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ORIGINAL ARTICLES

Electromagnetic Environmental Effects Testing of Medical Devices Including Those Used for the Treatment of Diabetes

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Abstract

Background:

Electromagnetic emissions from technologies that surround us can produce interference with implanted and externally worn medical devices. Electromagnetic environmental effects (E3) testing of medical devices at the Georgia Tech Research Institute (GTRI) began almost four decades ago and continues to incorporate new devices and new sources of electromagnetic emissions as they are developed and become available. The GTRI Medical Device Test Center provides real-world exposure fields to identify interactions and help manufacturers prevent disruptions from the environments in which their devices must function.

Methods:

Typically, the medical device is mounted in or on a torso simulator containing a saline solution that simulates the electrical characteristics of the body. The torso simulator and the device under test are then moved through the fields generated by production security and logistical system technologies using a computer-controlled positioning system. These tests are conducted with different orientations of the medical device to the electromagnetic source, simulating the way in which device wearers interact with these systems in representative situations.

Results:

Particular E3 test results measured on specific devices in the GTRI Medical Device Test Center are proprietary; however, the results of tests to date with current medical devices used for the treatment of diabetes have been encouraging. These devices have included implantable and externally worn insulin infusion pumps and continuous glucose monitoring systems from different manufacturers.

Conclusion:

Since E3 tests of diabetes treatment devices to date in the test center have centered on devices from only a few of the many current manufacturers, further testing is warranted. In addition, increased functionality, which is being added to existing devices, will create new possibilities for interference in the future.

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Abbreviations: (AAMI) Association for the Advancement of Medical Instrumentation, (E3) electromagnetic environmental effects, (EAS) electronic article surveillance, (EM) electromagnetic, (EMI) electromagnetic interference, (FDA) Food and Drug Administration, (RF) radio frequency, (RFID) radio frequency identification, (SLS) security and logistical system

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Brief History of Medical Device Testing to Electromagnetic Environments at Georgia Tech Research Institute

Electromagnetic (EM) environmental effects (E3) testing of implantable medical devices at the Georgia Tech Research Institute (GTRI) began in the late 1960s. Due to reports of Air Force radar interference with consumer electronics, in 1969 the U.S. Army initiated a program at GTRI to characterize civilian electronic systems responses to radar signals. Earlier, there had also been anecdotal reports of implanted pacemakers being cutoff when in the vicinity of microwave ovens. This aroused concern that pacemakers might also experience interference from microwave ovens as well as radars. Consequently, the Air Force School of Aerospace Medicine joined with the Army, pacemaker manufacturers, and GTRI to investigate pulsed radio frequency (RF) and broadband microwave interference to implanted cardiac pacemakers. GTRI developed a test method for implantable pacemakers that was gradually refined and incorporated into the Association for the Advancement of Medical Instrumentation (AAMI) Pacemaker Standard.[1] From the results of these tests, medical device manufacturers immediately began incorporating EM interference (EMI) hardening measures into their designs. Since that time, GTRI has been conducting measurements on the E3 susceptibility of implantable and externally worn medical devices to various radiated RF EM fields and to conducted power frequency currents.[2]

Over the past two decades, the growing use of security and logistical systems [which include electronic article surveillance (EAS) systems, EAS tag deactivators, metal detectors, and radio frequency identification (RFID) systems] in public areas has been such that a large segment of the general public is regularly exposed to their detection, interrogation, and deactivation/reactivation EM fields. With the current proliferation of medical devices for treating myriad medical conditions, there is a corresponding rise in the opportunity for wearers of such devices to be exposed to security and logistical systems' emissions. Potential disruption of the functioning of a medical device by the security and logistical system EM fields is of serious concern to the wearer of the medical device, the manufacturer of the medical device, and the manufacturer of the security and logistical system. To address these concerns, the Medical Device Test Center was established at GTRI in the early 1990s. The test center is an unbiased independent test facility that measures the interactions between medical devices and representative security and logistical systems under tightly controlled conditions. As an entity of a state university, funding for test center work is via standard contracts and purchase orders with limited internal support funds.

Current Work Conducted in the GTRI Medical Device Test Center

Medical Device E3 Testing

Since medical devices are constantly being exposed to different sources of potential interference, controlled evaluations must be performed to ensure that the devices continue to operate properly when they are in these environments. E3 testing is a three step process based on the protocol first set forth in the AAMI Pacemaker Standard.[1] First, the test specimen (the medical device and its leads, if they exist) is mounted in a physical arrangement that either simulates implantation (if it is an implantable device) or its presence on the human body (if it is an externally worn device) using a configuration that maximizes pickup from radiated EM environments. Next, the test specimen is programmed to simulate either a typical or a worst-case scenario and it is operated in one or more of its normal operational modes. The test specimen is then exposed to a known EM environment, its operation is monitored, and all responses are recorded.

For tests in the GTRI Medical Device Test Center, the physical test environment is a "torso simulator," which consists of a 0.03 *M* saline solution in a rectangular tank that is essentially transparent to the incident radiated EM field. The 0.03 *M* NaCl concentration has a resistivity of approximately 375 ohm cm, which simulates the electrical characteristics of human body tissue and fluid. For implantable devices, submersion in the conducting fluid facilitates monitoring of the implantable medical device's operation while minimizing the EM field distortion effects of directly attached probes. A Plexiglas® tank with dimensions of 37.5 × 37.5 × 46.5 centimeters is used; the test specimen's leads are arranged in a loop (emulating a typical implant scenario and also providing a "worst-case" pick-up configuration for external magnetic fields); and a 1-centimeter depth is maintained between the specimen and the inner surface of the tank's front wall. For externally worn devices, the device is mounted on the exterior of the "torso simulator" so that the presence

of the saline solution can perturb the incident EM field in much the same way that the presence of a human torso would.

As the test specimen moves through the exposure field, it is operated in each of its normal operating modes. If the test specimen has sensing inputs, external simulated biological signals are injected via the saline solution. Monitoring of an implantable medical device's responses to the applied EM environment is achieved by sampling the test specimen's output pulses via electrodes (extra catheters) submerged in the saline solution near the terminals of the specimen. Monitoring of an externally worn medical device is usually accomplished by observing audible and/or visible indications in the form of alarms and/or messages. Any change in the output of the test specimen during field exposure is recorded.

Typical Security and Logistical Systems

The first type of security and logistical systems (SLS) included in the GTRI Medical Device Test Center was the EAS system. EAS systems include both EM field emitters and receivers to illuminate and interrogate a uniquely identifiable EAS "tag," which is affixed to an object. When an object with an activated tag is in the EAS EM field, the EAS sensors detect the presence of the tag. Such systems are widely used to track and monitor merchandise for inventory control and theft prevention. They are typically located near the exit of retail stores and libraries. The test center currently has nine EAS systems from various manufacturers providing a wide range of frequencies, modulation types, power levels, and technologies. The test center has the capability of exposing medical devices to magnetic (also known as magnetoharmonic), acoustomagnetic (also known as magneostrictive), and radio frequency fields. The test center has shown that it is not uncommon for medical devices to be affected by EAS system EM fields.[3] Similar results have been documented by others.[4,5]

Another type of SLS is the EAS tag deactivator. EAS tag deactivators consist of EM sources that illuminate and deactivate an electronic device embedded in the EAS tag. Tag deactivators are typically installed in, or placed on, the checkout countertop, where the likelihood of a person wearing a medical device will be exposed to the interrogation and deactivation fields is high. As a result of the known interactions between EAS systems and medical devices, tag deactivators were deemed to cause similar effects; consequently, six tag deactivators from various manufacturers are now included in the test center.

The metal detectors used for airport and facility security applications can be either portals that a person walks through or hand-held "wands" that are passed over a person's body. Various magnetic field techniques are used to detect the presence of metal objects. The U.S. Food and Drug Administration (FDA) reports numerous instances where metal detectors appeared to interfere with the routine function of implantable pacemakers, implantable cardioverter defibrillators, and spinal cord stimulators.[4] The test center includes two walk-through and three hand-held metal detectors as E3 test sources.

Radio frequency identification techniques employ an RF field to interrogate an attached or embedded electronic device to detect and "read" information about the object. They are gaining popularity in many different commercial areas, including shipping, manufacturing, and inventory tracking. Currently, most RFID systems are found primarily in warehouses and shipping environments, somewhat limiting the exposure of the general public to their fields; however, as costs decline, plans are for RFID technologies to also move into stores and libraries, where they will provide more intimate exposure to patients with implanted and externally worn medical devices. (They are also being used for animal identification. Some have even proposed that such devices be embedded in persons for identification and other uses.) Preliminary testing at GTRI has shown that RFID fields can cause interference with cardiac pulse generators (including pacemakers and implantable cardioverter defibrillators) similar to what has been seen with EAS systems. Testing by the Japan Automatic Identification Systems Association[6] and the U.S. FDA[7] has shown analogous results. Therefore, as RFID technologies become ubiquitous, testing medical devices in RFID environments is essential. GTRI currently has one RFID system installed and is in the process of acquiring other RFID systems for inclusion in the test center.

Electromagnetic environmental effects tests in the GTRI Medical Device Test Center are performed at the field intensities generated by the security and logistical systems during their normal operation. Although it might be useful to compare the SLS field intensities to field level requirements found in published test standards, one has to be careful about making any assumptions based simply on peak field strengths or power levels. Based on results in the test center, it is not always simply the magnitude of the interfering signal that causes an inappropriate response in a medical device, but it may be any of the characteristics of the signal, including frequency, modulation, pulse repetition rate, and duty

cycle. Also, different test standards are applicable for different types of medical devices. For example, standards such as International Electrotechnical Commission 60601-1-2, which contains electromagnetic compatibility requirements for medical electrical equipment, do not apply to many of the devices currently tested in the test center, including implantable devices.

E3 Test Protocol for Medical Devices to Security and Logistical Systems

Since a patient typically interacts with SLS environments in a manner that may be different than some other environments, an E3 test protocol for medical devices to SLS's[8] has been defined to standardize these measurements. The test protocol defines the medical device mounting and monitoring configuration, the types of E3 tests performed, and the measurement process for each type of test. The standardized test protocol was initially written for cardiac pulse generators (including pacemakers and implantable cardioverter defibrillators) because these were the first devices tested in the test center and they constitute the majority of medical devices tested to date.

For E3 tests of other types of medical devices, including those used for the treatment of diabetes, test specimen mounting and monitoring are adapted to meet the requirements and operation of the device. Also, any required external simulated biological signals or unique device monitoring requirements are discussed and mutually agreed upon with the manufacturer prior to the tests.

Test Results for Medical Devices Used in the Treatment of Diabetes

To date, GTRI has performed E3 tests on a total of over 750 implantable and externally worn medical devices in the test center. These devices, which include test samples from prototype through production models, have included implantable cardiac pacemakers, implantable cardioverter defibrillators, implantable and externally worn drug infusion pumps, neurostimulators, implantable cardiac monitors, implantable hearing devices, ventricular assist devices, continuous glucose monitoring systems, and programmable valves.

Specific test results on identified device technologies and particular modes are proprietary to the manufacturer; however, the majority of test specimens typically exhibit some kind of response when exposed to one or more of the SLS's EM fields. The types of responses observed for implantable cardiac pacemakers are no effect, noise reversion, erratic pacing, maximum rate pacing, and inhibition. Responses from implantable cardioverter defibrillators, which are designed to deliver therapy when the heart goes into fibrillation, have included no effect, delivering undesired therapy, and inhibited therapy. The types of responses observed for neurostimulators are no effect, missed stimulation pulses, unexpected stimulation pulses, and stimulation pulse amplitude and shape changes.

With many implantable devices that do not have user interfaces, the only way the user can be notified that the device has been affected is if he/she notices a change in the functioning of the medical device. Obviously, if a pacemaker-dependent patient's pacemaker inhibits (stops pacing), the patient will notice. Similarly, a defibrillator patient will notice if it delivers undesired therapy. For other types of responses that are in between proper functioning and these worst-case effects, the clinical significance of the effect determines whether the user will notice or not. For other types of implantable and externally worn devices that do have user interfaces, including those with pager type controllers and/or receivers, messages and/or alarms can alert the user of EMI. It should be noted that nearly all responses observed in the test center in production devices have been temporary in nature, i.e., upon removal of the exposure fields, the devices return to their preexposure as-designed operational states. In other words, interference that causes the device to permanently change its operating state is rare.

In the treatment of diabetes, insulin pumps offer an attractive alternative to multiple daily injections by syringe or pen for some patients. The insulin pump can be implanted or worn externally. For externally worn pumps, the device includes the pump itself (including controls, processing module, and batteries), a disposable reservoir for insulin, and a disposable infusion set, including a cannula for subcutaneous insertion and a tubing system to interface the insulin reservoir to the cannula. Implantable pump systems are similar, except that the entire system is implanted in the body. Implantable pump systems are expected to be available soon in the United States. They offer treatment advantages for diabetes patients who have difficulty maintaining consistent glycemic control or who have not responded well to intensive insulin therapy, including multiple daily insulin injections or continuous subcutaneous insulin infusion using an external pump. Continuous glucose monitoring systems consist of a disposable glucose sensor placed just under the skin, a

link from the sensor to a nonimplanted transmitter, and an electronic receiver or insulin pump, which is worn like a pager. The continuous blood glucose monitors tested thus far in the test center measure the glucose of interstitial fluid.

Tests to date in the test center have emphasized externally worn insulin infusion pumps and continuous glucose monitor systems. The test results indicate that the devices tested are robust in their immunity to the EM fields emitted by the SLSs in the test center and these devices have demonstrated that they operate within required specifications with no discernible effects in simulated normal use environments. Only limited testing has been performed on implantable insulin infusion pumps. Implantable insulin infusion pumps pose special testing challenges for they usually do not give immediate indications of a malfunction.

It should be emphasized that testing to date has not included all manufacturers who currently have diabetes treatment devices on the market and that the tests have not included all the different device lines from those manufacturers who have participated. Testing with other types of medical devices, including pacemakers, implantable cardioverter defibrillators, and neurostimulators, has shown that it is not appropriate to extrapolate test results from the devices of one manufacturer to the devices from another manufacturer. Different design approaches on the same types of medical devices can result in radically different device responses to the same EM environments. Another lesson learned in the test center is that added functionality in existing types of devices can create new possibilities for interference. This is important to remember as the functionality of insulin pumps and continuous glucose monitoring systems is expanded to use the closed loop control that will be required for the development of a true artificial pancreas.

Benefits This Work Provides to Patients, Medical Device Manufacturers, Electromagnetic Emitter Manufacturers, and the FDA

The work in the medical device test center has been instrumental in establishing test procedures and in helping medical device manufacturers determine the RF immunity of their devices to the electromagnetic environments to which patients are likely to be exposed. The center's testing procedures have been used to develop a standardized test protocol that can stand as a baseline for testing various implantable and externally worn medical devices for both medical device and SLS manufacturers. The resulting test data can be used by the manufacturers' design and quality assurance departments to improve products while ensuring that they meet FDA requirements.

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