

In vitro tests reveal sample radiofrequency identification readers inducing clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators

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BACKGROUND The use of radiofrequency identification (RFID) systems is expanding and highlights the need to address electromagnetic interference (EMI) to implantable pacemakers and implantable cardioverter-defibrillators (ICDs).

OBJECTIVE This study sought to examine the electromagnetic compatibility (EMC) between RFID readers and implantable pacemakers or ICDs.

METHODS During in vitro testing, 15 implantable pacemakers and 15 ICDs were exposed to 13 passive RFID readers in 3 frequency bands: 134 kHz (low frequency [LF]), 13.56 MHz (high frequency [HF]), and 915 MHz (ultra high frequency [UHF]).

RESULTS While being exposed to LF RFID, a reaction was observed for 67% of all pacemaker tests (maximum distance 60 cm) and 47% of all ICD tests (maximum distance 40 cm). During HF RFID exposure, a reaction was observed for 6% of all pacemaker tests (maximum distance 22.5 cm) and 1% of all ICD tests (maximum distance 7.5 cm). For both pacemakers and ICDs, no reactions were observed during exposure to UHF RFID or continuous-wave RFID. Pacemakers and ICDs were most susceptible to modulated LF RFID readers.

Introduction

The use of radiofrequency identification (RFID) systems is expanding and highlights the need to assess the use conditions of this equipment in both public and occupational settings. Recent studies^{1,2} highlighted the potential for electromagnetic interference (EMI) to critical care medical equipment. This article describes the results of a study conducted by the Food and Drug Administration (FDA) Center for Devices and Radiological Health with the sup-

Data acquisition was performed by Seidman (FDA) and Guag (FDA), and each device manufacturer provided an engineer for testing of their devices (Clement, Kippola, Digby, Barber, Huntwork). Brockman, Lewis, and Shein (FDA) were responsible for analyzing the clinical significance of the results. No authors have any financial or personal relationships that would influence or bias the authors' decisions, work, or manuscript other than their employment and voluntary, nonpaid membership with the AAMI CRMD EMC Task Force. The mention of commercial products, their

CONCLUSION Although there is in vitro testing evidence for concern for implantable pacemaker and ICD EMI at LF and HF, the FDA has not received any incident reports of pacemaker or ICD EMI caused by any RFID system. We do not believe the current situation reveals an urgent public health risk.

KEYWORDS Implantable pacemaker; Implantable cardioverter-defibrillator; ICD; Electromagnetic compatibility; EMC; Electromagnetic interference; EMI; Radiofrequency identification; RFID

ABBREVIATIONS AAMI = Association for the Advancement of Medical Instrumentation; CRMD = cardiac rhythm management devices; EMC = electromagnetic compatibility; EMI = electromagnetic interference; FDA = Food and Drug Administration; HF = high frequency; ICD = implantable cardioverter-defibrillators; LF = low frequency; OSEL = Office of Science and Engineering Laboratories; RFID = radiofrequency identification; UHF = ultra high frequency; DUT = device under test

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port of the Association for the Advancement of Medical Instrumentation (AAMI) Cardiac Rhythm Management Devices (CRMD) Electromagnetic Compatibility (EMC) Task Force³ to assess the potential for interaction of RFID readers with implantable pacemakers and implantable cardioverter defibrillators (ICDs). The objective of this article is to determine any urgent public health risk and promulgate our findings for cardiologists, active implantable medical device manufacturers, and the RFID industry.

sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services. **Address reprint requests and correspondence:** Seth J. Seidman, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, White Oak Building 62 Room 1117, Silver Spring, Maryland 20993. E-mail address: seth.seidman@fda.hhs.gov. (Received June 16, 2009; accepted September 28, 2009.)

Background

In 2006, the FDA's Office of Science and Engineering Laboratories (OSEL) worked together with the AAMI CRMD EMC Task Force to draft a test protocol specifying an in vitro method for conducting EMC testing of pacemakers and ICDs exposed to RFID systems. This study was conducted at OSEL, and the results were presented⁴ and published⁵ to RFID industry.

The current study was initiated in 2008. The test protocol was expanded from the 2006 FDA/AAMI study to better evaluate the implantable device response under EMI. The updated protocol specified to save strips of recorded device outputs to grade the clinical significance of the EMI observed, change the lead loop layout from a spiral to a more anatomical layout, and to inject a cardiac signal to help determine the type of reaction. All testing was conducted with RFID readers from passive tag systems as their readers are generally known to emit higher radiated electromagnetic field levels than readers from active tag systems.

RFID

RFID is an identification system that is used to locate, identify, and track objects. These objects may be parts in inventory, medicine containers, patient records, hospital room equipment, vehicles, medical devices, animals or humans, envelopes, or packages. RFID has experienced substantial market growth during the last few years, and this trend is expected to continue.

RFID systems consist of transponders (tags) and interrogators (readers). Tags are the combination of an integrated circuit and an antenna. These tags can be inserted in or directly attached to products such as cards, badges, or labels. RFID readers are designed to read and write information to tags. Readers physically range from large portal antennas, to desktop pad workstations, to small handheld portable readers.

RFID systems operate at many different carrier frequencies. Low-frequency (LF) (125 to 135 kHz) RFID operates

under unlicensed frequency rules. Other RFID frequencies are in the industrial, scientific, and medical bands of the radiofrequency spectrum; high-frequency (HF) (13.56 MHz), 433 MHz, ultra high frequency (UHF) (915 MHz), and microwave (2.45 GHz). In general, 433 MHz is used for active tags and microwave RFID uses low power, so these systems were not included in the current tests. A summary of these bands, general characteristics, typical uses, and associated standards are presented (Table 1).

The range for reading RFID tags are constrained by many factors, including the output power of the reader. Although some RFID systems may transmit at the maximum power allowed under the regulatory limits to achieve the greatest read range, others will transmit at reduced power to restrict the read range. Although these systems meet their standards and telecommunications regulatory requirements, some of the RFID systems' outputs have modulation that can be interpreted as physiologic signals by implanted pacemakers and ICDs.

Implantable pacemakers and ICDs

The technology of implantable pulse generators (pacemakers and ICDs) has evolved from asynchronous pacemakers with limited concern for immunity to devices with titanium shielding, noise rejection circuits, improved sensing algorithms, and feed-through filters. These implantable pulse generators are highly sensitive low frequency receivers that monitor physiological signals at levels as low as 0.15 mV. Their susceptibility to emitters depends primarily on the emitter's carrier frequency, modulation scheme, duty cycle, field strength, proximity, and duration of the exposure.

The implantable cardiac device pass band is in the range of 0.1 Hz to 1 kHz and corresponds to the frequency content of the physiological signal of interest. Sustained EMI, including modulation content occurring in this physiological pass band, may be interpreted by the device as a signal of interest from the heart, potentially altering therapy. Implantable pulse generators are in many cases life-sustaining de-

Table 1 Summary table of RFID applications and standards

Carrier Frequency	Regulations Availability	Maximum Read Range	RFID Advantages	Typical RFID Uses	ISO Standard
<135 KHz (LF)	Unlicensed, worldwide availability	1 m (passivetags)	Good liquid penetration	Access control for animals and people, payment systems	18000-2
13.56 MHz (HF)	Industrial, Scientific, and Medical (ISM) Band, worldwide availability	1 m (passivetags)	Medium data rate, flat tags	Smart cards, access control, libraries, passports, payment systems	18000-3
433 MHz	ISM Band, not available worldwide	100 m (active tags)	Good metal compatibility	Active tags, military	18000-7
860–960 MHz (UHF)	ISM Band, non-uniform worldwide	3 m (passivetags)	High data rates, small flat tags	Retail and military supply chain tracking	18000-6
2.45 GHz (microwave)	ISM Band, worldwide availability	3 m (passivetags)	High data rates, small tags	Limited niche uses	18000-4

Note: 18000-5 Part 5—Parameters for Air Interface Communications at 5.8 GHz was withdrawn.

HF = high frequency; ISO = International Organization for Standardization; LF = low frequency; RFID = radiofrequency identification; UHF = ultra high frequency.

Table 2 Characteristics of RFID readers

RFID Reader Code	RFID Antenna Configuration (cm)	Governing ISO Standard	Carrier Frequency (MHz)	Max field intensity (A/m Peak) @ 2.5 cm	Output Power (Watts)	RF Usage		
						Pulse Repetition Rate (Hz)	Duty Factor	Pulse Width (ms)
1	Loop 85 × 50 × 5	—	0.134	68	—	—	CW	—
2	Loop 85 × 50 × 5	11785	0.134	162	—	14.3	0.72	49.9
3	Loop 20 × 20 × 2.5	11785	0.134	269	—	10.7	0.54	50.3
4	Loop 20 × 20 × 2.5	11785	0.134	257	—	7.0	0.69	97.8
5	Loop 20 × 20 × 2.5	11785	0.134	258	—	25.8	0.42	16.4
6	Loop 31 × 31 × 2.8	18000-3 mode 1	13.56	4.6	10	10.9	0.11	10.3
7	Loop 20 × 20 × 0.8	18000-3 mode 1	13.56	4.9	1	4.0	0.13	31.9
8	Loop 31 × 31 × 2.8	—	13.56	8.6	10	—	CW	—
9	Loop 31 × 31 × 2.8	18000-3 mode 1	13.56	8.7	10	0.9	1.0	1070
10	Loop 31 × 31 × 2.8	18000-3 mode 1	13.56	8.8	10	11.1	1.0	90
11	Handheld 19 × 11 × 7.8	18000-3 mode 1	13.56	7.8	0.5	3.5	0.92	264.0
12	Patch 31 × 31 × 4.8	18000-6B	915	—	1.6	56100	0.76	0.01
13	Patch 48.5 × 31 × 5	18000-6B	915	—	1	651	0.75	1.2

This table describes all RFID equipment tested. It describes the antenna configuration, governing ISO standard, carrier frequency, magnetic field intensity of LF and HF RFID systems, output power for HF and UHF RFID systems, and each reader's radiofrequency usage. The radiofrequency usage pulse width is the time the carrier is transmitting on (which is also defined by the duty factor and pulse repetition rate).

Abbreviations as in Table 1.

VICES, and the implications for patient safety are taken seriously by both FDA and device manufacturers.

Methods

Materials

Experiments were performed and data were collected in OSEL during the period from June 2008 to August 2008. Engineers from active implantable medical device manufacturers came to OSEL to assist in testing their particular devices. Fifteen pacemakers and 15 ICDs were tested from 5 of the largest manufacturers of pacemakers and ICDs. All implantable pacemakers and ICDs tested were manufactured in the past 5 years and provide a reasonable sample of presently implanted devices. The pacemakers and ICDs were tested for EMC with 13 different RFID readers. The RFID readers used in these tests were manufactured by 6 different companies, designed to read passive tags, and covered the 3 most common RFID frequency bands. They included 5 LF readers, 6 HF readers, and 2 UHF readers.

Characteristics of RFID readers

The spectrum and radiofrequency usage characteristics for each RFID reader were measured using a single-turn magnetic field loop probe (100C EMC Probe, Beehive Electronics, Sebastapol, California). The pulse repetition rate is defined as $1/\Delta T$ where ΔT is the total period that consists of an activation period (when the carrier wave from the reader is charging the tag) followed by a listen period (when the reader's carrier wave is off). For RFID readers that do not have a listen period, the pulse repetition rate may be defined by other parameters, such as radiofrequency resets. Some RFID readers can operate with the carrier continuously on (pulse repetition rate of 0 Hz). These readers are sometimes referred to as continuous-wave RFID readers and are not supported by current RFID standards.

The emitted magnetic field strength was measured for all LF and HF RFID readers. Parameters of the RFID readers evaluated in this study are summarized (Table 2).

Testing setup

The testing setup is a modified version of the AAMI PC69 Standard, a standard recognized for developing in vitro EMC test protocols for implantable pacemakers and ICDs.³ A similar human torso simulator was used (Figure 1). It was made from a polyethylene plastic box (58.5 × 42.5 × 15.2 cm) and filled with 0.18% saline solution. This salinity represents the electrical properties (conductivity) of body tissue in the frequency range of interest.³ A plastic grid was used to support the device under test (DUT) and the lead system. The top of the box provided a physical testing surface 2.5 cm above the DUT where the outermost surface of an RFID reader can reach. The distance simulates an RFID reader placed directly on a patient's chest, which typically represents a worst-case scenario. The grid level was adjusted to immerse the DUT 0.5 cm into the saline. All pacemakers were tested with a set of Medtronic leads (Capture Z Novus RV 58 cm, Capture Z Novus RA 52 cm), and all ICDs were tested with a set of Medtronic leads (Attain CS LV 65 cm, Capture SP Novus RA 52 cm, Sprint Quattro

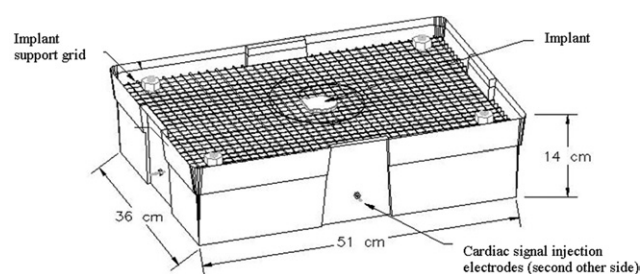


Figure 1 A drawing of the human torso simulator.

Secure Endo RV and SVC 65 cm) for consistency. Lead configurations were positioned in an anatomical pattern and had a loop area of 200 cm². The loop area is the area enclosed by leads and an imaginary straight line between the electrode tip (ring) and the case of the implant.³ The lead configuration differs from the 2006 FDA/AAMI study⁵ and is a more realistic approach.⁶

Two stainless steel electrode plates (50 × 50 × 2 mm) were mounted at the center of 2 inner walls of the human torso simulator. Stainless steel screws were threaded through each plate, extending outside the simulator box, providing external electrical terminals. The terminals were used to inject a simulated cardiac signal⁷ into the human torso simulator.

A bipolar pacing lead (not to be confused with the DUT lead system) was used to monitor the output of the DUT. The 2 electrodes at one end of the pacing lead were placed in the saline to pick up the DUT's pacing output. The other end of the pacing lead went to an oscilloscope for viewing during the tests and to an analog and digital I/O module (USB-1608FS, Measurement Computing, Norton, Massachusetts) to store the DUT's pacing output on a personal computer. A nonconductive fiberglass robotic arm was used to position the RFID reader antenna and was able to raise and lower the antenna for repeatable separation distances from the DUT.

Testing procedure

The salinity of the human torso simulator was measured and corrected to 0.18% prior to each day of testing. The DUT was connected to the appropriate lead system and then placed in the human torso simulator. The DUT depth was measured and corrected to 0.5 cm. The DUT was initially programmed to maximum sensitivity. The bipolar pacing lead (used to monitor the output of the DUT) was placed on the DUT support grid, and the DUT's output was verified on the oscilloscope. Next an RFID reader antenna was placed on the robotic arm, centered to the DUT's lead system. The robotic arm was raised 1 m away from the testing surface. The RFID reader was turned on, and proper operation was verified. The robotic arm was lowered at 1.3 cm per second until either a change in pacing behavior was observed or the robotic arm had reached the testing surface. If a change was observed, the robotic arm was raised 10 cm. The robotic arm was then lowered in 2.5-cm increments to the testing surface, dwelling 10 seconds at each step. Visual observations of the DUT output from the oscilloscope were recorded at each increment. Pacing output was recorded digitally to review for clinical significance. Testing was repeated with the DUT's pacing inhibited by use of a simulated cardiac signal.⁷ This concluded a single test of a specific DUT setting exposed to one RFID reader.

The test explained previously was repeated for all 13 RFID readers. If any reaction was observed for a particular test, it was repeated with the DUT reprogrammed from maximum sensitivity to nominal sensitivity. If no reaction was observed at maximum sensitivity, it was counted as no reaction at nominal sensitivity. If the DUT could be pro-

grammed in bipolar and unipolar mode, testing was performed for each. For example, a pacemaker with unipolar and bipolar lead configurations tested at maximum and nominal settings would be considered 4 tests for each RFID reader (unipolar maximum, unipolar nominal, bipolar maximum, bipolar nominal). A total of 1091 tests were recorded.

Clinical significance

All reactions observed during testing were later graded by FDA cardiologists who reviewed the electronically stored pacing output files. They did so based on 3 classes of clinical significance defined by Hayes et al.⁸ Class I reactions are definitely clinically significant and include transient ventricular inhibition for 3 seconds or more or any permanent change in programmed settings. A transient response means that once the RFID source is turned off, the DUT returns to normal operation. Class II reactions are probably clinically significant and include device reactions such as transient ventricular inhibition for more than 2 seconds, but less than 3 seconds (we scored no class II reactions). Class III reactions are probably not clinically significant and include inappropriate pacing, atrial inhibition, ventricular inhibition for 2 seconds or less, noise reversion mode, and all other types of device reactions not in class I or II. The classification scheme in Hayes et al.⁸ was designed for pacemakers only. To expand the classification to ICDs, any inappropriate delivery of tachycardia therapy was defined as class I (definitely clinically significant).

Results

EMI observed and clinical significance

Reactions from implantable pacemakers and ICDs included pacing inhibition, inappropriate pacing, noise reversion mode, changed pacing rates, inappropriate delivery of antitachycardia pacing, inappropriate delivery of high-voltage shocks, and a device programming change (specifically a change from bipolar pacing to unipolar pacing).

Percentage of tests with a reaction

Each test ran from 1 m to 2.5 cm, and the most clinically significant result was counted for each test. A reaction was observed in 174 of 260 pacemaker tests while being exposed to LF RFID readers (67%). Class I reactions were observed in 102 tests (39%), class III reactions were observed in 72 tests (28%), and 86 of the tests saw no effect (33%). While being exposed to HF RFID readers, a reaction was observed in 20 of 335 pacemaker tests (6%). Class I reactions were observed in 12 tests (4%), class III reactions were observed in 8 tests (2%), and 315 tests saw no effect (94%). There were no reactions (0 of 112) observed for pacemakers being exposed to either of the 2 UHF RFID readers. These results suggest that a reaction in a pacemaker is more likely to occur at HF than at UHF ($P = .0172$, chi-squared test) and more likely to occur at LF than HF ($P < .0001$, chi-squared test).

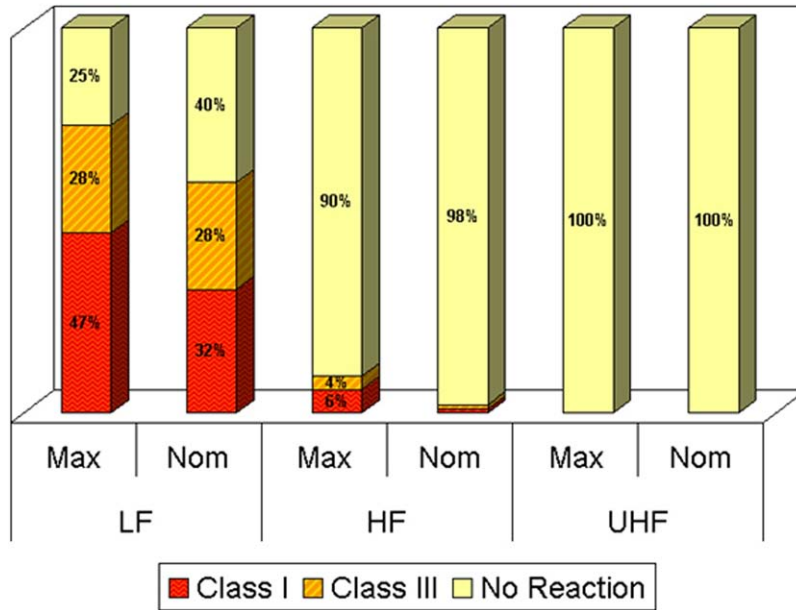


Figure 2 Percentage of pacemaker reactions graded for clinical significance. The percentage of tests with a reaction for pacemakers graded for clinical significance (there were no class II reactions). Pacemaker tests at nominal sensitivity during HF RFID exposure had 1% class I reactions and 1% class III reactions. HF = high frequency; LF = low frequency; RFID = radiofrequency identification; UHF = ultra high frequency; Max = maximum sensitivity; Nom = nominal sensitivity.

For ICDs, a reaction was observed in 69 of 146 tests while being exposed to LF RFID readers (47%). Class I reactions were observed in 62 tests (46%), class III reactions were observed in 7 tests (5%), and 77 of the tests saw no effect (53%). While being exposed to HF RFID readers, a reaction was observed in 2 of 178 ICD tests (1%). Both reactions were class III reactions. There were no reactions (0 of 60) observed for ICDs being exposed to either of the 2 UHF RFID readers. Based on these findings, it seems that a reaction is more likely with exposure to an LF RFID

reader than with exposure to HF or UHF RFID readers ($P < .0001$, chi-squared test).

Implant reaction data are presented for each DUT sensitivity level in each frequency band for pacemakers and ICDs (Figures 2 and 3). Percentages represent any reaction during a test from 1 m to 2.5 cm.

Distances of EMI

The separation distances where reactions occurred ranged from 2.5 to 60 cm. The percentage of pacemaker and ICD

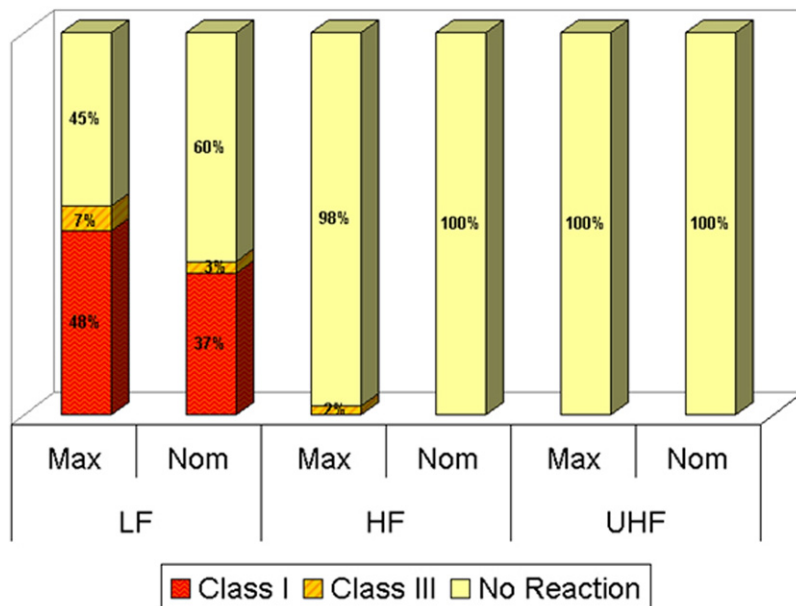


Figure 3 Percentage of ICD reactions graded for clinical significance. The percentage of tests with a reaction for ICDs graded for clinical significance (there were no class II reactions). ICD = implantable cardioverter-defibrillators; other abbreviations as in Figure 2.

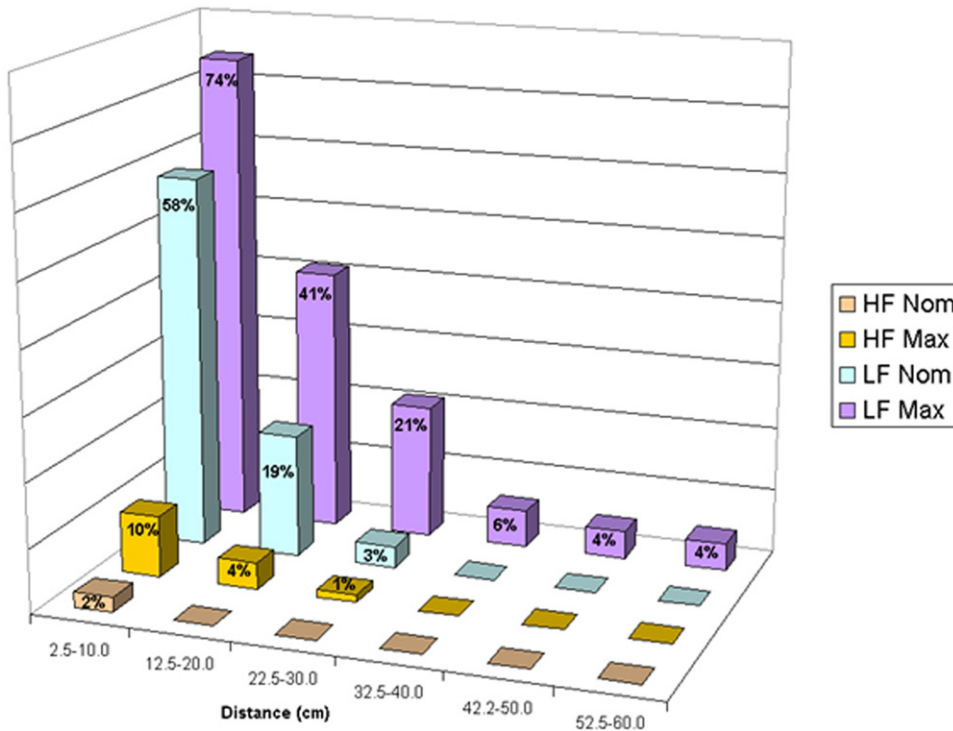


Figure 4 Percentage of pacemaker reactions versus distance. The percentage of pacemaker tests (at each sensitivity level) with a reaction within distance ranges during LF and HF RFID exposure. There were no pacemaker reactions caused by either of the 2 UHF RFID readers. Abbreviations as in Figure 2.

reactions for LF and HF (at each DUT sensitivity level) versus separation distance between the RFID reader and the DUT are presented (Figures 4 and 5).

While being exposed to LF RFID, a class III reaction was observed at a maximum separation distance of 60 cm away from a pacemaker and 40 cm away from an ICD. A class I reaction was observed at a maximum separation distance of 40 cm away from a pacemaker and 12.5 cm away from an ICD during LF RFID exposure. While being exposed to HF RFID, a class III reaction was observed at a maximum separation distance of 22.5 cm away from a pacemaker and 7.5 cm away from an ICD. A class I reaction was observed at a maximum separation distance of 20 cm away from a pacemaker, and there were no class I ICD reactions during HF RFID exposure.

Discussion

RFID comparison

LF RFID readers caused the most reactions, HF RFID readers caused fewer reactions, and UHF readers caused no reactions. These results can be partially explained by the use of feed-through filters in modern pacemakers and ICDs. Feed-through filters use capacitors to attenuate higher-frequency signals. UHF signals are filtered most effectively, followed by HF (Figure 6). There is no filtering (<0.1 dB) of LF signals with feed-through filters because their capacitance value is too low due to the limited size and technology of capacitors and by the design constraints of both pacemakers and ICDs. In addition to feed-through filters, implantable pacemaker and ICD device circuitry are specifically designed and optimized with filtration around the physiological signals of interest.

There are many factors aside from carrier frequency that can contribute to causing EMI to pacemakers and ICDs, including field intensity, power, antenna configuration, and pulse repetition rate. During the 2006 FDA/AAMI study, it was hypothesized that the pulse repetition rate was a significant factor in causing EMI to pacemakers and ICDs.

The pulse repetition rate for our LF RFID readers ranged from 0 Hz (continuous wave) to 26 Hz. RFID Reader 1, designed for this particular study, has a pulse repetition rate of 0 Hz (continuous wave). This RFID reader does not conform to any RFID standard, but can be used for many RFID applications. RFID Reader 1 caused no reactions in all pacemaker and ICD tests. The modulated LF RFID readers (Readers 2 through 5) caused reactions in 174 of 204 pacemaker tests (85%) and 69 of 116 ICD tests (60%).

The pulse repetition rate for our HF RFID readers ranged from 0 Hz (continuous wave) to 11 Hz. RFID Readers 8 through 10 are identical except for their pulse repetition rate. RFID Readers 9 and 10 are typical HF RFID readers. RFID Reader 8 uses a testing feature of the RFID reader's hardware to emit a pulse repetition rate of 0 Hz (continuous wave). RFID Reader 8 cannot read tags in this mode, but was tested to confirm that the pulse repetition rate is a key factor in determining EMC with implantable pacemakers and ICDs. RFID Reader 8 was the only HF RFID reader to cause no reactions to all pacemakers and ICDs tested. Current HF RFID standards do not support the use of continuous-wave readers.

It is possible that a pulse repetition rate outside the physiological band may cause less EMI to implantable pacemakers and ICDs. However, with the limited pulse repetition rate

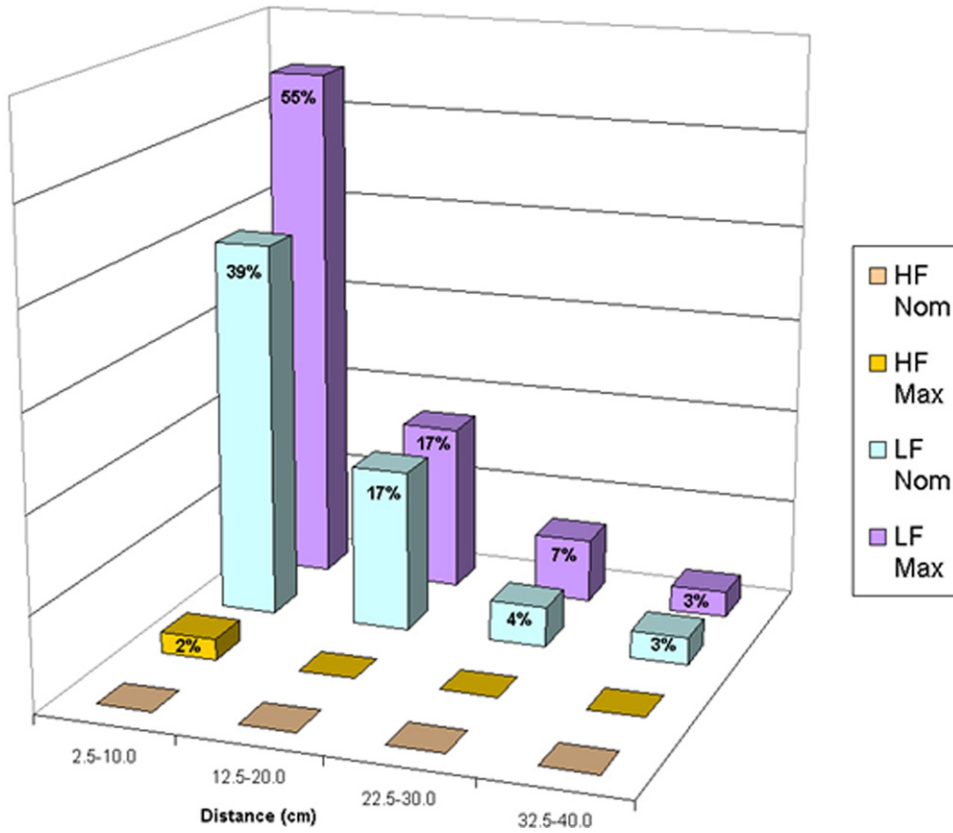


Figure 5 Percentage of ICD reactions versus distance. The percentage of ICD tests (at each sensitivity level) with a reaction within distance ranges during LF and HF RFID exposure. There were no ICD reactions caused by either of the 2 UHF RFID readers. Abbreviations as in Figure 2.

ranges of the tested LF and HF readers, we were not able to conclude such findings.

No comparison between UHF RFID readers is presented because no EMI occurred during exposure to either of the 2 UHF RFID readers. Unfortunately, UHF tags are not the first choice for tracking of humans because body tissues and fluids reflects and absorb energy at 915 MHz.

Active implantable medical device comparison

As expected, the percentage of reactions was less at nominal sensitivity settings than at maximum sensitivity settings for

both implantable pacemakers and ICDs. This is very encouraging because the majority of implantable pacemakers and ICDs are programmed with nominal sensitivity settings. No implantable devices tested reacted to either of the 2 continuous-wave RFID readers or to either of the 2 UHF RFID readers tested.

The majority of pacemakers and ICDs were susceptible to EMI while being exposed to modulated LF RFID readers. The reactions caused by HF RFID readers were observed from 3 of 30 devices tested. Testing results revealed that the

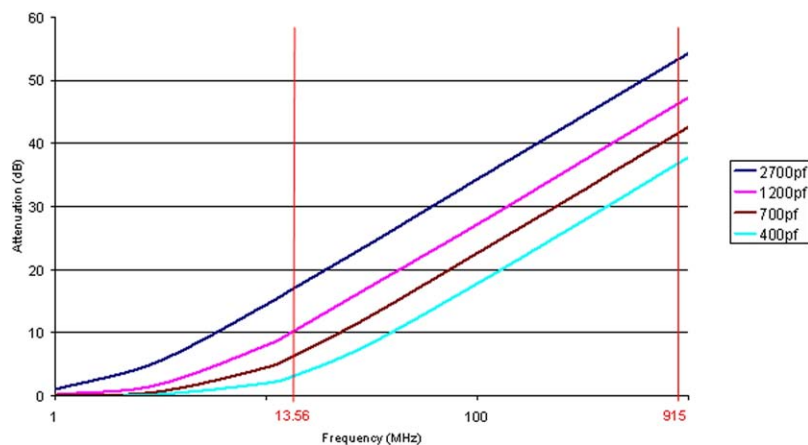


Figure 6 Feed-through filter performance. Performance of 4 different valued feed-through capacitors. The majority of attenuation occurs at 915 MHz (UHF RFID), less attenuation at 13.56 MHz (HF RFID), and less than 1 dB of attenuation at 134 kHz (LF RFID). Abbreviations as in Figure 2.

percentage of pacemaker reactions was greater than the percentage of ICD reactions. The AAMI CRMD EMC Task Force is currently investigating what may have made some types of devices more susceptible than others.

Separation distance

The separation distances where EMI was observed ranged from 2.5 to 60 cm. Some experts argued that the minimum separation distance between RFID reader and the DUT was unrealistic during the 2006 FDA/AAMI study. However, it was the authors' desire to test to the minimum separation distance because each RFID use case will be different. There are RFID medical applications in which a 2.5 cm separation distance is feasible. Test data at 2.5 cm can be valuable information for such RFID implementations. For most applications 2.5 cm may not be possible, and test data at this distance may have little clinical relevance. Larger separation distances will help mitigate implantable pacemaker and ICD EMI, and RFID implementation should take this into consideration.

Study limitations

Active implantable medical device manufacturers use different maximum and nominal sensitivity values for each device. Accordingly, it is difficult to compare pacemaker X with a nominal ventricular sensitivity of 2.0 mV and pacemaker Y with a nominal ventricular sensitivity of 2.5 mV. We choose not to equate each device's sensitivity value because most devices implanted are being implanted in their pre-set nominal sensitivity level. Sensitivity plays a critical role in a device's susceptibility to EMI. It is also difficult to compare bipolar and unipolar lead configurations for the same reasons.

Centering the RFID reader antenna may not be the worst-case scenario to induce EMI because stronger fields were measured at the corners of most RFID antennas.

One set of pacemaker leads and one set of ICD leads was chosen for test repeatability; however, varying the lead length, make, or type of lead could affect implantable pacemaker and ICD EMC.

The testing conducted as part of this project was performed entirely on the bench (i.e., *in vitro*). This represents a limitation in that bench testing may not be predictive of the clinical experience. Past experience with EMC testing between cell phones and pacemakers indicates that if the bench test detects interference, interference will also be seen clinically.⁹

This testing represents a static environment in which the patient is still.

Recommendations for future testing would include extending each distance test dwell time from 10 to 20 seconds, creating a more anatomical torso simulator, grading each distance for clinical significance as opposed to each test, modifying the pulse repetition rate of RFID readers outside the physiological band, and modifying the modulation depth of each RFID reader.

Conclusion

This article discusses the EMI susceptibility of 15 pacemakers and 15 ICDs caused by exposure to 13 RFID readers. It is not possible from our experience to predict EMI with other medical devices or to project to other RFID readers.

Although there is *in vitro* testing evidence for concern for implantable pacemaker and ICD EMI at LF and HF, the FDA has not received any incident reports of pacemaker or ICD EMI caused by any RFID system. This could reflect a low clinical risk due to a number of factors: class III reactions are probably not clinically significant, close patient proximity to RFID readers may not commonly occur, and most reactions observed are transient. This could also be the result of underreporting; EMI issues are difficult to recognize as they are typically transient. If a patient is experiencing symptoms (e.g., lightheadedness) that they believe are the result of EMI effects from an identifiable source, the best advice is to move away from that source.

To effectively mitigate implantable pacemaker and ICD EMI from RFID readers will require work on the part of both implant manufacturers and the RFID industry. During testing, some implantable pacemakers and ICDs were more susceptible to EMI than others. Active implantable medical device manufacturers are currently working to understand these issues, to develop industry requirements, and to design future devices appropriately.

The RFID industry should also take note with regard to medical device EMC. With so many promising health care applications for RFID, it is inevitable that RFID and medical devices will increasingly function in close proximity. Modulated LF RFID is a near-perfect source to cause EMI for implantable pacemakers and ICDs. The low carrier frequency allows the signal to enter the implant, bypassing commonly used feed-through filters. Once inside the implant, the RFID signal is interpreted as a physiologic signal due to the slow pulse repetition rates. The pulse repetition rate of each RFID reader varies greatly as it is not limited by the Federal Communications Commission or defined by most RFID standards. Limitations for implantable pacemaker and ICD EMC do exist as these devices must sense in the physiological band. If it can be predicted that an RFID system will be near pacemaker or ICD patients, appropriate RFID technology should be selected. The RFID technologies that were most compatible with implantable pacemakers and ICDs in our testing were UHF RFID and continuous-wave RFID readers. Maintaining a reasonable separation distance between RFID readers and implantable pacemakers and ICDs will also help mitigate EMI.

Although this article suggests a particular risk in the use of sample RFID systems, this is not the sole intended message. The potential advantages of RFID in health care seem promising, and the FDA is promoting RFID as a technology to reduce counterfeit drugs in the supply chain.¹⁰ An important message from the results of this study should be that RFID implementation should take implantable pacemaker and ICD EMC into consideration. Additionally, both pa-

tients and their cardiologists should be aware of the possibility of adverse reactions from RFID.

We do not believe the current situation reveals an urgent public health risk. However, we are concerned that the continued proliferation of RFID without taking implantable pacemaker and ICD EMC into consideration could potentially cause clinically significant events for patients.

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