GTRI is developing protocols for testing effects of RFID systems on medical devices

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GTRI researchers Ralph Herkert (shown) and Gisele Bennett are evaluating and determining the best method for measuring whether RFID systems interfere with medical devices. Credit: Georgia Tech Photo: Gary Meek

Radio frequency identification (RFID) systems are widely used for applications that include inventory management, package tracking, toll collection, passport identification and airport luggage security. More recently, these systems have found their way into medical environments to track patients, equipment assets and staff members.

However, there is currently no published standardized, repeatable methodology by which manufacturers of RFID equipment or medical devices can assess potential issues with electromagnetic interference and evaluate means to mitigate them.

To resolve these concerns, the Georgia Tech Research Institute (GTRI) recently began developing testing protocols for RFID technology in the health care setting. The test protocol development is being overseen by AIM Global, the international trade association representing automatic identification and mobility technology solution providers, and also includes MET Laboratories, a company that provides testing and certification services for medical devices.

"A comprehensive set of test protocols, which are sufficiently precise to permit repeatable results, is required to understand if there is an interaction between various types of RFID systems and active implantable medical devices, electronic medical equipment, in vitro diagnostic equipment and biologics. Only after the protocols are developed will we be able to investigate the cause of any interactions, the result of any interactions, and ways manufacturers might eliminate or mitigate interactions," said Craig K. Harmon, president and CEO of Q.E.D. Systems and chairman of AIM Global's RFID Experts Group. This group is overseeing the Health Care Initiative and includes representatives from 40 organizations in the United States, Europe and Asia.

GTRI researchers will test how RFID systems affect the function of implantable and wearable medical devices, such as pacemakers, implantable cardioverter defibrillators, neurostimulators, implantable infusion pumps and cardiac monitors.

"The internal components, firmware and hardware of every company's devices are different, meaning that each device can respond differently

to the same electromagnetic environment. Since there have been various preliminary tests and publications from different organizations indicating that there may or may not be issues with RFID system environments and these devices, it is important to standardize the way to test such devices," said Ralph Herkert, director of GTRI's Medical Device Test Center.

Herkert and Gisele Bennett, director of GTRI's Electro-Optical Systems Laboratory, will evaluate and determine the best method for measuring whether interference takes place as a result of RFID emission in both active and passive RFID technologies covering the spectrum from low-frequency to ultra high-frequency.

The researchers will test whether radio frequency-emitting devices cause any negative effects on the medical devices, and under what conditions these effects might occur. Testing will also determine whether specific medical devices are particularly susceptible to certain radio frequency identification characteristics and if any corrective actions can be taken to mitigate such susceptibility.

Medical device testing is not new for GTRI, which established its Medical Device Test Center more than 14 years ago. The facility was created to enable manufacturers of implantable cardiac pacemakers and defibrillators to work with providers of electronic article surveillance (EAS) systems, used by retailers, libraries and other establishments to prevent theft and track inventory. The center's original mission was to help manufacturers improve compatibility between implantable medical devices and EAS systems that radiate electromagnetic energy. In 2006, GTRI expanded its operations and facilities to test new types of security and logistical systems (SLS), including RFID.

To test the effects of RFID systems on medical devices, the researchers simulate real-world conditions by placing a medical device in a tank of

saline solution that simulates the electrical characteristics of body tissue and fluid. The medical device is then exposed to different RFID technologies. Several tests are performed with the device placed in different orientations to represent how people typically interact with the emissions.

"We think the testing procedure for RFID systems will be similar to the EAS system procedure, but there are a few more challenges with the RFID systems because a person doesn't always pass through a portal," noted Bennett, who is also a member of AIM Global's RFID Experts Group. "Medical devices can be affected by active tags with stronger signals or RFID systems reading passive tag signals."

The test protocols developed by GTRI will be submitted to the U.S. Food and Drug Administration for concurrence, after which a worldwide certification program will be launched and other testing facilities will be invited to participate.

Funding to develop these test guidelines is currently being provided by GTRI, but the researchers are actively looking for external funding.

"We have more than 35 years of experience at GTRI testing medical device interference and we think that testing the effects of RFID on medical devices is an important area to pursue," added Bennett.

Source: Georgia Institute of Technology