

# Comparison of Magnetic Fields Emitted from Security Screening Devices with Magnetic Field Immunity Standards

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## Abstract

*The Food and Drug Administration (FDA) received over 90 problem reports of medical device malfunctions due to electromagnetic interference (EMI) from magnetic field emitting security devices. The FDA took action to alert users and manufacturers of medical devices and security screening devices [7, 8]. These malfunctions were thought to be related to the electromagnetic fields emitted from the security device and judged serious enough by the reporters (clinical users of these devices) to potentially cause patient injuries. Measurements of magnetic field emissions from security devices reveal that some security screening devices can emit magnetic fields at strengths that exceed the test levels specified in some medical device standards.*

## Keywords

Security Screening, Anti-Theft Systems, Pacemakers, Implanted Cardioverter Defibrillator, Electronic Article Surveillance, Magnetic Field, Metal Detector.

## INTRODUCTION

The Food and Drug Administration (FDA) received over 90 problem reports of medical device malfunctions related to EMI from magnetic field emitting security devices since 1988. These malfunctions were judged serious enough by the reporters (clinical users of these devices) to potentially cause patient injuries. Examples of malfunctions with implanted devices [1-6] ranged from disturbances in the cardiac sensing operation of pacemakers, unintended firing of implanted cardioverter defibrillators (ICDs), changes in drug delivery rates of infusion pumps, and over-stimulation of patients with neurostimulators resulting in severe pain or falls. As a result, FDA undertook a study of the EM fields emitted from the security screening systems to determine the nature of the EM fields seen by electronic medical devices worn by, or implanted in, patients passing near these screening systems. The FDA took action to alert users and manufacturers of active medical devices and security screening devices [7, 8] of the potential for interactions.

## SECURITY DEVICES TESTED

FDA measured the spatial distribution and waveforms of the EM emissions from seven electronic article surveil-

lance systems (EASS) and, with support from the Federal Aviation Administration (FAA), measured EM emissions from nine walk-through metal detectors (WTMD). The EASS systems included two gated-radio frequency (RF) systems, three swept-RF systems and two continuous-wave low-frequency systems. The WTMDs included four pulsed systems and four continuous-wave systems. These are a representative sample of most of the systems found in use as of this writing.

## METHODS AND MATERIALS

The systems were surveyed and measured using detectors with small, three-axis magnetic field probes including a combination of the following instruments; 1) a Wandel-Goltermann (Eningen, Germany) Model EFA-2 Magnetic Field Analyzer, 2) a Holaday Industries (Eden Park, MN) Model 3627 ELF Magnetic Field Meter, 3) a Holaday Industries Model 3637 VLF Magnetic Field Meter, 4) a Holaday Industries HI-4433 LFH Broadband Isotropic Field Probe, 5) an Electric Research Management - ERM (State College, PA) Model 1678.002 Magnetic Field Sensor (with a sensor volume of 2 x 2 x 2 cm). After each system was manually surveyed to determine its frequency of operation, maximum field strength, and waveform, an appropriate magnetic field probe was chosen for detailed spatial mapping of the fields (usually with the high-spatial-resolution ERM system). Then the security system was placed within a linear, three-axis mechanical scanner. The scanner is capable of positioning a probe within a 2 meter x 2 meter x 2 meter volume within 3 mm absolute position. Data are collected at 5 cm increments for large systems, and at smaller increments for smaller systems. Each axis moves by stepper motors under computer control using stepper motors (Oriental Motor, Los Angeles, CA) Vexta PH268-E1.5B and Anaheim Automation (Anaheim, CA) 23D309). Each stepper motor uses a US Digital (Vancouver, WA) E2-400-250-HT Optical Encoder. The positioning system controller is a Personal computer with a Windows NT operating system and National Instruments (Austin, TX) LabView software controlling a NI PCI-7344 4-Axis motion control board, and a NI NuDrive SX 4-axis stepper motor driver.

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The data were acquired using a NI PCI-4452 DAQ card with a NI BNC-2140 dynamic signal acquisition signal-conditioning accessory and a LeCroy (Chestnut Ridge, NY) Waverunner-2 LT-264 Oscilloscope. The NI DAQ digitizes at a rate of 204.8 kHz per channel. An integral low-pass anti-aliasing filter limits the analog input signal to an upper frequency of 102.4 kHz. The system is configured to collect data using computer's serial port, an IEEE-488 interface, or the NI PCI-4452 DAQ, depending upon the magnetic field sensor chosen and the signal response bandwidth required. A scanning protocol was used [6] where EM measurements were made in seven different planes around the security system's transmitter pylon: one horizontal plane and six vertical planes. Horizontal-plane measurements were made at height ( $H$ ) of 130 cm above the base of the system (Figure 1). Vertical measurements were made in four planes that were parallel with the face of the transmitter pylon (Figure 2) and two planes that were normal to the face of the transmitter pylon (figure 3). The vertical planes were 195 cm high, starting 10 cm from the base of the transmitter pylon. The four "vertical-parallel" planes were parallel to the transmitter pylon face and separated by spacing ( $S$ ) of 6 cm, 15 cm, 30 cm, and 36 cm. The two vertical-normal planes were perpendicular to the face of the transmitter pylon. One plane was at the center of the transmitter pylon face, and the second plane was 5 cm from the system entrance as defined by the narrow edges of the pylons (Figure 3).

$$H \equiv \sqrt{H_x^2 + H_y^2 + H_z^2} \quad (1)$$

Where  $H_x$ ,  $H_y$ , and  $H_z$  are the orthogonal magnetic field measurements in Amperes/meter, and  $H$  is the magnitude.

A plot of the magnitude ( $H$ ) of the fields emitted from a single active, elongated loop system (similar to an EASS) for the horizontal plane 130 cm from the floor is shown (Figure 4). This plot (Figure 4) demonstrates how the fields fall off rapidly with distance from the transmitter pylon. A few screening systems have two "active" transmitting pylons. In such cases for each pylon the field strength falls off to half the distance between the pylons forming a saddle-back plot.

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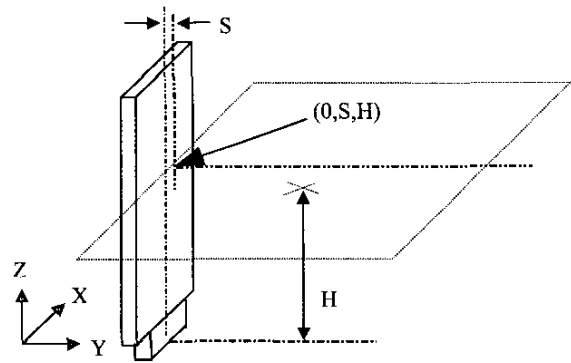


Figure 1: Horizontal plane, normal to the face of the security system transmitter pylon.  $H$  is the height from the base of the pylon.  $S$  is 6 cm from the pylon.

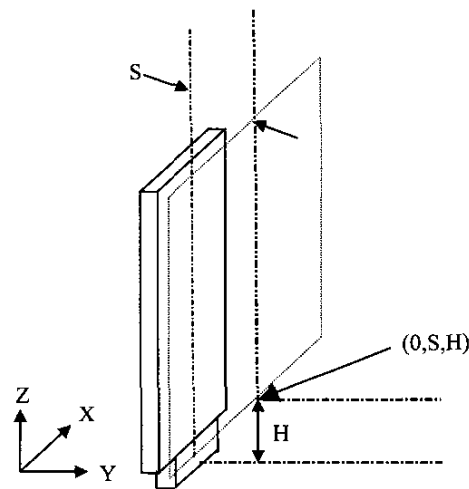


Figure 2: Vertical plane, parallel with the face of the security system transmitter pylon.  $H$  is 55 cm from the EASS base.  $S$  is 6 cm to 36 cm from the pylon.

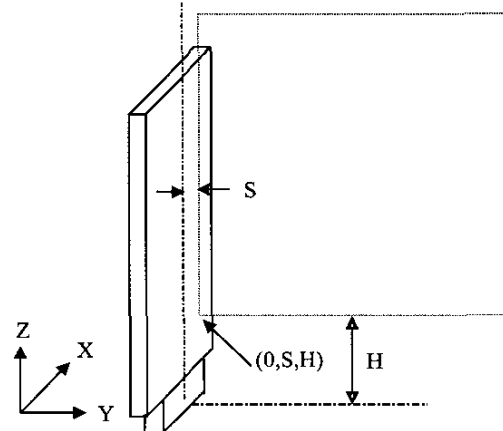


Figure 3: Vertical plane, normal to and on the centerline of the security system transmitter pylon face.  $H$  is 55 cm from transmitter base.  $S$  is 6 cm from pylon

## RESULTS, DATA ANALYSIS, PLUS A COMPARISON WITH EXISTING EMI STANDARDS

The maximum (peak-to-peak) magnetic field strength data for five of the EASS devices are presented (Figure 5). Data from eight EAS systems are identified with anonymous labels A-E. The data points represent measurements made at 5 cm increments beginning 6 cm from the face of the transmitting pylon. The second data point, 11 cm from the transmitter pylon, may be considered a reasonable maximum. No WTMD data are presented because of security concerns. Present EMI immunity standards for active implanted cardiac medical devices use a voltage injected into a tissue interface circuit and do not test the devices using radiated magnetic fields [9-12]. The graphs in figure 5 represent the magnetic field strength necessary to induce an equivalent voltage on a 200 cm<sup>2</sup> loop using Faraday's Law. The voltages are those specified in the implanted cardiac device standards [9-11]. We do not present test data on medical device malfunction near security systems in this paper; this work is in progress. Instead, we present results of a mathematical analysis to relate the measured magnetic field strength data to medical device EMI standards. The induced voltage in an implanted device was predicted using Faraday's Law and a 200 cm<sup>2</sup> loop area based on pacemaker leads, its pulse generator circuitry housing, and the conductive tissue of the human body. A composite diagram showing magnetic field immunity testing standards and our analysis is shown in figure 5. Testing levels specified in the cardiac device standards [9-11] are in volts, peak-peak. For this reason, the data presented for magnetic field strength were converted to Amperes/meter peak-peak.

Measurement data were analyzed and indicated that certain EASS models could induce voltages in the leads that could be sensed by the medical device. For example, if a patient with an active implanted cardiac medical device passes through some of the EAS systems, voltages induced on the sensing leads could exceed those established from international standards for immunity [9-11].

Measurements of implanted device-lead loop areas by Dawson [14] and others suggest that the actual loop areas could be somewhat less than those used in the standards [9, 11]. A loop area of 225 cm<sup>2</sup> is the practical maximum that can be formed by the pulse generator housing and the lead for most cardiac pacemakers. Some configurations of implanted devices use different leads and can describe much larger areas. This would occur when a cardiac pulse generator is placed in the abdomen instead of the typical site in the pectoral (chest) area. Work by Groh [16] indicated that cardiac pulse generators implanted in the abdomen were more likely to be susceptible to electromagnetic disturbances than the devices implanted in the pectoral region. Some neural stimulator pulse generators and leads can produce a much larger loop area when implanted.

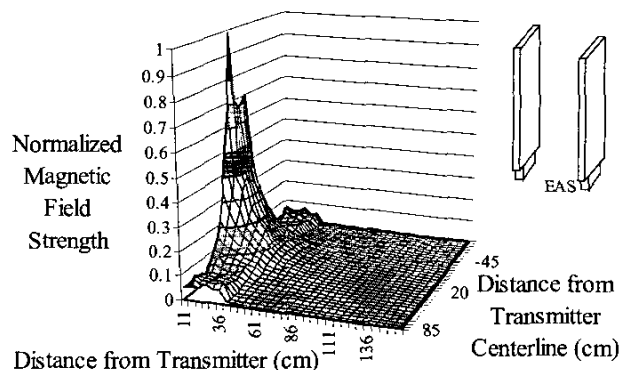


Figure 4: Horizontal plane, 130 cm from the floor, normalized magnetic field strength emitted from a single elongated loop.

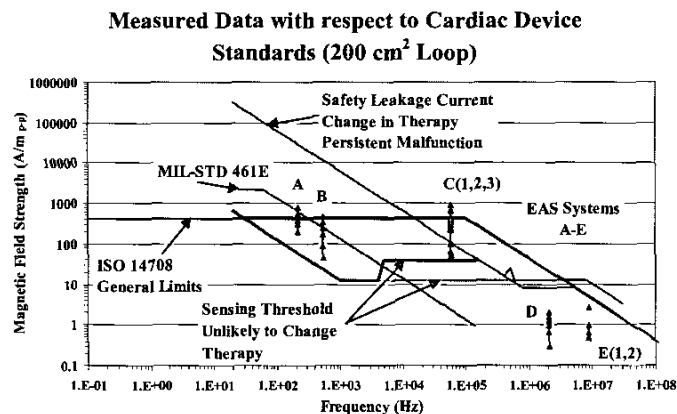


Figure 5: Magnetic Field immunity standards for implanted cardiac devices compared with Measured EASS data.

## CONCLUSION

Millions of patients have had active medical devices implanted. The number of adverse event reports received by FDA indicates a relatively small number of active implanted medical devices experience interactions with the magnetic fields emitted from security screening devices. Our measurements of the magnetic fields emitted from the security screening devices show that when induced voltages the leads of a 200 cm<sup>2</sup> loop near the transmitter pylon are calculated using Faraday's Law, these induced voltages may exceed the levels sufficient to "change the therapeutic behaviour", as specified in the implanted cardiac device standards [9,10]. These induced voltages could exceed levels where the electromagnetic fields could be confused with sensed beats and change the pacing pattern of the active implanted cardiac device [11]. FDA is currently pursuing research that will test the response of active implanted medical devices when exposed to the magnetic fields emitted from security screening devices.

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