Facing the Challenges of Electromagnetic Interference With Medical Devices in the Wireless World

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ABSTRACT

Electro magnetic interference (EMI) with medical devices has been confirmed through testing and linked with patient injury and death [1-8]. For example, EMI from cellular telephones recently caused drug infusion pumps to overdose patients [8]. FDA has championed the electromagnetic compatibility (EMC) of electrically powered medical devices, and performed research to help develop standardized testing methods and national and international consensus standards. This presentation focuses on medical device EMI problems associated with wireless technology (e.g.; EMI to wireless medical telemetry from digital TV, and EMI to implanted devices from electromagnetic security systems) and the solutions developed to address these problems, including the new Wireless Medical Telemetry Service (WMTS).

CHALLENGES FOR ELECTRICALLY POWERED MEDICAL DEVICES

Electromagnetic interference (EMI) can disrupt the function of active medical devices and has caused serious injury and death [1-8]. In addition, there have been over 90 reports collected by the US Food and Drug Administration (FDA) of injuries to patients wearing ambulatory medical devices (e.g., implantable pacemakers and neurostimulators) due to interference by electromagnetic field-emitting security systems (e.g., anti-theft systems and security metal detectors) [3]. With the rise in the use of wireless technology, the FDA has been increasingly concerned about the risks to patient safety and the effectiveness of medical devices because of the potential susceptibility of these devices to EMI. Further, there are increasing uses of potentially susceptible electronics in an ever-widening array of medical devices concurrent with the development of new digital (wireless) radio transmissions in, and around these potentially susceptible devices. An example of EMI related medical device malfunction was reported by Hahn et. al., who described the acute epinephrine overdose of a patient linked with EMI to the patient's infusion pump by the use of a cellular telephone nearby [8]. Others have presented results of in-situ clinical testing for medical device susceptibility, such as Juett who reported on the EMI effects on several susceptible medical devices from hand held radio transmitters and wirelessly connected equipment such as a Personal Digital Assistant (PDA) [9]. The testing done at Baylor Medical Center revealed that 42% of the critical care medical devices were disrupted by EMI from these "wireless" radio transmitters.

The susceptibility of medical devices to EMI is related to the frequency of the exposure field, the strength or magnitude of the fields, modulations on the electromagnetic disturbance, and other factors relating to how the disturbance is coupled into the device and disrupts the device function. Medical device can be susceptible to several different sources and types of electromagnetic disturbances, such as: radiated RF energy, conducted energy, and electrostatic discharge energy. Not only can medical devices be susceptible to EMI, they can be the source of emissions that may lead to EMI in other nearby devices. Thus, both the emissions and susceptibility of the medical devices must be addressed.

The international standard for medical electrical equipment electromagnetic compatibility (EMC) is the IEC 60601-1-2 (2001) [10], which is widely used to assess the emissions and susceptibility of electrically powered medical devices. This standard calls for emissions testing to the CISPR 11 standard, and radiated RF immunity testing at field strengths of 3V/m for non-life supporting devices and 10 V/m for life supporting devices. However, for radiated RF fields since the fields fall off inversely with distance (simplified equation below) the 3 V/m level can be exceeded by bringing the transmitter closer.

The simplified equation: $E = \frac{k\sqrt{P}}{d}$, based on a dipole antenna, can be used to estimate the radiated field strength in the far field from the transmitting antenna [11]. Here E is the electrical field strength in V/m, k is a constant dependant on antenna characteristics, P is the antenna input power in Watts, and d is the distance from the transmitting antenna in meters. For example, the fields radiated from a cellular phone operating at its full 1 W power output create about 2.6 V/m at 2 m, 5 V/m at 1 m and about 10 V/m at 0.5 m. Measurements of the radiated fields from hand-held transmitters

are reasonably consistent with these calculations. In addition, measurements in and around ambulances show that their powerful mobile radio transmitters can create field strengths up to 18 V/m outside, and 22 V/m inside, the ambulance where medical devices are used [12]. Thus, with the increase in the use of "wireless" communications medical devices can be exposed to electromagnetic fields well in excess of the immunity test levels from some widely accepted standards

WORK TOWARD SOLUTIONS

Over the years, FDA has championed the electromagnetic compatibility (EMC) of all electrically powered medical devices, and performed research and measurements in FDA laboratories to help develop solutions such as: standardized testing and measurement methods, participating in the development of national and international consensus standards, and facilitating cooperation among the medical device industry and the industries that produce the sources of the interfering electromagnetic fields. For example, FDA developed a test method for examining the susceptibility of powered wheelchairs and scooters to EMI, which became the basis of the ANSI/RESNA standard for radiated RF immunity testing that is widely used in the U.S. and recognized by FDA [11]. Staff from FDA has played major roles in the development of the new IEC 60601-1-2 second edition EMC standard and other medical equipment standards with EMC requirements. As well, the FDA is currently engaged with the medical device community in collaborative efforts to protect wireless medical telemetry from EMI by other radio transmitters, investigations of the susceptibility of ambulatory medical devices to EM emissions from security systems, and ways to minimize the risks of EMI to medical devices.

Wireless Medical Telemetry

An example of medical device EMI with wireless communications was the EMI disruptions to wireless patient monitoring devices (wireless medical telemetry) experienced at two U.S. hospitals from broadcasts of new digital television signals (DTV). Through quick actions by clinical engineers at the affected hospitals, no patients were harmed during these EMI incidents, but the conflict between new non-medical wireless technology and traditional wireless medical telemetry was clear. At the heart of the susceptibility of wireless medical telemetry was the delegation of these patient signals to the frequencies of vacant TV channels or the Private Land Mobile Radio Service (PLMRS), where the medical telemetry operates as a secondary user that must accept interference but not cause it to the primary licensed frequency users. Not only has DTV eliminated many of the vacant TV channels, but the Federal Communications Commission (FCC) is changing the PLMRS to narrower channel allocations, thus increasing the likelihood of interference with wireless medical telemetry equipment operating in previously available interchannel frequencies.

A solution to this conflict was developed in the creation of the new Wireless Medical Telemetry Service (WMTS) by the FCC that has separate carrier frequencies and usage rules for medical telemetry to minimize the risks of interference with the medical telemetry signals [12]. Creation of the new WMTS (key features summarized below) was created through unprecedented cooperative efforts among FDA, the American Hospital Association (AHA), the FCC, and medical device manufacturers. FDA recommends manufacturers and users assess and minimize the risks for EMI to their wireless medical telemetry, and use the WMTS because of the protections and coordination afforded to minimize EMI [13].

Key features of the Wireless Medical Telemetry Service:

Use of WMTS: by health care facilities and professionals, licensed by FCC rule
Frequencies bands and technical specifications:
608 – 614 MHz, 200 mV/m maximum field strength at 3 meters
1395-1400 MHz, 740 mV/m " " " "
1429-1432 MHz, 740 mV/m " " " "

- Uni- and Bi-directional transmission allowed, Voice and Video not allowed (physiological waveforms are not considered video)
- Limitations on out-of-band emissions
  - 1395-1400 MHz and 1429-1432 MHz bands, no channelization specified
  - 608-614 MHz (TV channel 37) band have limitations of Spread Spectrum technologies, and limitations on assignments of channels so that no facility can have exclusive frequency use. Operations in this TV channel band are not protected from adjacent band interference from channels above and below this TV channel.

Limitations of Use:

- Use of the 1395 – 1400 MHz and 1429 – 1432 band are restricted in some geographical location because of continued U.S. government use that will phase out in by 2009.
- Use of the 608-614 MHz band is restricted within 80 Km of several sensitive radio astronomy observatories noted in the FCC Report and Order. Written concurrence and frequency coordination near these observatories is required.

Frequency Coordinator: American Hospital Association

Information required by Coordinator:

- specific frequencies or range used
- modulation scheme used and bandwidth
- effective radiated power
- number of transmitters in facility and manufacturer and model numbers
- name of health care provider
- transmitter location (coordinates, street address)
- point of contact for authorized health care provider

Electromagnetic Security Screening Systems

In addition to the use of wireless technology for communications, other forms of wireless radiofrequency signals can cause EMI to medical devices. For example, the emissions from electromagnetic security systems have been reported to disrupt several medical devices [3, 14-16]. While these reports and other information do not suggest a major public health problem in this area, FDA is concerned and has been investigating the susceptibility of implanted neural and cardiac stimulation devices to the emissions of security systems. Casamento (from CDRH, FDA) has performed precision measurements of the electro magnetic fields emitted by both anti-theft systems (also known as electronic article surveillance systems or EASS) and metal detector type security screening systems [17]. Some of the laboratory research with implanted medical devices suggests that these emissions may be sufficient to couple into the medical device and disrupt the device function or alter the device output. FDA issued a Safety Alert to clinicians with patients who have active implanted cardiac and neurostimulation devices, to provide information and suggestions that were intended to help minimize the potential for EMI and possible patient interactions [18].

SUMMARY

Active, electrically powered medical devices can be susceptible to EMI from the emissions of "wireless" radio transmitters. The use of wireless technology in and around medical devices challenges the medical devices, because EMI can increase risks for patient safety and disrupt the effectiveness of the device. With the raise in the use of wireless technology, manufacturers of active medical devices must be aware, and protect against, the susceptibility of their devices to EMI. In addition, the industries that create the emissions and wireless technology must address the consequences of the emissions of their products on medical devices. Moreover, the new wireless technology presents opportunities for medical devices to communicate patient information and data with other devices and systems, and possibly control the delivery of medical treatment via wireless links. It is crucial, therefore, for all active medical devices to address electromagnetic compatibility (EMC) from concept, through design and testing, to use by the clinician and patient. With appropriate medical device EMC, and communications and cooperation among the medical device community and the industries that create the emissions, the problems of EMI to medical devices can be addressed and the risk for patients minimized.

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