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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

Keywords: continuous glucose monitoring system, diabetes, electromagnetic, E3, insulin infusion pump, medical device, testing

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