

Implantable Cardiac Pacemaker Electromagnetic Compatibility Testing in a Novel Security System Simulator

Wolfgang Kainz*, *Member, IEEE*, Jon P. Casamento, *Member, IEEE*, Paul S. Ruggera, *Senior Member, IEEE*, Dulciana D. Chan, and Donald M. Witters, *Senior Member, IEEE*

Abstract—This paper describes a novel simulator to perform electromagnetic compatibility (EMC) tests for active implantable medical devices (AIMDs) with electromagnetic fields emitted by security systems. The security system simulator was developed in response to over 100 incident reports over 17 years related to the interference of AIMD's with security systems and the lack of a standardized test method. The simulator was evaluated regarding field homogeneity, signal distortion, and maximum magnetic field strength levels. Small three-axis probes and a three-axis scanning system were designed to determine the spatial and temporal characteristics of the fields emitted by 12 different types of walk through metal detectors (WTMDs). Tests were performed on four implanted pacemakers with a saline phantom and correlated to a newly developed test method performed "in air" (without the phantom). Comparison of the simulator thresholds with tests performed in real WTMDs showed that the simulator is able to mimic the pacemaker interference. The interference thresholds found in the simulator indicate that pulsed magnetic fields are more likely to cause interference in pacemakers than sinusoidal fields. The security system simulator will help biomedical engineers, manufacturers of medical devices, and manufacturers of security systems to identify incompatible combinations of WTMDs and AIMDs early in the development stage.

Index Terms—EMC, EMI, metal detector, pacemaker, simulator.

I. INTRODUCTION

THIS paper describes for biomedical engineers, manufacturers of AIMDs, as well as makers of the security systems the use of a novel electromagnetic security system simulator to perform electromagnetic compatibility (EMC) testing of implantable cardiac pacemakers with electromagnetic fields emitted by security systems (electronic article surveillance systems and metal detectors). The simulator and test methods described below were developed to simplify the usually time consuming and complicated process for EMC testing of AIMDs near security systems. While the focus of this study is testing pacemakers, the simulator and the EMC testing approach are applicable to a wide variety of AIMDs, ambulatory medical

devices, including implanted cardiac defibrillators, implanted electrical neurostimulators, and drug infusion devices. In this paper, the term "security system" is used as a general term for electronic article surveillance systems (EAS) and metal detectors [both walk-through metal detectors (WTMD) and hand-held metal detectors (HHMD)]. If a security system is walk through system it will be referred as "security gate." Both of these types of security systems use generally low-frequency magnetic field emissions to detect the presence of objects passing through.

Concerns about the EMC of medical devices and security systems arise out of several reports of patient problems when passing through the security systems. The Food and Drug Administration (FDA) has received 109 problem reports since 1987 of AIMD's malfunctions in the vicinity of security systems. Several of these reports state explicitly electromagnetic interference (EMI) to the medical device. Examples of malfunctions with AIMDs include disturbances in the cardiac sensing operation of pacemakers, unintended firing of implanted cardioverter defibrillators, changes in drug delivery rates of infusion pumps, and over-stimulation of patients with neurostimulators resulting in severe pain or falls [1]. Fig. 1 shows the problem reports categorized by the type of AIMD. 2003 includes a recent report of a ventricular peritoneal shunt device, which is implanted in a patient's head to help relieve pressure build-up from Hydrocephalus. 13% of the reports (14 of 109) involve implanted cardiac pacemaker problems during or after metal detectors (WTMD and HHMD) exposure. FDA addressed the concerns for security systems and medical devices in their September 1998 letter to physicians recommending that patients with AIMDs be made aware that security systems may not always be visible, and to minimize exposure when practical [2].

Fig. 2 illustrates the breakout of these reports by security system type. Most reports mention either the EAS or metal detectors (WTMD and HHMD). However, there are also reports that only mention "security system" or some other unidentified security gate, which are categorized separately.

In general, EMC testing of AIMDs within a security gate can be a time consuming and problematic task. To simulate an AIMD within the human body the implant has to be immersed in saline, which results in a heavy and cumbersome phantom. This phantom must then be used in several locations and positions in and around the security gate, and repeated for each security gate. A simple to use simulator was developed to mimic the signals emitted by security systems to simplify EMC testing of AIMDs

Manuscript received May 20, 2004; revised August 19, 2004. This work was supported in part by the Federal Aviation Administration. Asterisk indicates corresponding author.

*W. Kainz is with the Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD 20851 USA (e-mail: wxk@cdrh.fda.gov).

J. P. Casamento, P. S. Ruggera, D. D. Chan, and D. M. Witters are with the Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD 20851 USA (e-mail: jpc@cdrh.fda.gov; psr@cdrh.fda.gov; ddc@cdrh.fda.gov; dmw@cdrh.fda.gov).

Digital Object Identifier 10.1109/TBME.2004.843293

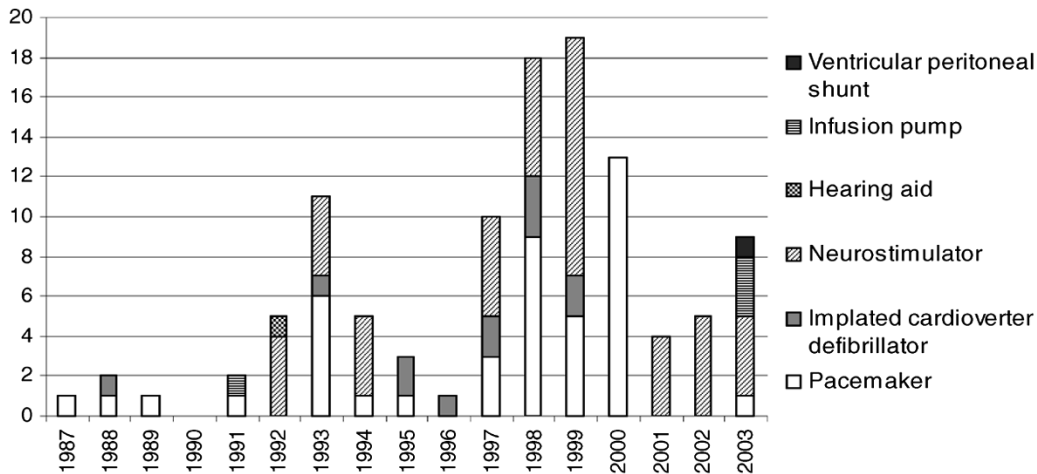


Fig. 1. Number of medical device event reports between 1987 and 2003 linked to EMC problems with security systems, categorized by the type of AIMD.

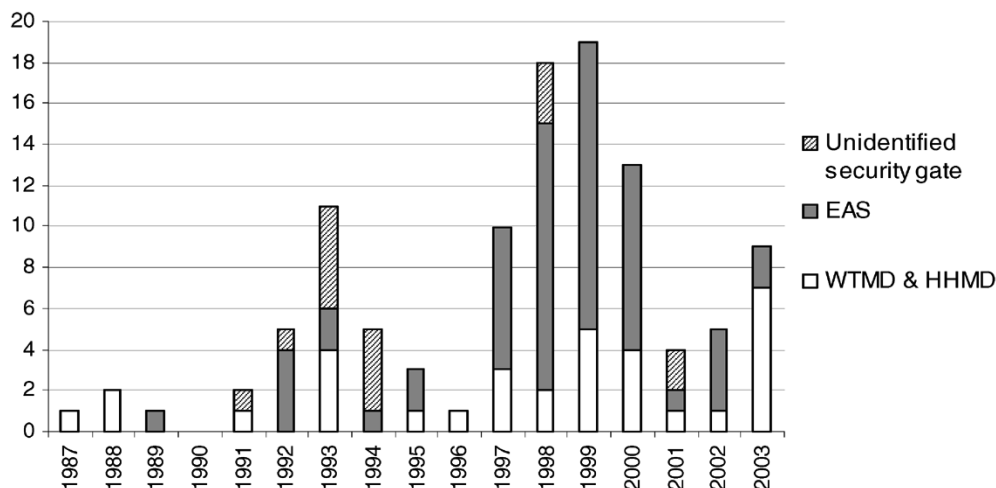


Fig. 2. Number of AIMD event reports between 1987 and 2003 linked to EMC problems with security systems, categorized by the type of security system.

and other active medical devices. The simulator enables EMC testing over a wide range of frequencies and field strengths. In addition, the EMC testing for AIMDs can be simplified even further if the saline phantom is replaced by a test “in air” simulating the worst case situation. For the in air testing a resistor can act as the return path of the current from the lead tip to the implant case.

There are few published reports that describe measurements and analysis of the effects of security system emissions on implanted cardiac pacemakers. Unfortunately, these reports do not always fully describe the security system or the emissions, but they do note that the pacemakers can be affected by the security system and generally advise caution.

Copperman *et al.* [2] tested 103 pacemaker patients *in vivo* in one metal detector. No specifications about the metal detector are given. The authors only state: “The gate was identical to that used at airports.” The patients had to walk through the metal detector in both directions at least three times. Electrocardiogram (ECG) recordings were made continuously during the procedure, and impulse rate and duration were recorded before and after the procedure. No case of pacemaker inhibition or inappropriate stimulation was seen in any of the 103 patients examined.

Wilke *et al.* [3] evaluated possible interactions of two security systems and different pacemaker types. The authors do not

specify their terminology of “security systems.” It is not clear if they mean walk through metal detectors or anti-theft systems. No information is given on the frequency of these two security systems, if the systems emit pulsed or continuous wave (CW) fields and if the specified field strengths are peak, peak-to-peak, or root mean square (rms) values. They specify magnetic field strengths for both systems for three different distances: 20, 50, and 100 cm. No information is given where and how these field strengths were measured. 53 pacemaker patients were asked to stand before and then to pass through the security gate. The patients were monitored by a six-channel ECG. For the security system emitting the stronger magnetic field (2.7 A/m in 50 cm) 13% of the pacemakers showed dysfunctions. Using the security system with the lower magnetic field (1.6 A/m in 50 cm) only 4% of the pacemaker showed dysfunctions in form of inhibitions. No information indicates which pacemaker showed which dysfunctions in which of the two security systems. The dysfunctions noted were not described. The authors conclude their findings that patients with pacemakers can be at risk from common security systems.

Irnich [4] presents in a recent publication simple calculations to predict interference situations based on the magnetic field in CW and pulsed security systems. He concludes that from measurements at security systems, it is possible to derive a “max-

TABLE I
SUMMARY OF THE EMISSION MEASUREMENTS FOR 12 DIFFERENT WTMDs. PRIMARY FREQUENCY,
WAVEFORM, AND SHORTEST FALL TIME FOR PULSED WTMD SIGNALS OF THE EMITTED SIGNAL

WTMD		A	B	C	D1 D2	E1 E2	F1 F2	G	H	I	J	K	L	
Frequency	Hz	100 - 600							300 - 8000					
Waveform		pulsed							multiple CW	CW				
Maximum Transition Time	μ s	5 - 50							-					

imum allowed field” curve over the whole frequency range, below which no interference will occur.

II. WALK THROUGH METAL DETECTOR EVALUATION

Walk through metal detectors are designed to detect concealed metal objects such as weapons or tools using magnetic fields. WTMDs usually consist of a transmit coil and a receive coil on opposite sides of a gate or portal. Some WTMDs have a transmit and a receive coil on both sides of the gate while others have multiple coils on one or on both sides of the gate. The emissions are either pulsed or CW.

The WTMD’s emissions were measured using detectors with small, three-axis magnetic field probes provided by Electric Research Management—ERM (State College, PA). The magnetic field probes consist of three nested square-segment wound Faraday induction coils and an integrator electronics in a plastic enclosure. We used probes with a bandwidth from 30 Hz to 300 kHz and with a sensitivity of 5 Volts per Gauss. Using these probes the minimum detectable signal was 0.1 A/m. Following the manual emissions survey each WTMD was then placed within a linear, three-axis mechanical scanner and emissions data were collected every 5 cm. The scanner is capable of positioning a probe in a $2 \times 2 \times 2$ meter volume within 3 mm absolute positional accuracy. A scanning protocol was used [5] to make measurements in seven different planes around the WTMD’s transmitter pylon: one horizontal plane and six vertical planes. Horizontal-plane measurements were made at a height of 130 cm above the base of the WTMD, which corresponds to approximately the height above the ground where an implanted pacemaker would be typically located. Vertical measurements were made in four planes parallel with the face of the transmitter pylon and two planes that were normal to the face of the transmitter pylon. The vertical planes were 195 cm high, starting 10 cm from the base of the transmitter pylon. Four vertical planes, parallel to the transmitter pylon face, were placed at 6, 15, 30, and 36 cm from the transmitter pylon. The two other vertical planes were perpendicular to the face of the transmitter pylon. One plane was at the center of the transmitter pylon face, while the second plane was 5 cm from the WTMD entrance as defined by the narrow edges of the pylons. Details of the scanning system are outlined by J. Casamento in [6].

With the WTMD scanning system described above the emissions characteristics of 12 different WTMDs were evaluated. The WTMDs emitted with either pulsed or sinusoidal signals. The pulse emissions were either mono-phase or bi-phase signals

with transition times in the range of 5μ s to 50μ s resulting in a frequency spectrum with components up to 70 kHz. WTMDs with sinusoidal signals (CW signals) emit fields at either a single frequency or multiple frequencies, ranging from 300 Hz up to 8 kHz (Table I). The waveforms of WTMDs emitting pulsed signals with multiple coils were especially difficult to identify, because different waveforms are present at different spatial locations. The difficulties were overcome for three of the metal detectors by defining two different waveforms. The first waveform consists of basic pulses whereas the second, more complex waveform consists of either multiple basic pulses or the vector magnitude of the capture field. The first waveform was designated the “simple signal” and the second the “complex signal.” To define and test different waveforms, it is necessary to simulate the different waveforms found in actual WTMDs at different spatial locations. In general, a spatial location where the emitted field is dominated by one transmitter coil the waveform is dominated by the signal emitted by this coil. In a different location where the fields of two or more coils are superposed, the resulting waveform have components of each contributing coil. To generate those WTMD waveforms, the signal of the emitted fields was monitored during the measurements at different spatial locations.

For this paper all given field values refer to the peak-to-peak (pp) value of the magnetic field defined as

$$H_{pp} = \sqrt{H_x^2 + H_y^2 + H_z^2}.$$

To assess possible interference scenarios with AIMDs we defined a reasonable maximum exposure for the pacemaker. This reasonable maximum is defined as the exposure field strength averaged over a 225-cm^2 quadratic area (in the shape of a square). The exposure field strength can be related to the induced voltage using

$$U_{ind,max} = \mu_0 A \left. \frac{dH}{dt} \right|_{max}.$$

In case of WTMDs emitting CW fields, the maximum induced voltage in the lead of the AIMD can be calculated using

$$U_{ind,pp} = \mu_0 A \omega H_{pp}$$

with A as the loop size formed by the AIMD can and the lead, ω as the frequency, and H_{pp} as the peak-to-peak value of the magnetic field.

A typical value for the lead area of implanted cardiac pacemaker of 225 cm^2 was chosen. Because it is not reasonable that a pacemaker exposure occurs at arbitrary spatial locations within

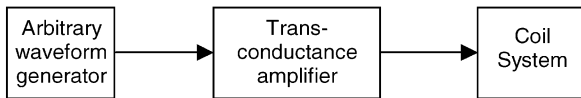


Fig. 3. Block diagram of the simulator. The waveform is generated by the arbitrary waveform generator, which feeds the trans-conductance amplifier. The trans-conductance amplifier acts as current source driving the current through the coil system which produces the magnetic field.

the WTMD we restricted the location for the reasonable exposure. We defined the location for the reasonable maximum as more than 50 cm but less than 150 cm above the floor and more than 15 cm away from the transmitter pylon. Averaging the field strength over several measurement points only makes sense if the field vectors point at each location in the same direction. To estimate the impact of the field on the loop formed by the pacemaker can and the pacemaker lead one has to calculate the dot product between the field vector and the pacemaker lead plane. In general, the pacemaker lead configuration is not plane and usually unknown, which makes it impossible to exactly calculate the averaged field relevant for the pickup in the pacemaker lead. We overcome this problem by defining two reasonable maximum field strengths. First the *reasonable maximum normal to the pylon* and second the *reasonable maximum vector magnitude*. Both maxima are shown for each WTMD in the interference threshold figures (Figs. 6–11). Gray bars indicate the *reasonable maximum normal to the pylon* and black bars indicate the *reasonable maximum vector magnitude*.

The average over the vector magnitude, ignoring the direction of the field, clearly overestimates the exposure. The average over the field values normal to the pylon may underestimate the exposure but gives the lower exposure limit. Interference in the real WTMD is possible if the pacemaker shows interference below this lower limit (*reasonable maximum normal to the pylon*). Interference in the real WTMD is unlikely in case the pacemaker does not show interference above the reasonable maximum, averaged over the vector magnitude. For most of the evaluated WTMDs (9 out of 12) the maximum averaged over the vector magnitude is less than 20% above the maximum normal to the pylon. Only one WTMD (“F”) shows a 65% higher maximum averaged over the vector magnitude than the maximum normal to the pylon. This indicates a complex magnetic field generated by multiple coils. For the majority of the WTMDs (11 out of 12) the magnetic field at the location of the reasonable maximum is mainly orientated normal to the pylon. In these cases, both maxima are a good representation of the magnetic field responsible for the pickup in the pacemaker lead.

III. THE SECURITY SYSTEM SIMULATOR

The security system simulator was designed to mimic electromagnetic fields emitted by security systems, and allow simulated exposures of AIMDs. The simulator consists of a wave generator, an amplifier and the coil system. The coil system was designed by staff at the National Institute of Standards and Technology using analytic calculations and built using five coaxial coils. Per amp (A) of drive current the coil is capable to generate a magnetic field of 2.3 A/m. Details about the design and dimensions of the coil are published in [7].

Fig. 3 shows the block diagram of the simulator which can generate magnetic fields with waveforms recorded from the

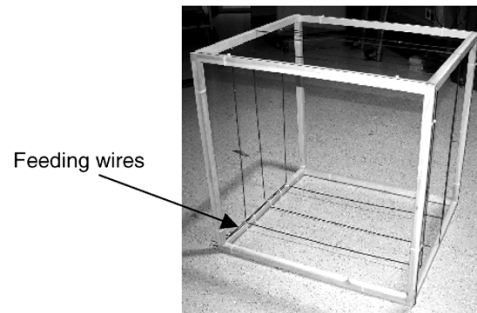


Fig. 4. Photo of the coil system. The five loops are mounted on a wooden frame. The feeding wire can be seen on the bottom left side of the picture. These wires lead to a slightly asymmetry in the field distribution as shown in Fig. 5.

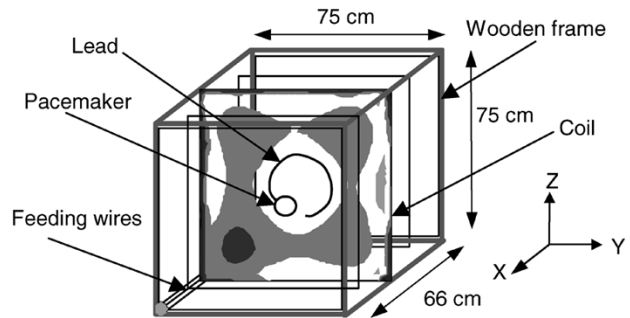


Fig. 5. Measured magnetic field distribution in the x-direction of the center plane of the simulator normalized to the magnetic field value in the center of the simulator. The pacemakers and the leads were placed in this center plane for the EMC testing. The field homogeneity in the middle part of the center plane (the white part of the field distribution where the pacemaker and the lead is placed) the field homogeneity is better than $\pm 1\%$. One gray step represents a change in the field magnitude of 2%. The dark spot in the lower left corner shows a 4% increase of the magnetic field due to the feeding wires.

actual WTMDs. The arbitrary waveform generator HP 33120A (Hewlett-Packard, Palo Alto, CA) provides a voltage signal with the desired waveform to drive the trans-conductance amplifier (Clarke-Hess, New York, Model 8100, 100 A max). The trans-conductance amplifier operates as the voltage controlled current source. The coil system can produce uniform magnetic fields (-5% to $+10\%$) over a volume 57 cm long, 42 cm wide, and 14 cm deep.

The coil inductance of $6.1 \mu\text{H}$ in combination with the output capacitance of the trans-conductance amplifier represents a resonant structure. This resonant structure produces a ringing after the falling edge of the pulsed signal. A $2.2\text{-}\Omega$ resistor was added in parallel to the coil to dampen the ringing without distorting the pulses.

Ideally, a trans-conductance amplifier will produce an output current proportional to an input voltage, independent of the load impedance. The voltage developed by the amplifier that forces the current into the load is referred to as the amplifier’s compliance voltage. Most commercial wideband trans-conductance amplifiers have an upper limit compliance voltage of 7 V rms. Depending on the maximum time rate-of-change of the current needed to produce the desired time-varying magnetic field, this upper limit of the compliance voltage introduces a number of constraints on the design of the coil system. For the present simulator the inductance L of the coil system and the current I required to produce the peak magnetic field must be made sufficiently small such that the voltage that develops across the load,

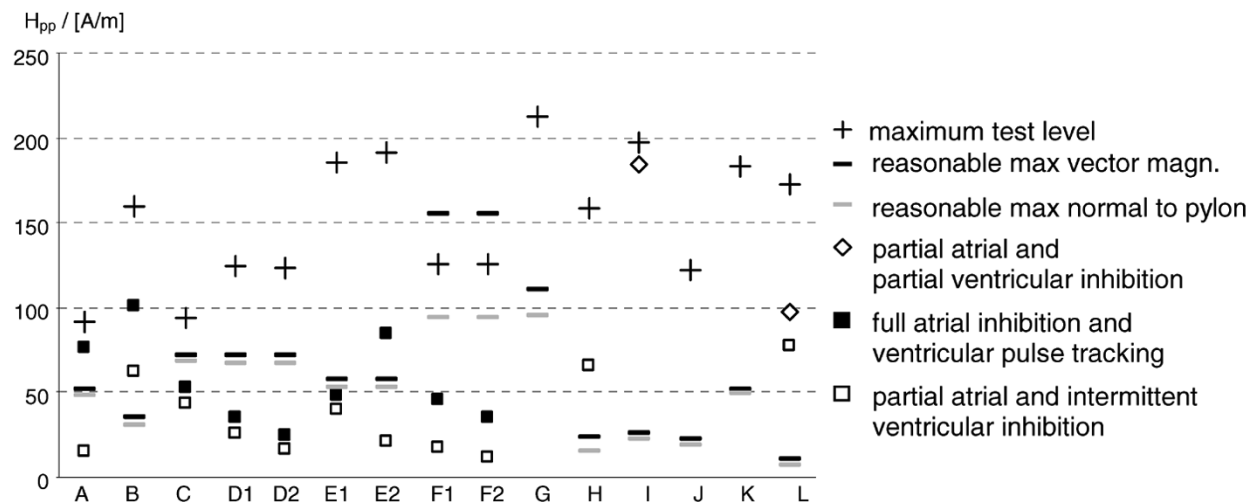


Fig. 6. Interference thresholds for the testing in air of the pacemaker *PMI*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

$L(dI/dt)$, does not exceed the compliance voltage limit of the trans-conductance amplifier.

Model calculations that considered different coil designs and provided information on field uniformity, current requirements, and approximate inductance values [7] led to a design which was found to provide adequate uniformity and acceptable compliance voltages for the desired magnetic fields. Fig. 4 shows a photograph of the coil system which consists of 5 coaxial square loops made of 3.2 mm diameter copper rods, separated by distances of 16 cm, and mounted on a wooden frame with dimensions of $75 \times 75 \times 66$ cm. The two outer loops and the middle loop are connected in series and have nominal side dimensions of 75 cm. The other two loops are connected in series and have nominal side dimensions of 70 cm. The smaller dimensions of these loops produce a more uniform magnetic field in the volume of interest ($57 \times 42 \times 14$ cm). To produce the magnetic field, the two sets of loops are connected in parallel to the trans-conductance amplifier and have a combined measured inductance of $6.1 \mu\text{H}$.

The simulator performance was evaluated for field homogeneity and temporal characteristics of the signal using the WTMD scanner described in Section II. The simulator coil is able to generate a highly uniform, linearly polarized magnetic field in a volume 57 cm long, 42 cm wide, and 14 cm deep, with modulation characteristics and field strengths such as those generated by security systems. To check the uniformity of the simulator magnetic fields, the magnetic field distribution was measured in five planes within the simulator coil. The field strength measurements in the specified volume ($57 \times 42 \times 14$ cm) were found to be uniform within $+10\%$ and -5% . These largest field strength variations occur only at the boundaries of the specified volume. The magnetic field uniformity varied only $+4\%$ to -1% in the central plane where all pacemaker tests were performed (see Fig. 5).

The security system simulator is able to mimic magnetic fields emitted by WTMDs up to the reasonable maximum for 10 of the 12 WTMDs evaluated. The performance of the simulator regarding maximum field values was evaluated with both CW and pulsed signals with the same waveform as emitted

by the WTMDs. We define the maximum test level for pulsed signals as the magnetic field level in the simulator coil center plane when the waveform begins to distort. The waveform distortion of the magnetic field was visually monitored on an oscilloscope. For the CW WTMDs the maximum test level was determined by the compliance voltage of the trans-conductance amplifier. The maximum test levels are shown for each WTMD in the pacemaker interference threshold charts (Fig. 6–11).

IV. PACEMAKER TESTING IN THE SIMULATOR

The pacemaker settings were chosen according to the ANSI/AAMI PC69:2000 [14] to simulate worst case conditions for the device EMI behavior. The settings we used are basically to set the pacemaker to unipolar stimulation and to the maximum sensitivity. Single channel pacemakers come in a variety of designs and configurations from the simple single channel devices to devices that can stimulate two (dual) or more heart chambers. Most implanted pacemakers supply electrical stimulation “on demand,” that is only when the pacemaker senses and determines the stimulation is needed. This approach allows the pacemaker to conserve precious battery capacity and, thus, last longer before it must be replaced. Thus, disruption of the cardiac sensing of the pacemaker by exposure to security systems could lead under certain circumstances (e.g., prolonged exposure) to serious concerns for the patient. Dual chamber devices are set to DDD (dual pace, dual sense, dual response to sensing) or DDDR (same as DDD plus rate modulating) mode and single chamber devices to VVI mode (ventricular paced, ventricular sensed, response to sensing is inhibition). The loop size formed by the pacemaker can and the lead was chosen to be 225 cm^2 . The lead was laid out in the form of a circle with a gap of 70 mm between the lead tip and the can.

We tested four modern pacemakers.

- Pacemaker 1 (PM1) dual channel, DDDR sensitivity setting atrial: 0.5 mV, ventricular: 1 mV;
- Pacemaker 2 (PM2) single channel, VVI sensitivity setting: 1 mV;
- Pacemaker 3 (PM3) dual channel, DDD sensitivity setting atrial: 0.5 mV, ventricular: 1 mV;

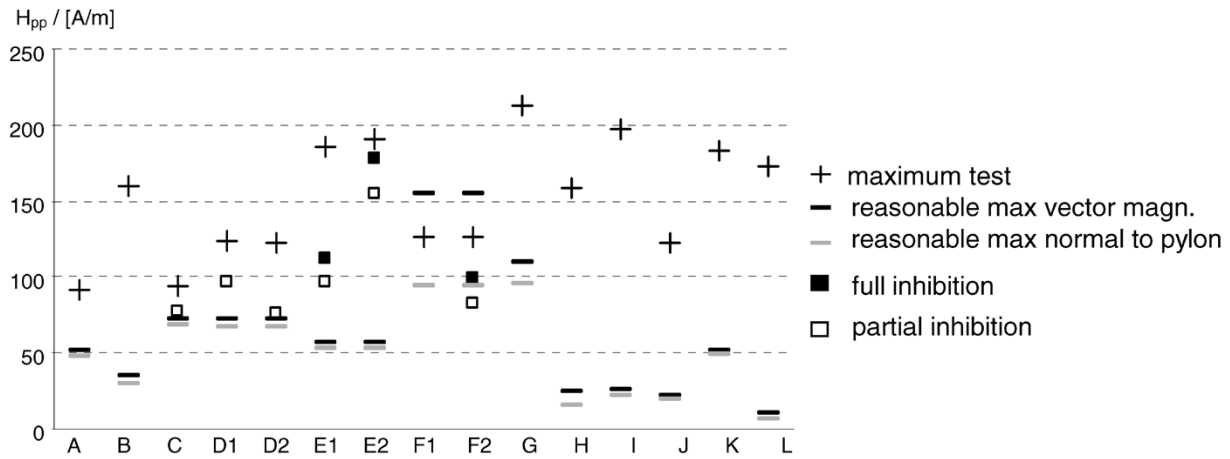


Fig. 7. Interference thresholds for the testing in air of the pacemaker *PM2*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

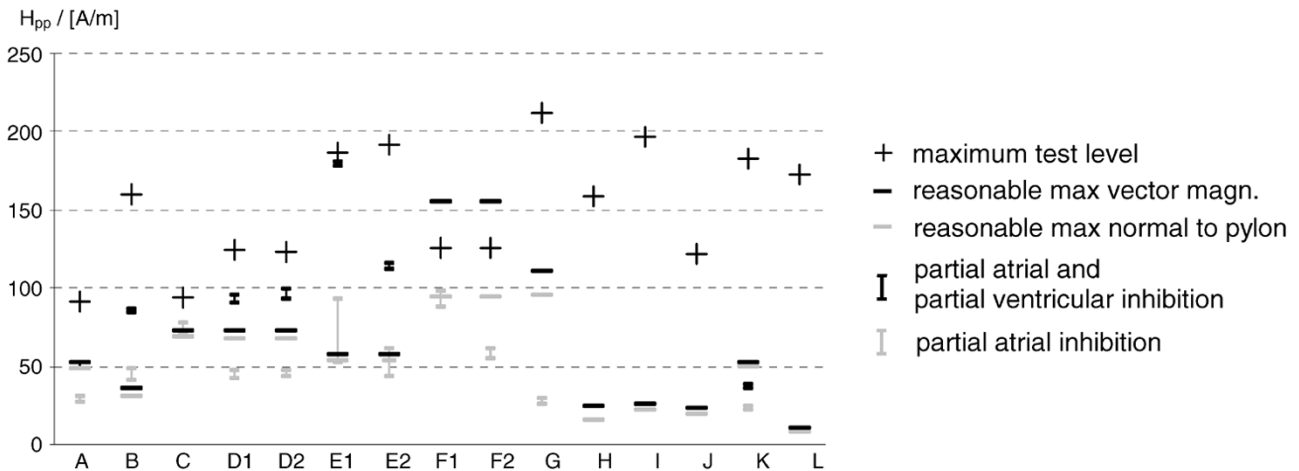


Fig. 8. Interference thresholds for the testing in air of the pacemaker *PM3*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

- Pacemaker 4 (PM4) dual channel, DDDR sensitivity setting atrial: 0.5 mV, ventricular: 1 mV.

The pacemaker output was monitored on a digital oscilloscope “Waverunner-2 LT-264” from LeCroy (Chestnut Ridge, NY). For interference tests in air we monitored the pacemaker using a twisted cable. The loop from the lead tip to the pacemaker was closed using a 500-Ω resistor. The pacemaker output was monitored across this 500-Ω resistor.

In case of testing the pacemaker in saline, the pacemaker output was monitored using a fiber optical system. We used the “Optical Voltage Probe and Receiver,” Model 400-02M from Srico, Inc. (Columbus OH). With this optical probe it is possible to monitor a signal without having a galvanic connection between the source and the monitoring device. The electrical signal is converted into an optical signal and transferred via fiber cables to the receiver. The pacemaker output was monitored across two electrodes which were put in the saline near the tip of the lead. With this optical monitoring we guaranteed that the monitoring cable could not pickup any signals which is possible in the case of testing in air. In comparison, the simple resistive load circuit used in the “in air” testing may be susceptible to picking-up some of the exposure field signals in the cable mon-

itoring the pacemaker output that may contribute to, or possibly lower, the device interference threshold. All EMC testing of the pacemakers were double checked to minimize any artifacts or unwanted pick-up. In principle, interference tests could also be performed in air using the fiber optical system or in saline using a twisted cable to monitor the pacemaker output. We compared the most simple and fastest approach (air testing using a twisted cable) with the most sophisticated approach (using saline and the fiber optical system).

The saline box has dimensions of 42 × 57 × 30 cm and is filled with a 0.14% saline solution with a conductivity of 0.266 S/m to a height of 5 cm. For the following three pulsed WTMDs we define a complex signal in addition to the simple signal:

- WTMD “D” simple signal: D1 complex signal: D2;
- WTMD “E” simple signal: E1 complex signal: E2;
- WTMD “F” simple signal: F1 complex signal: F2.

The complex signals D2 and E2 contain two pulses of the simple signals D1 and E1. Such double pulses occur on spatial locations where the magnetic field is generated by the fields of two different loops. On spatial locations where the magnetic field is dominated by one loop the signal contains only one pulse. For the WTMD “F” the situation is more complicated.

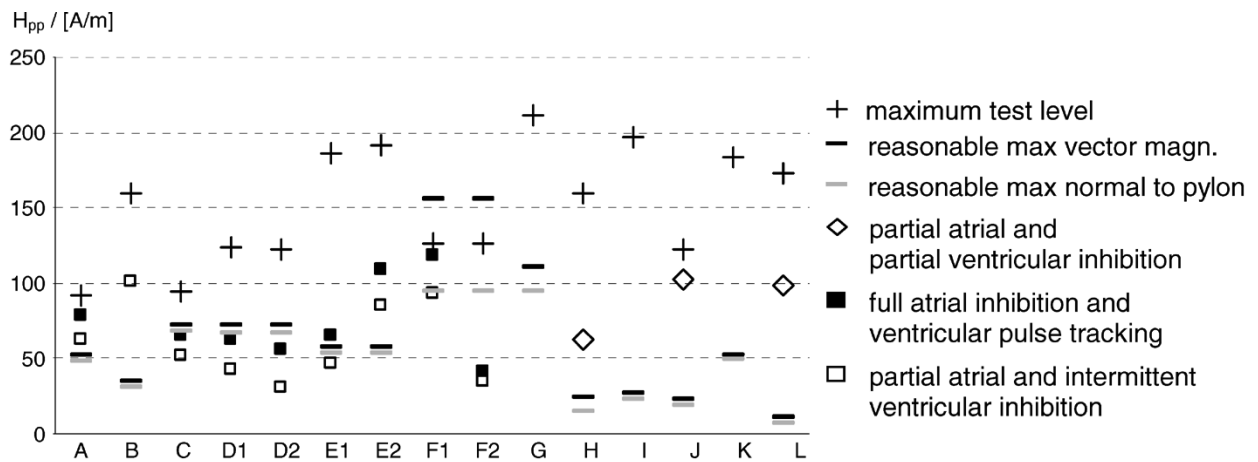


Fig. 9. Interference thresholds for the testing in saline of the pacemaker *PM1*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

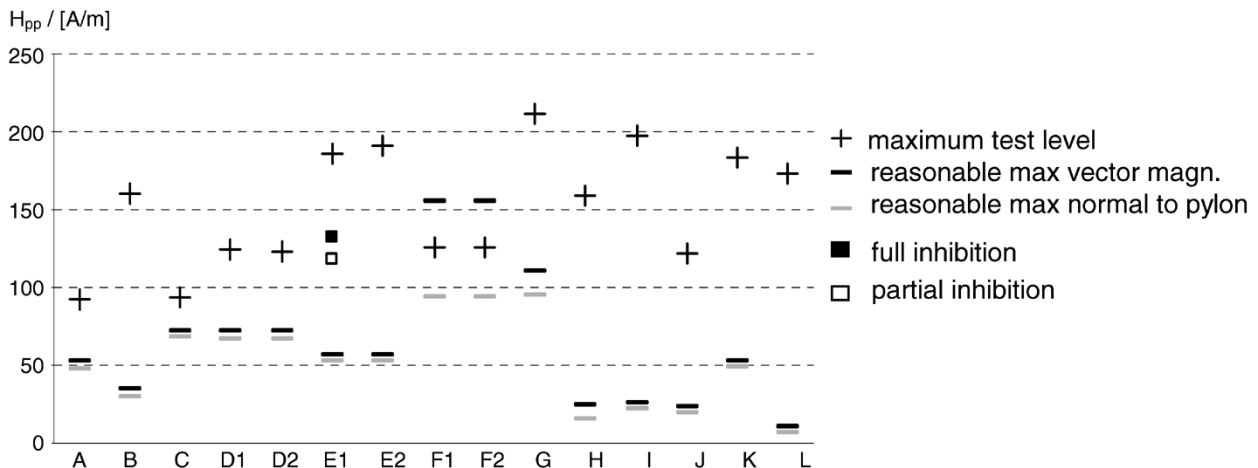


Fig. 10. Interference thresholds for the testing in saline of the pacemaker *PM2*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

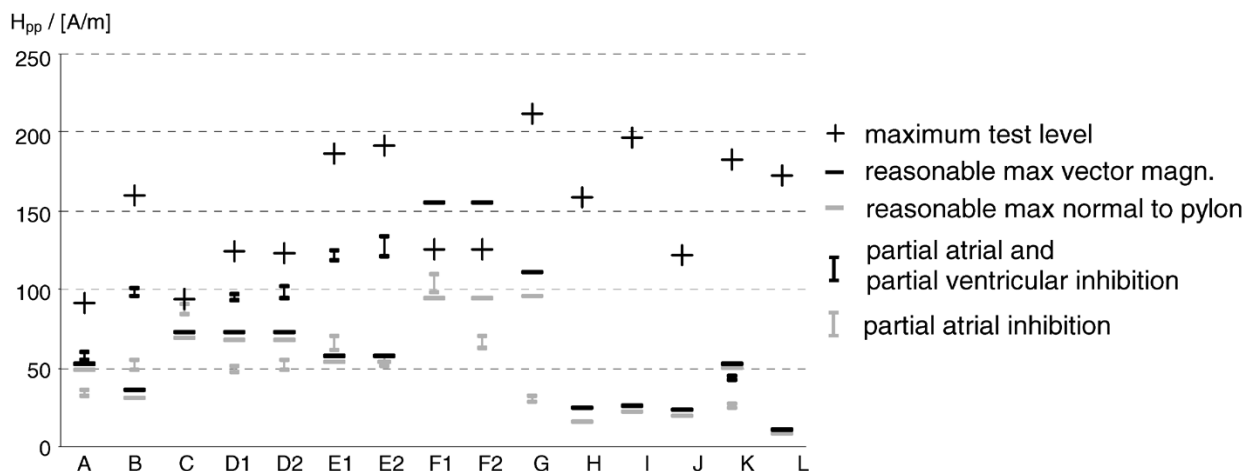


Fig. 11. Interference thresholds for the testing in saline of the pacemaker *PM3*, reasonable and absolute maximum for each WTMD, and the maximum test level for each of the 15 tested WTMD signals. The magnetic field is given as the peak-to-peak value in A/m. A missing interference symbol for a particular WTMD signal indicates that no interference was observed up to the maximum test level for that WTMD signal.

Multiple coils produce a signal dominated by one coil on one location but a complex superposition of several coils on other locations. We could not identify locations where the complex signal is a clear repetition of the simple one, like those found in the WTMDs “D” and “E.” Therefore, we defined for WTMD “F” the complex signal as the vector magnitude found on the spatial location where the signal contains most pulses. With respect to the pacemaker EMI behavior such a complex signal, containing multiple pulses, represents the worst case scenario.

An indication of no interference threshold shown in Figs. 6–11 means that the device under test did not appear to be disrupted by the exposure signals up to the maximum test level. Since the interference behavior for all four pacemakers is the same for the testing in air and saline we only describe it for the testing in air. One of the four tested pacemakers, the *PM4*, showed no interference from all tested WTMD signals up to the maximum test levels for all testing in air and in saline.

We started the interference testing at the lowest possible field value, at approximately 1–2 A/m. To determine the interference thresholds we increased the magnetic field in 2 A/m steps at 10 second intervals until interference was visually observed. The magnetic field was monitored in the center plane of the simulator using the magnetic field probes described.

A. Pacemaker Testing in Air

1) *PACEMAKER 1*: The *PM1* showed two interference thresholds for nine of the ten tested pulsed WTMD signals. At the first threshold partial atrial and intermittent ventricular inhibition was observed. This behavior continued until the second threshold was reached. Then the *PM1* showed full atrial inhibition and ventricular pulse tracking at the maximum rate. Intermittent inhibition means that a pulse is missing only once in a while. Partial inhibition means that more than one consecutive missing pulse was observed. The behavior of the *PM1* for CW WTMD was different. In addition to intermittent ventricular inhibition, partial atrial and partial ventricular inhibition was also observed. These inhibitions occurred only at very high field levels that were much higher than the absolute maximum for the particular WTMD.

2) *PACEMAKER 2*: The interference behavior of the single channel pacemaker *PM2* was similar to the behavior of the dual channel *PM1*. For both the pulsed and the CW WTMD signals the pacemaker showed partial atrial inhibition combined with intermittent ventricular inhibition at the first threshold. This behavior continued until the second threshold was reached. The second threshold was characterized by full atrial inhibition combined with ventricular pulse tracking at the maximum rate. No interference for CW WTMD signals was observed.

3) *PACEMAKER 3*: The *PM3* showed an entirely different interference behavior. Two interference windows at different field levels were found. Above and below the interference window no interference was observed. The first window was characterized by partial inhibition only. Once the upper limit of the first window was reached the pacemaker returned to normal pacing until the second window was reached. The second window was characterized by partial atrial and partial ventricular inhibition. Above the upper limit of the second interference window the pacemaker returned to normal function.

B. Pacemaker Testing in Saline

In general, the interference behavior of the pacemakers during the testing in saline was similar to the behavior during the testing in air. The main difference we observed was that all interference thresholds found in saline occurred at higher field values than during the testing in air. We also noticed that in some pacemaker-WTMD combinations interference occurred during the testing in air, but no interference could be observed for the same combination up to the maximum test level during testing in saline. Details about the different interference behavior and the interference thresholds for the different pacemaker-WTMD combinations tested in saline are given in Figs. 9–11.

V. COMPARISON BETWEEN SIMULATOR AND ACTUAL WALK THROUGH METAL DETECTORS

Pacemaker testing in real WTMD is a time consuming and problematic task. Especially the testing in saline is tedious, because the pacemaker has to be immersed in saline and the saline box is heavy and difficult to move and place. Furthermore the actual WTMD has to be available and interference in this WTMD model must be possible. Interference is only possible if the threshold found in the simulator is at a field level which can be found in the real WTMD. Our simulator results show that WTMD “D” and “F” are good candidates for the comparison between simulator results and real WTMD. Both WTMDs are available in house and for both signal types (simple and complex) the interference levels found in the simulator are below the reasonable maximums. Therefore, we chose WTMD “D” and “F” to find the interference threshold for the pacemaker *PM1*.

Both WTMDs emit a pulsed signal. The interference tests in the actual WTMDs and in the simulator were performed and compared in air and in saline. We used the same test configuration as used in the simulator. The pacemaker was fixed on a plastic grid with a loop size of 225 cm². The same resistance for bridging the gap between the lead tip and the can and the same monitoring cable as in the testing in air were used. To find the interference threshold we moved the pacemaker in the WTMD until interference could be seen. Then we measured the magnetic field at the location of the pacemaker and compared it to the interference threshold found in the simulator. Depending on the distance from the pacemaker to the pylon of the WTMD and, therefore, on the magnetic field strength both kinds of interference were found. Closer to the pylon full atrial inhibition and ventricular pulse tracking was seen. Further away from the pylon, at lower field levels, partial atrial and intermittent ventricular inhibition was found. This is the same interference behavior as seen in the simulator. The interference levels found in the actual WTMD and in the simulator are given in Figs. 12 and 13.

VI. CONCLUSION

The work presented here shows that the security system simulator is able to mimic the pacemaker interference behavior. Both, the interference thresholds and the kind of interference found in the simulator can be correlated to the interference found in the actual WTMD. The interference threshold found in the actual WTMD lies between the threshold for the simple signal and

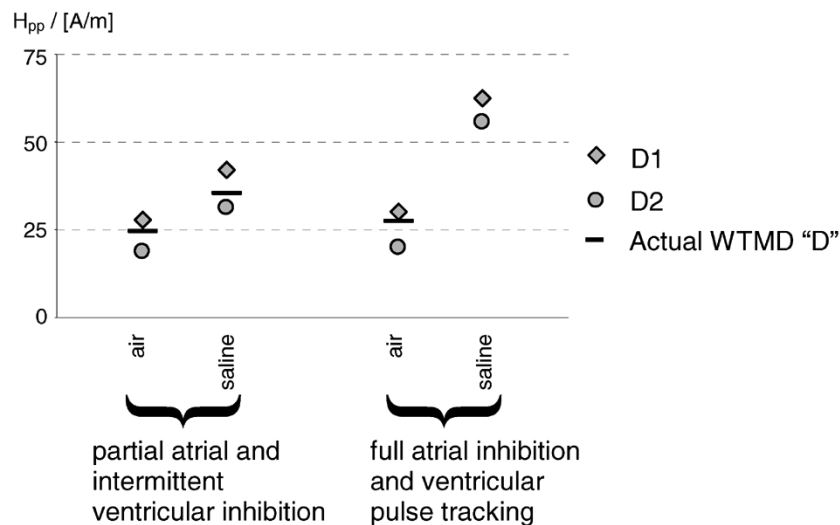


Fig. 12. Interference thresholds for the pacemaker *PMI* found in the simulator for the simple signal (D1) and the complex signal (D2) compared to the interference threshold seen in the actual WTMD “D”. Interference levels are shown for the in air and the testing in saline.

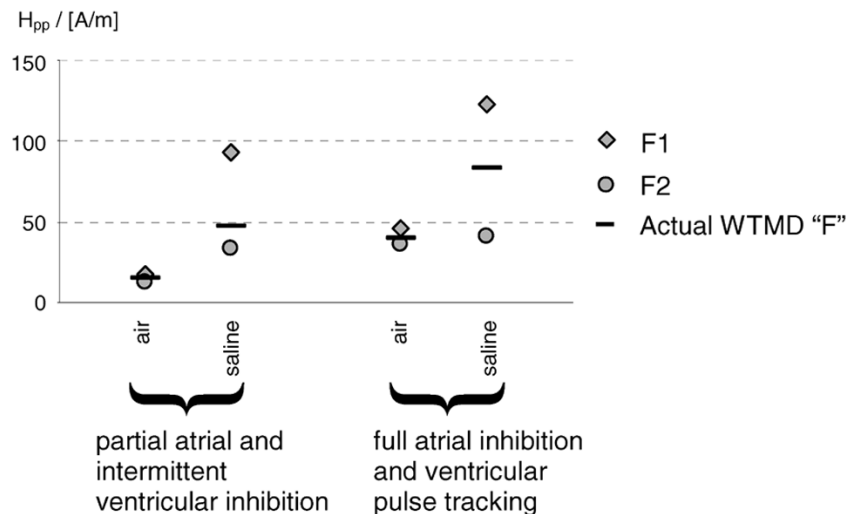


Fig. 13. Interference thresholds for the pacemaker *PMI* found in the simulator for the simple signal (F1) and the complex signal (F2) compared to the interference threshold seen in the actual WTMD “F”. Interference levels are shown for the in air and the testing in saline.

the threshold for the complex signal, except for one situation where we could not find an interference in the actual WTMD (see Fig. 12). There are several advantages of performing implanted pacemaker EMC testing in the security system simulator. For example, the simulator is able to easily switch among different types of WTMDs by simply changing to a different exposure signal and to adjust the magnetic field amplitude stepless. These features allowed the discovery of “windows” of device interference.

In general, the interference levels found in the simulator do not indicate that complex signals produce interference at a lower magnetic fields. However, for all pacemakers the interference level for the complex signal which is vector magnitude (“F2”) was lower than the interference level for the simple signal (“F1”). This behavior could not be confirmed when the complex signal consists of two pulses of the simple signal. Some of the interference thresholds for the complex signal “D2” and “E2” are lower than for the corresponding simple

signals “D1” and “E1” while others were higher. In order to find the lowest interference threshold, tests with both kinds of signals need to be performed.

Pacemaker EMC tests using the “in air” method proved to be the worst case scenario for all tests performed. In all the simulator and actual WTMD testing, interference thresholds in air are lower than the thresholds found using the “in saline” test method.

Although we have not evaluated the “in air” method using the fiber optical probe or the “in saline” method using the twisted cable method to monitor the pacemaker output it seems reasonable to hypothesize that testing using the “in air” method should be sufficient to demonstrate that the EMC of a specific pacemaker and lead system is compatible with a particular WTMD. We assume that the “in air” method using the fiber optical probe or the “in saline” method using the twisted cable method will result in interference thresholds somewhere between the thresholds found in this study. If the threshold found using the “in

air” method is higher than the exposure at the reasonable maximum field strength the pacemaker will likely be compatible with that particular WTMD. If the threshold found using the “in air” method is lower than the exposure at the reasonable maximum field strength a test “in saline” can confirm if the pacemaker will likely be incompatible with that particular WTMD. Conversely, if the threshold found using the “in saline” method is higher than the exposure at the reasonable maximum level then the particular pacemaker-WTMD combination can likely be considered as compatible.

The interference levels found in the simulator indicate interference with WTMDs emitting pulsed signals is more likely than the interference with WTMDs emitting CW signals. Except for one pacemaker-WTMD combination (*PM3* and WTMD “K”) all interference levels found for WTMD emitting CW signals are higher than the reasonable maximum normal to the pylon and the reasonable maximum vector magnitude. These results suggest that pacemaker disruptions is more unlikely from CW WTMD in most typical situations. Interference in the real WTMD is possible in cases where the interference level found in the simulator is below the maximum normal to the pylon during the testing in saline.

Although the two WTMDs “F” and “G” have similar signal properties (waveform, frequency, and fall time), their impact on the tested pacemakers is quite different. WTMD “G” only showed influence of the pacemaker *PM3* when testing in air. In all other tests, no interference threshold was found up to the maximum test level. WTMD “F” showed interference well below the interference levels found for WTMD “G.” This suggests that simplified tests with standardized sinusoidal or amplitude modulated sinusoidal signals, as proposed in some draft standards, may not be adequate for EMC tests of AIMDs exposed to pulsed magnetic fields. Thus, as long as no generalized test method for pulsed signals is available EMC tests of a certain pacemaker or other AIMD with a certain security system emitting pulsed signals should be evaluated using the actual security system signals. The compatibility and safety margin can be determined by comparing the interference level with the reasonable maximum magnetic field of the security system.

Several standards are addressing EMI of AIMDs: EN 45 502-1:1997 [8], prEN 45 502-2-1:2003 [9], prEN 45 502-2-2:1998 [10], ISO 14 708-1:2000 [11], EN 50 061:1988 [12], and ANSI/AAMI PC69:2000 [13]. The only current standards covering pacemaker interference in the frequency range of WTMDs are EN 45502-1:1997 and ISO 14708-1:2000. The other standards are either preliminary (“pr”) standards, available as a draft, or they do not cover the specific frequency range of WTMDs. Several standards are under revisions (e.g., ANSI/AAMI PC69:2000, ISO 14 708-1:2000, prEN 45 502-2-2:1998) and prEN 45 502-2-1:2003 is expected to be published soon. EN 45 502-1:1997 and ISO 14 708-1:2000 specify a test level for magnetic fields in a note: “As a first guide, consider a magnetic intensity of 150 A/m falling inversely with frequency above 100 kHz to a maximum test frequency of 30 MHz. The electric field need not be investigated.” Both standards do not provide specific information on test methods. prEN45502-2-1:2003 specifies tests for pacemakers for various physical agents. Clause 27 of prEN45502-2-1:2003 specifies tests to protect the pacemaker from electromagnetic non-ionizing radiation. Sub-Clause 27.4 of prEN45502-2-1:2003

specifies tests to determine malfunction during the exposure to ambient CW electromagnetic fields. For the frequency range 16.6 Hz to 167 kHz prEN45502-2-1:2003 specifies the maximum test level to be 1 V peak-to-peak. A 1 V induced voltage for a CW WTMD operating between 0.3 kHz and 7.4 kHz with a loop size of 225 cm² gives a magnetic test level from 760 A/m up to 18 800 A/m peak-to-peak. Such unrealistic test levels are much higher than human exposure limits in this frequency range, difficult to generate and much higher than the electromagnetic field levels a pacemaker would be typically exposed to. Sub-Clause 27.5 of prEN45502-2-1:2003 specifies tests to determine changes of the therapeutic behavior of implantable pulse generators during the exposure to commonly encountered modulated electromagnetic fields. None of the standards mentioned above [8]–[13] specifies how to test pacemaker or other AIMDs against pulsed electromagnetic fields. The obvious difference in the interference thresholds between pulsed and CW magnetic fields requires a standardized test method for pacemaker, and other AIMDs, exposed to pulsed magnetic fields. The Center for Devices and Radiological Health in cooperation with the Federal Aviation Administration is working on such a standardized test method for AIMDs exposed to pulsed electromagnetic fields. This study with 120 evaluated thresholds (4 pacemaker models * 15 WTMD signals * “in air” versus “in saline” testing) may not have enough data to establish an EMC test method for pulsed signals. Nonetheless, it was a first approach to obtain relevant information about interference behavior of pacemakers exposed to pulsed magnetic fields and to evaluate the security system simulator performance. More testing using a larger number of pacemaker is necessary to find appropriate generic pulsed signals and to establish a practical test method.

Because the electronic components are “off-the-shelf” and the coil can be readily fabricated, the security system simulator can be used by biomedical engineers and manufacturers of AIMDs to conduct their own EMC tests or adapt the system to simulate other magnetic field emitting security systems. It is hoped that the simple design and easy use of a security system simulator will help to identify incompatible combinations of WTMDs and pacemakers early in the development stage.

ACKNOWLEDGMENT

The authors would like to thank Dr. K.-S. Tan from the Medical Devices Bureau, Health Canada for lending them several pacemakers.

REFERENCES

- [1] W. Kainz, G. Neubauer, F. Alesch, G. Schmid, and O. Jahn, “Electromagnetic compatibility of electronic implants—Review of the literature.” *Wiener Klinische Wochenschrift*, vol. 113, no. 23–24, pp. 903–914, 2001.
- [2] *Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICD’s, and Spinal Cord Stimulators*, <http://www.fda.gov/cdrh/safety/easnote.html>, Sept. 1998. Food and Drug Administration, Center for Devices and Radiological Health, Letter to Cardiologists Cardiovascular Surgeons, Emergency Physicians, Neurologists, and Neuro Surgeons.
- [3] Y. Copperman, D. Zarfati, and S. Laniado, “The effect of metal detector gates on implanted permanent pacemakers,” *Pacing Clin. Electrophysiol.*, vol. 11, pp. 1386–1387, Oct. 1988.
- [4] A. Wilke, T. Kruse, H. Hesse, R. Funk, and B. Maisch, “Interactions between pacemakers and security systems,” *Pacing Clin. Electrophysiol.*, vol. 21, pp. 1784–1788, Sept. 1998.

- [5] W. Irnich, "Electronic security systems and active implantable medical devices," *Pacing Clin. Electrophysiol.*, vol. 25, no. 8, pp. 1235–1258, Aug. 2002.
- [6] J. Casamento, "Characterizing electromagnetic fields of common electronic article surveillance systems," *Compliance Eng.*, pp. 42–52, Sept./Oct. 1999.
- [7] —, "Comparison of magnetic fields emitted from security screening devices with magnetic field immunity standards," in *Proc. IEEE Int. Symp. Electromagnetic Compatibility*, Aug. 2002, pp. 937–940.
- [8] M. Misakian, J. P. Casamento, and O. B. Laug, "Development of emulator for walk-through metal detectors," *IEEE Trans. Electromagn. Compat.*, vol. 44, no. 3, Aug. 2002.
- [9] European Committee for Standardization/European Committee for Electrotechnical Standardization—CEN/CENELEC, "EN45502-1:1997, Active Implantable Medical Devices, Part 1: General requirements for safety, marking and information to be provided by the manufacturer," Aug. 1997.
- [10] European Committee for Standardization/European Committee for Electrotechnical Standardization—CEN/CENELEC, "prEN45502-2-1:2003, Final Draft, Active Implantable Medical Devices, Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)," Apr. 2003.
- [11] European Committee for Standardization/European Committee for Electrotechnical Standardization—CEN/CENELEC, "prEN45502-2-2:1998, Draft, Active Implantable Medical Devices, Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (Includes implantable defibrillators)," Mar. 1998.
- [12] International Organization for Standardization (ISO), "ISO 14708-1:2000, Implants for surgery—Active implantable medical devices, Part 1: General requirements for safety, marking and for information to be provided by the manufacturer," 2000.
- [13] European Committee for Electrotechnical Standardization (CENELEC), "Safety of implantable cardiac pacemakers," EN50061:1998, May 1988.
- [14] American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI), "Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators," ANSI/AAMI PC69:2000, May 2000.



Wolfgang Kainz (M'02) received the M.S. and Ph.D. degrees in electrical engineering from the Vienna University of Technology, Vienna, Austria.

After working for the Austrian Research Centers Seibersdorf on electromagnetic compatibility of electronic implants and exposure setups for bio-experiments he joined The Foundation for Research on Information Technologies in Society—ITIS (Zurich, Switzerland) as Associate Director. He managed ITIS together with Prof. Niels Kuster (ITIS Director and Founder) and worked on the development of *in vivo* and *in vitro* exposure setups for bio-experiments. In 2002, he moved to the USA where he is currently working for the U.S. Food and Drug Administration in the Center for Devices and Radiological Health. His research interest is focused on safety and effectiveness of medical devices and safety in electromagnetic fields. This includes computational electrodynamics (FDTD and FEM simulations) for safety and effectiveness evaluations, MRI—Magnetic Resonance Imaging safety, performance and safety of wireless technology used in medical devices, electromagnetic compatibility of medical devices, especially electronic implants, and dosimetric exposure assessments.



Jon P. Casamento (S'77–M'79) received the B.S. degree in electrical engineering from the University of Maryland at College Park, in 1979.

He has worked for the U.S. Food and Drug Administration, Center for Devices and Radiological Health since 1980. He has been active in measuring electromagnetic fields and in evaluating the electromagnetic compatibility of medical devices to low-frequency and radio frequency electromagnetic fields since 1991.



Paul S. Ruggera (S'63–M'66–SM'91) received the B.S. degree in electrical engineering with a biomedical option and the M.S. degree in bioengineering from the University of Wyoming, Laramie, in 1966 and 1968, respectively.

He then accepted a commission in the United States Public Health Service from which he retired after a 30-year career. Currently, he is employed by the U.S. Food and Drug Administration in the Center for Devices and Radiological Health.

Throughout most of his career he has worked in the area of electromagnetic compatibility for medical devices beginning in the early 1970s when the concern for microwave oven interference to implanted cardiac pacemakers arose. In recent years, he has published papers discussing cardiac pacemaker and implanted defibrillator interference associated with various radio frequency and microwave sources including wireless telephones. He has performed electric field strength measurement surveys in the hospital environment, measured electric and magnetic emissions from electrosurgical and diathermy units, and investigated electromagnetic interference to electroencephalogram machines, apnea monitors, and motorized wheelchairs. He holds two patents in the area of hyperthermia treatment for cancer therapy, and has worked in applying this radio frequency heating technology to the rapid warming of vitrified organs for transplant.

He is a member of its EMC society and a registered professional engineer in Virginia.



Dulciana D. Chan received the B.S. degree in biomedical engineering from Johns Hopkins University, Baltimore, MD.

After graduation she joined the U.S. Food and Drug Administration in the Center for Devices and Radiological Health to conduct research concerning medical device safety. Her areas of interest include electromagnetic compatibility of medical devices, computer modeling of nerve electrophysiology, and evaluating the safety and efficacy of electrical stimulators.



Donald M. Witters (M'80–SM'93) received the B.S. degree from the University of Maryland, College Park, and the M.S. degree in biomedical engineering from Georgetown University, Washington, DC, and is a senior member of the Institute for Electrical and Electronics Engineering.

He is a biomedical engineer with over 25 years experience in the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH). He is the chairman of the FDA/CDRH Electromagnetic Compatibility Working Group charged with developing and coordinating the CDRH activities to assure medical device EMC.

He has written several articles on medical device EMC and precision microwave calibrations, and has helped write and develop several national and international standards. He has performed research dealing with medical device electromagnetic compatibility, nonionizing electromagnetic radiation, and electrical nerve stimulation. He was instrumental in the development of the wireless medical telemetry service (WMTS) that is the first radio spectrum created to protect wireless medical telemetry from electromagnetic interference.