

**IEEE Committee on Man and Radiation**

**COMAR Technical Information Statement**

**RADIOFREQUENCY INTERFERENCE  
WITH MEDICAL DEVICES**

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**ABSTRACT**

The past few years have seen increased reports that medical devices, such as pacemakers, apnea monitors, electrically powered wheelchairs, etc., have failed to operate correctly because of interference from various emitters of radiofrequency energy. This condition is called radiofrequency interference (RFI). The consequences of these failures range from inconvenience to serious injuries and death. Reasons for this problem are twofold: 1) increasing numbers of electronically controlled medical devices with inadequate electronic protection against RFI, and 2) a significant increase in the number of RF sources in the environment. Medical devices are widely used outside the hospital and may be attached to, or implanted in, patients. Portable wireless communications equipment, including cellular phones, handheld transceivers, and vehicle mounted transceivers, comprise one of the largest sources of RFI. Some medical devices are especially sensitive to the type of digital modulation that some of the wireless communications devices utilize.

The prevailing international standard for the RF immunity of medical devices is the 1993 revision of the International Electrotechnical Commission (IEC) Standard IEC 601-1-2. This standard sets a minimum immunity level of 3 volts per meter (V/m) in the 26-1000 MHz frequency range. For non-life supporting devices, testing is required only at the specific frequencies of 27.12, 40.68, and 915 MHz. Technology exists to protect, or "harden," most medical devices from RF fields that are much more intense than the 3 V/m level specified in present RFI standards. Most of these techniques, including shielding, grounding and filtering, are not costly if they are incorporated into the initial design of the electronics system.

COMAR recommends that the various parties involved in the manufacture and use of RFI prone medical devices take steps to avoid serious RFI problems that may lead to safety hazards. Medical device manufacturers should design and test their products to ensure conformance with current RFI standards and educate the users of their devices about the possible symptoms of potential RFI. If there exists the possibility of RFI problems to medical devices, steps should be taken to ensure that all sources of RF energy be kept at a sufficient distance.

## INTRODUCTION

Since the early 1990s, reports of medical device failure from electromagnetic interference have increased [1-4]. This is due to several factors. The number of electronically controlled medical devices has burgeoned in hospitals and other medical facilities. Newer instruments are often more sensitive to radiofrequency interference (RFI) because they incorporate low power integrated electronic circuitry that can be much more sensitive to electromagnetic fields than their electrical and electromechanical predecessors. In this document, RFI refers to radiated interference from electromagnetic fields that are coupled from a source to a medical device through the air (i.e. without connections via conductors such as wires or cables).

There has also been a significant rise in the use of electronically controlled medical devices outside the clinical environment. These devices are often used in homes, attached to patients, or implanted in their bodies. In addition, portable wireless communications equipment, such as cellular phones, handheld transceivers, and vehicle mounted transceivers, is a major source of RFI. The number of land mobile transmitters in the US alone currently exceeds 10 million and personal communications systems are burgeoning throughout the world. To an ever increasing extent, wireless communications equipment (e.g., cellular phones) is likely to be used in close proximity to medical devices without the knowledge of the patient or attending medical personnel.

Digital mobile communications systems often utilize pulsed amplitude modulation, a type of modulation, that can enhance the potential for RFI. For example, cellular telephones based on some digital technologies generate peak powers of up to 8 watts and are modulated at 2 to 217 pulses per second. This range spans the physiological frequencies of the human body, from about 0.5 Hz to several hundred Hz, that are monitored by many medical devices. This is often termed the "physiological passband." While modulation at very low frequencies is critical, this document does not address RFI from sources with very low carrier frequencies. Thus, AC power

line fields (50-60 Hz) are excluded from discussion. Also excluded are transient fields, such as pulsed gradient fields from magnetic resonance imaging (MRI) systems, where most of the frequency content is below a few MHz. The frequencies discussed in this statement are in the range of 30 to 3,000 MHz.

## REPORTS OF PROBLEMS ENCOUNTERED

Hundreds of incidents of RFI induced medical device failure have been reported, studied, and summarized [1,5]. The most likely source of those failures has been RFI from mobile radio transmitters. The consequences have ranged from inconvenience to serious injuries and death. However, many more incidents may occur that are not reported because most users of medical devices are unaware that RF fields are present when problems are recognized and because of the intermittent nature of the failures that could cause them to be unobserved.

In the mid-1980s, the US Food and Drug Administration (FDA) had become aware that approximately 60 infants died in the United States while being monitored for breathing cessation by one model of apnea monitor. Subsequent tests have shown that this particular monitor is extremely susceptible to low level RF fields [6], including those from mobile communication base stations several hundred meters away and FM radio broadcast stations more than one kilometer away. Other apnea monitors have been shown to be similarly susceptible to malfunction. This has resulted in voluntary recall of more than 16,000 apnea monitors.

Another device that has demonstrated RFI susceptibility is the electrically powered wheelchair. Unintended motion has been initiated by RFI from transceivers in nearby emergency vehicles [7], causing persons to be ejected from their wheelchairs or propelled into traffic. New draft performance standards for wheelchairs are being developed by the Rehabilitation and Assistive Technology Society of North America (RESNA) to address these problems; many manufacturers are developing products that conform to these standards.

An additional problem area involves implanted cardiac pacemakers and defibrillators. Teams of engineers and cardiologists in several countries have independently studied these devices, either in patients or tissue simulating models, demonstrating that nearby digital cellular phones sometimes induce undesirable effects [8-11]. The dominant effect observed has been loss of pacemaker adaptive control, causing the device to deliver stimuli either irregularly or at a preprogrammed fixed rate. This is not usually detected by the patient and, when the cellular phones are moved away, the pacemaker resumes its normal operation. Interference with pacemakers has not been observed when the phones are held at the ear. A panel of researchers has concluded that phone/pacemaker interference should not be considered a major public health concern and has offered specific recommendations for pacemaker wearers [12-13]. Cellular phones have also been shown to cause unintended firings of implantable cardiac defibrillators [14].

Recently, handheld digital cellular telephones, that use pulse modulated time division multiple access (TDMA), have been found to disrupt the proper operation of in-the-ear hearing aids.

TDMA phones include international Global System for Mobile (GSM) communications and North American Digital Cellular (NADC) pulse modulation formats, which utilize schemes that produce 100% amplitude modulated pulses of the RF carrier at frequencies within the audible hearing range. Subjective perception of interference varies from barely perceptible to annoying and loud, starting when the phones are within one meter of the hearing aids and becoming louder when the phones are several centimeters away [15]. This type of interference also occurs in behind-the-ear hearing aids, making it impossible for wearers of this device to be able to use this type of phone.

Recently, warnings have been published concerning the use of wireless communications equipment in the clinical environment. Hospitals worldwide have recommended that cellular phones and two way radios not be used in intensive care units, operating theaters, and patient rooms, where critical care medical equipment is in use [16-17]. Measurements that have been made inside an ambulance, where electronic patient monitoring equipment is used, have yielded field strengths of up to 22 V/m in the region of 800 MHz [18]. Recommendations have also been made that patients using medical equipment at home be educated about possible hazards from the simultaneous use of portable telecommunication devices. Extensive measurements have been made to determine the field strengths produced by common RF sources in actual or simulated non-clinical environments, many that are greater than 3 V/m. [19].

## FACTORS THAT AFFECT THE OCCURRENCE OF RFI

Many factors affect the severity of RFI in medical devices, including 1) the coupling between a source of interference and the medical device, 2) the frequency of the RF carrier, 3) the modulation imposed on the fields from each source, and 4) the distance between the RF source and the susceptible medical device. Effects of coupling occur primarily when the susceptible device is in the near field of the source. Capacitive coupling occurs in a region near the source where the electric field is dominant (e.g. the tip of a dipole antenna). In contrast, inductive (magnetic) coupling between the base of the cellular phone antenna and implanted cardiac pacemakers has been demonstrated by Carillo et al. [11] to prevail over capacitive coupling for this situation. While coupling is a critical factor for RFI under near field conditions, in the far field it is the carrier frequency that is crucial to the introduction of RF into a device. Generally, the frequencies with the greatest ability to induce RFI are those whose wavelengths are comparable to the maximum dimension of a medical device's physical housing, or to the length of the external cables and leads connected to the patient.

Modulation also affects the degree of interference for a given set of exposure conditions; amplitude modulation (including pulsed RF) is usually the most significant for RFI. The amplitude modulated RF carrier can be detected at the semiconductor junctions in the device; significant interference occurs if the modulating frequencies are within the physiological passband of the device.

## STANDARDS FOR RF IMMUNITY OF MEDICAL DEVICES

The predominant international standard for the RF immunity of medical devices is the IEC Standard 601-1-2; the 1993 revision of this standard requires a minimum immunity level of 3 V/m in the 26-1000 MHz frequency range [20]. For devices that are not life supporting, testing for compliance is required only at the specific frequencies of 27.12, 40.68, and 915 MHz. Sinusoidal amplitude modulation of 80% of the carrier is required. The modulating frequency should represent the most significant interference source to the specific device under test, or in lieu of that, 1 kHz. Susceptibility to lower frequencies should be evaluated using standardized test methods.

Test methods for radiated RFI are specified in IEC standard 1000-4-3 [21]. The primary test method involves the use of a semi-anechoic chamber and a biconical, log periodic, or other linearly polarized transmitting antenna. Exposure of the device under test must be performed in a "uniform area" of field strength that measures 1.5 x 1.5 meters, is at least 0.8 meters above the floor, is at least one meter from the exposure antenna, and is at least 0.8 meters away from any RF reflecting objects. The front surface of the device under test and all wires and cables must be placed in the uniform area. To calibrate the field strengths in this area, measurements must be

made at 16 evenly spaced points (including the four corners of the plane) with the device under test absent. The uniformity of the field must be within 6 dB for 12 of the 16 points. Wires should be arranged to be consistent with the manufacturer's recommendations. The first meter of each signal carrying cable and power cable must be extended in the planar area. The next two meters of the cable must be arranged in a non-inductive bundle. Exposures with four orientations of the device under test must be performed for both a horizontal and vertical polarization of the electric field. At least one exposure should be performed with the leads and cables aligned with the electric field vector.

Other device specific RFI standards are being, or have been, developed, including standards that address hearing aid interference from cellular phones [22] and powered wheelchair RF immunity (RESNA).

## FAILURE PREVENTION AND RFI AVOIDANCE

For many years, military, aircraft, and automotive electronics systems have been required to meet strict RFI requirements for immunity to up to 200 V/m because these systems could encounter such levels during normal operations. The technology has already been developed to "harden" most medical devices against fields that are much more intense than the 3 V/m level specified in present RFI standards for medical devices. Most hardening techniques are not costly if they are incorporated into the initial design of the electronics system. Standard RF immunization techniques include the use of shielding, grounding, and filtering. Shielding includes enclosing the device in metal boxes or in plastic boxes coated with metallic paint. Use of RF shielded cables is standard practice in commercial audio and video devices. Grounding of electronics circuitry and cable shields is an inexpensive but necessary step toward ensuring RFI

immunity. RF filtering of signal carrying conductors, especially in sensitive patient monitoring equipment, should be performed carefully. The potential for the success of these techniques has been demonstrated in implanted cardiac pacemakers, which commonly achieve immunity of up to 200 V/m even though these devices monitor weak electrophysiological voltages.

The use of capacitive "feed through" RF filters preceding the input circuitry of an implanted medical device is straightforward [23-24]. However, patient connected medical devices, which are powered by 60 Hz AC, must accommodate the safety requirements for electrical leakage currents as well as RFI immunity requirements. Therefore, patient connection leads on devices that obtain power from AC lines must utilize special techniques to simultaneously meet both types of safety requirements. Techniques for isolating patients, which incorporate optical or transformer coupling, may be required. In addition, designers can add interference recognition and fail-safe circuitry to their medical devices [25]. For example, many cardiac pacemakers are protected from erratic operation by being programmed to revert to a fixed rate when RFI is detected.

Mobile RF and wireless communications systems can be optimized for compatibility with medical electronics. The modulation frequencies of RF transmitters should be outside the physiological passband of most or all medical devices. Digital modulation schemes that use TDMA, and the associated amplitude modulation pulses, should be carefully designed to avoid RFI. Frequency modulation, or non-pulsed, spread spectrum modulation techniques (such as certain forms of code division multiple access, or CDMA) can be used.

Managers of facilities where sensitive medical devices are used should control RFI by careful planning and system design. For example, the radiated power of many modern handheld and portable cellular phones is under the control of the base station. When close to a base station, handheld and portable phones may operate at power levels far lower than the maximum power of 600 mW (for handheld phones) or 3000 mW (for portable bag phones). Thus, when a base station is located near a health care facility or when low power base stations (microcells) are used within the facility, cellular phones will normally operate at low power. However, the base station itself must be properly sited to avoid causing RFI. If deemed necessary, RF sources can be restricted from the more sensitive areas of a hospital, such as intensive care units.

Administrators of healthcare facilities can impose restrictions on the use of mobile RF transceivers. The concept of a specific "minimum separation distance" for each type of mobile transceiver has recently been proposed [2,4]. For example, handheld cellular phones that radiate 600 mW would have to be kept at least one meter from a medical device that is immune to 3 V/m. A 5 watt handheld transceiver would have to be kept 2.6 meters from the same device. In practice, an additional safety factor should be required to account for enhancement of signals by field reflections.

To address RFI problems with implanted cardiac pacemakers, certain control techniques can be implemented. Even though pacemakers have been designed to be immune to very intense electric fields (200 V/m), some may still malfunction when certain cellular phones are placed within a few centimeters of the pulse generator. Therefore, government agencies have issued recommendations to health care providers and patients with pacemakers [26]. Cellular telephone

manufacturers and pacemaker manufacturers have independently developed similar recommendations that indicate how to minimize the occurrence of RFI in patients with implanted cardiac pacemakers when they use cellular phones. Users should avoid placing cellular phones directly over pacemakers (such as in the breast pocket) when the phone is turned on. Also, the cellular phone should be used with the right ear if the pacemaker is implanted in the left side of the chest

## RECOMMENDATIONS

COMAR recommends that manufacturers and users of both medical devices and radiofrequency transmitters work together to ensure that medical devices can operate in a safe and effective manner while in the presence of RF fields.

Medical device manufacturers should design and test their products to ensure conformance with current RFI standards so that their devices are not excessively sensitive to RFI. This will require that the products be shielded in electrically conductive, or conductor coated, enclosures that incorporate feed through filters and other techniques to increase electromagnetic compatibility. Even when medical devices conform to existing standards, manufacturers should warn both medical professionals and patients of situations where RFI failure may occur. The warning should include information that describes how to recognize the symptoms of RFI, how to deal with RFI problems, and how to report incidents.

Dialogues between manufacturers of RF emitters and manufacturers of medical devices, conducted through national and international manufacturers' organizations and standards setting committees, are encouraged to maximize timely exchange of information about new product designs and release dates. Such organizations in the United States include the Cellular Telephone Industry Association (CTIA), the Association for the Advancement of Medical Instrumentation (AAMI) and the Health Industry Manufacturer's Association (HIMA).

Continuing vigilance by both manufacturers and users of medical devices is essential to ensure RFI immunity. If a manufacturer modifies the design or physical housing, RFI immunity can change drastically. Also, during repair, the RFI immunity of a device may be altered significantly by inadvertent modifications, such as failure to replace shielding gaskets. As a general rule, users of medical devices should keep RF emitters as far away from medical devices as is practical.

A standardized RFI test method has been developed to enable engineers in clinical environments to estimate the susceptibility of medical devices to specific radio frequency transmitters in a setting comparable to that of actual use [27]. This method should be used to identify potentially problematic situations in hospitals where transmitters are repeatedly used in close proximity to critical medical devices.

All incidents of suspected interference, especially those involving injury, should be reported in detail to the appropriate person, facility, or agency so that the manufacturer may be informed

about the problem in a timely fashion. In the United States, the FDA maintains a Medical Device Reporting System [28] and other services for this purpose. All concerned parties should participate in the development or revision of performance standards that address medical device RFI. If specific concerns arise, they should be submitted, in writing, to the appropriate Standard Development Committee.

## CONCLUSIONS

Today, many medical devices that are tested for susceptibility to RFI cannot meet the 3 V/m minimum immunity requirements of the current IEC Standard 601-1-2. Handheld cellular telephones produce field strengths greater than 3 V/m at distances of up to 1 meter, while higher power transceivers produce 3 V/m fields at distances of up to 2.6 meters. This situation may be responsible for serious failures of life sustaining medical devices. It is imperative that immunity to RFI be designed into new medical devices. Because mobile transceivers can generate field strengths of hundreds of volts per meter at close range, fail-safe mechanisms should be designed into medical devices that cannot be made immune to such high RF field strengths.

The field strength to which a medical device may be exposed depends on many conditions that are beyond the control of the designer or manufacturer. Therefore, administrative controls should be implemented that include education of the user, both in the clinic and at home. The possibility of incomplete RF compatibility between RF transceivers and medical devices must be recognized and dealt with. In health care facilities, mobile transceivers should be restricted to distances that have been determined to be safe, especially in areas where critical devices are operated. By developing both short and long term solutions like those suggested above, electromagnetic compatibility between mobile RF sources and medical devices can be maximized.

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