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Electromagnetic Interference with Implanted Medical Devices: An Update

Technical Update - EMF Health Studies

Electric and magnetic fields (EMF) and contact currents at both power and radio frequencies can interfere with the functioning of implanted medical electronic devices. The potential for electromagnetic interference (EMI) with implanted cardiac pacemakers has been a concern since their advent in 1958. Pacemakers and implanted cardiac defibrillators are now commonplace, and a number of other implanted devices are in use or in development to treat a variety of medical conditions. Medical and technological advances have made a quick return to work possible for people receiving these devices. In many workplaces, however, an increasingly complex electromagnetic environment has led to greater opportunity for EMI. In the electric power industry, workers may also be exposed to levels of EMF that exceed interference thresholds.

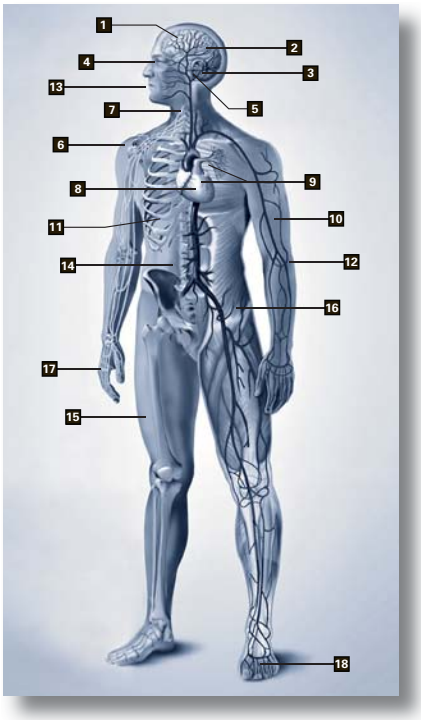

Figure 1. Sites for implantable and wearable medical devices subject to electromagnetic interference. 1, brain-machine interface; 2, deep brain stimulator, 3, implantable hearing aid; 4, synthetic retina; 5, cochlear implant; 6, assistive exoskeleton; 7, vagus nerve stimulator; 8, ventricular assist device; 9, implantable cardiac defibrillator/pacemaker; 10, radio-frequency identification tag; 11, respiratory pacemaker/stimulator; 12, bionic arm; 13, oral control interface; 14, implantable drug delivery system; 15, bionic leg; 16, sacral nerve stimulator; 17, artificial hand; 18, artificial foot. Modified from: U.S. Food and Drug Administration 2007, www.fda.gov/cber/inside/annrpt.htm

Although implanted device malfunctioning due to EMI can lead to illness, injury, and even death, effective management can minimize the risk of interference. Sound management rests on both characterization of workplace exposures and knowledge about the types of implanted devices workers may have. Building on a 2001 EPRI technical brief and 1997 and 2004 technical reports that described device operation and discussed potential interference with cardiac pacemakers and defibrillators, this update describes more recently developed classes of devices and those that are in development. The update also discusses potential sources of interference and the effects of interference on the functioning of implanted devices. A concluding section recommends future work to ensure the electromagnetic compatibility of sources and devices.

Implantable Devices

Currently, nearly twenty either totally implantable systems or systems with implantable sensors or actuators exist that are potentially susceptible to electromagnetic interference. Most, if not all, of these devices could appear in the workplace and thus are likely to encounter EMI sources producing fields whose strengths may exceed the values to which the devices were originally designed and tested. Devices may be implanted in a number of sites in the body, as shown in Figure 1.

Brain-Machine Interface

The brain-machine interface (also called the brain-computer interface or direct neural interface) is a device designed to allow physically disabled persons to directly communicate, by thought alone, with external computers. The brain-machine interface provides a means for people with neurodegenerative diseases, brain and spinal injuries, and other severely disabling conditions not only to communicate, but also to control external devices; for example, wheelchairs and prostheses.

One type of brain-machine interface involves surgical implantation of electrodes on the cerebral cortex of the brain. Electrical signals from neural activity in the brain are detected by the electrodes and sent to a computer, which analyzes the signals and translates them into physical actions. Clinical trials with this type of implantable device are under way. However, current research is exploring a second approach. The new approach is non-invasive, using external electrodes placed on the scalp instead of electrodes placed directly on the cerebral cortex.

Brain-Healing Stimulator

Brain-healing stimulators use electric current to stimulate neural repair in patients with

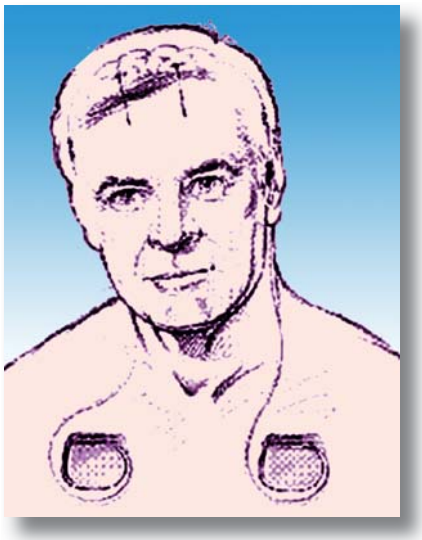

Figure 2. Deep brain stimulator. Electrical impulses from neurostimulators implanted near the collar bone move along extension wires to leads implanted in the brain. Modified from: U.S. Food and Drug Administration 2004, www.fda.gov/cdrh/annual/fy2003/ode/part1.html

chronic brain injury or chronic pain and to treat depression and other disorders. Brain stimulation may involve any of several techniques. In deep brain stimulation (described next), electrodes are surgically implanted deep inside the brain; a less invasive technique involves placing electrodes just under the skull. Noninvasive techniques use electrodes placed on the scalp or a time-varying magnetic field applied to the head. All of these processes generate micro-currents in the brain that stimulate healing. Brain-healing stimulation differs from deep brain stimulation for treating various brain and psychiatric disorders in that stimulus currents are significantly lower and are not adjusted on the basis of subjective behavioral analysis. A pre-marketing approval request for brain-healing stimulators has been submitted to the U.S. Food and Drug Administration (FDA).

Deep Brain Stimulator

This surgically implanted device, shown in Figure 2, is designed to treat Parkinson disease, dystonia (impairment of muscular tone), epilepsy, depression, and essential tremor, a common neurological movement disorder.

The deep brain stimulator works by electrically stimulating targeted areas in the brain, blocking abnormal nerve signals that cause symptoms. The device consists of three components: a lead, or electrode; an extension; and a battery-operated neurostimulator. The lead is a thin, insulated wire inserted through a small opening in the skull and implanted in the brain, with its tip positioned within the targeted area. From the lead, the extension passes under the skin of the head, neck, and shoulder to connect to the neurostimulator, which is usually implanted under the skin near the collarbone. Electrical impulses from the neurostimulator move along the extension wire and the lead into the brain. Deep brain stimulators are currently in use for Parkinson disease and under investigation for other applications.

Synthetic Retina

Synthetic retinas have been developed to restore limited vision to people with age-related macular degeneration and other diseases that cause vision loss by destroying photoreceptor cells in the retina at the back of the eye.

In normal vision, retinal photoreceptor cells convert light entering the eye into electrical impulses, which travel through the optic nerve to the brain for interpretation into visual images. The artificial retina device mimics this process. Using a miniature camera mounted in a pair of eyeglasses to capture images, the device wirelessly sends image data to a microprocessor worn on a belt. The microprocessor converts the data into electronic signals and sends them to a transmitter mounted on the glasses. From the transmitter, the signals are wirelessly sent to an implanted receiver that relays them through a tiny cable to a microelectrode array implanted on the retina. Electrical signals from the array are transmitted to healthy photoreceptor cells remaining in the retina and sent as impulses to the brain via the optic nerve. The brain perceives patterns of light and dark spots corresponding to the electrodes stimulated in the array, and the patient learns to interpret these patterns.

Synthetic retinas are in clinical trials or under development in the United States and several other countries. A model that has been implanted in patients provides rudimentary vision using a 16-electrode array and a receiver implanted behind the ear. A second model with a 60-electrode array and a much smaller receiver implanted around the eye is in clinical trials, and a less invasive model with higher resolution is under development.

Implantable Hearing Aid

External hearing aids direct amplified sound through the auditory canal to the eardrum, which transfers sound vibrations to the inner ear via a set of tiny bones (ossicles) located in the middle ear. Implantable hearing aids send sound vibrations to the inner ear by a more direct route.

Implantable hearing aids consist of a microphone, amplifier, battery, and transducer, some or all of which are implanted either behind the ear or in the middle ear. There are two types of implantable hearing devices, designed to treat different types of hearing loss. Middle ear implants are used to treat sensorineural hearing loss due to damage to the inner ear or to nerves connecting the inner ear to the brain. This type of implant is attached to one of the bones in the middle ear and strengthens sound vibrations by moving these bones. Bone-anchored hearing aids, on the other hand, are used to treat conductive hearing loss, which occurs when sound is not conducted efficiently through the auditory canal to the inner ear. This type of device is attached to the bone behind the ear and transmits sound vibrations to the inner ear through the skull rather than through the middle ear. Both middle ear implants and bone-anchored hearing aids are currently in use.

Cochlear Implant

Cochlear implants differ from implantable hearing aids in that they provide direct electrical stimulation to the auditory nerve. These implants are particularly suited for patients with sensorineural hearing loss involving damage to the hair cells of the cochlea of the inner ear. These cells are the sensors that convert mechanical sound energy into electrical neural signals for transmission to the brain via the auditory nerve.

As Figure 3 illustrates, the cochlear implant device is a combination of an externally worn microphone, sound processor, and transmitter, a receiver implanted under the skin behind the ear, and an electrode array implanted in the cochlea. Signals from the external sound processor are inductively coupled to the internal receiver and then distributed as electrical impulses along the electrode array. From the electrodes, impulses are transferred to auditory nerve endings distributed along the cochlea and sent on to the brain, where they are perceived as sound. Because sounds received through a cochlear implant differ from normally heard sounds, recipients must learn to interpret them. This device is currently marketed by several companies. Fully implantable devices are in development.

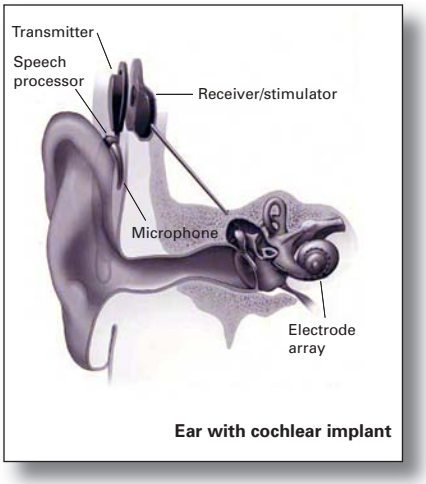

Figure 3. Ear with cochlear implant. In a cochlear implant, an external sound processor converts sound picked up by a microphone into signals that are transmitted to an internal receiver. The receiver sends electrical impulses to an electrode array implanted in the cochlea of the inner ear. Source: Medical Illustrations by NIH, Medical Arts & Photography Branch.

Vagus Nerve Stimulator

This device stimulates the vagus nerve, which extends from the brainstem to the abdomen on each side of the body and affects the functioning of the heart, gastrointestinal system, and other organ systems. The device consists of an electrode array that encircles the left vagus nerve in the neck, an electronic stimulator/battery pack typically implanted under the skin of the chest, and a lead from the stimulator to the electrode array. The stimulator sends electrical pulses through the vagus nerve into the brain. Because vagus nerve stimulation alters activity in areas of the brain that appear to be related to both depression and epilepsy, the stimulator has been used in attempts to manage these conditions. The exact mechanism of therapy is not well understood. Currently, vagus nerve stimulation is used to treat epilepsy when other methods fail to help and to treat severe or chronic depression. Clinical trials are under way to test the device for treating obesity.

Cardiac Pacemaker

Cardiac pacemakers monitor heart rhythm and provide electrical stimulation to trigger contraction of heart muscle during bradycardia, or slow heart rate, arising from several clinical conditions. Pacemakers may also be used to treat some cases of myocardial infarction.

There are several types of pacemakers. Single-chamber (monopolar) pacemakers have a single lead placed in the right atrium of the heart; dual-chamber (bipolar) devices have two leads, one placed in the right atrium and the other in the right ventricle. The pulse generator, leads, and electrodes of a dual-chamber pacemaker are shown in figure 4B. Pacemakers with greater complexity have evolved from single- and dual-chamber devices; for example, cardiac resynchronization therapy (biventricular) pacemakers. These devices have three leads: one in the right atrium and one in each ventricle for synchronized ventricular contractions. Modern biventricular pacemakers can also work as implantable cardioverter defibrillators (ICDs, described next). Devices with more highly sophisticated functioning and increased clinical applicability are in development.

Implantable Cardioverter Defibrillator

The implantable cardioverter defibrillator is a device that monitors cardiac electrical activity and automatically delivers an electrical stimulus to the heart if it detects arrhythmias, or abnormal rhythms. ICDs are used to treat ventricular tachycardia (excessively rapid beating of the ventricles of the heart) or ventricular fibrillation (continuous uncoordinated contraction of ventricular muscle); if either of these conditions is untreated, the heart may be unable to pump blood. These devices usually include standard cardiac pacemaker function.

The battery/pulse generator of an ICD is implanted under the skin near the shoulder or in the abdomen. As shown in Figure 4A, leads from the pulse generator are threaded through veins leading to the heart, with electrodes at the ends of the leads placed within the heart. Signals from the electrodes trigger different responses from the pulse generator. In its pacemaker capacity, the pulse generator delivers very small electrical pulses to correct bradycardia. Either electrical pulses or a mild shock may be delivered for ventricular tachycardia, depending on its severity, whereas a powerful shock is delivered for ventricular fibrillation. Delivery of an electrical shock interrupts abnormal cardiac rhythm, allowing more normal rhythm and electrical activity to resume (cardioversion). Many people have

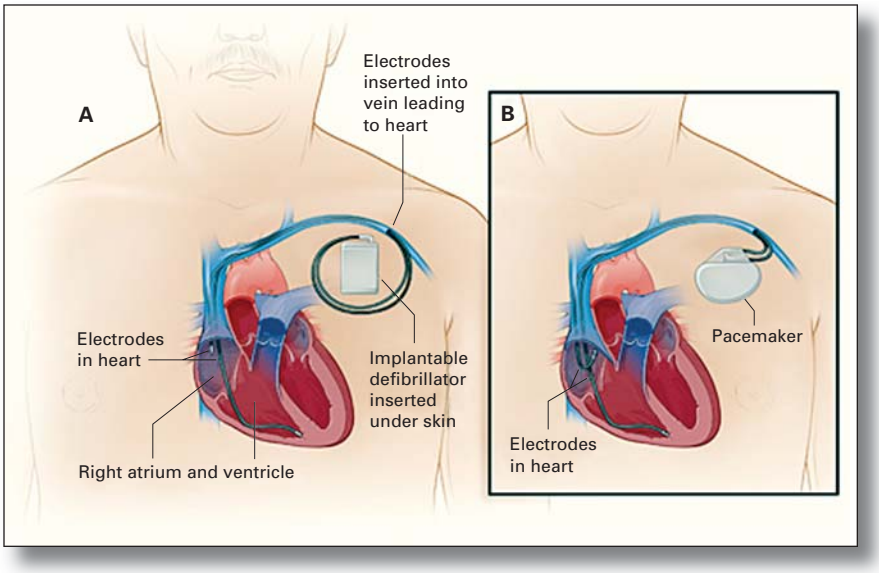

Figure 4. Implanted cardioverter defibrillator (A) and cardiac pacemaker (B). These devices, implanted in the chest, connect to leads with electrodes at the ends implanted in the right atrium and ventricle of the heart. Source: National Heart, Lung, and Blood Institute 2007.

ICDs; Vice President Cheney is probably the most famous recipient and has received multiple devices.

Ventricular Assist Device

A ventricular assist device (VAD) may be implanted within the thorax to assist the heart in its pumping function during heart failure. Different types of VADs assist either the left or right ventricle of the heart, or both; the most common type is the left ventricular assist device. Surgically connected between the pulmonary vein and the aorta, this device may be either electrically or pneumatically powered by an external system. Most often, the device is used for temporary function to allow healing of injured or infected cardiac muscle. Some patients have had devices for up to five years, with sufficient cardiac function restored to allow them to return to work. Thus, portable energy sources have been developed, including wearable battery packs that allow patients to resume normal activities.

For short-term applications the VAD pump may be located outside the body, but for long-term applications the pump is implanted, usually under the skin near the stomach; however, the energy source remains outside the body. Efforts are under way to develop a totally implantable device, with energy inductively coupled from an outside energy source (fixed to a belt) to operate the pump.

RFID Tag

Radio-frequency identification (RFID) tags are small electronic devices that contain an integrated circuit, or microchip, and a coil of wire that receives and modulates an interrogating electromagnetic field. Tags may be active or passive (that is, battery-powered or not), and they may be attachable, wearable, or implantable. Implantable RFID tags, which are about the size of a grain of rice, are passive tags injected just under the skin with a hypodermic needle. To prevent migration once implanted, the tags are encased in a glass capsule whose surface has been treated to encourage overgrowth of surrounding tissue.

Information stored in the microchip in a passive RFID tag can be read at distances of 1–10 feet by a hand-held or wall-mounted RFID reader. Although different types of readers operate according to different principles, those that scan implantable tags use inductive coupling: a coil in the reader generates a time-varying magnetic field that couples to the coil in the tag, inducing a minute electrical current that provides enough power for the tag to modulate the magnetic field. The modulated signal transmits a unique identification number that can be used for various purposes, such as accessing personal health records in a password-protected database or verifying identities for entry into high-security areas.

RFID tags are rapidly becoming ubiquitous. Early forms of attachable tags were used to identify cattle in lieu of branding; applications rapidly expanded into pet identification, fish and game tracking, cargo tracking, hospital equipment and merchandise inventory control, automated toll collection, passport verification, and employee access ID verification. In 2004 the FDA approved RFID tags for implantation in people. Approximately 2000 people worldwide, according to RFID tag producer VeriChip Corporation, have had implants, and more are expected to have them pending the outcome of studies currently under way. It is very likely that implanted RFID tags will soon be present in the general working population—although serious concerns about privacy have been raised.

Respiratory Pacemaker

The respiratory, or diaphragmatic, pacemaker is used to electrically stimulate contraction of the diaphragm in patients with respiratory insufficiency who would otherwise require mechanical ventilation. Typically used in cases of high spinal cord injury and in patients with neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS), the respiratory pacemaker is similar to other neurostimulation devices. The device has four electrodes that are laparascopically implanted either directly in the muscle of the diaphragm or in the phrenic nerve, which innervates the diaphragm and causes it to contract so that

inhalation can occur (exhalation occurs when the diaphragm relaxes). Leads under the skin connect the electrodes to a pulse generator that, owing to a relatively high energy demand, is typically located externally to permit frequent battery replacement. The pulse generator regulates electrical stimulation to produce diaphragmatic ventilation at rates based on the lung function of each patient. Because the respiratory pacemaker has limited clinical applications at present, there is very little likelihood of its appearance in the workplace.

Capsule Endoscopy

Capsule endoscopy is a noninvasive, pain-free procedure that uses a miniature camera inside a large but swallowable capsule to photograph the esophagus and small intestine. In addition to a camera, the capsule contains light-emitting diodes, a transmitter, and batteries. As the capsule passes through the gastrointestinal tract, its diodes flash to capture images at a rate of 1–4 times per second. The images are transmitted via sensors with wire leads to a recorder worn on a belt around the waist. The disposable pill-camera is propelled through the digestive tract by normal peristaltic action and passed from the body during normal excretion. The belt is returned to the physician's office for review of the images. The device is currently approved for imaging the upper portion of the intestine but is not yet approved as an alternative to colonoscopy for the lower portion.

A patient undergoing capsule endoscopy can return to work during passage of the capsule through the body, which takes 12–24 hours. The manufacturer of the first version of the device to be marketed (Given Imaging Ltd.) reports that over half a million people have undergone the procedure; thus, the capsules are very likely to turn up in workplace environments.

Implantable Drug Pump

The implantable drug pump is a drug delivery system that has a medication reservoir, battery, pump, and controller to deliver medication directly to a target region in the body. Drug delivery is controlled by an external transmitter or by an external or implantable controller that is preset at installation. The device may be surgically implanted near the organ where the therapy is to be applied or in an area remote from the target organ, with a drug delivery tube connecting the reservoir/controller and the target site. In one system used to manage chronic back pain, a pump surgically placed in the abdominal area is connected to a catheter inserted into either the sac of cerebrospinal fluid surrounding the spinal cord or the spinal canal just outside the sac of fluid (the epidural space). A catheter in the epidural space is usually reserved for patients with pain from terminal cancer.

Multiple variations of implantable drug delivery systems are in clinical use for pain management. Clinical trials for other uses, including targeted delivery of chemotherapy, are under way. A variation of the implantable drug delivery pump, the external wearable pump, is very likely to be found in the workplace among employees with diabetes. The pump delivers a steady flow of insulin throughout the day via a catheter with a needle at its tip that is inserted into the fatty layer of the abdomen. Trials are currently in progress to test an implantable glucose sensor to control the external pump.

Sacral/Spinal Nerve Stimulator

Implantable devices that electrically stimulate the spinal cord, the sacral nerve, or other large sensory nerves are frequently used for pain management and are very likely to be found in the working population. These devices generate an electrical stimulus that, for some types of pain, masks or blocks pain signals. A nerve stimulator consists of an internal or external, programmable pulse generator and battery housed in a single package, leads connecting the pulse generator to one or more electrodes placed within the body, and a programmable external controller with limited adjustment for users.

Sacral nerve stimulation attempts to correct multiple body malfunctions, including poor bladder or bowel control, and to manage pain. Spinal cord stimulation has been used for chronic back or leg pain following lower back surgery, pain due to nerve damage, and intractable angina (acute chest pain resulting from insufficient blood flow to cardiac muscle). Nerve stimulation at the same nerve and location can be helpful for different conditions owing to the presence of different types of nerve fibers in the same nerve bundle and to the colocation of nerves transmitting impulses to and from the central nervous system in the bundle. Both stimulus levels and frequency are heuristically adjusted to elicit the desired physiologic response.

External Devices

Although they are outside of the realm of implantable medical devices, a whole new class of prosthetic devices is worthy of mention. These devices are susceptible to electromagnetic interference, which can lead to potentially significant consequences. The devices typically sense either neural or muscular activity and respond appropriately to assist or enable movement. Among them are the oral control interface and intelligent prosthetic devices.

Oral Control Interface

The oral control interface is a dental prosthesis that wirelessly controls everyday electronic and mechanical equipment, such as wheelchairs, appliances, telephones, and computers. One such device has a battery-operated oral appliance, worn unobtrusively on the roof of the mouth, with nine pressure-sensitive keys activated by the tongue. The ap-

pliance transmits radio-frequency signals to a nearby receiver and control system that translates the signals into commands. The device provides mobility and functionality to quadriplegics and may also serve as a nurse or attendant call button. Although oral control interfaces are in limited use in educational and occupational settings, they may appear in many nonmedical environments.

Intelligent Prosthetic Devices

Prosthetic devices have been developed that can sense either motion of partial limbs, electrical activity associated with muscle movement, motor nerve signals, or a combination of these to provide ever more "biologic" movement assistance. These intelligent prostheses include artificial legs, feet, arms, and hands and powered exoskeletons, robotic systems that can dramatically augment a person's physical abilities. The number of users of these devices is currently in the thousands and is rapidly increasing.

One exoskeleton-like suit already on the market contains actuators, an energy backpack with rechargeable batteries, and advanced motion sensors. The suit, designed for use in patients with lower-extremity paralysis or muscle weakness, requires that the user have full functionality and strength in the upper body and extremities in order to maintain balance and achieve adequate control. Fabricated with advanced control algorithms and advanced composite materials, the device is partially concealed under the user's clothing. Walking is achieved with the assistance of crutches, and the suit's contribution to movement is controlled by upper body movements and by changes in the center of gravity.

Electromagnetic Interference

Effects of Interference

EMI can produce various types of malfunctions in medical devices:

- Abnormal or undesired functionality. In implantable drug delivery systems, EMI may lead to a loss of preprogrammed setpoints of operation, resulting in either over- or understimulation of drug delivery. In other types of devices, EMI may confuse the device's normal sensing of physiologic signals, either preventing it from sensing the need for therapy (as in pacemakers) or confusing it such that it delivers inappropriate therapy (as in defibrillators).
- Inhibited functionality. EMI may prevent a device from sensing normal command inputs. For example, commands from oral prosthetic devices for controlling wheelchairs may be blocked, preventing normal control of chair functioning.
- Device failure. EMI may cause excess device stress that results in electronic component failure, necessitating surgical replacement of the device. Alternatively, a device may reset into an inappropriate mode, resulting in either failure of therapeutic delivery or altered operation that compromises battery life and necessitates early surgical replacement.

Although standards exist that provide for testing of medical devices for these types of failures, all require only laboratory testing of uninstalled devices. Experimental protocols cannot adequately address in vivo conditions. Furthermore, the standards cannot anticipate all possible forms and levels of EMI that a patient with an implanted device may encounter. Investigations of abnormal behavior or failure of medical devices are frequently unable to determine causality with any degree of certainty—especially when devices are deliberately designed with fail-safe resets that restore functionality after a temporary fault condition.

U.S. FDA regulations require a failure mode effects analysis during a device design cycle. The device manufacturer must to try to anticipate the possible manners in which a device may fail and the probability and consequences of each possible type of failure; in addition, the manufacturer must determine appropriate mitigation measures. Most manufacturers believe that conformity to compliance testing standards provides an adequately reduced risk of interference with device operation and assume that precautionary warnings (labeling) complete the mitigation of risks or consequences. However, patients, employers, and others may not be able to anticipate changes in EMI environments or the movement of medical devices into those environments that existing standards do not currently address.

Sources of Interference

Previous generations of medical devices were most likely to encounter EMI from sources operating in the extremely low frequency range (3–3000 Hz), especially the power frequency (50–60 Hz). During the last decade, however, radio-frequency (RF) sources have proliferated. The greatest risk of EMI from RF sources most likely comes from cellular telephones and other wireless communications equipment that uses multiple modulation modalities and a growing portion of the frequency spectrum. Communication devices operating at radio frequencies can also produce potentially interfering signals in the extremely low frequency range. In addition to cell phones, wireless Internet equipment, wireless headsets, and personal area network equipment, sources of RF interference in public environments include antitheft devices in consumer goods, RFID interrogation systems, and security systems. In electric power company environments, additional RF sources include paging, point-to-point microwave, two-way radio, and power line carrier. Electric power company workers may also encounter power-frequency electric and magnetic field strengths exceeding limits in current electromagnetic compatibility standards.

The spectral content of modulation used for wireless voice and data communication and in carrier multiplexing techniques often overlaps the frequency range of biologic signals monitored by implanted medical devices to determine appropriate functionality. As the complexity of these devices increases, the failure modes that may be induced by false signals will need to be carefully examined. Neural signal amplitudes are extremely small, making susceptibility to interference with devices that detect them even more likely, either by confusion or amplitude masking. As implantable device technology advances, enhanced device intelligence will be necessary to prevent inappropriate operation due to interfering signals and to control types of electromagnetic communication modalities to reduce the risks of interference.

Conclusion

In 1994 Jeffrey Silberberg of the U.S. FDA's Center for Devices and Radiological Health prepared a report titled *Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations*. All of the issues cited in the report remain issues today. In occupational settings, the importance of these issues is magnified by the increasing likelihood of implanted medical device use among a workforce that includes older, more experienced workers who may want or need to work to a later age than in the past.

Interference issues are now exacerbated by the exponential increase in sources of EMI, an increasing variety of types of susceptible devices, and greater potential for unintended consequences. Moreover, radio-frequency modulation modalities that were only beginning to appear 10 years ago are now ubiquitous. These developments have also made problem reporting more complex. Reports of adverse events due to interference with medical devices are increasingly difficult to investigate, especially with the multitude of mobile sources now distributed throughout our environment. Another problem is that EMI standards have not kept pace with changes in the electromagnetic environment or with advances in medical device technology. Performance standards for consumer devices and mandates to not interfere with other devices do not require manufacturers to consider and test against medical devices. Immunity guidelines for medical manufacturers are still based on laboratory testing of uninstalled devices rather than testing of in vivo installations. Finally, none of the standards consider the potential confluence of multiple sources, the effects of spread spectrum communication techniques, or the effects of tissue or body contact with electrical leads.

Establishing electromagnetic compatibility for electronic medical devices will require a coordinated effort by manufacturers of medical devices, manufacturers of devices that may produce electromagnetic fields, testing laboratories, and medical care providers; realistic modifications of test standards to assure testing in environments that emulate in vivo conditions; and both training in and accountability for understanding sources of EMI.

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