

REVIEW

Interference in Implanted Cardiac Devices, Part I

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Introduction

Sensing intrinsic cardiac electrical activity is essential for the function of pacemakers and implantable cardioverter defibrillators (ICDs). Examples of undesired triggering or inhibition of pacemaker output by extraneous signals were identified early after the introduction of noncompetitive, "demand" pacemakers. Hermetic shielding in metal cases, filtering, and interference rejection circuits, together with a preference (much more marked in the United States¹ than in Europe²) for bipolar sensing, made contemporary pacemakers and ICDs relatively immune to electromagnetic energy sources in homes and workplaces. Sources of electromagnetic interference (EMI) remained ubiquitous in the medical environment. However, they were predictable and avoidable.

New technologies that use more of the electromagnetic spectrum (i.e., wireless telephones, electronic article surveillance [EAS] devices) have rekindled interest in EMI risks for patients with implanted cardiac devices. Although these technologies do not constitute a major public health threat, adverse interactions can occur. The counterpart to EMI is electromagnetic compatibility, a science aimed at avoiding interference potential by adding shielding or redesigning circuits against specific EMI sources. There are three essential elements to any electromagnetic compatibility problem. There must be an electromagnetic source, a receptor or victim (in our case the implanted cardiac device) that cannot function properly due to the electromagnetic phenomenon, and a path between them that allows the source to interfere with the receptor. Each of these three elements must be present, although they may not be readily identified in every situation. Identifying at least two of these elements and eliminating (or attenu-

ating) one of them generally solves electromagnetic compatibility problems. Collaboration among industry, physicians, regulatory agencies, and consumer groups will hopefully achieve full compatibility between implanted devices and other technologies. This will require adoption of international standards establishing the upper limit of permissible field intensities for the whole electromagnetic spectrum. Implanted devices should not react to fields below this limit; more intense fields will be prohibited.

This two-part review discusses EMI with implanted cardiac devices. The first part of the review addresses general concepts and specific sources of EMI in everyday life and the workplace. The second part focuses on medical sources of EMI, highlighting preventive measures.

Classification of Sources of EMI

Sources of EMI can be classified according to type and spectral frequency of energy emitted, and the environment in which the source is encountered (Table I). A detailed discussion of the physics of electromagnetic fields is beyond the scope of this review.^{3,4} For clinical purposes, it is useful to recognize radiated and conducted sources of EMI.

Radiated EMI can result from energy emitted for communication purposes or as an unintended effect of other electrical activity (e.g., motor operation in an electric razor). Electromagnetic fields have both an electric field measured in volts per meter and a magnetic field measured in amperes (A) per meter. Their sources can be broadly divided into radiofrequency waves with frequencies from 0.1 Hz to 100 MHz (e.g., electric power, radio and television transmitter, electrocautery), and microwaves from 100 MHz to 12 GHz (e.g., radar transmitters, cellular telephones, microwave ovens) (Fig. 1). The frequency of EMI determines the efficiency of energy coupling to the device and the resulting effect. The signal may be modulated in amplitude or frequency, and it may occur in bursts or single long pulses. A radiofrequency carrier with amplitude modulation induces voltages in the signal processing and detection circuitry of an implanted device that can be misinterpreted as

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Table I.

Documented Sources of Electromagnetic Interference

Electromagnetic fields

Daily life: Cellular telephones, electronic article surveillance devices, metal detectors, some home appliances (e.g., electric razor), toy remote controls, improperly grounded appliances held in close contact to the body, slot machines

Work and industrial environment: High voltage power lines, transformers, welders, electric motors, induction furnaces, degaussing coils

Medical environment: Magnetic resonance image scanners, electrosurgery, defibrillation, neurostimulators, TENS units, radiofrequency catheter ablation, therapeutic diathermy

Ionizing radiation

Medical environment: Radiotherapy

Acoustic radiation

Medical environment: Lithotripsy

intracardiac signals. The modulation on the carrier is converted (demodulated) to a low frequency voltage waveform, allowing entry to the signal processing and detection circuitry. If the amplitude modulation has frequency components in the device's physiological passband, significant interference occurs. Although electromagnetic fields could also mimic radiofrequency telemetry and modify programmable parameters in an implanted device, this is unlikely with current systems. Programming requires access codes to establish the telemetry link, parity checks of transmitted messages, and often simultaneous magnetic reed switch closure by a steady magnetic field.

Directly conducted galvanic currents (measured in A/m^2) are most commonly introduced in the body therapeutically (e.g., transcutaneous electrical nerve stimulation), but they can also result from physical contact with improperly grounded electrical equipment. A wide range of frequencies may affect implanted devices, including the power frequencies of 50 Hz (Europe), 60 Hz (United States), and 400 Hz (aircraft). Sensitive pacemakers or ICDs can react to galvanic currents below the perception threshold ($\sim 1 \text{ mA/cm}^2$ for moist skin). Clinically, this will result in oversensing in the channel where sensing is occurring.

Static magnetic fields are measured in units of tesla (T), which equals 10,000 gauss (G). The ionizing radiation dose is the amount of energy absorbed per unit mass of material, with units of joule per kilogram or gray (Gy). Radiation found in the environment and medical imaging equipment has no effect on implanted electronic devices. Therapeutic radiation used in oncology can dam-

age the oxide layers of CMOS semiconductor circuits in ICDs and pacemakers, and the effects are cumulative. Acoustic radiation from lithotripsy machines is used to disintegrate kidney and gallbladder stones. About 1,500 discharges form a 20-kV spark gap generate pressure shock waves that are typically 45 Mpa at the 12-mm diameter focal area. If pressure waves of this magnitude are applied directly to a pacemaker or ICD, the electronic circuits could be damaged.

Sources of Knowledge Regarding EMI

Knowledge of EMI effects on implanted devices arises from three sources. Anecdotal reports highlight the possibility of interactions but provide little information regarding overall risk. The interaction may have depended on idiosyncratic programming or device malfunction. In the United States, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health maintains a database of reported incidents of deleterious interactions (Manufacturer and User Facility Device Experience [MAUDE]) that is searchable on-line.⁵ However, reporting is largely voluntary and documentation uneven. Case reports pub-

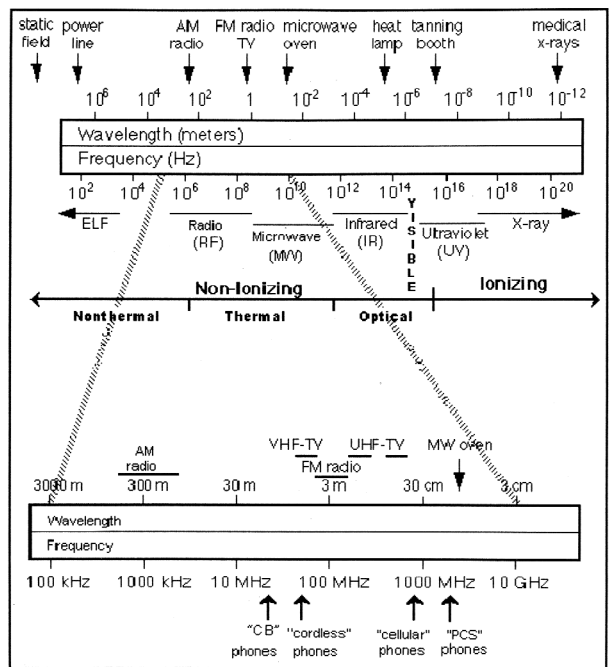


Figure 1. Electromagnetic spectrum. Frequencies used for communications in the radio and microwave range 100 KHz–10 GHz (detailed in the lower bar) can interact with implanted cardiac devices. (Adapted from Moulder JP. Cellular phone antennas and health. <http://www.mcw.edu/gcrc/cop/cell-phone-health-FAQ/toc.html#2> with permission. Accessed August 16, 2002.)

lished in peer-reviewed journals (especially when including a rechallenge in a controlled environment) can be most valuable.

Prospective studies can be performed *in vitro* (i.e., bench testing) or *in vivo*, using laboratory animals or patient volunteers. *In vitro* studies are performed with the implantable device submerged in a saline filled tank (to emulate electrical properties of tissue), with the source of radiated EMI in close proximity. These studies allow expeditious study of interactions between various EMI sources and devices. Multiple iterations of the experiment permit examination of the effects of distance, position, field strength, and device programming on the frequency and severity of the interaction. Although simulation studies predict interference *in vivo*, they do not match clinical exposures identically. Discrepancies may be related to the inability to replicate the strength and path of induced body fields, body position and movements, and shielding effects of the body. The orientation of the air gap between the source and the saline tank (i.e., perpendicular versus parallel) can dramatically influence the distance threshold for interaction.⁶ More recently, the development of anatomically based electromagnetic models of the human body has allowed the use of numerical modeling to quantify the relationship between an external electromagnetic field and the voltage induced in the leads of an implantable device.⁷ Such modeling can greatly strengthen the clinical relevance of *in vitro* simulation studies.

In limited, high risk circumstances (e.g., magnetic resonance imaging [MRI]), *in vivo* testing has been first conducted in laboratory animals implanted with a pacemaker system. More commonly, *in vivo* simulation studies require controlled patient exposure to potential sources of EMI while the cardiac rhythm is monitored. Patient exposure studies clarify the clinical significance of *in vitro* interactions. However, because of the time and effort involved, the number of assessed permutations is, by necessity, limited. It is important to recruit patients representative of the general population with implanted devices to avoid inadvertent biases. The fact that many sources of EMI also interfere with real-time or Holter electrocardiographic (ECG) recordings also complicate *in vivo* studies. Bipolar asynchronous pacing pulses that do not elicit a QRS complex are particularly difficult to ascertain. Special recording techniques are often necessary. Furthermore, real-time telemetry between the implanted device and the programmer is often compromised by EMI, even when device function remains otherwise normal. Critical review of the literature suggests that many purported instances of EMI resulted from this inconsequential phenomenon.⁸

Furthermore, the programmer wand placed directly over the device can act as an artificial shield. When available, analysis of annotated stored electrograms is the ideal method to evaluate device behavior during exposure to potential sources of EMI.

Pacemaker and ICD Responses to EMI

The most frequent responses to EMI are inappropriate inhibition or triggering of pacemaker stimuli, reversion to asynchronous pacing, and spurious ICD tachyarrhythmia detection. Reprogramming of operating parameters and permanent damage to the device circuitry or the electrode to tissue interface are much less frequent.

Pacing Inhibition

Sustained pacing inhibition is potentially catastrophic in pacemaker dependent patients. Depending on the duration of inhibition and emergence of escape rhythms, lightheadedness, syncope, or death could result. Prolonged inhibition is uncommon because of the protective algorithms available in pacemakers. Furthermore, the majority of patients currently undergoing pacemaker implantation are not completely dependent. Patients dependent on their ICD for bradycardia pacing (e.g., after atrioventricular [AV] junction ablation to prevent spurious shocks for supraventricular tachyarrhythmia) may be more vulnerable to catastrophic pacing inhibition from EMI. In ICDs, automatic adjustment of the gain or sensing threshold according to the amplitude of the intrinsic R wave ensures sensing of low amplitude (at times < 1 mV) ventricular depolarization signals during ventricular fibrillation without oversensing of T waves and extracardiac signals.^{9,10} In the absence of sensed complexes, two potentially life-threatening diagnoses must be considered: asystole (requiring pacing) and fine ventricular fibrillation (requiring amplifier gain adjustments for proper detection). To ensure detection of ventricular fibrillation, pacing onset triggers an increase in sensitivity in most devices. These high sensitivity levels (~ 0.2–0.3 mV) can promote oversensing of extracardiac signals. Oversensing perpetuates because the absence of spontaneous large amplitude escape beats maintains the high operating sensitivity.¹¹ Asynchronous pacing will not occur due to lack of reliable ICD noise reversion modes. Therefore, EMI induced prolonged inhibition and spurious tachyarrhythmia detection become likely (see below). Simulation studies of the interactions between sources of EMI and ICDs require recreation of a “worst-case scenario” (inducing maximum sensitivity during continuous pacing).

Triggering of Rapid or Premature Pacing

Oversensing of EMI by the atrial channel of a pacemaker or ICD programmed to a tracking mode (DDD, VDD) can trigger ventricular pacing at or near the upper tracking rate limit. Alternatively, automatic mode switching may occur if this function is enabled. In some pacemakers, detection of noise in the atrial channel can trigger a noise reversion mode. Preferential detection of EMI is not uncommon because atrial sensitivity is usually programmed higher (more sensitive) than ventricular sensitivity. It is possible to observe rapid pacing due to atrial oversensing as the patient approaches an electromagnetic field, followed by a period of ventricular oversensing (inhibition or mode reversion) as the field becomes stronger. If sustained, inappropriate pacemaker acceleration induced by atrial oversensing may cause palpitation, hypotension, or angina.

Less commonly, EMI can induce rapid pacing via other mechanisms. In QT sensing pacemakers, oversensing of EMI early in the QT window could induce the pacemaker to increase the pacing rate. EMI can also trigger rapid pacing (up to the sensor-triggered upper rate limit) by activating the sensor in minute ventilation pacemakers. The signal emitted by acoustomagnetic EAS systems is at the same frequency of the pulses used by some minute ventilation pacemakers to measure transthoracic impedance. Minute ventilation pacemakers may also erroneously interpret the signals generated by certain monitoring and diagnostic equipment, including cardiac monitors, echocardiography equipment, apnea monitors, and respiration monitors, that also use bioelectric impedance measurements.^{12,13} Pacing returns to normal once the patient is disconnected from the monitors or the minute ventilation sensor in the pacemaker is deactivated.

Very strong electromagnetic fields could induce voltage in the lead(s) that may directly capture the myocardium. For example, 58-kHz acoustomagnetic EAS systems are capable of inducing 3.7 V in pacemaker leads.¹⁴ Isolated premature paced beats (but no sustained rapid pacing) have been observed in patients. *In vitro* and *in vivo* animal studies¹⁵ have shown that application of 64 MHz radiofrequency power, required to produce MRI scans, can result in rapid pacing at pulsing periods between 200 and 1,000 ms. Rapid pacing requires an intact lead connected to a pacemaker. Apparently, energy is coupled to the pacemaker defibrillation protection diodes or the output circuit, bypassing the runaway protection mechanisms. Very rapid pacing could induce ventricular fibrillation. Irregular rapid pacing at a rate \sim 100 beats/min, temporarily related to radiofrequency pulses during MRI, has been observed in a patient

with a VVI pacemaker programmed at subthreshold output.¹⁶

Spurious Tachyarrhythmia Detection

EMI signals can satisfy ICD tachyarrhythmia detection criteria and lead to spurious ICD discharges (with associated psychological morbidity, battery consumption, and occasional proarrhythmia¹⁷). As noted, pacemaker dependent patients can suffer concomitant catastrophic inhibition of pacing. In a follow-up study of 341 patients with contemporaneous ICDs who received education regarding avoidance of sources of EMI, spurious tachyarrhythmia due to EMI occurred five times in four patients.¹⁸ The incidence was of 0.75% per patient-year of follow-up. Intermittent EMI can result in shock delivery even in noncommitted devices. Many "noncommitted" devices will not abort two consecutive discharges during the same "episode" (i.e., sinus rhythm not redetected in between), and therefore, will deliver shocks for repetitive but self-limiting EMI. Biotronik (Berlin, Germany and Lake Oswego, OR, USA) and previous generation Guidant (St. Paul, MN, USA) ICDs functioned "de facto" as committed in pacemaker dependent patients.¹⁹

In dual chamber ICDs that use atrial channel information to discriminate between atrial and ventricular tachyarrhythmias, simultaneous oversensing of EMI could result in varied and, for the most part, unpredictable arrhythmia detection. Pacemakers and defibrillators capable of detecting and treating atrial tachyarrhythmias have been recently introduced in clinical practice. Selective oversensing in the atrial channel could result in spurious pacing or shock interventions for atrial tachyarrhythmia. In turn, the spurious intervention could result in atrial, or more rarely, ventricular proarrhythmia. However, because the duration of atrial tachyarrhythmia required for detection is in general programmed longer than for ventricular arrhythmias,²⁰ transient EMI is unlikely to satisfy atrial tachyarrhythmia detection criteria.

Noise Reversion Mode

Pacemakers incorporate protective algorithms against prolonged inhibition from spurious signals. A common response is transient reversion to asynchronous pacing.²¹ These algorithms are based on the fact that rapid frequencies are unlikely to represent myocardial activation. In most pacemakers, a noise sampling or noise interrogation window (also known as relative refractory period) occupies the second part of the ventricular refractory period. Pacemakers do not respond to signals during the initial portion of the ventricular refractory period (i.e., ventricular blanking),

which is usually nonprogrammable and fixed or adjusted automatically by the generator based on the strength and duration of the ventricular event. Signals recognized during the noise sampling window cannot reset the lower rate timer (therefore preventing inhibition), but affect other timing intervals, most importantly, the ventricular refractory period. In some models, a noise sampling period exists in the atrial and ventricular channels (Table II). The types of responses to signals sensed within the noise sampling period implemented by different manufacturers include resetting of the entire (retriggerable) refractory period (e.g., Medtronic, Minneapolis, MN, USA), resetting of the noise sampling period only (e.g., St. Jude, Minneapolis, MN, USA), and reversion to asynchronous pacing for one full cycle (e.g., Intermedics, Angleton, TX, USA). In the first two types of responses, repetitive triggering of the noise sampling period eventually leads to asynchronous pacing.²²

During simulation studies, a variable but narrow window of inappropriate pacing or inhibition is frequently observed at field or current strengths immediately below the reversion thresholds because of intermittent oversensing. This phe-

nomenon appears relatively unimportant during real-life EMI exposure. Occasional inhibition over a range of external field strengths is possible because EMI induced body currents can fluctuate widely with changes in posture, respiratory phase, and other natural circumstances.²³

Although generally safe, transient asynchronous pacing is not completely innocuous. Symptoms secondary to loss of AV synchrony and an irregular heart beat can occur. Competition with the spontaneous rhythm may induce ventricular tachyarrhythmias if the pacing stimulus captures the ventricle during its vulnerable period.²⁴ This is extremely uncommon in pacemaker patients, as attested to by the routine use of a magnet during clinic or transtelephonic pacemaker checks. In patients with separate pacemaker and defibrillator systems, pacemaker reversion due to repetitive sensing of ventricular fibrillation depolarizations in the noise sampling window can lead to asynchronous pacing and interfere with ICD detection.²⁵

Implementation of noise protection algorithms is much more difficult in ICDs (Table III). By design, these devices must be able to recognize the rapid rates of ventricular tachycardia of fibril-

Table II.
Noise Reversion and Electrical Reset Responses of Contemporary Dual Chamber Pacemakers*

| Manufacturer | Model | Detection of Noise in the A Channel | Detection of Noise in the V Channel | Partial Reset | Full Reset |
|-----------------------|--------------------------------|-------------------------------------|-------------------------------------|--|---|
| Biotronik | Phylos/Actros | Switch to DVI(R) | Switch to DAD(R) | None | VDD, 11% decrease in programmed rate, programmed polarity |
| Guidant | Discovery/Pulsar/ Contak TR | Switch to DVI | Switch to DAT | None | VVI 65, detected polarity |
| Ela Medical | Talent/Brio | Switch to DVI | Switch to DAD | None | VVI 70 beats/min, uni [†] |
| Medtronic | Sigma | None | Switch to DOO(R) | None | Programmed mode and polarity, 65 beats/min [†] |
| | Kappa 400 | None | Switch to DOO(R) | Programmed mode and polarity, 65 beats/min | VVI 65 beats/min, detected polarity |
| | Kappa 600/700 | None | Switch to DOO(R) | Programmed mode, rate and polarity | VVI 65 beats/min, detected polarity |
| St. Jude | Trilogy | Switch to DVI(R) | Switch to DOO(R) | None | VVI 70 beats/min, programmed polarity |
| | Integrity | Switch to DVI(R) | Switch to DOO(R) | None | VVI 67 beats/min, uni |
| Vitatron [‡] | Diamond II | Switch to DOO(R) | Switch to DOO(R) | None | VVI 62.5 beats/min, uni |

*Assumes programming in the DDD(R) mode. [†]"Dedicated bipolar" model (Brio DR222) reverts to bipolar. ^{††}In rare circumstances ventricular polarity could reset to unipolar. [‡]Vitatron, Deren, the Netherlands. Other manufacturers are listed in text. (R) = pacing at the sensor-indicated rate if rate-responsive pacing enabled; uni = unipolar.

Table III.
Noise Reversion, Asynchronous Pacing and Electrical Reset Responses of Contemporary ICDs

| Manufacturer | Model | Noise Reversion | Asynchronous Pacing | Electrical Reset |
|--------------|------------------------------------|---|---|--|
| Biotronik | Belos VR | VOO | None | VVI 70 beats/min, 7.5 V @ 1.5 ms Single zone at 270 ms, 30 J × 8 |
| | Tachos DR | Asynchronous pacing in the chamber with noise | Only AOO | VVI 70 beats/min, 7.2 V @ 1 ms Single zone at 150 beats/min, 30 J × 6 |
| Guidant | Ventak AV III, Contak CD | Programmable: AOO, DOO*, VOO, inhibit | AOO(R)†, VOO(R)†, DOO(R)† | VVI 60 beats/min, 7.5 V @ 1 ms Single zone at 165 beats/min, maximum energy × 5 |
| | Prizm VR, Prizm II VR | Programmable: VOO*, inhibit | VOO(R)† | VVI 60 beats/min, 7.5 V @ 1 ms Single zone at 165 beats/min, maximum energy × 5 |
| | Prizm DR, Prizm II DR | Programmable: AOO, DOO*, VOO, inhibit | AOO(R)†, VOO(R)†, DOO(R)† | Nonrate responsive mode (i.e., DDDR to DDD) 60–120 beats/min 7.5 V @ 1 ms Single zone at 165 beats/min, maximum energy × 5 |
| Ela Medical | Defender IV | Ventricular sensitivity ↓ until noise (i.e., cycle < 63 ms) no longer detected | None | VVI 60 beats/min, 4.8 V, 0.37 ms Single zone at 297 ms, 33 J × 4 |
| Medtronic | GEM III VR 7231 | None | None | VVI 65 beats/min, 6 V, 1.6 ms |
| | GEM III DR 7275 | | | Single zone at 320 ms, 30 J × 6 High urgency alert sounds every 20 hours until cleared |
| | InSync 7272 | | | |
| | GEM III AT 7276 | None | Programmable [¶] DOO, VOO | VVI 65 beats/min, 6 V, 1.6 ms Single zone at 320 ms, 30 J × 6 |
| St. Jude | Angstrom II, Countour II, MD | Programmable: VOO or OFF | None | VVI 50 beats/min, 5 V, 0.5 ms Defib Only: detection rate 146 beats/min; 650 V × 1, 705 V × 5 |
| | Photon | Programmable: VVI(R): VOO or OFF* DDD(R), DDI(R): VOO, DOO, or OFF*, fixed rate of 50 beats/min | Programmable [¶] AOO, VOO, DOO | VVI 60 beats/min, 5 V Defib only: detection rate 146 beats/min; 800 V × 3 |

*Nominal; [¶]available only when tachyarrhythmia detection is disabled; †requires continuous telemetry link. (R) = pacing at the sensor-indicated rate if rate-responsive pacing enabled.

lation.¹⁰ Therefore, long refractory periods after sensed events are not feasible. Asynchronous pacing is undesirable in patients vulnerable to reentrant ventricular arrhythmias.¹⁷ Saeed et al.²⁶ studied stored electrograms from 268 episodes of monomorphic VT among 52 patients, and found that 13 (5%) were induced by asynchronous ven-

tricular pacing after undersensing of the previous beat.

Among current ICDs, those manufactured by Medtronic lack noise reversion capabilities. Guidant devices provide a programmable noise reversion mode (Off, VOO, DOO). However, the short (40 ms) retriggerable noise sampling win-

dow affords imperfect protection from inhibition by exogenous interference. ICDs from Ela Medical (Montrouge, France and Plymouth, MN, USA) and St. Jude also provide noise reversion modes, but their performance against common sources of EMI is not well documented. As ICDs are increasingly implanted in pacemaker dependent patients, the lack of reliable noise reversion modes may become clinically detrimental.

Electric (Power-On) Reset

Momentary strong EMI, by inducing very high voltage within device circuits, or triggering special microprocessor timers, may cause reset of DDD and VVIR pacemakers to the VVI or VOO mode, a condition called power-on or electric reset (Table II).²⁷ Electric reset is less recognized in ICDs, generally resulting in a "shock-box" configuration with VVI pacing at 60 beats/min and maximum energy shocks for rates > 145–170 beats/min (Table III). Electrosurgery and external or internal defibrillation are the most common causes of the reset phenomenon. In the reset mode, the pulse generator functions only with basic factory preset instructions (pacing mode and parameters) stored in the nonvolatile read-only memory, as communication between the random access memory (containing the programmable settings) and the microprocessor has been interrupted. In some pacemakers, the pacing mode and rate are similar during electrical reset and elective replacement indicator. In devices with different replacement and reset parameters, strong EMI may activate either one. In some pacemakers, two levels of electrical reset (partial and full) exist. Partial reset tends to occur with less intense interference, generally preserving the programmed pacing mode and rates (Table II). In some pulse generators, there will be no response to magnet application in the reset mode. The reset mode does not revert back when EMI is discontinued. A DDD(R) device reset to the VOO or VVI mode might cause hypotension, particularly in patients with pacemaker syndrome. Resolution of the problem requires a specific programmer command. A cardiomyostimulator used in dynamic cardiomyoplasty can also revert to asynchronous stimulation in response to EMI.²⁸ Electric reset can be differentiated from battery depletion by telemetry of battery voltage and impedance. When reset is due to EMI, the battery voltage should be normal (approximately 2.8 V) and battery impedance normal or slightly raised according to battery age (Fig. 2).

Closure of the Reed Switch

Most pacemakers and ICDs contain a magnetic reed switch that is closed by a ~ 10-G mag-

| | | |
|--|-----------------|--------------------------|
| MEDTRONIC 9790 PROGRAMMER 9891A220 | | 4/20/99 13:57 |
| Copyright (c) Medtronic, Inc. 1993 | | |
| ----- PARAMETER VALUES REPORT ----- | | Page 1 of 2 |
| Pacemaker Model: Elite II 7084 | | Serial Number: 3U0000000 |
| Parameter | Temporary | Permanent |
| ----- | | |
| Pacemaker Battery | | Replace Pacer |
| Pacing Mode | VOO | VVI |
| Rate | 65 | 70 ppm |
| | | |
| V. Amplitude | 1.6 | 1.6 V |
| V. Pulse Width | 0.54 | 0.54 ms |
| V. Sensitivity | | 2.5 mV |
| Mode & Rate printed may differ from actual pacer operations at ERI | | |
| | | |
| MEDTRONIC 9790 PROGRAMMER 9891A220 | | 4/20/99 13:57 |
| Copyright (c) Medtronic, Inc. 1993 | | |
| ----- REAL-TIME TELEMETRY REPORT ----- | | Page 1 of 1 |
| Pacemaker Model: Elite II 7084 | | Serial Number: 3U0000000 |
| Real-Time Telemetry Values: | | Collected: 4/20/99 13:57 |
| Battery Status | OK | |
| Battery Voltage | 2.64 V (+/-4%) | |
| Battery Current | 11.7 mA | |
| | | Atrial Ventricular |
| | Pulse Duration | 0.65 ms |
| | Pulse Amplitude | 1.76 V |
| | Output Energy | 2.7 uJ |
| | Lead Current | 2.9 mA |
| | Lead Impedance | 559 ohm |

Figure 2. Pacemaker interrogation after electrical reset (in this case triggered by a shock from an implantable cardioverter defibrillator). Although the initial screen reads "Replace Pacer," the battery is not depleted (2.64 V). Normal operating function was restored by a programmer command. (From Pinski SL, Trohman RG. Interference with cardiac pacing. *Cardiol Clin* 2000; 18:219–239, with permission).

netic field. This results in temporary asynchronous pacing in pacemakers and temporary suspension of tachyarrhythmia detection and therapy in most ICDs. Normal function returns when the magnetic field dissipates. Prior ICD models from CPI/Guidant were deactivated by continuous application of a magnetic field > 10 G for ≥ 30 seconds. Reactivation required reapplication of the magnet for ≥ 30 seconds or a programmer command. Several items that generate inconspicuous strong magnetic fields, like magnetized screws,²⁹ stereo speakers,^{29,30} and bingo wands³¹ have inadvertently deactivated Guidant ICDs. In current models, this function is programmable (nominally off). Magnet application increasingly is being used to trigger specific behaviors in newer devices, including storage of electrograms and event markers or replay of alert tones. Exposure to

a strong magnetic field in patients who have these functions activated can result in eccentric (but clinically inconsequential) device behavior.³²

Static magnetic fields strong enough to close the reed switch are unlikely to be present in industrial environments. For example, in a petroleum refinery, peak fields close to 2 G were measured close to large compressors and in power distribution centers. However, the fields dropped off to < 0.1 G at a distance of 4 feet.³³ A variety of so-called therapeutic magnets are commercially available for the treatment of arthritis and other musculoskeletal ailments. Despite manufacturers' claims of strong magnetic field strengths (up to 30,000 G), *in vitro* testing showed that the magnets were able to close the reed switch only when placed at < 1 inch from the generator.³⁴ Prosthetic dental minimagnets can activate the reed switch only when close (1 cm) to the pacemaker.³⁵ Therefore, they do not represent a risk to pacemaker patients.

Damage to the Generator or to the Electrode-Myocardial Interface

In the overwhelming majority of cases, the effects of EMI are temporary, lasting only as long as the device is within range of the source. However, strong EMI (e.g., electrosurgery and external defibrillation) can cause permanent damage to an implanted device. Circuitry damage, (resulting in output failure, pacemaker runaway, and other malfunctions) can occur, requiring generator replacement (at times emergent). Increases in pacing thresholds secondary to local heat related injury at the myocardium lead interface are also possible.

Clinical Consequences of EMI

The effects of EMI on pacemakers and ICDs depends on the intensity of the electromagnetic field, the frequency spectrum of the signal, the distance and positioning (angle) of the device relative to the source, the electrode configuration (unipolar or bipolar), nonprogrammable device characteristics, programmed settings, and patient characteristics (Table IV).

Transient EMI producing 1-beat responses (e.g., inhibition of a single ventricular pacing pulse) is of no clinical significance. Symptoms can occur with longer exposure. The spatial proximity and orientation of the patient with an implanted device to the potential source of EMI are important. Electric and magnetic fields decrease inversely with the square of the distance from the source. Some sources restrict emission of energy to a particular direction.⁴ It has been repeatedly demonstrated that devices from different manufacturers differ in susceptibility to various sources of EMI, depending on circuitry design. EMI from

Table IV.

Factors Influencing Electromagnetic Interference

| |
|--|
| Intensity of the field |
| Signal spectrum |
| Distance and position of the patient |
| Duration of exposure |
| Nonprogrammable device characteristics |
| Lead configuration |
| Programmed parameters |
| Sensitivity |
| Mode (baseline, noise reversion) |
| Committed versus noncommitted (ICDs) |
| Patient characteristics |
| Pacemaker dependency |
| Susceptibility to asynchronous pacing |
| Susceptibility to rapid pacing rates |

digital cellular telephones, in particular, can be suppressed by incorporation of simple radiofrequency feedthrough filters to the circuitry (Fig. 3). Manufacturers should supply information regarding EMI susceptibility. Implanters should select devices less susceptible to EMI.

A higher programmed sensitivity level increases device susceptibility to EMI. Unipolar pacemakers are more vulnerable to EMI from sources in the lower range of the frequency spectrum (e.g., power lines³⁶). Left-sided unipolar implants are particularly susceptible because of the larger loop for voltage induction between the lead and the generator. The impact of the sensing configuration decreases with a shorter radiation wavelength. For cellular telephones, for example, the greatest interaction occurs when the antenna is placed over the device header. Neither the sensing electrodes near the distal tips of the leads, nor the coated lead body, are susceptible. Ventricular oversensing appears more common with "integrated bipolar" than with "true bipolar" defibrillator leads.³⁷

The degree of pacemaker dependency is a crucial determinant of the clinical sequelae of EMI. Prolonged pacing inhibition will be asymptomatic in a patient with a good escape rhythm, but could result in catastrophic asystole in a pacemaker dependent patient.

Daily Life Sources of EMI

Cellular Telephones and Other Wireless Communication Devices

It has been estimated that by the year 2003, there will be 1 billion subscribers to wireless communication services worldwide. Although cellular telephones will continue to be the most popu-

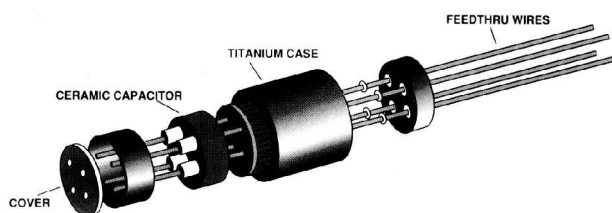


Figure 3. Filtered four-wire feed through assembly available in St. Jude pacemakers. Similar filters are now also present in pacemakers from Medtronic and Guidant. (From Selznick L, Mueller H, Chávez T. *Cellular telephone technology and its effect on implantable cardiac pacing systems*. Sylmar, CA, Pacesetter, Inc, October, 1996, with permission).

lar wireless communication devices, personal digital assistants, laptop computers, satellite telephones, and other appliances will be increasingly used for wireless voice, data, and video transmission. Assessment of the effects of cellular telephones on implanted cardiac devices has been complicated by the wide variety of technologies in use.³⁸ Analog cellular telephones predominate in the United States, but a gradual shift toward digital technology is occurring, due to the saturation of analog networks and the advantages afforded by digital transmission in terms of privacy, clarity of reception, and bandwidth for data transmission. In Europe, > 90% of cellular telephones in use are of the digital type. Digital technology in use in the United States include Time Division Multiple Access [TDMA]-11Hz, and TDMA-50Hz (also called North American Digital Cellular, NADC), Code Division Multiple Access (CDMA), and Personal Communication Services (PCS). It should be noted that NADC and CDMA default to analog transmission when a digital signal is not present. PCS telephones are incompatible with analog transmission unless a dedicated “dual-mode” device is used. The Global System for Mobile Radio (GSM) is the digital modality predominant in Europe. Analog cellular telephones, as well as TDMA, CMDA, and GSM operate in the 820–960 MHz spectrum. PCS uses the 1.8–2.2 GHz band. As of the time of this writing, the spectrum for future third-generation multimedia networks has not been adjudicated in the United States. In the United States, the maximal power of hand held telephones is limited to 0.6 W. The power level used by the telephone (and the consequent emitted electromagnetic field) fluctuates throughout the call, according to distance from the base station and the number of telephones being used on the system at a time. Generally, the power generated from European telephones is higher due to a lower density of base stations. Vehicle mounted

units can transmit at higher power (up to 8 W), but are not in common use by the general public.

Although isolated case reports have suggested the potential for severe interactions,³⁹ most research suggests that deleterious interactions are unlikely to happen with normal cellular telephone use. Large scale bench testing of the effects of wireless telephones on pacemakers has been conducted in Germany,⁴⁰ at the FDA’s Center for Devices and Radiological Health,⁴¹ the Medical Devices Bureau of Canada,⁴² and at the University of Oklahoma Wireless Electromagnetic Compatibility Center.⁴³ These studies encompassed several thousand runs of telephone and pacemaker combinations and provided consistent results. The internal filters in most implanted devices are highly effective in rejecting the constant carrier frequency of analog telephones. Interference is nonexistent or only occurs during the brief “shake hand” period before ringing. Although digital telephones transmit on the same carrier frequencies as the analog telephones, the *pulsed* component of the transmission (in the 11–200-Hz range), can be detected by the pacemaker sensing circuitry when the field is strong enough. PCS or similar technologies produced interactions in < 1% of tests, while other digital technologies (GSM, NADC, TDMA-11) produced interference in 0–25% of tests. In all studies, a few models were responsible for a disproportionately large number of interactions, whereas others were largely immune. The overwhelming majority of interactions occurred at distances < 10 cm. Pacemakers always reverted to normal operation when the telephone was turned off.

Several investigators have systematically studied the effects of cellular telephones in patients with pacemakers. Although there have been discrepancies in the reported frequencies of EMI (explained by differences in wireless technologies tested, exposure protocols, pacemaker models, pacemaker sensing polarity, programmed sensitivities, and definitions of interference), it can be concluded that severe interactions are improbable with most technologies during regular telephone use. In a comprehensive multicenter study, Hayes et al.⁴⁴ tested 980 pacemaker patients for potential interference with five types of telephones (one analog and four digital: NADC, TDMA-11, PCS, and CDMA). Telephones were tested in a simulated worst-case scenario; in addition, NADC telephones were tested during transmission to simulate actual use. Patients were monitored while the telephones were held at the ipsilateral ear and in a series of maneuvers directly over the pacemaker. The incidence of any type of interference was 20% in the 5,533 tests. Tracking of interference sensed in the atrial channel, asynchronous pacing, and

ventricular inhibition were the most common reactions observed (14%, 7%, and 6%, respectively). Interference was least frequent with analog (2.5%) and PCS (1.2%) systems. Clinically significant EMI was observed in 7% of tests, and was considered severe in 1.7%. *There was no clinically significant EMI when the telephone was placed in the normal position over the ear.* The presence of feedthrough filters in the pacemakers almost abolished the risk of EMI (from 29–56% to < 1%). In a study of 39 patients, Naegeli et al.⁴⁵ demonstrated that EMI was more common with portable 8-W GSM telephones than with hand held 2-W models (7% vs 3% of tests) and that atrial or ventricular oversensing were more frequent with pacemakers programmed at maximal sensitivity than at nominal sensitivity (6% vs 2% of tests). In a subset of 14 patients with VVIR pacemakers and programmable polarity, the same authors showed that pacing inhibition was more common in the unipolar mode. Additional studies showed that GSM telephones do not induce inappropriate rapid pacing in patients with minute ventilation pacemakers,⁴⁶ or atrial oversensing in single-lead VDD pacemakers programmed at maximum atrial sensitivity (0.1–0.25 mV).⁴⁷

Potential interactions between ICDs and wireless telephones have also been studied in vitro and in vivo. It should be noted that feedthrough filters present in pacemakers from several manufacturers are not as common in ICDs. Bassen et al.⁴⁸ exposed ICDs from three manufacturers to maximal power fields from analog and digital telephones (TDMA-11 and NADC). ICDs were programmed to pace in the VVI mode at nominal sensitivity. No device reacted to the analog telephone, while all three models reacted to the TDMA-11 telephone at minimal distances between 2.3 and 5.8 cm. Interference from the NADC was observed only when the most sensitive ICD was placed at close distance (≤ 2.3 cm) from the source. Another in vitro study involved all (analog and digital) wireless telephone technologies in use in the United States and Europe and ICDs from four manufacturers.⁴⁹ Interactions occurred (between a small number of wireless telephones and some ICDs) only at close proximity. No interactions were noted between ICDs and telephones that operate in the 1,800–1,900-MHz bands. All observed interactions involved two ICDs from one manufacturer or the TDMA-11 technology. Subsequent refinements in TDMA-11 technology (used only for specialized business applications like trucking, delivery, and construction in the United States) that allowed reduction in maximum operating power from 1 to 0.6 W should have reduced the incidence of interaction. Jiménez et al.⁵⁰ demonstrated that analog and GSM telephones

did not induce oversensing or interfere with the detection of simulated ventricular tachyarrhythmias in Medtronic and Guidant ICDs.

Clinical “worst-case scenario” testing has not disclosed significant interactions between ICDs and analog⁵⁰ or digital NADC,⁵¹ GSM,^{50,52–54} or PCS⁵³ telephones. In small studies, digital cellular telephones did not interfere with the detection of induced ventricular fibrillation in the electrophysiology laboratory.^{54,55} Inconsequential intermittent loss of telemetered electrograms and surface ECGs and inscription of erroneous event markers (i.e., “pseudo-oversensing”) recorded via the programmer is common. Inductive hospital pager systems may overlap with the carrier frequencies of some pacemaker programmers (32–37 kHz) and also interfere with pacemaker telemetry.⁵⁶ This may result in inaccurate battery voltage, current and impedance measurements, disturbances in intracardiac electrogram tracings, or total interruption of telemetric communications.

It can be concluded that cellular telephones can potentially interfere with the function of implanted cardiac devices. This interference does not pose a health risk when telephones are placed over the ear. Maintaining an activated cellular telephone at least 6 inches (15 cm) from the device is key to avoid interactions. The FDA has issued simple recommendations to minimize the risks. Patients should avoid carrying their activated cellular telephone in a breast or shirt pocket overlying the implanted device. A wireless telephone in use should be held to the ear opposite the side where the device is implanted. A recent survey of 1,567 Japanese pacemaker patients revealed that although 94% were right-handed, 41% used their left hand preferentially to hold a wireless telephone.⁵⁷ Not-so-obvious reasons for choosing one hand versus the other to hold the telephone included one side hard of hearing (10%) and use of the opposite hand for dialing or writing memos (22%). It appears that, at least in some patients, the hand preferentially used to hold the wireless telephone should also be considered when selecting the site for pacemaker implant.

In the past, some investigators favored the use of analog telephones by patients with implanted devices.³⁸ With digital transmission modes becoming dominant worldwide, such recommendation is no longer practical. Current evidence suggests that as long as FDA recommendations are followed, the use of digital wireless telephones (especially those of PCS or similar technology) is safe. Individual patient testing in the clinic is not recommended because of the likelihood of “false-positive” (e.g., interference with ECG monitoring equipment producing artifact) and “false negative” (e.g., low signal intensity from the telephone,

which depends on several factors, including distance to the nearest base station) results. It is more reliable to contact the device manufacturer to determine the results of formal testing with specific models.⁵⁸ As other wireless communication devices become prevalent, their effects on implanted cardiac devices should be carefully scrutinized. For example, in third-generation handsets, the transmission of high speed data will require increased power at the antenna. Limited *in vitro* and *in vivo* testing suggests that 3-W GSM telephones do not interfere with the function of an implantable ECG loop recorder.⁵⁹

EAS Devices

EAS devices (also known as antitheft devices or antishopping gates) are ubiquitous in retail stores and libraries. The transmitter in these devices emits an electromagnetic field designed to interact with a "tag" in a store item. As a result of the interaction, the tag emits back a signal that is then detected by the receiver. Customers are exposed to an electromagnetic field as they walk through the gate that consists of a pair of transmitter and receiver pedestals. EAS systems differ greatly in the frequency and strength of emitted fields. High frequency swept radiofrequency (e.g., Checkpoint QS 2000, 8.2 MHz; Sensormatic Saver, 8.4 MHz), low frequency acoustomagnetic systems (e.g., Sensormatic Ultramax, 58 kHz), and extremely low frequency electromagnetic systems (e.g., Knogo MM-85, 218 Hz; Sensormatic Aisle Keeper, 534 Hz) constitute the leading technologies worldwide. The technologies serve different retailers' needs in terms of area covered, cost, detection and "false alarm" rate, and are not strictly interchangeable. The general consumer cannot differentiate them by their external appearance. Electromagnetic fields from these devices have the potential to induce interference signals in the sensing circuit of implanted cardiac devices. Several case reports have indicated the possibility of clinically important interactions between EAS systems and pacemakers or ICDs.^{60,61} There has been controversy over the frequency and severity of those interactions.⁶² Prospective studies have clarified the incidence, severity, and risk factors for EMI from EAS systems.

An *in vitro* study from the Canadian Medical Devices Bureau⁶³ showed that 20 of 21 pacemaker models reacted to the field of an acoustomagnetic EAS system, while 10 reacted to an electromagnetic system. Responses included inhibition and noise reversion. Interference occurred when the simulator was within 33 cm of the transmission panel for the acoustomagnetic system, and 18 cm for the electromagnetic system. Dodinot et al.⁶⁴ exposed 32 patients with 26 different pacemaker

models to the fields of radiofrequency (7.4–9 MHz) and magnetic (300 Hz and 10 KHz) EAS systems. No interactions were observed with the radiofrequency system, while 50% of dual chamber pacemakers (all unipolar) exhibited significant pacing inhibition when exposed to the fields from the magnetic system. Mugica et al.⁶⁵ exposed 204 pacemaker patients to two different EAS systems (acoustomagnetic at 58 kHz and electromagnetic at 73 Hz) for up to 30 seconds, unless undesirable interference occurred earlier. At least one type of interaction occurred in 17% of patients. Interference was twice as likely with the acoustomagnetic system. Atrial tracking, asynchronous pacing, and single beat inhibition were observed. All the interactions were transient and deemed benign. McIvor et al.¹⁴ studied the effects of six EAS systems in 50 patients with pacemakers from seven different manufacturers. One exposure protocol mimicked the most common real-life situation, walking at a normal pace midway between the gates. A "worst-case scenario" protocol required the patients to lean against the transmitter gate with the body parallel and then perpendicular to the transmitter. Interactions occurred with 48 pacemakers, almost exclusively with acoustomagnetic systems. No pacemaker reacted to the swept radiofrequency systems. Only two patients presented transient asynchronous pacing while exposed to an electromagnetic system. The frequency of interactions with the acoustomagnetic system increased with the duration and closeness of the exposure. It was 16% when walking through the gates and 96% when leaning against the pedestal. Transient asynchronous pacing was the most common response, followed by atrial oversensing with tracking, ventricular oversensing with inhibition, and "voltage-induced" paced beats. Changing the sensing configuration from unipolar to bipolar or programming a lower sensitivity setting did not abolish the interactions, but limited them to closer distances from the center of the gate..

EAS systems can trigger spurious ICD shocks. Particularly concerning is a report by Santucci et al.⁶⁶ A patient with complete heart block and a Ventak AV ICD in an abdominal pocket developed multiple shocks and near-fatal inhibition of pacing on exposure to an acoustomagnetic EAS system. Provocative testing with similar equipment in a controlled environment reproduced the interaction. The maximum distance at which ventricular oversensing occurred was 30 cm. When sensitivity was reprogrammed from "nominal" to "least sensitive," the interaction only occurred at closer proximity. McIvor et al.¹⁴ did not find instances of false tachyarrhythmia detection in 25 patients with ICDs exposed to different types of antitheft

devices, but the ICDs were not programmed to pace during the testing. Groh et al.⁶⁷ studied the interaction between ICDs and two electromagnetic and one acoustomagnetic EAS devices in 169 patients. No spurious detections occurred during a 10–15-second walk through the gates. False ventricular fibrillation detection occurred in three patients (one Medtronic 7219 and two Guidant 1746) during a 2-minute exposure to the acoustomagnetic system. When the 2-minute exposure was repeated during continuous pacing in 126 patients, oversensing was observed in 19 (15%). Oversensing was severe (complete or prolonged pacing inhibition) in 7 (6%), including the same three patients who had spurious tachyarrhythmia detection at baseline and four additional patients with Ventritex (Sunnyvale, CA, USA) ICDs during exposure to an Aislekeeper electromagnetic system (programmability precludes determination of spurious detections in Ventritex devices.) In 12 (9%) patients, intermittent delayed pacing (compatible with noise augmented T wave oversensing) was seen. All the patients with serious interactions had an abdominal implant, but by multivariate analysis, diminished R wave amplitude and a Ventritex ICD were the only predictors of interactions. The effect of antitheft devices on detection of ventricular tachyarrhythmias has not been studied.

Available evidence suggests that although severe interactions between EAS systems and implanted cardiac devices can occur, they are unlikely when patients walk through the gates at a normal pace. However, interactions are likely with prolonged, close exposure to acoustomagnetic or electromagnetic systems. Patients should be instructed not to linger in proximity or lean against theft deterrent gates. Retailers should avoid placing systems where people are required to linger, like checkout counters. Merchandise or information (e.g., store floor plans) should not be displayed in close proximity to antitheft systems. The FDA recommends that all manufacturers of electronic antitheft systems develop labeling or signage to post on or near all new and currently installed systems, indicating that an electronic antitheft system is in use. The labeling or signage should be positioned so that it is visible before an individual enters the monitored area.⁶⁸

Metal Detectors

Handheld and walkthrough metal detectors are used for security applications. They function by sensing disturbances in electromagnetic fields. Handheld metal detectors typically operate at a frequency of 10–100 kHz and produce weak fields (≤ 4 A/m at a distance of 1 inch). Weapons are detected only within 1–4 inches. Walkthrough metal

detectors have coils on one or both sides of the equipment. They operate in a continuous wave (5–10 kHz) or pulsed mode (200–400 Hz). Magnetic fields measured at the chest level inside the arch are < 2 G.⁶⁹ Typically, a person walking through will be exposed for 3 seconds. Copperman et al.⁷⁰ monitored 103 patients with a variety of pacemakers (mostly nonprogrammable VVI units) crossing an airport metal detector gate and found no interactions.

The FDA has received one report of a spurious ICD shock triggered by a handheld metal detector in an airport. In several other instances, ICDs from Guidant/CPI reverted to “monitor only” mode after being exposed to metal detectors.⁵ Current FDA recommendations state that it is safe for patients with implanted cardiac devices to walk through a metal detector gate, although the alarm may be triggered by the generator case. If scanning with a hand held metal detector is needed, the patients should ask the security personnel not to hold the detector close to the implanted device longer than absolutely necessary. An alternate form of personal search can also be requested.⁷¹

Electric Power

EMI from electric power can occur if patients come in proximity to high voltage overhead power lines (accidentally or by occupation) or it may be caused by electrical appliances held close or in direct contact with the chest. Implanted devices are susceptible to interference signals of 50–60 Hz, frequencies that lie within the bandwidth sampled for detection of intracardiac signals.

Detrimental effects from incidental exposure to high voltage lines are unlikely. For example, even at 40-m distance from a 400-kV line, the electric field strength is low (< 1 kV/m). Only field strengths > 5 kV/m influence pacemaker behavior. Patients working in close proximity to high voltage sources (e.g., lines, distribution transformers) can suffer EMI.⁷² In vivo studies disclosed that all kind of responses (inhibition, triggering, noise reversion) could occur, depending on the strength of the field, the generator model, the sensing configuration, and the programmed sensitivity.^{36,73,74} Bipolar sensing protects from EMI in all but the most extreme environmental conditions, like power generating stations, while with unipolar sensing inappropriate pacemaker behavior can occur during routine daily exposures. Mehdirad et al.⁷⁵ reported a television cable line installer with an ICD, who, while kneeling on damp ground in a utility tunnel, accidentally grasped a 60 V/30 A alternating current power line with his bare left hand, causing immediate electrocution. He remained conscious but was unable to release the

power line. He then received a shock from his ICD, causing him to be thrown back and as a result, the power line was released from his hand. The stored intracardiac electrogram revealed normal sinus rhythm followed by detection of 60-Hz electrical noise, detected with shortest intervals of 120 ms (the blanking period of the device). After confirmation, a 12-J shock was delivered. Upon release of the power line from his hand, the electrical noise detection was no longer present.

EMI from household appliances is more likely with improper grounding. Anecdotal reports have incriminated toy remote controls,⁷⁶ electric razors,⁷⁷ current leak from a water boiler (manifesting when opening the hot water faucet),⁷⁸ and vibrators.¹⁸ A report by Seifert et al.⁷⁷ on a patient with spurious ICD discharges while using an electric razor is especially illuminating. Provocative testing confirmed oversensing of 50-Hz power with the patient's razor and a brand-new similar unit. Further evaluation suggested an insulation break, which was located (at operative revision) by the ventricular coil of the "integrated" bipolar Endotak (Guidant Inc.) lead. The system was operating "de facto" in a unipolar mode.

Slot Machines

A report by Madrid et al.⁷⁹ suggests that slot machines represent another source of EMI. Over a 2-year period, they encountered four ICD patients who received shocks while playing with slot machines. Stored electrograms or RR interval histories were compatible with electrical noise. Characteristics of the culprit slot machines were not reported. These observations have not been reproduced, nor were simulation studies undertaken. Until the issue is clarified, it is prudent to warn ICD patients of this potential interaction.

Working Environment Sources of EMI

Industrial Equipment

Although in general desirable, the return of the patient with an implanted cardiac device to a work environment suspected of high level EMI can be challenging. Among the myriad potential EMI sources, arc or spot welders, industrial welding machines, degaussing coils, and electric motors are frequent cause of concern. These sources do not only emit energy in the radiofrequency spectrum, their associated magnetic fields could potentially

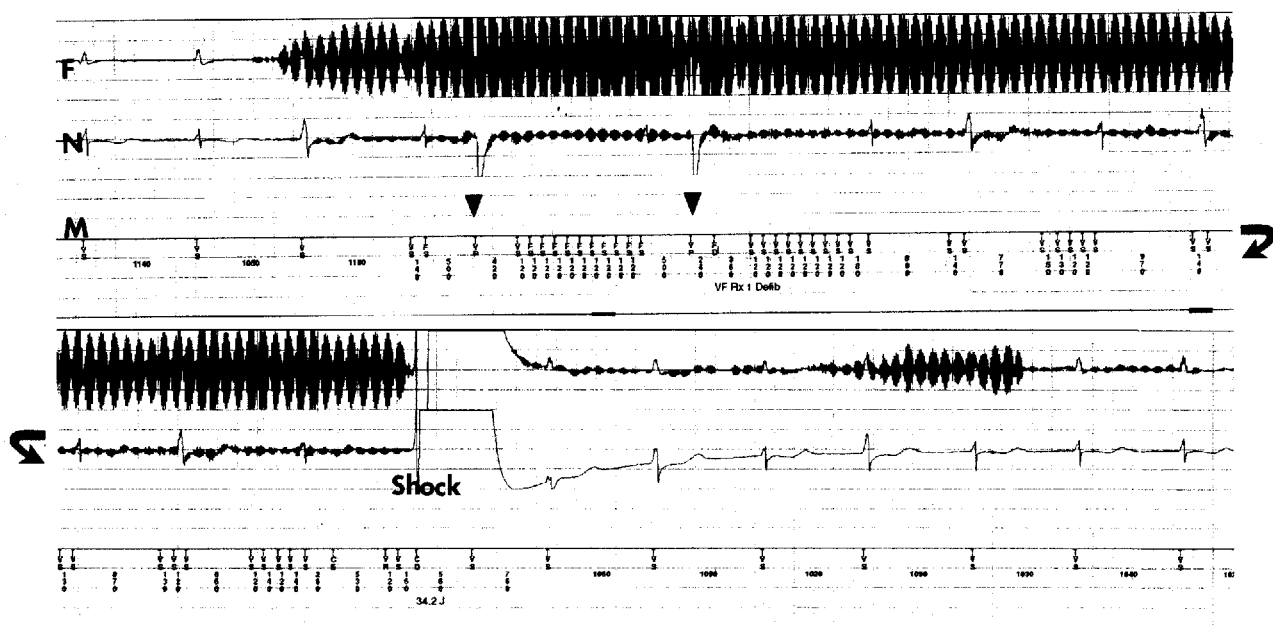


Figure 4. Spurious implantable cardioverter defibrillator shock due to electromagnetic interference (EMI) from electric power. Stored far-field (F, coil-to-can) and near-field (N, tip-to-coil) electrograms plus annotated event markers (M) in a patient who received a shock while using a power drill in a flooded basement. The maximal ventricular sensitivity was programmed to 0.3 mV; 60-Hz interference is clearly visible. Premature paced beats (arrowheads) represent operation of the ventricular rate stabilization algorithm. The patient released the drill immediately after the shock. EMI in the sensing channel disappears promptly.

close the reed switch in pacemakers and ICDs. Each patient should be evaluated individually, but a few generalizations can be made. Bipolar sensing systems with close-coupled (≤ 1 cm) electrodes should be used preferentially in patients who may be exposed to high levels of EMI at work. Newer dual coil defibrillation leads with dedicated bipolar sensing may be useful in this setting, as they make the prior trade-off between defibrillation efficiency and susceptibility to interference no longer necessary. The sensitivity should not be programmed very high in relation to the intrinsic electrogram amplitude. Implant testing of ventricular fibrillation detection at the least sensitive setting (e.g., 1.2 mV with Medtronic ICDs) allows estimation of the sensing "safety margin" and appropriate reduction in the chronically programmed sensitivity. It is useful to ask a technical consultant from the device manufacturer to conduct a comprehensive EMI test at the patient's work site. However, this service may not be generally available due to liability issues. There is no professional reimbursement provided for an on-site visit by clinic staff. Testing should include measuring of magnetic fields at different distances from the source plus re-

view of telemetered and stored electrograms and event markers while the patient is operating the equipment (ICDs should be programmed "monitor-only" to avoid spurious shocks).⁸⁰ In pacemaker dependent patients, testing a device identical to the one implanted coupled to a heart simulator represents a safe, sensitive preliminary step.⁸¹ In patients with Guidant ICDs, a simple screening strategy that included listening to QRS synchronous beep tones (a programmable feature) after extending the detection duration while the patient routinely operates the equipment is safe and effective.⁸² In patients with ICDs from St. Jude and Guidant that are exposed to intense magnetic fields at work, inhibition of tachyarrhythmia therapy in response to magnet application can be disabled. Additional general precautions include ensuring appropriate grounding of the equipment and avoiding close contact with the EMI source. Arc welders, for example, should not carry the cables on their shoulder. If they experience light-headedness or an ICD shock (Fig. 4), patients should be instructed to stop operating the equipment and to contact their physician. Many patients can safely return to work with these precautions.⁸³

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