

Electromagnetic Interference (EMI) Testing of Medical Devices

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EMC Testing of Implantable Cardiac Pacemakers *In Vitro* for EMI from Digital Cellular Telephones

Key words: pacemaker, digital cellular phone, electromagnetic interference

An *in vitro* study was undertaken to investigate the potential for digital cellular phones to interfere with implantable cardiac pacemakers. A major thrust of this study was to determine which combinations of pacemakers and cellular phones produce interference. In addition, the separation distance between the phone and the pacemaker at which interference would cease was determined. Cardiac pacemaker manufacturers were invited to supply samples of their devices, and seven device manufacturers responded. As a result, 30 models of pacemakers were tested. Three digital cellular phone technologies were used, including a Global System for Mobile (GSM) phone and two different types of U.S. Time Division Multiple Access (TDMA) phones. One U.S. TDMA phone operated with a 11-Hz pulse modulation, the second U.S. TDMA operated with a 50-Hz pulse modulation. The GSM phones operated with a 217-Hz pulse modulation. All phones were operated at their maximum output powers of 1.3, 0.6, and 0.6 Watt, respectively.

Minimum separation distances between a phone and each pacemaker (immersed in a saline-filled tank) necessary to prevent interference were determined, and this distance was recorded for each device. These data are presented in **figures 5 and 6** which also show those pacemakers for which no EMI was observed. When the digital U.S. TDMA (11 Hz) cellular phone was located very close (4 cm or less) to single-chamber pacemakers, inhibition was the most frequent effect. For dual-chamber and the VDD pacemakers, simultaneous atrial inhibition with ventricular tracking were the most often observed effects.

Figure 5. No-Effect Distance TDMA (11 Hz) Phone

Results of testing using the TDMA (11 Hz) phone. The pacemakers which experienced EMI at the minimum test distance of 2.8 cm are identified with a circle. Those not so marked did not have EMI at this test distance.

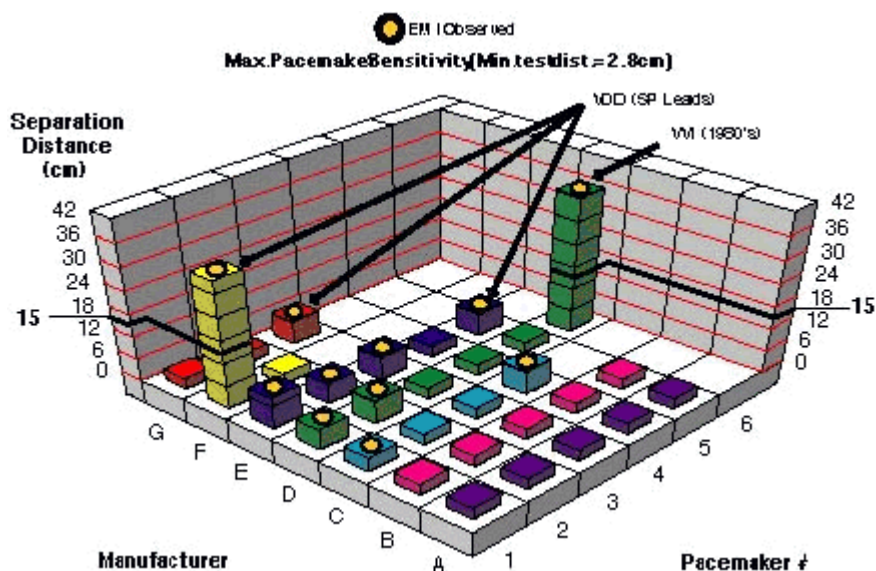
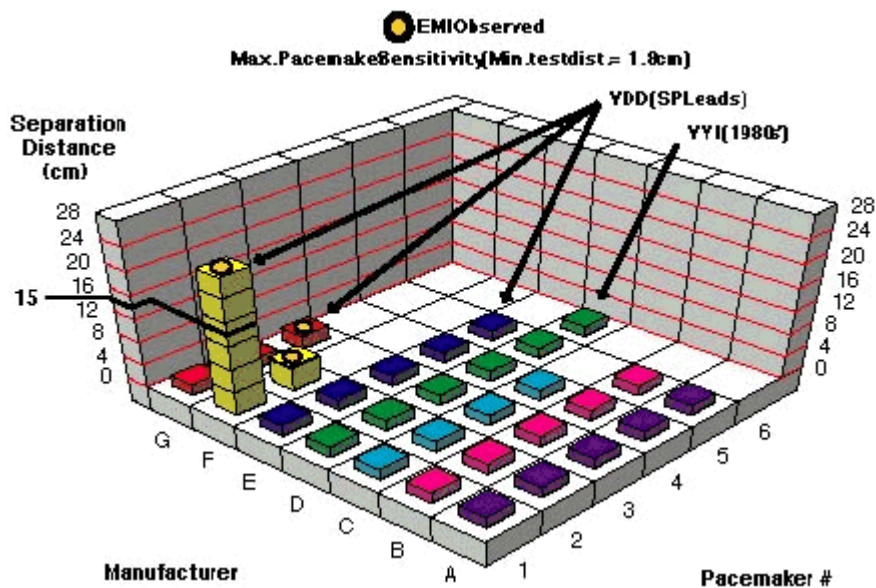


Figure 6. No-Effect Distance TDMA (50 Hz) Phone

Results of testing using the TDMA (50 Hz) phone. The pacemakers which experienced EMI at the minimum test distance of 1.8 cm are identified with a circle. Those not so marked did not have EMI at this test distance.



Using maximum pacemaker sensitivity settings, and separation distances of 9 cm or less, the TDMA (11 Hz) cellular phone caused EMI to varying degrees in 11 of the 30 devices (36%). This EMI ceased for nine of the sample devices when a pacemaker-to-phone separation distance of 9 cm was exceeded. Two of the pacemakers interacted beyond a 6-inch separation. One was an older VVI device (out of production for more than 5 years), and the other was a VDD device using a single pass (SP) lead at maximum device sensitivity (0.1 mV). These two units ceased interactions with the phones at separation distances of 33 cm to 36 cm. Twenty-seven of the sample pacemakers (90%) did not interact with the TDMA (50 Hz) digital cellular phone. Interactions occurred in the remaining three devices only when these devices were set at, or very near, their maximum sensitivity. Only the VDD pacemaker with a single pass (SP) lead exhibited ventricular tracking beyond a 4 cm separation distance (**figure 6**). This only occurred when the pacemaker was set at its maximum sensitivity (0.1 mV).

The vast majority of pacemakers did not interact with the cellular phones when separated by 6 inches (15.24 cm) or more. No device EMI was observed in this study using either the U.S. TDMA cellular phone in its analog mode or the GSM cellular phone. From these tests, it appears that the a "safe separation distance" of 6 inches (15.24 cm) is valid for most pacemaker designs and any cellular phone now on the market in the U.S. European researchers have reported interactions between some pacemaker models when very close to GSM-type phones. OST findings would appear to be inconsistent with the European studies. OST tests were performed only in the test mode where the phone is pulse-modulated at a rate of 217 Hz. This is well above the normal cardiac rate of 1 to 1.5 Hz (60 to 90 beats per minute). There are also other realistic operating modes that were used by the European researchers. Their GSM phones operated in these modes with low frequency (2 Hz) pulse modulation. To operate at a 2-Hz pulse modulation rate, the phone must be in the vicinity of a European base station or a base station simulator, neither of which were available to CDRH. [[PostMS, ProA](#)]

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Interference of Medical Devices by Electronic Article Surveillance Systems

Key words: electronic Article Surveillance, EAS, magnetic fields, electromagnetic interference

Electronic Article Surveillance (EAS) systems are used to detect shoplifting in retail stores by sensing a special tag attached to each piece of merchandise. A review of MDR reports reveals at least 28 incidents where implantable

cardiac pacemakers, automatic implantable cardiac defibrillators (AICD), spinal stimulators, hearing aids and ambulatory infusion pumps have malfunctioned in the presence of EAS systems. This electromagnetic interference is generated by the relatively strong magnetic fields emitted by EAS systems. An ongoing study by a cardiologist with the American Heart Institute in Miami indicated that three different EAS systems can cause implantable cardiac pacemakers to malfunction in volunteer patients. OST engineers contacted the cardiologist and initiated a collaborative study of the strengths and the spatial distribution of the magnetic fields around EAS systems. Through this collaboration, OST engineers assembled a collection of seven EAS systems from three manufacturers. These systems are a representative sample of the majority of the EAS systems currently used in the marketplace. They have been characterized for magnetic field strengths, frequencies of operation, and modulation schemes.

Initial measurements were performed manually with simple instrumentation. Data are presented in the table below. To improve the accuracy of the data, and increase the amount of data that could be collected, OST engineers designed a mechanical system that is capable of scanning a volume measuring almost two meters square by one meter deep. This spatial scanner and a three-axis magnetic field probe were used to determine the field strength distribution in and around the EAS system. A saline-filled human torso phantom has been developed for *in vitro* testing of pacemakers, ICDs, and other implantable devices in EAS systems. Preliminary tests have been performed on the field mapping. Data are presented in the following table.

Table 1.

Electronic Article Surveillance Magnetic Field Data

EAS System Frequency	Operational	Modulation	Field Strength in Center (micro Tesla)	Separation
Checkpoint QS-2000	7.2-9 MHz	FM 150 MHz/sec	0.32	36"
Sensormatic - Isle Keeper	535.7 Hz	CW	107	29"
Sensormatic - Saver	7.6-8.9 MHz	FM 108 MHz/sec	0.3	36"
Sensormatic - Ultra-Max	58 kHz	Pulsed - 1.66 msec pulse width, 10% duty cycle	12.3 (39*)	72"
Sensormatic - Pro-Max	58 kHz	Pulsed - 1.66 msec pulse width, 10% duty cycle	13 (39.7*)	108"
Knogo #1	1.83-2.11 MHz	FM 0.067	0.26	72"
Knogo #2	219 Hz	CW	220	32"

Upon completion of the field mapping, OST can then correlate exposure field strengths with clinical data on pacemaker interference in patients at various locations near each EAS system. [\[ProA\]](#)

* Peak pulse magnetic flux density.

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Electromagnetic Compatibility in the Hospital Setting

Key words: electromagnetic interference (EMI), electromagnetic compatibility (EMC), ad hoc EMI testing, wireless communications, cellular phone

CDRH has been concerned about the interactions between electrically powered medical devices and sources of electromagnetic energy for many years. This concern is based upon several incidents that have demonstrated the high susceptibility of numerous medical devices to electromagnetic interference (EMI). The EMI issue has become a greater concern as medical devices increasingly utilize sensitive electronics at the same time that radio and other electromagnetic sources are proliferating. Wireless communications and computer links are rapidly becoming widespread, bringing these sources ever closer to sensitive and susceptible medical devices. Nowhere is this growing proximity more prominent than in hospitals, particularly those installing new wireless communications systems throughout their facilities. These systems would bring a source of EMI very close to potentially susceptible devices. As a result, many health care facilities have sought a quick and easy way to gauge the extent of EMI problems in their facility. Because of the need for such a tool, OST scientists have taken the lead in developing a qualitative test procedure for Radiofrequency Interference (RFI). This is being done through the ANSI C63 EMI standards committee.

To study this issue in a clinical setting, OST initiated a collaboration with two hospitals: Johns Hopkins Hospital (JHH) and Walter Reed Army Medical Center (WRAMC). Clinical testing of a variety of commonly used medical devices was performed at JHH and WRAMC using available handheld radio transmitters following the draft C63 *ad hoc* RFI test procedure. Each health care facility performed its own independent testing and then participated with CDRH engineers in performing precise EMI testing at the CDRH EMC laboratories. The testing was done on a number of medical devices chosen by JHH or WRAMC. The types of RF sources chosen for the tests varied according to the needs of the JHH and WRAMC. JHH is considering the new Personal Communications System (PCS) hand-held phones, so they chose to include a PCS cellular telephone, along with a conventional cellular phone and a guards' handheld radio transceiver. WRAMC is considering a new two-way paging system; so they used this as an RF source, as well as cellular phones and guard radios. The JHH medical devices were separately tested in the precision GTEM exposure system in OST. This enabled a comparison of results from the *ad hoc* qualitative testing with a quantitative EMC laboratory test method.

The results of testing at the two clinical institutions were compared with the findings of testing at CDRH. Data were compared for consistency between the clinical tests and the laboratory tests of the same medical devices. It was found that the draft C63 *ad hoc* RFI test procedure can indeed be a relatively consistent screening tool for device EMI problems. Based on this experience, OST members of ANSI C63 introduced many important changes into the draft standard. This will enable the *ad hoc* test method to become an accurate and useful tool in determining the relative susceptibility of specific medical devices in their clinical setting to local RF transmitters. This procedure can be used as part of a larger plan to minimize the risk from medical device EMI. The draft C63 *ad hoc* procedure is presently undergoing balloting and comment within the C63 committee. All indications point to a valuable tool for the clinical engineer to examine EMI in the clinical setting. [[ProA, Stds](#)]

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Testing of Hearing Aid Interference from Digital Cellular Telephones

Key words: electromagnetic interference, hearing aids, cellular phones

Laboratory screening of over 20 models of hearing aids has revealed that all hearing aids tested were susceptible to radiofrequency (RF) interference from the digital cellular phones that are now used in the U.S. Extensive testing was conducted on eight hearing aids (four behind-the-ear and four in-the-ear) using five different types of digital cellular telephones. The volume control on the hearing aids was set for maximum gain to demonstrate a worst case interference scenario and each aid was tested in both microphone (M) and telephone (T) coil where applicable. Tests were performed in a microwave anechoic chamber where extraneous radiofrequency and audio background levels were negligible. RF interference from the cellular phones induced sound pressure levels (SPLs) that were recorded at various separation distances between the hearing aid and cellular phone. Phones were oriented relative to the hearing aids to approximate typical use of the phone.

Measurements of interference-induced SPLs were made using a frequency analyzer coupled to the hearing aid via a piece of plastic tubing, an acoustic coupler, and a pressure field microphone. The five digital cellular telephones employed in tested were Global System for Mobile Communications (GSM) , Personal Communication System (PCS), U.S. Time Division Multiple Access (TDMA), and Code Division Multiple Access (CDMA). The GSM phone operated at a frequency of 902 MHz, with a 217-Hz pulse modulation rate. The PCS phone operated at a frequency of 1.88 GHz with a 217-Hz frame rate. There were two U.S. TDMA phones. One operated at a frequency of 835 MHz, and a 50-Hz pulse modulation rate. The other operated at 814 MHz, with an 11-Hz modulation. The CDMA phone operated at 847 MHz and was tested in both full and variable vocoder rates during testing. Each phone was operated in test mode and transmitted its maximum power without the need for a base station.

The interference level was recorded as a function of separation distance between the phone and hearing aid. The range of values of SPL from this interference varied greatly, depending on the type of phone and hearing aid tested as well as their separation distance. The highest interference-induced SPLs were measured from an output-compression, behind-the-ear hearing aid when placed within 2 cm of each cell phone's antenna. At this separation distance, all of the phones tested, with the exception of the CDMA phone in full rate vocoder, produced very high sound pressure levels of 120 dB +/- 2.5 dB from this hearing aid. The CDMA phone in full rate vocoder produced an interference-induced SPL of 111.8 dB. The interference SPL drop off rate with respect to distance was two to three times more rapid for the CDMA phones. In general, behind-the-ear hearing aids experienced higher levels of interference than the in-the-ear aids.

The testing methods that are developed and the information gained through these experiments will assist in the development of hearing aid standards and CDRH reviewer guidance documents. Further work will include testing with the hearing aids set to a gain level representative of typical use and an analysis of the effect of the hearing aid user's head on interference levels. [[PostMS, Stds](#)]

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