Electromagnetic compatibility of pacemakers and implantable cardiac defibrillators exposed to RFID readers

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Abstract: A test method was adapted to test the Electromagnetic Compatibility (EMC) between active implantable cardiac devices and Radio Frequency Identification (RFID) readers. A total of 18 pacemakers and 19 Implantable Cardiac Defibrillators (ICDs) from five of the leading pacemaker and ICD manufacturers were tested for immunity to Radio Frequency (RF) emissions generated by seven RFID readers. The seven RFID readers came from five manufacturers and operated at one of the following frequencies: 134 kHz, 13.56 MHz or 915 MHz. The pacemaker (or ICD) was placed in a saline bath filled with 0.18% saline solution. The output signal of the implantable device was observed on an oscilloscope during exposure to electromagnetic fields from the RFID readers. Any change in output signal was noted as a reaction from the pacemaker (or ICD). Reactions ranged from non-clinically significant events to the potentially harmful inappropriate tachyarrhythmia detection and delivery of therapy or complete inhibition of cardiac pacing.

Keywords: Electromagnetic Compatibility; EMC; Electromagnetic Interference; EMI; Radio Frequency Identification; RFID; pacemaker; defibrillator.

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1 Introduction

1.1 Background

The technology used in active implantable cardiac devices, including implantable pacemakers and implantable cardiac defibrillators (ICDs), continues to advance with time. Composed of complex digital circuitry, these devices are susceptible to Electromagnetic Interference (EMI). Despite these devices' Electromagnetic Compatibility (EMC) design, which includes titanium casing and filters, there have been numerous Food and Drug Administration (FDA) incident reports of EMI to both pacemakers and ICDs. The sources of interference from the incident reports (MaudeDatabase, 2007) are Radio Frequency (RF) type devices such as antitheft devices, metal detectors and cell phones. A new entry to the list of possible sources of interference is Radio Frequency Identification (RFID) technology. RFID technology is gaining popularity in many different commercial areas including shipping, manufacturing and inventory tracking. Ad hoc experiments conducted by the Association for the Advancement of Medical Instrumentation (AAMI) PC69 EMC Task Force revealed possible interference issues between an active RFID reader and both pacemakers and ICDs and the need for proper test methods. FDA's Office of Science and Engineering Laboratories (OSEL) had previously collaborated with the AAMI PC69

EMC Task Force to develop EMC test methods between pacemakers and ICDs and cellular telephones. OSEL's expertise in this area was requested by the AAMI PC69 EMC Task Force to investigate the potential EMI effects of pacemakers and ICDs to active RFID readers. The investigation involved pacemakers and ICDs from five medical device manufacturers versus seven active RFID readers from five companies.

1.2 Objective

The objective of this paper is to report on the EMC of pacemakers and ICDs and RFID readers. The pacemakers and ICDs tested were from five medical device manufacturers. The RFID readers that we used represented the frequencies and modulations currently in use. A preliminary test method is presented with results. The test method is currently being refined by the AAMI PC69 EMC Task Force.

1.3 Medical device background

A pacemaker is a medical device that is designed to regulate the patient's heart rate. It is implanted in a patient and has leads that carry electrical stimulation pulses to the heart. An ICD is similar to a pacemaker in that it is also implanted in a patient and has leads to carry electrical impulses to the heart. However ICDs are much more sophisticated than pacemakers. Pacemakers can sense intrinsic low heart rates and provide therapy to maintain a heart rate appropriate to patients' needs. ICDs are designed to monitor the heart rhythm and, in addition to acting as a pacemaker, deliver a therapy to correct undesirable fast cardiac rhythms. More detailed information about pacemakers and ICDs can be found on the AAMI website (*AAMI Glossary*, 2007).

1.4 Why the concern?

Previous studies (Carey and Ruggera, 1998; Cortner, 2004; Elshershari et al., 2002; Kainz et al., 2005; Irnich, 2002) have shown that pacemakers and ICDs are susceptible to EMI from sources with strong RF magnetic and electric fields. Incident reports filed to the FDA document clinically important reactions of active implantable cardiac devices to electromagnetic fields from nearby cell phones, electronic article surveillance systems (EASS), metal detectors and other less common RF emitters (*MaudeDatabase*, 2007). FDA has published the recommendations for patients who have cardiac and other active electronic implants, about some of these potential sources of interference (Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICDs and Spinal Cord Stimulators, 1998). To avoid complications with EASS, a patient should walk through at a normal pace, and not linger near the EASS for an extended period of time. To avoid exposure to electromagnetic fields from walking through metal detectors, a patient with an implantable device can ask for a hand screening. Although a hand screening still puts the patient at risk to exposure from electromagnetic fields, the maximum magnetic field strengths from hand wands are typically much less than walking through metal detectors and the area immediately surrounding the pacemaker or ICD can be avoided. This is possible because these systems are generally visible and known to be in areas such as store fronts and security checkpoints. However the concern for patients being exposed to RFID systems is potentially greater because these systems can be hidden behind walls and ceilings leaving the patient unaware of their presence.

Thorough EMC testing must be performed and a test method adapted to allow both for the development of better protection for pacemakers and ICDs and to alert potential emitters to the limits of protection.

2 Methods and materials

2.1 What was tested?

Experiments were performed and data were collected in OSEL during the period from May 2006 to September 2006. Engineers from medical device manufacturers came to OSEL to assist in testing their particular devices. There were 18 pacemakers and 19 ICDs that were tested. These were supplied by five of the leading manufacturers of pacemakers and ICDs. The pacemakers and ICDs were tested for compatibility with seven different RFID readers. The collection of RFID readers used were manufactured by five different companies, designed to read passive tags and covered three distinct RF bands. They included two 134 kHz readers, four 13.56 MHz readers and one 915 MHz reader. This means that for pacemakers exposed to 134 kHz readers there were 36 possible tests (two 134 kHz RFID readers times 18 pacemakers). A matrix of the number of possible tests for both pacemakers and ICDs characterised by RFID reader frequency can be seen in Table 1.

Table 1 Number of possible tests for each implantable device

Device type	*# of implants exposed*	*# of RFID readers (LF. HF. UHF)*	*# of possible tests (LF. HF. UHF)*
Pacemaker	18	2,4,1	36,72,18
ICD	19	2,4,1	38,76,19

Note: Multiply the number of implants exposed to the number of RFID readers tested to get the total number of possible tests for each implantable device. LF = 134 kHz, HF = 13.56 MHz, UHF = 915 MHz.

2.2 Magnetic field measurements

For each of the RFID readers, the spectrum, pulse frequency and duty factor were captured using a single turn 1.5 cm diameter electric field shielded loop and a real time spectrum analyser (Tektronix RSA 3308A). The pulse frequency is defined as $1/\Delta T$ where ΔT is the total period that consists of an activation period (when reader is charging the tag) followed by a pause period (when reader is listening for tag). The activation and pause period make up a square wave that is fully defined by the pulse frequency and duty factor of the particular reader. For example RFID Reader I has a pulse frequency of 14.3 Hz (ΔT = 70 ms) and a duty factor of 0.72. Multiplying the total period by the duty factor equates to an activation period of 50 ms (70 ms × 0.72 = 50 ms). This activation period is followed by a pause period of 20 ms to give the total period of 70 ms. For RFID readers that do not have a pause period the pulse frequency may be defined by other parameters such as RF resets. The emitted magnetic field strength at a distance of 2.3 cm from the surface of the reader's antenna was also determined. One vector component of the magnetic field emissions of each of the RFID readers was measured in a plane normal to the area of the reader's antenna surface.

This 2.3 cm distance represents the closest possible distance between a RFID reader and a pacemaker or ICD, which will be called the Device Under Test (DUT) when they need no distinction. Table 2 displays the RF parameters (carrier frequency, modulation frequency, duty factor and magnetic field strength) and the particular International Standards Organization (ISO) standard of the different RFID readers evaluated. Note that the one 915 MHz reader was a Generation 1 (Gen1) product and uses far-field technology. All other readers use near-field technology.

Table 2 RF characteristics of RFID readers

RFID reader	*ISO standard*	*Carrier frequency (MHz)*	*Pulse frequency 1/ΔT (Hz)*	*Duty factor*	*Max H-field 2.3 cm (A/m)*
I	11,785	0.134	14.3	0.72	65
II	11,785	0.134	10.6	0.52	60
III	15,696	13.56	10.9	0.11	4
IV	15,696	13.56	3.5	0.92	6
V	15,696	13.56	2.2	0.99	2
VI	15,696	13.56	6.5	0.92	7
VII	18,000-6C	915	56,100	0.77	3

2.3 Human torso simulator

The testing protocol is a modified version of the ANSI/AAMI PC69 Standard (ANSI/AAMI, 2000). The same human torso simulator was used. It was made from a polyethylene plastic box (26.5 l, 58.5 × 42.5 × 15.2 cm) and filled with 0.18% saline solution. Two rectangular grids were cut from inexpensive protection grids used in large fluorescent lighting fixtures. The bottom grid supports the DUT and the lead system. The top grid provided a physical testing surface 2.3 cm above the DUT where the outermost surface of an RFID reader can be placed. The distance simulates an RFID reader placed directly on the patient's clothing and is a worst case scenario. The bottom grid was supported by four threaded nylon rods (legs) that were adjusted to immerse the DUT in the saline leaving 1 cm between the DUT and the testing surface (see Figure 1). The entire human torso simulator can be seen in Figure 2. Two separate grid systems were made to support the different lead layouts between the pacemakers and ICDs. Both lead configurations were positioned in a spiral pattern and can be seen in Figure 3. This lead configuration fits well within the grid area and is easily repeatable.

Figure 1 Drawing of grid layout to be placed inside torso simulator box. Implant is submerged in 1 cm of saline and is 2.3 cm from the testing surface

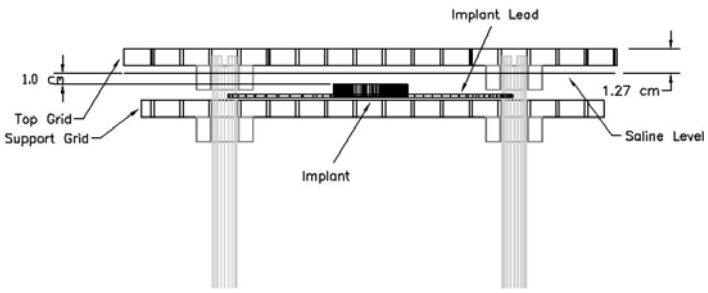


Figure 2 Drawing of human torso simulator with grid and implantable device

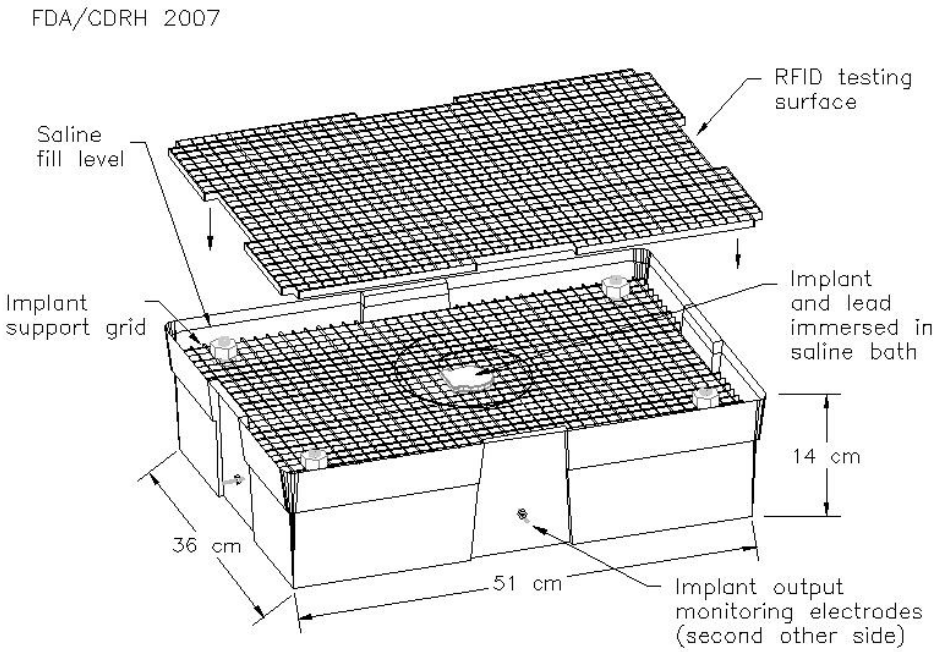
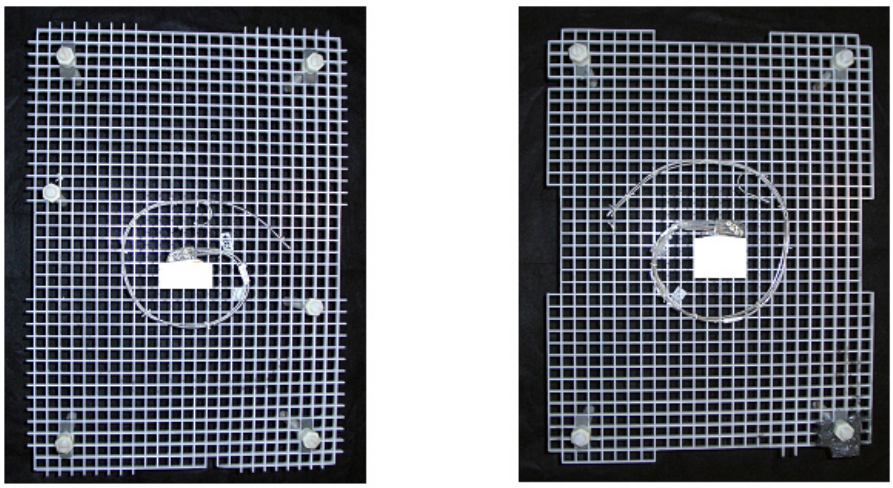


Figure 3 Pacemaker and ICD lead configuration. A simple configuration was chosen to provide easy repeatability



2.4 Signal monitoring system

Two stainless steel electrode plates (50 × 50 × 2 mm) are mounted at the centre of two inner walls of the human torso simulator. Stainless steel screws are threaded through each plate extending outside the simulator box providing external electrical terminals.

The terminals are used to monitor the output of the DUT. The terminals are then connected with insulated wire, outside the box, to a low pass filter to filter out the RF from the RFID reader. The filtered signal then goes to a differential amplifier plug-in of an analog oscilloscope (Tektronix 7904A) having an input impedance of one mega-ohm.

2.5 Test procedure

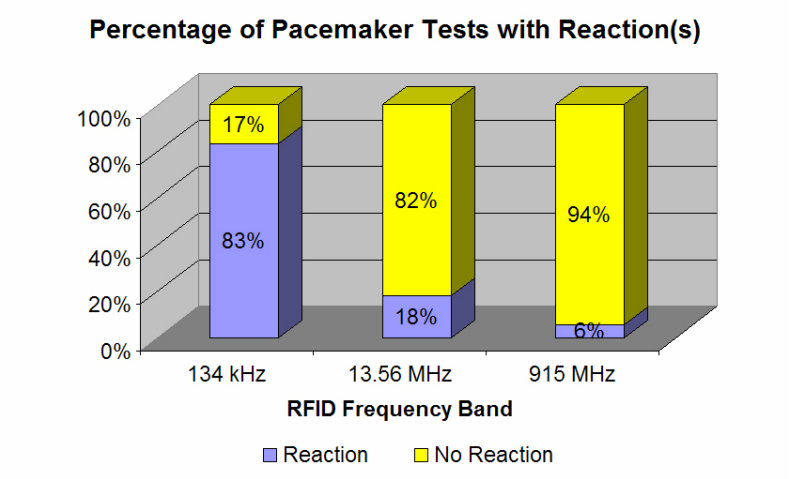
First the DUT was connected to the appropriate lead system and then placed in the human torso simulator. The DUT depth was measured and corrected to 1 cm for each DUT. The DUT was initially programmed to maximum sensitivity. Next, the signal monitoring leads were connected from the human torso simulator to the oscilloscope and the DUT's output pulses were verified. Then, one of the seven RFID readers was turned on and proper operation was verified by reading a tag with its appropriate software. The reader was held directly above the implantable device at a distance, 1 m away from the testing surface. The RFID reader was then lowered slowly by hand towards the DUT, carefully monitoring the oscilloscope for any change in the DUT's output signal. The RFID reader was also moved side to side to look for the worst case change in the DUT's output signal. If a change occurred, the distance (height from DUT) was recorded and the type of change (reaction) was noted. A reaction was classified as oversensing that led to pacing inhibition, inappropriate tachyarrhythmia detection and delivery of therapy or other events that were less or not clinically significant. Regardless of the recorded events, the RFID reader continued to be lowered toward the testing surface located 2.3 cm above the DUT. Each time a different reaction was observed, it was recorded. If any reaction was observed for a particular DUT, the test was repeated with the DUT reprogrammed to nominal sensitivity. All possible lead configurations (unipolar, bipolar) were tested for each DUT. The salinity of the human torso simulator was measured and corrected to 0.18% prior to each day of testing.

3 Test results

3.1 Implantable pacemaker reaction

At least one reaction was observed in 17 of the 18 pacemakers tested. The majority of reactions were observed while the pacemakers were exposed to the lower frequency RFID readers. While being exposed to each of the two 134 kHz RFID readers, a pacemaker reaction was observed for 30 of the 36 possible tests (83%). While being exposed to each of the four 13.56 MHz RFID readers, a pacemaker reaction was observed for 13 of the 72 possible tests (18%). Finally, while being exposed to the one 915 MHz RFID reader tested, a pacemaker reaction was observed in only 1 of the 18 possible tests (6%). These data are summarised in Figure 4. There was not a clear correlation between the lead configuration (unipolar or bipolar) and pacemaker susceptibility. It should be noted that when a pacemaker reaction occurred, the maximum distance between a RFID reader and a pacemaker was 51.3 cm. Pacemaker susceptibility was not significantly affected by a change from maximum to nominal sensitivity.

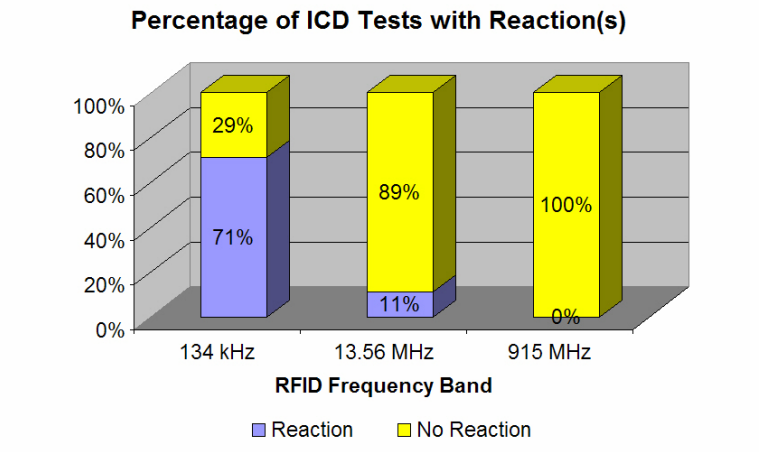
Figure 4 Pacemaker reaction with RFID. The percentage of possible tests that caused a reaction or no reaction, respectively



3.2 Implantable cardioverter defibrillator reaction

At least one reaction was observed in 18 of the 19 ICDs that were tested. Again the majority of reactions were observed while the ICDs were exposed to the lower frequency RFID readers. While being exposed to the two 134 kHz RFID readers, an ICD reaction was observed for 27 of the 38 possible tests (71%). While being exposed to the four 13.56 MHz RFID readers, an ICD reaction was observed for 8 of the 76 possible tests (11%). Finally while being exposed to the one 915 MHz RFID reader tested, an ICD reaction was observed in zero of the 19 possible tests (0%). These data are summarised in Figure 5. It should be noted that when an ICD reaction occurred, the maximum distance of a RFID reader from an ICD was 61.3 cm. ICD susceptibility was not significantly affected by a change from maximum to nominal sensitivity.

Figure 5 ICD reaction with RFID. The percentage of possible tests that caused a reaction or no reaction, respectively



4 Discussion

Testing verified that both pacemakers and ICDs are susceptible to EMI from the various RFID readers tested. This is particularly of concern for RFID readers operating at 134 kHz and 13.56 MHz. Discussions with pacemaker and ICD manufacturers revealed that current pacemakers and ICDs are less effective at filtering these frequencies. The pulse frequency of the RFID readers tested was typically less than 15 Hz. This induces interference since pacemakers and ICDs are designed to sense human cardiac electrical activity with frequency components in the range of about 0.5 to several hundred Hz. It is worth noting that we saw very little device susceptibility from RFID Reader VII operating at both a high carrier frequency (915 MHz) and a high pulse frequency (56.1 kHz). Previously, feed-through filters were developed to address EMI issues with wireless communication devices (including cell phones that can operate at 915 MHz) and pacemakers and ICDs (Stevenson, 1997).

As discussed earlier, a reaction was classified as oversensing that led to pacing inhibition, inappropriate tachyarrhythmia detection and delivery of therapy or other events that were less or not clinically significant. Each one of these events occurred during the testing of at least one device. Some reactions recorded were unlikely to have substantial clinical impact (e.g. an ICD recognising an interfering source and pacing regularly without sensing). Other reactions were more concerning (e.g. complete inhibition of pacing therapy or an ICD inappropriately detecting a tachyarrhythmia resulting in the delivery of therapy/shock). In clinical use for susceptible patients, these more concerning reactions have the potential to cause major illness, including possible life-threatening complications. To summarize, there were multiple reactions observed, some of which were clinically significant, while others were not. A detailed assessment of the clinical significance of reactions observed is ongoing, but it should be noted that the clinical significance of these reactions will also depend on the patient's specific circumstances.

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Disclaimer

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