

© Engineers test implantable medical devices, such as pacemakers, against electronic article surveillance systems to help reduce interference issues.

Close Encounters of an Electromagnetic Kind

GTRI's testing center helps manufacturers reduce interference between medical devices and electromagnetic emissions.

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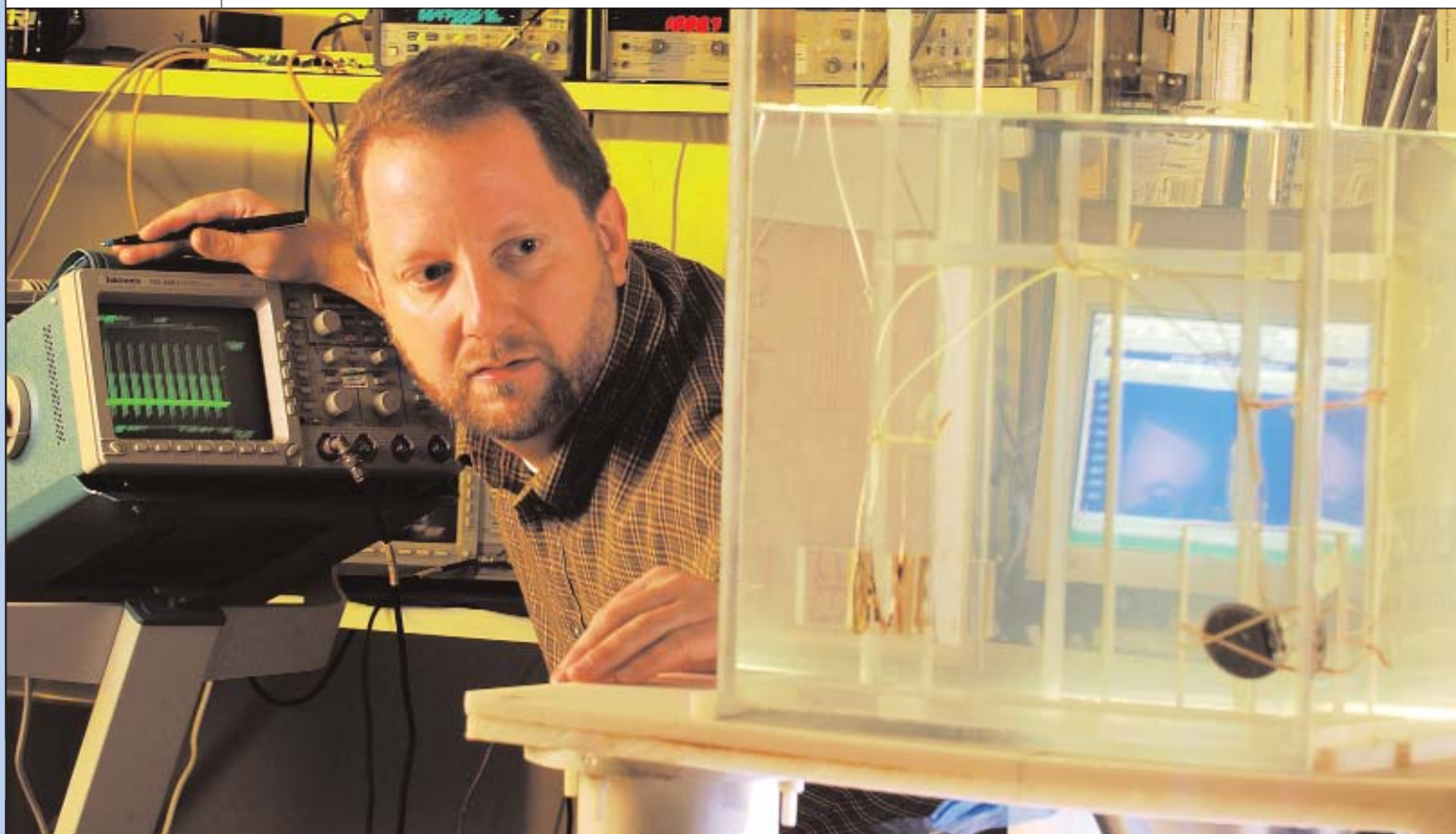
BELOW: GTRI Senior Research Engineer Ralph M. Herkert monitors the output of a pacemaker, which is mounted in a torso simulator in the EAS/Medical Device E3 Test Center.

In our increasingly wireless world, the air is chock-full of electromagnetic signals carrying data from one place to another. Yet while new wireless technologies advance our options in security, commerce and entertainment, they also produce interference that may cause problems for people with implanted medical devices.

Take electronic article surveillance (EAS) systems, which retailers, libraries and post offices use to prevent theft and track inventory. "EAS systems may cause medical devices to do anything from shutting down to invoking therapy at the

wrong time — not a good thing if you're wearing a defibrillator, which is supposed to shock the heart when needed," says Ralph Herkert, manager of the EAS/Medical Device E3 (electromagnetic environmental effects) Test Center at the Georgia Tech Research Institute (GTRI).

Housed within GTRI's Electro-Optical Systems Laboratory, the Center works with manufacturers of EAS systems and medical devices to increase product compatibility. Typically, manufacturers can use filters to reduce electromagnetic interference, but medical devices can pose



special challenges. The operating frequencies and modulation characteristics of EAS systems and tag deactivators may be in the same frequency band as biological signals, such as heart beats or arrhythmias.

"Simply filtering out the EAS signals is not an option because the very signals the device is designed to detect would also be filtered out," Herkert explains. "Instead, medical device manufacturers must deal with the interference in other ways, such as refining their firmware algorithms."

Researchers at the Center expose medical devices to EAS systems and tag deactivators in a manner that simulates real-world conditions. The resulting data is used by the manufacturers' design and quality assurance departments to improve products and make sure they meet Food and Drug Administration (FDA) requirements.

"By enabling manufacturers of EAS systems and medical devices to work together, the Center reduces adversarial roles and minimizes problems before they occur," says Jimmy Woody, who spearheaded the establishment of the Center and served as its manager through 2001. The Center's testing procedures have been used to develop a standardized test protocol for medical device and EAS manufacturers.

At the Center, a medical device is mounted in a torso simulator (a tank containing saline solution that simulates electrical characteristics of body tissue and fluid) using a configuration that mimics how it would be implanted in the body. Then the simulator moves along a track that exposes the medical device to nine EAS systems and five tag deactivators. This equipment represents technologies currently in use, including magnetic, acoustic-magnetic and radio-frequency systems.

Several tests are performed with the device placed in different orientations that represent how people typically interact with EAS field emissions. For example, if shoppers stand near an EAS system in a store, they may be parallel to the EAS pedestal, which maximizes the amount of electromagnetic exposure to the device. When shoppers pass through the system, they are usually perpendicular to the pedestal, which minimizes the amount of exposure.

Since its inception in 1995, researchers in GTRI's EAS/Medical Device E3 Test Center have tested more than 600 medical devices. In the beginning, the Center focused



Devices tested for potential interference with electronic article surveillance systems include cochlear implants and cardiac pacemakers, shown here. The EAS/Medical Device E3 Test Center at the Georgia Tech Research Institute conducts these studies.



on pacemakers and defibrillators, but now it conducts research for a variety of devices including implantable hearing devices, drug-infusion pumps, neurostimulators, cardiac monitors and glucose monitors.

"Not only are there more devices to test, but today's medical devices are constantly adding functionality, which creates new possibilities for interference," Woody says.

Indeed, interaction between different types of medical devices has become a new concern as patients may use more than one medical device. The Center has been evaluating possible interactions between bone-healing stimulators and implanted cardiac devices.

The Center is also expanding its testing capabilities as new types of security and logistics systems become potential emission sources. For example, more companies are using radio-frequency identification (RFID) systems for inventory control. Right now these devices are primarily found on warehouse and shipping containers. Yet as the technology's cost lowers, RFID technology will become more pervasive and may soon be used in stores on individual products.

"Less is known about the effects of RFID," Herkert says. "However, preliminary research has shown it may cause interference with medical devices similar to EAS systems."

GTRI is acquiring RFID systems, which will be set up for use with the center's EAS test protocols.

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contract

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PACEMAKER PHOTO BY CAROLINA K. SMITH, M.D., COURTESY OF ISTOCKPHOTO.COM

BELOW: Researchers at the EAS/Medical Device E3 Test Center expose medical devices to electronic article surveillance systems (sample model shown) and tag deactivators in a manner that simulates real-world conditions. The manufacturers' design and quality assurance departments use the data to improve products and make sure they meet Food and Drug Administration requirements.



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