
5. Leeds, C. J., Akhtar, M., and Damato, A.: Flouroscope-generated electromagnetic interference in external demand pacemakers. *Circulation 55:*548-50, 1977.
6. Lehnert, B. E.: A hazard of magnetic interference with normal cycling of the Bourns infant ventilator (letter). *Resp. Care 21:*576-78, 1976.
7. Huhta, J. C. and Webster, J. G.: 60-Hz interference in electrocardiography. *I.E.E.E. Trans. Bio-Med. Eng. BME-20:*91-101, 1973.
8. Kostinsky, H.: Hazards in the use of external pacemakers. *J. Electrocard. 11:* 306, 1978.
9. Childress, D. S.: Powered limb prostheses: Their clinical significance. *I.E.E.E. Trans. Bio-Med. Eng. BME-20:*200-07, 1973.
10. Kreifeldt, J. G. and Yao, S.: A signal to noise investigation of nonlinear electromyographic processors. *I.E.E.E. Trans. Bio-Med. Eng. BME-21:*298-308, 1974.
11. Bridges, J. E., Frazier, M. J., and Hauser, R. G.: *The Effect of 60 Hertz Electric Fields and Currents on Implanted Cardiac Pacemakers.* IIT Res. Inst. Prog. No. E 8167, October 1977.
12. Lesch, M. and Greene, H. L.: Electrocardiographic artifact due to malfunction of electronic watch. *J.A.M.A. 228:* 26, 1974.
13. Lichstein, E. and Gupta, P. K.: Television set distortion of an electrocardiogram. *J.A.M.A. 223:*1285, 1973.
14. Tell, R. A., Nelson, J. C., and Janes, D. E.: An Observation of Radiofrequency Interference to an Electronic Thermometer. Unpublished report, Environmental Protection Agency, March 14, 1975.
15. Vreeland, R. W., Shepard, M. D., and Hutchenson, M. D.: The effects of FM and TV broadcast stations upon cardiac pacemakers. *I.E.E.E. Electromagnetic Compatability Symp. Rec.* 74 Ch 0803-7 EMC: 99-106, July 1974.
16. Jenkins, B. M., Williamson, F. R., Sentz, D. R., and Toler, J. C.: Survey of Electromagnetic Environments in Major Medical Facilities. Ga. Inst. Tech. Engr. Exp. Sta. Rep. #1, Proj. E-200-904.
17. Hoff, R. J.: An EMC standard for medical devices. *Electromagnetic Compatibility Symposium.* Montreux, Switzerland, June 1971.
18. Denny. H., Susceptibility of cardiac pacemakers (unpublished presentation). *Workshop on Electromagnetic Compatibility, Nat. Bur. Std.,* November 2-3, 1978.