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Comparison of Injected and Radiated EMC Testing of Active Implanted Cardiac Medical Devices at the Boundary Frequency of 450 MHz

Howard Bassen and

Life Fellow IEEE, U. S. Food and Drug Administration Center for Devices and Radiological Health

Gonzalo Mendoza

CNI Technical Services

Abstract

We compared testing via radiated vs. injected susceptibility methods specified in the ISO 14117 standard for electromagnetic compatibility of implantable cardiac medical devices. Injected testing is specified at and below 450 MHz and radiated testing is specified at and above this boundary frequency. Experimental and computational studies were performed to determine voltages induced in a model of an implant. The device under test (DUT) was a model with a metal case (5.0 x 4.5 x 3.4 cm high) containing a diode detector and a fiber optic link plus an insulated wire simulating a unipolar lead. We evaluated induced voltage in the model for radiated versus injected testing. The voltage from experimental measurements agreed with computed values within ± 1.4 dB or less. Radiated testing with 12.25 Watts delivered to the dipole specified in the standard induced the same voltage as the injected test requirement (14 Vp-p). This is in strong contrast to the specified radiated test power of 120 mW or even the optional worst-case radiated test level of 8 Watts. Lateral displacement of the dipole by 2 cm changed the voltage induced in the DUT by 20% or less. For depth changes below saline surface from 5 mm to 10 mm voltage variations were 12.5%. There is poor agreement (by a factor of 9.9 or more) for radiated vs. injected testing at the border frequency of 450 MHz separating the two methods. Our computational model can also be used at other frequencies and for EMC studies of other types of active implants that use the ISO14117 standard's radiated test method, such as neuro-stimulators.

Index terms

electromagnetic compatibility; injected testing; ISO 14117 standard; radiated testing

I. Introduction

This paper reports on studies related to EMC testing standards for medical devices. It deals specifically with two related methods for testing active implantable cardiac devices (devices that utilize electronic circuitry) as specified in ISO 14117 [1]. Injected testing is specified at

and below 450 MHz and radiated testing is specified at and above this boundary frequency. Testing to this standard is performed by all major manufacturers in the U.S. and other countries. Other implantable device EMC standards such as ISO 14708-3 for implantable neurostimulators [2] specify test methodologies similar to ISO 14117. The predecessor to 14117 is AAMI/ANSI PC69 [3]. It was developed to address concerns about interference of implanted cardiac pacing and defibrillation devices from cellular phones and numerous lower frequency electromagnetic field emitters [4]. EMC testing of implanted cardiac devices is needed because of the concern for interference from EM emitters such as metal detectors, handheld radio transceivers, cellular phones, anti-theft/ electronic article surveillance systems, and radiofrequency identification devices (RFID). The ISO 14708-3 implantable neurostimulator standard has concerns for this type of EMC and uses the methods in ISO 14117 for radiated testing. For the frequency range of 450 MHz to 3000 MHz a radiated susceptibility test is prescribed in both the ISO 14117 and ISO 14708-3 standards.

A test configuration is used as shown in fig. 1. The standard specifies use of a torso simulator consisting of a non-conductive plastic container filled with saline (measuring at least 51 cm × 36 cm × 14 cm) and two plastic grids placed in the container. The saline had conductivity at 450 MHz of 0.33 S/m (375 ohm-cm at 1 kHz) and a dielectric constant of 79. The grids contain square holes that are approximately 1.27 cm (0.5 in) on each side. The lower grid is positioned in the saline and allows the saline to pass through the holes. It supports the device under test (DUT). The upper grid is positioned above the saline and supports a dipole antenna. For efficiency we only used one grid (in the saline) in the computational model. The omission of the upper grid changed the computational results of induced voltage in the DUT by less than 2.5 %.

The dipole is driven by a radiofrequency (RF) generator. The (DUT) is positioned on the top surface of the lower grid at the center of the torso simulator. Testing is performed with 120 mW net power to the dipole for the frequency range 450 MHz $f < 1\,000$ MHz. For worst-case testing an optional level of 8 W is used. The dipole antenna is placed on the top grid (above the saline) with the axis of the antenna elements parallel to the X-axis.

For frequencies at and below 450 MHz the ISO standard prescribes an injected susceptibility technique. No antennas or leads of the DUT are involved in the injected test. A “tissue injection network” is specified by the 14117 standard and is composed of coaxial components. For frequencies of 10 – 450 MHz, a signal generator is connected through a 50 Ω network to the pulse generator of the cardiac device (fig. 2). A peak to peak voltage of 14 V (open circuit) is injected into the connectors of each set of leads of the DUT. Per Annex-A of ISO 14117 the magnitude of the voltage is based on calculations for magnetic field strengths that were estimated for worst-case RF emitters.

The goals of our study included addressing the following. One goal was to determine the correlation between radiated testing versus injected testing as prescribed by the ISO 14117 standard. This was done in the narrow range of frequencies (425 and 450 MHz) that separate these two distinct tests methods. We evaluated the voltage induced in a DUT at the prescribed dipole input power or injected voltage. This was done for radiated testing by

using an experimental model of a simulated implant to validate a computational model that we developed. Once validated, the computational model would allow many more configurations of the simulated implant and leads. Another goal was to determine, for radiated testing, the variability when slight deviations from the standard exist, e.g. dipole height above the saline, depth of the implant below the surface of the saline, and lateral position of the dipole with respect to the DUT. Another goal is to determine the effects of different input impedances on voltage induced in an implant, for both injected and radiated testing. To address these questions we performed computational modeling. The radiated model was validated by experiments for a subset of the configurations of the DUT for radiated testing. For injected testing, only computational modeling was used since the configuration of physical electronic components is quite simple and computed results are reliable.

II. Methods and Materials

The test systems (both experimental and computational) for radiated testing consisted of a dipole antenna placed above a saline-filled tank, and above a submerged model of an implant (figs. 1 and 3). The height of the dipole above the surface of the saline was either 15 mm or 20 mm to study the effects of this parameter. The 20 mm height follows ISO 14117 test specifications for radiated fields above 450 MHz. The experimental model consisted of a metal case (5.0 cm x 4.5 cm x 3.4 cm high) with an insulated solid conductor wire to represent a unipolar lead that penetrated the case through a waterproof hole. An RF voltage sensor was connected at the proximal end of the lead, inside the case. The implant case rested on a grid and the top of the case was 5 mm below the surface of the saline. We used a lead with a length of 58.5cm, composed of a solid-conductor insulated wire with a diameter of 1.6 mm (fig. 3). Another configuration used a short lead (4 cm long). The outer diameter of the insulated wire was 4.6 mm. The spiral lead configuration on the grid is specified by the ISO 14117 standard. The position of the lead below the lid of the implant was 8.5 mm. At the distal end of the lead, 3mm was stripped bare. At the proximal end of all leads, inside the case, a connection to the RF sensor was made. For all cases, both experimental and computational, the lead for the DUT was positioned at the centerline of the dipole.

A. Experimental Studies

The purpose of the experimental system for radiated testing was to validate the computational model of the system. The experimental model was limited to a few configurations, whereas the validated computational model could be configured more easily in many different ways. We used a dipole antenna placed above a saline-filled tank, (51 cm × 36 cm × 14 cm) and a submerged simulated implant containing a fiber optic voltage monitoring link. For both experimental and computational studied the DUT was positioned directly on center under the dipole. We followed the method specified in ISO 14117 for frequencies above 450 MHz. We evaluated the induced voltage at 450 MHz and 425 MHz at the input to the implant model to see if significant changes occur slightly below the prescribed frequency range for radiated testing. The dipole antenna (Stoddart Electro Systems 91598-2) was adjusted so each of its arms was a quarter wavelength of the specific frequency used. It was driven by a radiofrequency (RF) signal generator with 1 kHz

amplitude modulation (Aeroflex, Model: IFR 3416), and an RF power amplifier (Amplifier Research, Model: 10W1000). A 20 dB dual directional coupler (ANZAC, Model: CH-132) was used along with coaxial cables and two power meters (Hewlett Packard 8482A). This setup was used to monitor forward and reflected power into the dipole. We delivered a series of net powers from 1 mW to 500 mW to the dipole antenna during testing. Multiple power levels were used since the detector in our simulated implant was slightly nonlinear in its input to output response. The DUT was a simulated pacemaker/ defibrillator but also could represent a neurostimulator or other medical implant. It consists of a metal case radiofrequency detection circuitry and a simulated lead. The top of the DUT was positioned in the saline filled tank at a depth of 5 mm and 10 mm.

The saline had a 0.18% NaCl concentration (resistivity of 375 ohm-cm at 1 kHz) as specified in the 14117 standard. At the proximal end of the implant, the metallic case contained a peak detector circuit, an optically linked analog transmitter and fiber optic cables that entered the metallic case. These were encapsulated in paraffin wax to waterproof the entire assembly. The proximal end of the simulated lead connects to a 50 Ω load inside the metal case of the implant. While the input impedance of a pacemaker can vary greatly, we used a 50 Ω load in the experimental study because of the following. When delivering 450 MHz RF via coaxial cables to a load much higher than 50 ohms, the reflected power will approach 100% of the forward power, thus making the power and voltage into the load undeterminable. One end of the load is grounded to the case. The voltage induced in the 50 Ω load is measured with an RF diode detector circuit. The detector is composed of a zero bias Schottky diode detector (Advanced Semiconductor, Inc., ASI 3486) with axial leads plus a passive impedance matching circuit (fig. 4). Using a 50 Ω load in the experimental model allowed us to calibrate the case radio-frequency detection circuitry and validate a computational model that also had a 50 Ω load at its input port. After validation the computational model was changed to a 10 k Ω input impedance for the rest of the studies.

The voltage is measured with a fiber optically linked analog transmitter connected to the detector. The detector delivers a demodulated 1 kHz signal from the RF signal received by the DUT to a custom designed analog optical link (Z-Axis Phelps, NY 14532, U.S.). The transmitter of this link carries detector analog voltage data out of the saline tank via a fiber optic cable. The transmitter is a 0.6 inch aluminum cube, with an input range of 10 m Vp-p, and an input bandwidth of 2 Hz – 50 KHz. The receiver for the fiber optic link was placed 5 meters from the saline tank to avoid it from RF interference. Calibration of the detector circuit was performed as follows. The input to the detector was an SMA coaxial connector. This allowed calibrated net power to be fed into the 50 Ω resistor and the rest of the detector circuit. We calibrated the detector circuit using an external signal generator (425 MHz and 450 MHz). Net power into the detector was measured versus voltage out. The power versus voltage data was fitted to a polynomial curve to allow interpolation of measured data. This allowed us to characterize the power delivered into the implant versus voltage out of the implant. With this information we computed the ratio of volts into the dipole antenna vs. volts received at the 50 Ω load of the DUT.

B. Computational Studies

1) Radiated testing. For an analysis of radiated immunity testing we used SEMCAD X 14.8 electromagnetics software that utilizes the finite difference time domain (FDTD) method (Schmid & Partner Engineering, AG Zurich, Switzerland). We used a Windows PC workstation with hardware GPU acceleration the NVIDIA Tesla K40 GPU Accelerator (NVIDIA Corporation, Santa Clara, CA, U.S.). Simulations were performed at 425 MHz and 450 MHz. Spiral and short lead configurations were evaluated with different input impedances in the implant. The short lead consisted of a straight, 40 mm length of the same wire and insulation as the spiral lead. We used a 3D computational electromagnetics software model that replicated the physical model very closely (figs. 1 and 5). It consisted of a dipole and a saline filled tank with a single plastic grid in the saline. The tank was filled with saline with a relative permittivity of 79 and a conductivity of 0.33 S/m corresponding to 0.18% NaCl at 450 MHz.

The dipole antenna was driven by a source with an impedance of 50 Ω . The software provided the reflection coefficient at the input to the antenna that enabled the net input power to be determined. The model of the implant included a metallic case and a unipolar pacemaker or neurostimulator lead. The case was penetrated by a 1.6 mm diameter wire surrounded by 4.6 mm diameter insulation.

A feed through connector for the patient lead was modeled to replicate our hardware model. We used various lumped element input impedances with our computational model. Pacemakers and implantable defibrillators have an input impedance for the sensing lead to the device's case (ground) with values on the order of tens of thousands of ohms in parallel with capacitances of 0 to over 10 nF. The higher values represent a feed through filter capacitor usually used for electromagnetic interference (EMI) protection. We used input resistances from 50 Ω to 10 k Ω and capacitances of 0 to 10 nF. The 50 Ω input resistance was used to enable comparison of results with our 50 ohm coaxial hardware. Higher reactances or resistances would create an RF mismatch that would make it impossible to measure net power to the diode detector on the experimental device. A software voltage probe was connected between the lead and the ground (case) in parallel with the input impedance to measure received voltage.

The computational model used throughout this study was made to match the experimental model's dimensions. The experimental model's size was as small as possible to house the components inside it.

We developed a more realistic model of a pacemaker or neurostimulator case for computational simulations (thin computational model). This model had a reduced height (thickness) of 9 mm versus 30.5 mm for the original computational and physical models (fig. 6). This small height is fairly representative of modern cardiac and neurological implants. We calculated the received voltage of this unit with an immersion depth of 5 mm. results are presented later.

2) Injected Testing. The ISO standard's injection test specification uses a coaxial setup as shown in fig. 7. It requires monitoring only forward power with a directional coupler. For the

analysis of injected immunity testing we used Multisim simulation and circuit design software (National Instruments Corporation, Austin, TX 78759-3504, U.S.).

III. Results

A. Validation of the radiated computational model – comparison with measurements

In order to validate the computational model we normalized experimental and computational results to 1 volt peak into the dipole at 425 MHz and at 450 MHz. Then we obtained the received voltage of the implant. The results are shown in Table I. The table shows the ratio of measured to computed voltages out of the DUT. This demonstrated the validity of the computational model. Agreement by a factor of 1.38 or less is acceptable due to the wide range of uncertainties in both computational modeling and experimental measurements. If we assign uncertainties to both computations and measurements equally, a variation of $\pm 19\%$ results.

There are many sources of uncertainties for both computational modeling and for experimental measurements. For computations, errors are introduced due to the resolution of the FDTD grid. The resulting voxels of objects are not exactly equal in shape or size to the objects being modeled. For experimental measurements, there are errors and uncertainties in the calibrations of voltage that are measured. Also there are errors in the values of received voltages due to residual non-linearities in the detector. Finally, there are errors due to dimensional and positional uncertainties in objects within the measurement setup.

B. Effects of variations of specific parameters on received voltage

Once the computational model was validated, we used data from this model to study the effects of slight deviations of the test setup dimensions on the results of radiated testing that a user of the standard might experience.

We studied the effects of variations of a number of parameters on the voltage received by our computational model. This was done to identify the range of uncertainties that could be encountered when the measurements prescribed by the 14117 standard are performed. These measurements were performed with various placements of the implant and the leads. The resulting uncertainties were studied.

1) Effects of depth of the implant case below and dipole height above saline surface

We studied the effects of the depth of the case below the saline surface on received voltage. For a depth of 5 mm vs. 10 mm the ratio of the received voltage was 1.12. We concluded that this demonstrates relative insensitivity to changes in the depth of the case below the saline surface. We studied the effects of the height of the dipole above the saline surface on received voltage. The results were that for a dipole height of 15 mm vs. 20 mm the ratio of the received voltage was 1.04. This was for the depth of case below saline surface of 5 mm. We concluded that this demonstrates insensitivity to changes in the height of the dipole above the saline surface.

2) Effects of lead length on the received voltage. We studied the effects of different lead configurations on the received voltage of the implant using computational modeling. A short straight lead (4 cm long) was compared to a 58.5 cm long lead in the spiral configuration. The depth of the case below saline surface was 5 mm. The computed received voltage for the standard spiral lead was actually lower (by 5%) than the voltage received for the short lead. The ISO 14117 standard states that in vitro test studies have shown that the primary RF coupling to the implant at these frequencies is through the device connector and therefore the layout of the lead is not critical at these test frequencies.

3) Effects of frequency on received voltage. For the DUT box 5mm below the surface of the saline, with a spiral lead configuration and a dipole 2 cm above the saline surface the received voltage at 450 MHz is larger than 425 MHz voltage by a factor of 1.10.

4) Effects of implant input impedance on received voltage and current for radiated and injected testing. We studied the effects of implant input impedance on received voltage and current. Pacemakers use much higher values of input resistance than 50 Ω . In the experimental study we only used a 50 Ω input impedance. We did not use other values of resistors and capacitors since they would make it impossible to measure net power to the diode detector. In our computational modeling of radiated testing we used input resistances of 10 k Ω and 50 Ω . These were in parallel with capacitances of 0 and 10 nF, representing feed through filter capacitors used by most modern implanted active cardiac medical devices. For radiated testing the source voltage was scaled to represent 120 mW and 8 Watts delivered to a dipole antenna. These powers are prescribed by the 14117 standard for the basic (120 mW) and worst-case (optional 8 W) radiated testing. We used a spiral lead configuration with a 5 mm immersion of the top of the implant case below the saline surface. The height of the dipole above the saline surface was 2 cm (as prescribed by the standard). Results are shown in Table II. We used the received voltage results of our computational model as input data for calculating current in the load current using a simple lumped impedance model in Multisim software.

For our modeling of the injected test system of the ISO 14117 standard, we used the same DUT input resistances and capacitances as in the radiated computations. We injected 7 Vp-p into a DUT with a 50 Ω input impedance and 14 Vp-p into a DUT with an input impedance of 10 k Ω (approximately open circuit). These voltages are prescribed by the standard. The results in Table II are presented for both injected and radiated calculations. We observed the expected dramatic decrease in induced voltage into cardiac devices with large capacitors. In general, implanted neurostimulators and other active implants other than cardiac devices often do not use filter capacitors. Therefore, the voltage induced into these devices is relatively high compared to those cardiac devices that incorporate filters.

5) Effects of various lateral implant locations for radiated testing. Another set of computations was performed for the DUT in multiple locations, displaced 2 cm from the center in the horizontal (X) and vertical (Y) directions. Results are presented in Table III for the simulated implant immersed 5 mm below the saline surface exposed to 450 MHz. Variations of 20 % or less were seen for the various 2 cm displacements so it was concluded

that small lateral displacements of the implant with respect to the dipole were not a major source of errors.

C. Results for the thin computational model

We calculated the received voltage of the thin (9 mm thick) model at an immersion depth of 5 mm. This was excited by a dipole antenna 20 mm above the saline driven with 1 V peak at 425 MHz. The received voltage was 0.095 V peak. In comparison, the original computational model, when exposed under the same conditions, received 0.083 V peak. This served to validate the use of the rather thick experimental and original computational models (30.5 mm thick) versus real-world implants. The slight increase in received voltage for the thin model is due to the fact that in making the case thinner, the lead was placed higher in the saline than the standard model. The overall finding was that a thin computational model received the same voltage as our original model. The original computational model was made thicker to replicate the experimental model. This physical model was limited to a minimum size that could be fabricated to house the optical link and RF detector.

IV. Analysis and Discussion

A. Comparison of radiated with injected voltages

1) The ratio of the radiated to injected received voltages. The ratio of the radiated to injected received voltages was evaluated for various input impedances of the DUT with our computational models. Our findings are presented in Table II where the voltage and current induced at the input of the implant are indicated. These are for various load impedances and 120 mW into the dipole for radiated testing. The ratio of the radiated to injected voltages ranges from 0.55 to 0.82.

For radiated testing, comparison of measured vs. computed tests is that the two methods differ by ± 1.4 dB or less. Causes of this difference include uncertainties for both the computational and experimental models. The uncertainties in the computational results include the resolution of the FDTD grid causing loss of voxel resolution, and inexact shapes or sizes of small features of the objects being modeled. Also there are unknown factors in the proprietary software. Uncertainties for experimental measurements include lack of perfect compensation for non-linear behavior of our detector, positioning errors, and calibration of RF equipment.

Based on the comparison above the computational model was validated. This enabled the use of the computational model to simulate a wide range of parameters relatively easily, without requiring physical models to be built, as would be the case for experimental studies.

2) Evaluation of results with respect to the ISO 14117 standard. The ISO standard requires radiated testing with 120 mW delivered to the dipole. With an implant with a 10 k Ω input impedance and no capacitive filters present, 1.39 V_{p-p} is induced at the input. For the standard's optional 8 Watts delivered to the dipole 11.28 V_{p-p} is produced. The injected test prescribes 14 V_{p-p} to be delivered to the input of a DUT with a high (open circuit) input impedance at 425 MHz. The difference between the radiated and injected test is significant by a factor of 9.9 or more. In order for the radiated test to match the injected test's 14 V_{p-p}

requirement for a 10 k Ω (high impedance) input impedance DUT, it would take 12.25 Watts into the dipole. For both radiated and injected testing according to the ISO 14117 standard, the voltage induced in the load of the implant is affected significantly by low input impedances such as a feedthrough capacitor. Higher input impedances create higher voltages in the implant and lower reactive impedances (larger capacitances) create lower voltages in the implant. For injected testing this is especially true since the injected test does not monitor reflected power back from the DUT; therefore, the voltage at the input of an unknown DUT cannot be calculated or estimated. Thus the effects of load impedances other than 50 Ω are not monitored. This is in contrast to most RF measurement practices using directional couplers.

V. Conclusions

We developed a computational model of an active implanted cardiac device that was validated with an experimental model at 425 and 450 MHz. For the specified radiated test conditions, the induced voltages from a dipole antenna for these two models differ by ± 1.4 dB or less. We used these to compare radiated with injected EMC testing according to the provisions of the ISO 14117 standard. At the border frequency of 450 MHz separating the two methods the radiated and injected tests do not agree well (by a factor of 9.9 or more) in terms of the voltage induced at the input of an implanted device. This is for the prescribed injected voltage and radiated test power for an implant with a 10 k Ω input impedance and no feedthrough filter capacitors. Injected testing at 425 MHz with 14 V_{p-p} is equivalent to radiated testing at 12.25 Watts into the dipole antenna for radiated testing. The radiated testing specification for the ISO 14117 standard is 120 mW into the dipole, with an optional worst-case test of 8 Watts. The radiated and injected tests do agree moderately well if the much higher 8 W optional power for radiated testing is used. When our injected and radiated models included filter capacitors the induced RF voltage was reduced greatly, as expected. Filter capacitors reduce RF input voltage for both radiated and conducted testing and are used in most cardiac devices, but not in all neurostimulators or other implanted devices.

In another phase of this study, we found that a short 40 mm lead produces a voltage that was 5% greater than that produced by a long lead. This is due to the fact the majority of the longer lead is distal to the case in saline. This is where electric fields are generated by the dipole are weaker. We also studied the effects of variations of a number of parameters on the voltage received by the simulated implant using our computational model for radiated testing. These were performed with various placements of the implant and the leads. This was done to identify the magnitude of uncertainties that could be encountered when the measurements prescribed by the ISO 14117 standard are performed. For the radiated tests we found that small changes in position of the dipole and the depth of the DUT in the saline do not affect significantly the induced voltage at the input of the DUT. For lateral displacement of the dipole of 2 cm, changes in this voltage were 20% or less. For depth changes from 5 mm to 10 mm changes were 12.5%.

Our computational model can be used to study other variations in the radiated test method such as far field exposures of the DUT or induced voltages at other test frequencies. It can

also be used for other types of active implants such as neurostimulators that use the ISO14117 standard's radiated test method.

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Biographies

Howard I. Bassen (M'77–SM'78–F'92–LF'11) received his BS in electrical engineering from the University of Maryland, College Park, MD, USA in 1965 and his MS in management of science and technology in 1980 from George Washington University, Washington D.C., USA.

From 1972 to 1980 he was an electronics engineer and a supervisory engineer in the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). He led original research for 15 other scientists, engineers and technicians in the measurement of electromagnetic radiation induced in the human body by radiation emitting electronic products.

He was Chief Engineer of the Microwave Research Laboratory at the Walter Reed Army Institute of Research from 1985 to 1990. He returned in 1990 to FDA/CDRH to lead the Electromagnetics and Wireless Laboratory. He has published over 84 papers, including over 22 journal papers and three book chapters. He holds four patents on means for measuring, transmitting, or shielding electromagnetic fields.

Mr. Bassen is a Fellow of the IEEE - Selected by the Engineering in Medicine and Biology Society. He chaired ANSI C95 Subcommittee 1-Techniques, Procedures, and Instrumentation - Non-ionizing Radiation and IEEE Standards Coordinating Committee 34,

Subcommittee 2 (Cellular telephone safety dosimetry techniques). He chaired the Committee on Man and Radiation (COMAR) in the IEEE Engineering in Medicine and Biology Society.

Gonzalo G. Mendoza was born in Cochabamba, Bolivia. He received the B.S. degree in Biomedical Engineering from the Central University of Cochabamba in 1997. He obtained the M.Sc. degree in Biomedical Engineering from The Catholic University of America (Washington DC, USA) in 2002. From 2000 to 2003 Mr. Mendoza was a Research Assistant and then a Research and Development Biomedical Engineer at The Catholic University of America. Since 2003, he has been a Biomedical Engineer Contractor with the U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories (OSEL), Silver Spring, MD, US. Mr. Mendoza research interests include electromagnetic compatibility and numerical modeling of medical devices and human subject safety, in which he has authored several journal articles and conference proceedings.

Fig. 1.
The ISO 14117 standard radiated susceptibility test configuration: torso simulator, plastic grid, dipole antenna, (DUT).

Fig. 2.
Tissue injection network.

Fig. 3.
Experimental system - simulated implant: metal case, insulated solid conductor wire, spiral lead configuration - unipolar lead.

Figure 4a.

Figure 4b.

Figure 4.
Figure 4a. RF detector: hardware implementation,
Figure 4b. RF detector: circuit diagram.

Figure 5a.

Figure 5b.

Figure 5.

Figure 5a. Computational model of implant.

Figure 5b. Computational model of radiated test setup.

Figure 6.
Realistic size pacemaker model.

Figure 7.
Computational circuit model for injection testing.

Table I

Validation of computational model – comparison with measurements

Frequency (MHz)	Depth of case below saline surface (mm)	Height of dipole (mm)	Measured vs. Computed Ratio / (dB)
425	5	15	1.33 / 2.47dB
425	5	20	0.93 / -0.63 dB
425	5	20	0.93 / -0.63 dB
425	10	15	1.38 / 2.79 dB
450	10	20	0.95 / -0.44 dB

Table IIa
Pacemaker input impedance vs. received voltage for radiated and injected testing with 120 mW into dipole

R (Ω)	C (nF)	Rad recvd ¹ Volt (V _{p-p})	Rad recvd Cur (A _{p-p})	Inject recvd ² Volt (V _{p-p})	Inject recvd Cur (A _{p-p})	Ratio rad to inject (V)	Ratio rad to inject (A)
50	0	0.581	0.011	6.96	0.14	0.08	0.08
50	10	0.001	0.020	0.010	0.28	0.10	0.07
10,000	0	1.39	0.000	13.8	0.001	0.10	0.00
10,000	10	0.001	0.020	0.010	0.28	0.10	0.07

Notes:

* for 120 mW into dipole,

** for injected (7 V_{p-p} 50 Ω load, 14 V_{p-p} 10 kΩ load), Frequency = 425 MHz, Lead configuration = spiral, Depth of case below saline, Surface = 5 mm, Lead depth = 8.6 mm.

¹ Radiated received

² Injected received

Table IIb

Pacemaker input impedance vs. received voltage for radiated and injected testing for the optional 8 Watt radiated test conditions

R (Ω)	C (nF)	Rad recvd ¹ Volt* (V _{p-p})	Rad recvd Cur* (A _{p-p})	Inject recvd ² Volt** (V _{p-p})	Inject recvd Cur** (A _{p-p})	Ratio rad to inject (V)	Ratio rad to inject (A)
50	0	4.74	0.092	6.96	0.14	0.68	0.66
50	10	0.0056	0.16	0.010	0.28	0.55	0.58
10k	0	11.38	0.001	13.8	0.001	0.82	0.81
10k	10	0.005	0.16	0.010	0.28	0.55	0.58

Notes:

* for 8 W into dipole

** for injected (7 V_{p-p} 50 Ω load, 14 V_{p-p} 10 kΩ load), Frequency = 425 MHz, Lead configuration = spiral, Depth of case below saline, Surface = 5 mm, Lead depth = 8.6 mm.

¹ Radiated received

² Injected received

Table III

Effects on the received voltage of the implant by lateral displacements of the pacemaker

X (cm)	Y (cm)	Relative Received Voltage
0	0	1
2	-2	0.8
-2	2	0.9