ELECTROMAGNETIC COMPATIBILITY TESTING OF ACTIVE IMPLANTABLE MEDICAL DEVICES AGAINST RADIO FREQUENCY IDENTIFICATION INTERROGATORS

by

Joshua R. Stachel

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This thesis was presented

by

Joshua R. Stachel

It was defended on

July 23, 2010

and approved by

Zhi-Hong Mao, Assistant Professor, Electrical and Computer Engineering

Ronald G. Hoelzeman, Associate Professor, Electrical and Computer Engineering

Thesis Advisor: Marlin H. Mickle, Professor, Electrical and Computer Engineering

ELECTROMAGNETIC COMPATIBILITY TESTING OF ACTIVE IMPLANTABLE MEDICAL DEVICES AGAINST RADIO FREQUENCY IDENTIFICATION INTERROGATORS

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Over the past few years radio frequency identification (RFID) technology has experienced substantial market growth. Over this time RFID technology has been incorporated into an ever increasing number of applications and products in the everyday environment such as smart card access control systems, inventory tracking, and real-time tracking and location systems. Also, over the last few decades the number of patients requiring active implantable medical devices (AIMD) such as implantable cardiac pacemakers and implantable cardioverter defibrillators has been steadily increasing due to advances in pacing technology as well as the aging populace of many countries around the world. If these trends continue, as they are expected to, this will place the AIMD patient at an ever increasing risk of encountering electromagnetic interference (EMI) to their AIMD caused by the electromagnetic fields (EMF) produced by these RFID devices. This highlights the importance of electromagnetic compatibility (EMC) testing of these technologies.

This research focuses on EMC testing of many different types of AIMDs subjected to EMF emitted by several different, commercially available RFID interrogators. The testing presented here differs from that in the literature in that it is accomplished by use of three different in vitro models of the human body rather than a singular model. The use of three

different models will facilitate a more complete assessment of the risks associated with AIMD patients coming in close contact with RFID technologies. Additionally, EMI mitigation techniques are explored, and a novel mitigation technique based on ramped amplitude carrier waves is proposed and tested.

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PREFACE

I would like to extend my sincere gratitude to Dr. Marlin Mickle for accepting me onto his research team and guiding my thesis research. I would also like to thank Dr. Peter Hawrylak and Dr. Ajay Ogirala for their support and assistance throughout this process. Finally, I would like to thank Dr. Ronald Hoelzeman and Dr. Zhi-Hong Mao for sitting on my thesis committee.

1.0 INTRODUCTION

According to the American Heart Association, in 2002 there were approximately three million people worldwide dependent upon pacemakers and 600,000 new pacemakers being implanted annually [9]. These figures are only expected to increase due to advances in cardiac pacing as well as the aging populace of many countries around the world [1]. Also in the past few decades there has been a marked rise in the number of everyday objects that emit electromagnetic fields (EMF). As a number of studies indicate, the proliferation of everything from cell phones to radio frequency identification (RFID) security devices has placed the AIMD patient at an ever escalating risk of encountering electromagnetic interference (EMI) due to the EMF generated by these devices [5][6][12][13][15][16]. As such, it is essential to study the interaction between AIMDs and these sources of EMF in order to ensure a safe environment for these patients.

1.1 BACKGROUND

Current literature suggests many possible sources of EMI in AIMD systems. Many have explored the EMI caused by cellular telephones [5][12][15]. According to the findings in these studies, the incorporation of ceramic feed-through capacitors and band pass filters has all but eliminated the risk of EMI due to cellular telephones in modern AIMDs. Other studies have implicated various medical procedures such as electrocautery and magnetic resonance imaging

as being possible sources of EMI [6][13][17]. These procedures have the capacity to cause clinically significant interference and should be avoided by the AIMD patient. Some have even explored the effects of household items such as microwave ovens and induction ovens; though it is believed that such items do not pose a serious risk to AIMD patients [6][13].

A number have also indicated Radio Frequency Identification as a possible source of clinically significant interference [1][2][7][8][9]. Over the past few years RFID technology has been incorporated into an increasing number of everyday items and applications such as access control systems, retail inventory tracking, and real-time tracking and location systems. As the use of RFID technology becomes ever more pervasive in everyday situations, the need for EMC testing with RFID interrogators and AIMDs becomes ever more important. The rest of this thesis focuses mainly on three such studies. The testing methodologies of which were adopted for the EMI tests discussed later in this thesis.

1.1.1 RFID Studies

The studies discussed in this thesis all deal with EMC testing of various AIMDs exposed to EMF created by RFID emitters. Each has a unique in vitro tissue equivalence model in order to approximate the effects of the human body on the interaction between the EMF and the AIMD being tested.

1.1.1.1 Hokkaido

The first study considered comes from Hokkaido University in Japan [1]. The in vitro model used in this paper is a saline tank torso simulator (torso phantom). The torso phantom is simply a clear acrylic box filled with saline solution. The tank measures 360 X 340 X 25 mm.

The concentration of the saline solution, 1.8g/l NaCl, was chosen to most closely match the electrical properties of the human body when it is exposed to RF radiation. The AIMD is placed into the torso phantom in a vertical orientation, as if the patient is standing. The advantages of the vertical-type phantom over horizontal-type include being easier to handle when testing with RFID interrogators that use two antennas (1 transmitting antenna, 1 receiving antenna), additionally the flat shape of this torso model yields more conservative estimates of maximum interference distances as opposed to a more realistically shaped torso [1].

1.1.1.2 FDA

The second study, conducted by the FDA uses a torso phantom similar to the Hokkaido phantom [2]. Like the Hokkaido torso, the FDA torso is an acrylic box filled with saline solution. This torso, however, has a horizontal orientation, as if the patient were lying down. The tank measures 58.5 X 42.5 X 15.2cm and was filled with 0.18% saline solution. A plastic grid supports the AIMD at a depth of 0.5 cm into the saline solution. The FDA torso facilitates testing of AIMDs at varying depths of saline solution yielding more realistic estimates of maximum interference distances, simulating a more typical torso shape.

1.1.1.3 Tissue Interface Circuit

The last study conducts EMC testing using a "Tissue Interface Circuit" (TIC) [3]. The TIC is an electrical circuit designed to approximate the electrical properties of human tissue. The TIC was developed in ANSI/AAMI PC69 as an American National Standard for EMC testing of AIMDs. Unlike the two torso tank simulators discussed above, the TIC does not facilitate over-the-air testing. Rather, an RF signal is directly injected into the TIC via an SMA

port. The signal then travels through the TIC to the AIMD connected on the output of the circuit. The AIMD itself is also connected to the TIC via SMA connections. The output of the AIMD can then be monitored for interference.

1.1.2 EMI characteristic

EMI in AIMDs is caused when alternating magnetic fields produced by the RFID reader induce a voltage in the "one turn coil" formed by the AIMDs lead system and the surrounding human tissue. This induction effect due to alternating magnetic fields is called magnetic coupling. This magnetic coupling can cause low frequency components to appear in the AIMD lead system which the AIMD may interpret as a legitimate physiological event of interest causing inappropriate functioning of the AIMD. Many different manifestations of EMI have been reported in the literature, such as pacing inhibition, asynchronous pacing, noise reversion, tracking, and mode switching [5][15]. The types of interference investigated in this research are focused on inhibition and asynchronous pacing. Inhibition is the inappropriate suppression of a pacing signal when the AIMD mistakes an external signal for a genuine heart beat signal. Asynchronous pacing is the inappropriate discharge of a pacing signal in the presence of a genuine heart beat signal when the AIMD should be inhibited. Each of these EMI effects is tested independently in the tests discussed later in this thesis.

1.1.3 Mitigation methods

The field strength of RF signals produced by RFID interrogators attenuates with distance from the emitter and can be approximated by free space attenuation equations [1]. Because of this the

standard EMI mitigation method employed is the use of standard proximity guidelines. It is generally advisable for the AIMD to come no closer than 22cm to any device that emits RF signals with the capacity to interfere with the AIMD system [1]. In order to determine this safe distance EMC testing of AIMDs typically seeks to determine the maximum interference distance (MID). The MID is the maximum distance at which the emitter begins to interfere with the AIMD system. The testing in this research employs this convention of determining MIDs when the AIMD is subjected to over-the-air EMF.

Literature also suggests that continuous wave (CW) signals cause fewer incidences of interference as compared to modulated or pulsed RF waves [1][2][11]. This is largely believed to be due to the fact that the modulation frequency or pulse repetition rate lies in the pass band of the sensing circuitry of the AIMD. This modulation effect results in low frequency components to be induced in the AIMD lead system and can be sensed, incorrectly, as a genuine heart beat signal.

The mitigation technique evaluated in this research modifies the modulated signals typically used in RFID systems. It is based on ramping the amplitude of the modulated carrier wave bursts so as to reduce the magnitude of the voltage induced in the AIMD lead system. This method is explored and tested for EMI mitigation performance.

1.2 OBJECTIVES

The main objective of this work is to determine the electromagnetic compatibility (EMC) of various AIMDs with different RFID interrogators, and to ultimately asses the risks associated with AIMD patients coming in close contact with RFID technologies. The EMI tests developed

in this research are proposed to offer a standard testing framework for the evaluation of EMC between AIMD and RFID systems, as well as providing reliable and realistic maximum interference distances. The three in vitro models used in testing were chosen to offer a broad range of coverage under differing torso simulation conditions. The Hokkaido torso, with its flat shape and vertical design, yields conservative MID estimation for applications where EMI must be avoided. The FDA torso offers more realistic estimations of the MID due to its more realistic torso shape. Finally, the TIC can offer realistic modeling of the EM characteristics of human tissue through the choice of circuit components.

A secondary objective of this thesis is to evaluate a novel method of mitigating the effects of EMI due to RFID interrogators on AIMDs. The mitigation method to be evaluated, a modification of the on-off keying modulation method commonly used in RFID systems, aims to reduce the occurrence of EMI by ramping the amplitude of the modulated carrier wave being emitted by the interrogators. The goal of this method is to reduce the induced voltage levels commonly caused by on-off keying modulation methods. Tests are run to assess the performance of this technique in mitigating EMI effects.

Some of the general goals of this research used to realize these objectives are outlined below.

- RFID interrogators must be gathered and tested prior to EMC testing to ensure proper functioning and to record device capabilities
- AIMD to be tested must be monitored in all lead configurations and device's baseline performance noted in each configuration

- EMC testing configurations will be designed to marginalize the effects of any external source of EMF
- Standard testing configurations for each in vitro model will be defined so as to facilitate test repeatability and reliability
- Interference characteristics will be defined for each AIMD tested in order to categorize observed interference
- Both the AIMD and RFID interrogator under test will be monitored for proper functioning prior to each EMC test
- Factors contributing to EMI in AIMDs tested, such as programmable AIMD parameters, in vitro model used, and carrier wave frequency, will be identified
- Test results will be recorded and compared according to factors contributing to EMI that have been identified

2.0 ACTIVE IMPLANTABLE MEDICAL DEVICES

Cardiac pacing is the practice of electrically stimulating the heart in patients with irregular heartbeats that would otherwise prohibit normal living. Typical AIMDs, such as implantable pacemakers and implantable cardioverter defibrillators (ICDs), consist of the pacing circuitry hermetically sealed in a titanium case which both shields the pacing circuitry from external electrical signals as well as from body fluids [11]. AIMDs can contain anywhere from one to five channels, each with its own platinum lead wire used to stimulate the cells of the heart. A typical AIMD is implanted in the chest of a patient a few centimeters below the skin with the lead wires attached to the pertinent areas of the heart muscle; either the atrium, ventricle, or in the case of dual chamber AIMDs, both atrium and ventricle. Figure 1 shows a typical pacemaker.

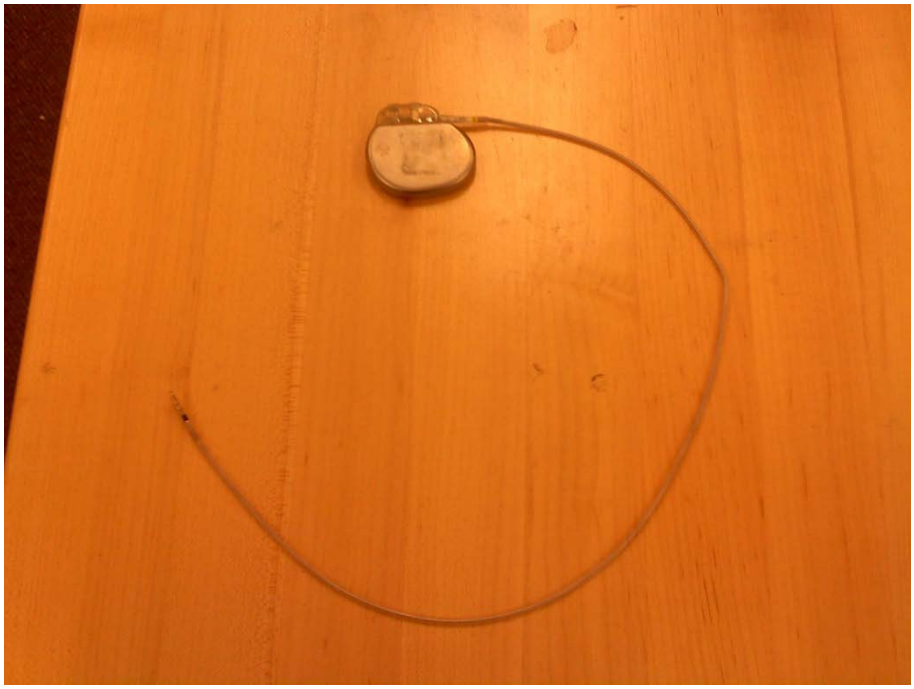


Figure 1. A typical pacemaker/lead system

An AIMD has two main functions; sensing and pacing. In the sensing phase the AIMD monitors very low level (as low as 0.1 mV) physiological signals with frequencies ranging roughly between 0.1 Hz up to several hundred kHz [3]. The purpose of this sensing phase is to determine if a normal heart beat signal can be detected and if pacing is appropriate. If the AIMD determines pacing is appropriate, the AIMD battery provides an electrical current that travels through a conducing lead wire to an electrode at the tip of the lead wire. This electrode, typically connected to the cathode of the AIMD battery, is attached to the heart muscle and delivers the electric current to the area to which it is attached. The electrical current then travels through the myocardium to a second electrode that is connected to the anode of the AIMD battery, thus completing the circuit [17]. Figure 2 shows the pacing signal of a typical pacemaker. A typical pacing discharge can have a magnitude up to 5 – 7 volts and lasts anywhere from 0.5 to 2ms.

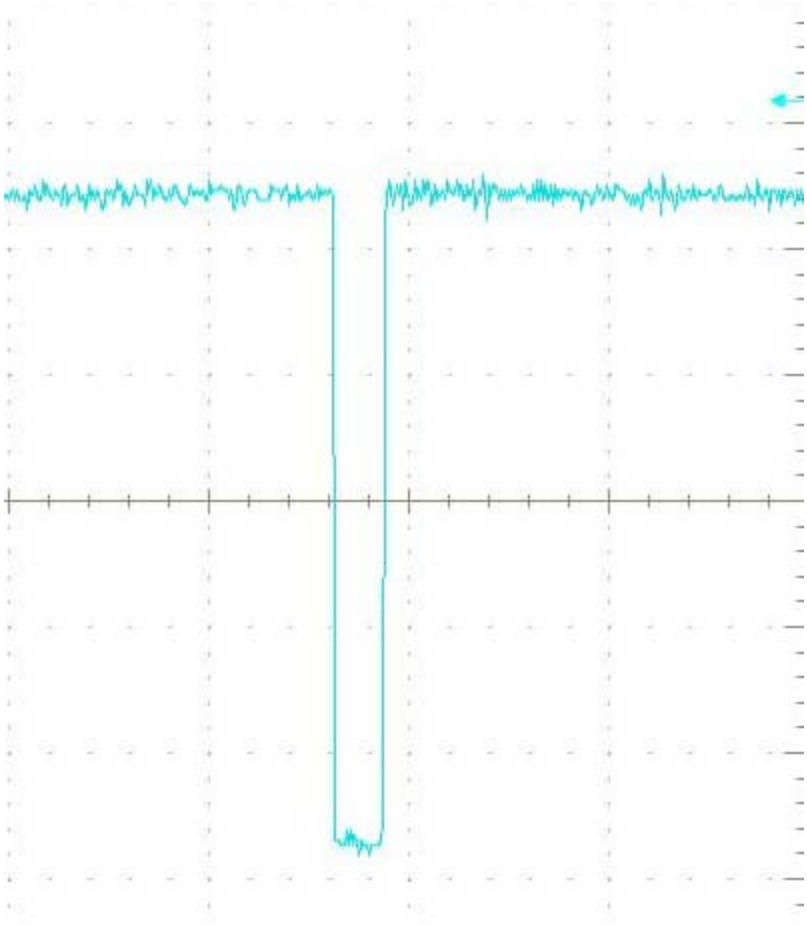


Figure 2. A typical pacing signal from an AIMD

Most modern AIMDs incorporate substrate mounted band pass filters with a pass band spanning roughly from 0.1 Hz to 1 kHz in order to filter out any external signals. It has been shown, however, that these filters can easily be overwhelmed by a strong external EMF [15]. In order to improve EM immunity beyond that which can be provided by the band pass filters, modern AIMDs also incorporate a ceramic feed-through capacitor through which the internal AIMD circuitry is connected to the pacing terminals. This feed-through capacitor prevents most external signals outside of the pass band from reaching the internal sensing circuitry of the

AIMD and overwhelming the internal band-pass filter. The incorporation of these feed through capacitors has been shown to improve the EM immunity of AIMDs greatly [15].

AIMDs have many programmable parameters. Table 1 shows some of the typical programmable parameters in modern AIMDs. Modern AIMDs incorporate magnetic switches to enable non-invasive remote RF programmability of these parameters. These magnetic switches have been shown to be affected by EMI resulting in a type of interference called mode switching, or the inappropriate alteration of one or more of the AIMDs programmable parameters.

One parameter that has significant impact on the EMC of the AIMD is operating mode. AIMDs have many different operating modes (AAI, VVI, DDO, etc.). These codes can have a maximum of five positions (DDIRD) although only three or four positions are typically used [17]. These codes detail how the AIMD will operate. The first position indicates what chamber of the heart is being paced; A for atrium, V for ventricle, D for dual (only in AIMDs with two or more lead wires), S for single, indicating it can be used to pace either the atrium or ventricle. Position 2 indicates the chambers being sensed (A, V, D, S, O). O corresponds to no sensing. Position 3 is the response to sensing; I for inhibit, T for trigger. Position 4 (R) signifies the AIMD is rate adaptive, and position 5, which is rarely used, details the use of antitachyarrhythmia pacing [17]. Another programmable parameter that has an effect on the EMC of the AIMD is sensitivity. The sensitivity parameter indicates at what voltage level a signal being sensed will trigger or inhibit the AIMDs pacing operation. The sensitivity is usually in the range of 0.5mV to 2.5mV.

Table 1. Common programmable parameters

Parameter	Values
Stimulation Mode	AAI, VVI, DDI
Pacing Rate	60 bpm
Sensing Polarity	unipolar or bipolar
Pulse Amplitude	~ 3-5 V
Pulse Duration	~ 0.5 ms
Sensitivity	0.5 - 2.5 mV
Refractory Period	~ 25 ms

Sensing polarity is another programmable parameter that has a large impact on the occurrence of EMI. The sensing mode of an AIMD can be either unipolar or bipolar. The sensing polarity defines how heart beat sensing is accomplished in the lead system of the AIMD. More specifically, the sensing mode defines which electrodes are connected to the anode and cathode of the AIMD battery

2.1 UNIPOLAR SENSING

In unipolar sensing the cathode electrode is the tip of the lead wire while the anode electrode is the metal casing of the AIMD itself [17]. Figure 3 shows a diagram of unipolar sensing. In general, unipolar pacing is more susceptible to EMI from external sources; however, the lead itself can be smaller since unipolar leads require only one conducting wire to be contained in the lead.

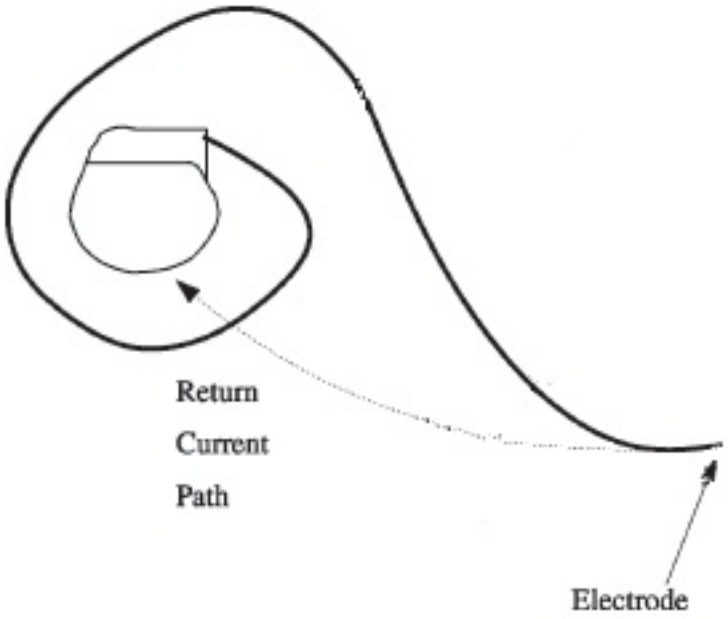


Figure 3. Depiction of Unipolar sensing mode

2.2 BIPOLAR SENSING

In bipolar sensing mode the lead contains two wires, one connected to the cathode and the other to the anode. In bipolar mode the cathode electrode is still the tip of the lead wire but the anode electrode is a metal ring located very near (typically around 10mm – 3cm) from the end of the lead wire. Figure 4 shows a diagram of bipolar sensing. Bipolar sensing has some clear advantages over unipolar sensing. The bipolar system is less susceptible to EMI, and is more resistant to damage. Due to these advantages, most AIMDs being implanted today are bipolar systems, though the use of unipolar mode still remains in certain circumstances.

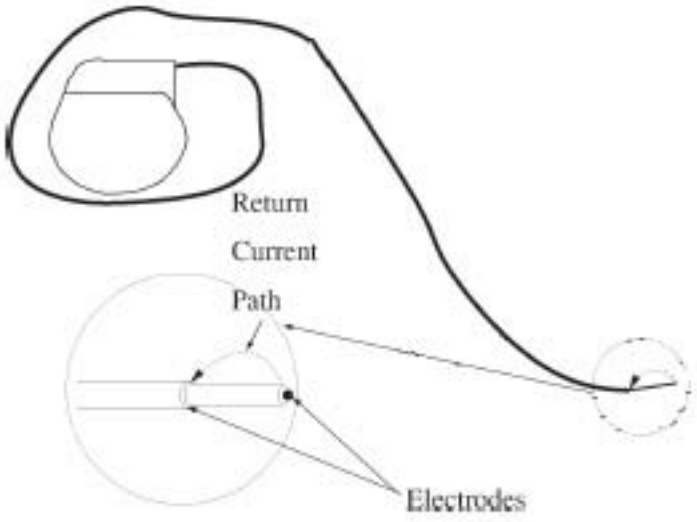


Figure 4. Depiction of bipolar sensing

2.3 AIMD TESTED

Four pacemakers and two ICDs were tested in this thesis. Each AIMD was tested for inhibition and asynchronous pacing in each in vitro model.

2.3.1 Pacemakers

Pacemakers provide electrical stimulation to either the atrium or ventricle (or both in the case of dual chamber pacemakers) when an abnormal heart rhythm or complete absence of heart signal is detected. Two of the pacemakers tested are dual chamber devices while the others have a single channel. The pacemakers were tested in both unipolar and bipolar sensing modes and at differing sensitivity levels. Figure 5 shows an example pacemaker.

Figure 5. Typical Pacemaker

2.3.2 Implantable Cardioverter Defibrillators

An implantable cardioverter defibrillator (ICD) is a tiered therapy device. ICDs provide cardiac pacing, low-energy cardioversion, and defibrillation [17]. Two ICDs were tested in this research. The pacing functions of the ICDs were the only function tested and each was tested at varying sensitivity levels. Figure 6 shows an example of an ICD.

Figure 6. Typical Implantable Cardioverter Defibrillator

3.0 RFID INTERROGATORS

Radio frequency Identification (RFID) enables the remote identification of items through the use of radio frequency (RF) signals. Over the past decade RFID technology has enjoyed rapid market growth. In 2007 the global RFID market was valued at $917.3 million and is expected to nearly quadruple by 2012 [18]. RFID systems have a wide range of applications such as; inventory tracking, access control systems and real-time tracking and location systems. This trend of increased market penetration suggests that the need for EMC testing of AIMDs against RFID emitters will only increase in the coming years.

RFID technology consists of an interrogator that emits a radio frequency signal and a tag from which the interrogator reads and or writes data. An example interrogator and tag are shown in Figure 7. The general operation of RFID systems functions by the interrogator producing RF signals that are detected by tags. Each tag then modulates this RF signal in a unique and identifiable way and transmits this modulated signal back to the interrogator. The interrogator then receives this uniquely modulated signal and can identify from which tag the signal originated. Tags consist of an antenna and an integrated circuit and can either be active or passive. In active tag systems the tags incorporate their own power source, such as a battery, in order to communicate with the interrogator. Conversely, passive tags harvest power from the RF signal emitted by the interrogator in order to communicate. This thesis considers only passive RFID systems as they typically operate at higher power levels than those of active tag systems.

Figure 7. An example RFID system showing interrogator, antenna, and tag

Six RFID readers were utilized in the testing discussed in this thesis. Four UHF readers, one HF reader, and one interrogator in the LF range. Two of the interrogators are used in medical applications while the other four are commercially available stationary readers. The medical RFID interrogators are stand-alone systems where as the commercial readers require a computer in order to run. Two of the commercially available readers are gate type readers utilizing two antennas, one for transmitting and the other for receiving, while the other four interrogators use a single antenna for both functions. In all cases the interrogators were tested with their default settings except when the power was programmable. In that case the interrogator was programmed to operate at maximal power in order to obtain conservative results. Table 2 shows the specifications of the RFID interrogators tested in this thesis.

Table 2. RFID Interrogators tested

Reader Model	Carrier Wave Frequency
LF 1	143.75 kHz
HF 1	13.56 MHz
UHF1	902 - 928 MHz
UHF2	902 - 928 MHz
UHF3	902 - 928 MHz
UHF4	868– 870 MHz

4.0 INTERFERENCE CHARACTERISTICS

A number of studies have been conducted investigating the occurrence of EMI in active implantable medical devices. There have been many that study the microwave interference caused by cellular telephones [5][12][15]. One such study conducted in 1997 by Hayes et al. consisted of 980 patients subjected to 5,533 tests using five types of mobile phones [5]. The study found a 20% interference rate. Moreover, cellular telephone signals are typically in the UHF range (300 MHz – 3 GHz) and the carrier waves (CW) lie well outside the pass band of the AIMD. As the study showed, those AIMDs with feed-through filters suffered only 0.4% – 0.8% occurrence of interference while those without feed-through filters fared considerably worse with 28.7% - 55.8% occurrence of EMI. A follow-up study conducted by Trigano et al. in 2005 investigated the reliability of EM filters on cardiac pacemakers by cellular telephone signals [12]. The study found that due to the proliferation of ceramic feed-through filters in AIMDs the overall incidence of interference due to cellular telephone signals was far lower at 1.5%. Additionally, the study reported interference only in those AIMDs without feed-through filters. Other studies largely agree with these findings indicating much higher incidences of interference in the LF (30 – 300 kHz) and HF (3 – 30 MHz) ranges than that of UHF [1][15]. These findings highlight the importance of investigating the EMI of AIMDs caused by RFID systems, many of which have applications in the LF and HF ranges.

There are a number of factors contributing to the susceptibility of AIMDs to EMI including; sensitivity setting, pacing mode, sensing polarity, carrier frequency, modulation scheme, field strength, proximity to emitter, and duration of exposure. It is largely believed that the mechanism of interference in the LF and HF ranges is the electromagnetic coupling due to alternating magnetic fields produced by the antenna of the RFID interrogator [1]. A voltage, V_i, is induced in the "one turn coil" created by the pacemaker lead system and the human body according to Faraday's law of induction:

$$V_i = -N \frac{d\Phi_t}{dt} \qquad (4.1)$$

Φ_t is the magnetic flux through an area perpendicular to the coil and N is the number of turns in the coil. If the frequency of this induced voltage lies within the pass band of the AIMDs electromagnetic filters and is of equal or greater magnitude than the sensitivity of the AIMD during the sensing phase, the sensing circuits may interpret this signal as physiological event of interest and cause the AIMD to operate inappropriately.

Studies have also shown that a bipolar lead configuration is much less susceptible to EMI than a unipolar configuration [17]. This is due to the area of the loop formed between the sensing and stimulating electrodes. In unipolar mode the sensing electrode (the metal case of the AIMD) and the stimulating electrode (the tip of the lead) can be up to 25cm away from one another. This can result in a loop with an area up to 250cm^2 [11]. By contrast, the electrodes in a bipolar configuration are roughly 3cm away from one another resulting in a much smaller loop area. Because magnetic flux is directly proportional to the area of the loop, it follows that the induced voltage in a unipolar configuration will be significantly larger than that of a bipolar system resulting in a higher occurrence of interference.

Many studies have also shown that modulated or pulsed EM fields generally cause greater interference than continuous wave (CW) fields [1][11]. It is believed that this is due to the parasitic demodulation of these signals by the nonlinear circuit elements contained in the AIMD [15]. Figure 8 shows how the modulated fields are demodulated by the AIMD. This unintended demodulation of the carrier wave causes low frequency elements to be induced in the AIMD circuitry which can be misinterpreted as a heart beat signal causing the AIMD to operate inappropriately. One study presents an EMI mitigation technique called radio filler [1]. In this technique a modulated carrier wave is converted into a continuous wave by filling in the gaps between the carrier wave bursts with the same frequency signal as the carrier wave. Figure 9 details how the radio filler technique works. Using this method the study reports marked improvement in the occurrence of EMI in AIMDs.

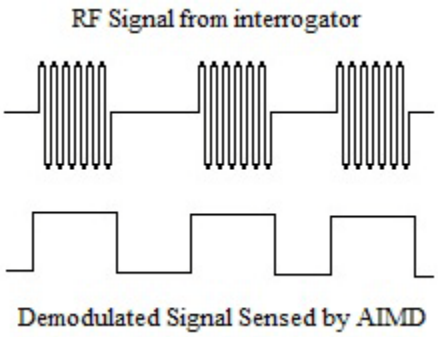


Figure 8. Demodulation of RF signal in AIMD

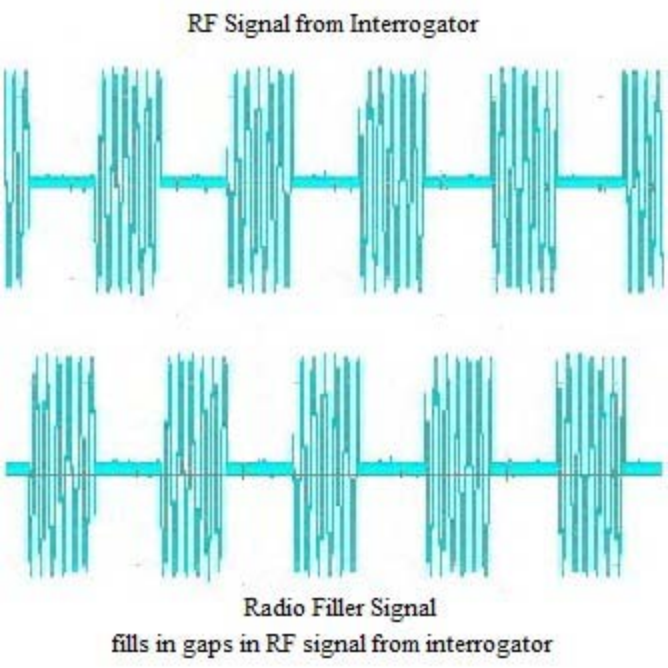
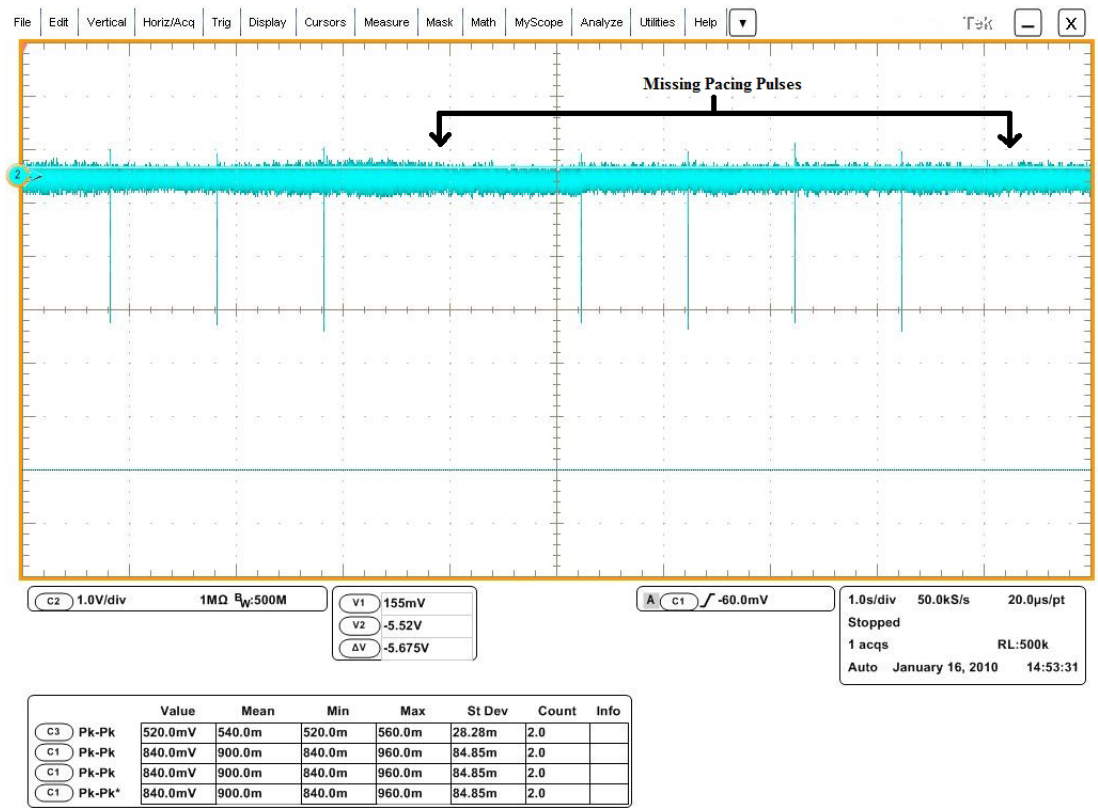


Figure 9. Radio Filler Mitigation Technique

Many different types of interference have been reported such as; pulse inhibition, asynchronous pacing, noise reversion, oversensing, and tracking. Interference observed in the tests discussed in this research fell into two categories; inhibition and asynchronous pacing. Inhibition occurs when the AIMD senses an external EM signal and misinterprets it as a heartbeat signal. The result of this misinterpretation is a missing pacing signal as shown in Figure 10. The other type of interference observed is asynchronous pacing. Asynchronous pacing is the inappropriate discharge of a pacing signal when it should be inhibited due to the presence of a genuine heart signal. A depiction of asynchronous pacing can be seen in Figure 11. In the tests discussed in this thesis in which asynchronous pacing was observed, an artificial heart beat signal was injected into the in vitro models in order to inhibit the pacing signal.



	Value	Mean	Min	Max	St Dev	Count	Info
C3 Pk-Pk	520.0mV	540.0m	520.0m	560.0m	28.28m	2.0	
C1 Pk-Pk	840.0mV	900.0m	840.0m	960.0m	84.85m	2.0	
C1 Pk-Pk	840.0mV	900.0m	840.0m	960.0m	84.85m	2.0	
C1 Pk-Pk*	840.0mV	900.0m	840.0m	960.0m	84.85m	2.0	

Figure 10. Example of pacemaker inhibition

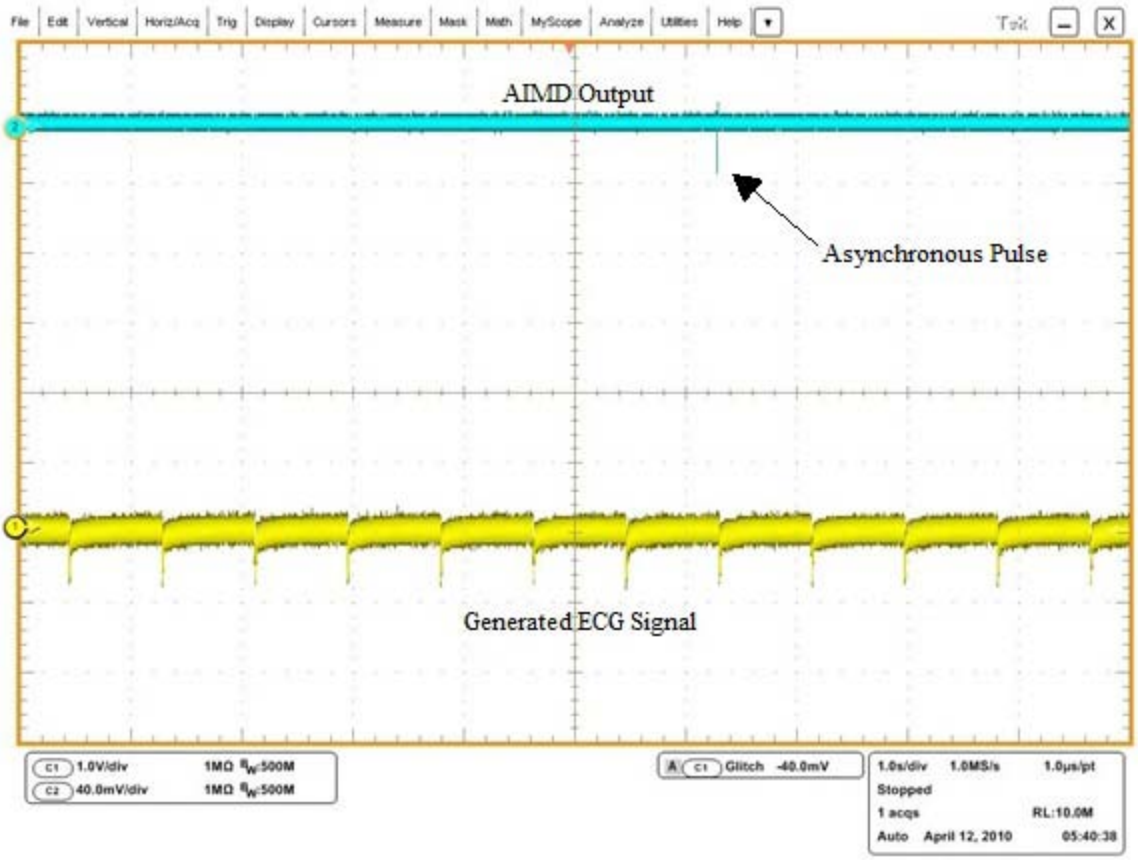


Figure 11. Example of Asynchronous pacing signal

5.0 IN VITRO MODELS

Studies investigating EMI in AIMDs fall in two general categories. The first category, in vivo studies, involves the testing of AIMD EMC on living AIMD patients [1]. One such investigation studied pacemaker reactions to cellular telephone signals by placing an active phone at the ear, as if talking, as well as directly over the pacemaker carried in a breast pocket [5]. The second category of EMI studies is in vitro. In vitro studies utilize human tissue equivalent models rather than live patients in order to study the interaction between AIMDs and EMF sources. This research considers only in vitro studies as they are more easily handled and yield more conservative results.

Three in vitro models of human tissue were utilized in the testing of AIMDs. The Hokkaido torso developed by researchers at Hokkaido University in Japan is an upright saline tank torso simulator [1]. The FDA torso is the second in vitro model considered here [2]. This model, used in EMC testing of AIMDs by the food and drug administration, is a horizontal saline tank torso simulator. The third in vitro model is an RC circuit built to model the EM dynamics of human tissue developed in ANSI/AAMI PC69 [3] as an American national standard for EMC testing of AIMD.

5.1 HOKKAIDO TORSO

The Hokkaido torso, shown in Figure 12, is a vertical saline tank torso simulator. The tank is filled with saline solution in order to approximate the electrical properties of the human body. The advantages of this torso simulator lie in its vertical orientation. Being upright, it is fairly thin and easily handled especially when using gate type RFID readers that have two antennas. Also, its slim design yields more conservative results than a typical horizontally oriented tank [1].

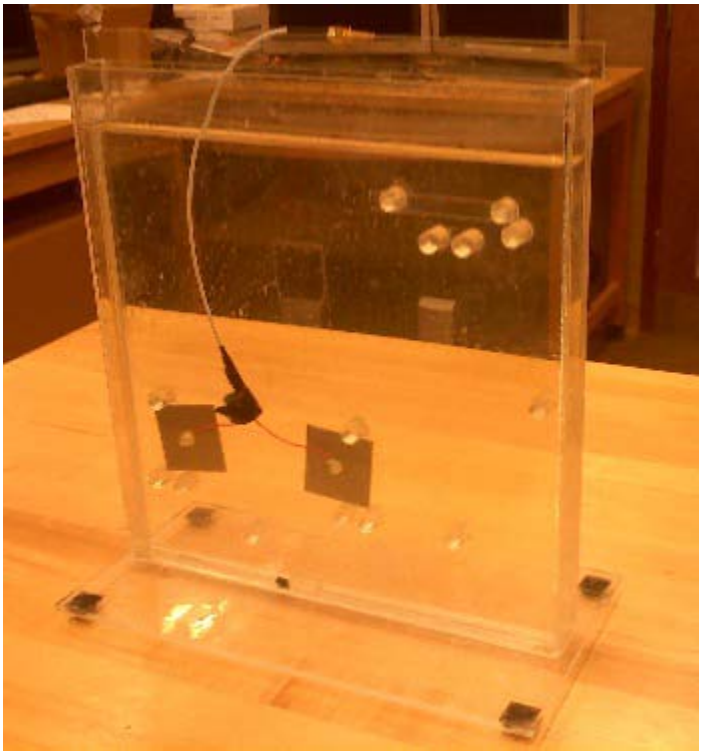


Figure 12. Hokkaido Torso Simulator

5.1.1 Construction

This tank was constructed using clear acrylic and measures 34cm X 36.2cm X 3.8cm. It has a clear acrylic insert slip to which cylindrical acrylic posts were attached in order to support the AIMD in the tank. This insert slip also facilitates easier AIMD insertion and removal from the tank. Two stainless steel electrodes are also supported by the insert slip and connected to an SMA cable in order to directly inject any external signals. The AIMD is placed in the upper right hand corner of the torso and the leads are fed around the acrylic support posts terminating at one of the two stainless steel electrodes which represent the positions of the atrium and ventricle of the heart. Figure 13 shows how the AIMD is inserted into the Hokkaido torso.

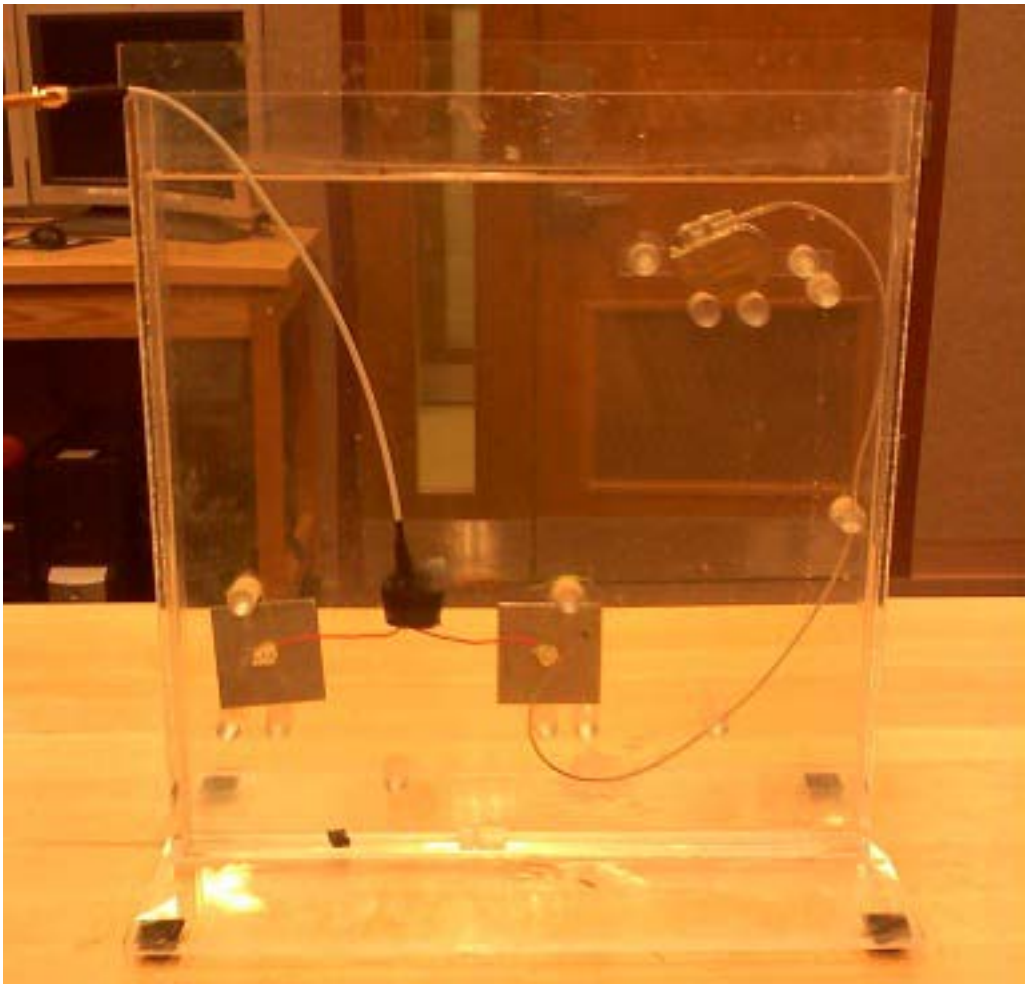


Figure 13. AIMD placed into Hokkaido Torso Simulator

5.1.2 Test Procedure

AIMDs placed in the Hokkaido torso are tested in two ways. First, the RF signal is introduced over-the-air. In over-the-air tests, the output of the RFID reader is passed through an antenna held parallel to the face of the torso simulator. Figure 14 shows a depiction of an over-the-air testing configuration. In the over-the-air test, the antenna of the RFID system is initially held at a distance of 1 meter from the torso simulator. The antenna is then brought increasingly closer to

the simulator while monitoring AIMD performance. When a change in AIMD performance is observed, the antenna is moved away from the torso simulator until baseline performance is again achieved. The distance at which this occurs is referred to as the maximum interference distance (MID) and is recorded along with device performance. The test is then repeated with the emitting antenna held at 45 and 90 degree angles to the front of the torso simulator. This constitutes one test. Any interference observed during the course of this test will be considered one incident of interference.

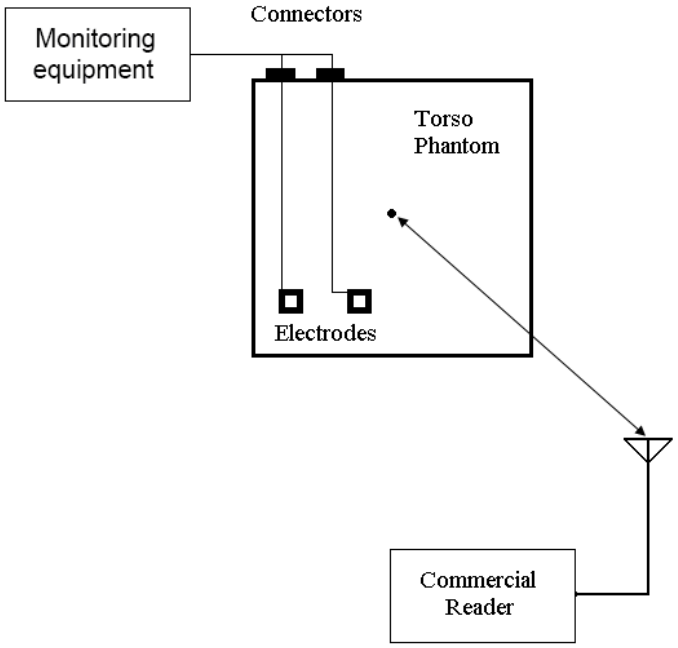


Figure 14. Over-the-air test setup with Hokkaido Torso Simulator

The second type of test with the Hokkaido torso is the direct injection test. In this testing configuration, the output of the RFID interrogator is directly connected to the SMA cable attached to the two stainless steel electrodes in the torso simulator. In this test, RF signals are injected and device response (interference/no interference) is recorded. Figure 15 is a depiction of the direct injection testing method.

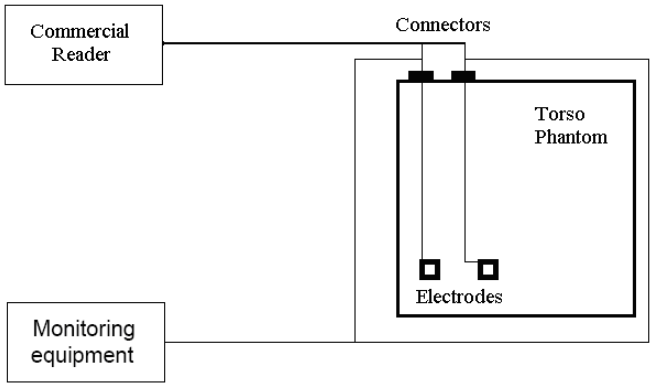


Figure 15. Direct Injection test setup with Hokkaido Torso Simulator

5.2 FDA TORSO

The second torso simulator is the FDA torso [2]. This torso simulator is a saline tank torso similar to the Hokkaido torso; although it has a horizontal orientation rather than vertical, simulating a patient lying down. This torso simulator does not have the advantage of being upright and easy to manipulate however, due to its depth, it makes it possible to record tests of EMI with the AIMD at varying depths in the saline solution. Figure 16 shows a depiction of the FDA torso.

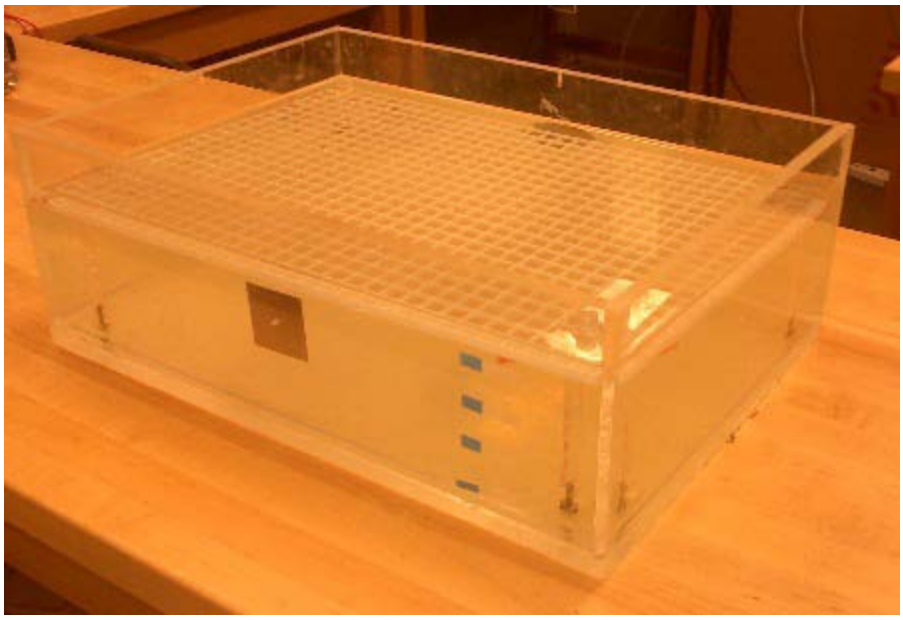


Figure 16. FDA Torso Simulator

5.2.1 Construction

This torso too is made of a clear acrylic. It measures 53.3cm X 38.1cm X 19.1cm. It contains a plastic grid supported by four acrylic posts in order to support the AIMD under test. The acrylic support posts have been drilled with holes each a quarter inch apart in which to insert plastic zip ties in order to hold the grid at varying levels within the saline solution. It also contains two stainless steel electrodes along the long sides of the tank. These electrodes are connected to an SMA cable in order to inject external signals. Figure 17 shows how the AIMD is placed in the FDA torso.

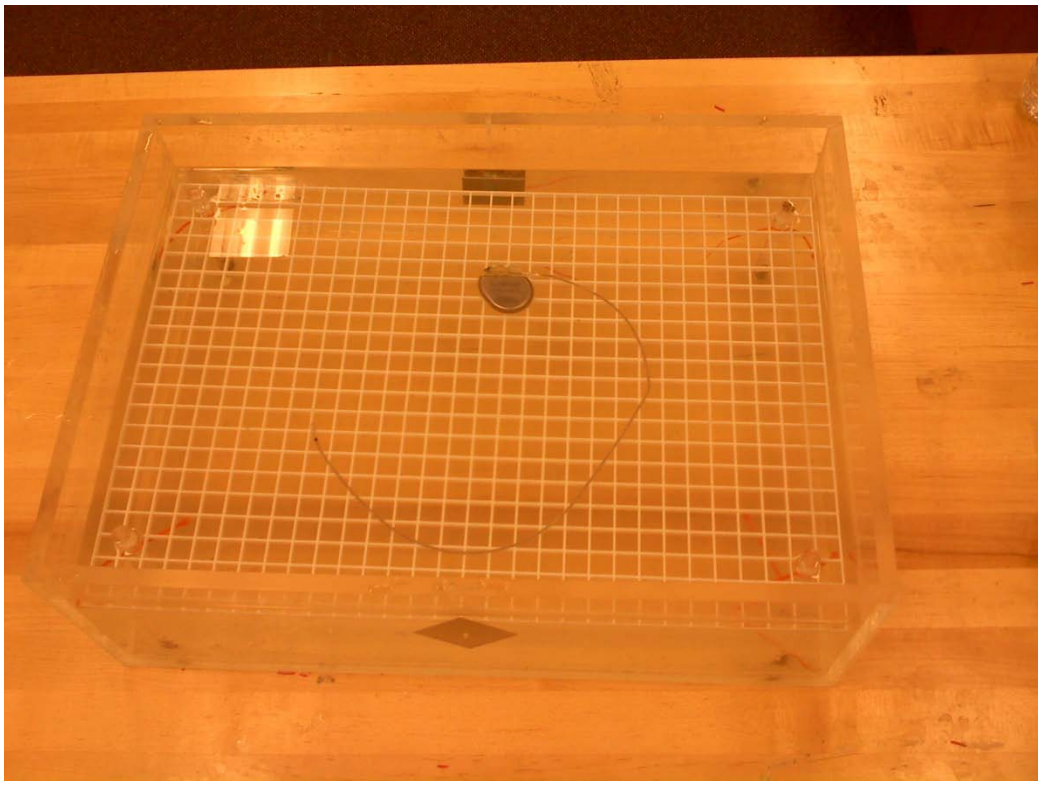


Figure 17. AIMD placement in FDA Torso

5.2.2 Test Procedure

Similar to the test procedure of the Hokkaido torso, the FDA torso is also tested for over-the-air and directly injected interference. In over-the-air tests, the antenna connected to the RFID interrogator is held directly above the testing surface. It is then lowered incrementally and device performance is monitored. Device performance as well as the MID is recorded. The plastic grid supporting the AIMD is then lowered and the test is repeated. The test is repeated at four different levels under the saline solution (1 – 4 inches). This constitutes a single test, and any interference observed in this test is counted as one incident of interference. Figure 18 shows a depiction of an over-the-air test configuration with the FDA torso.

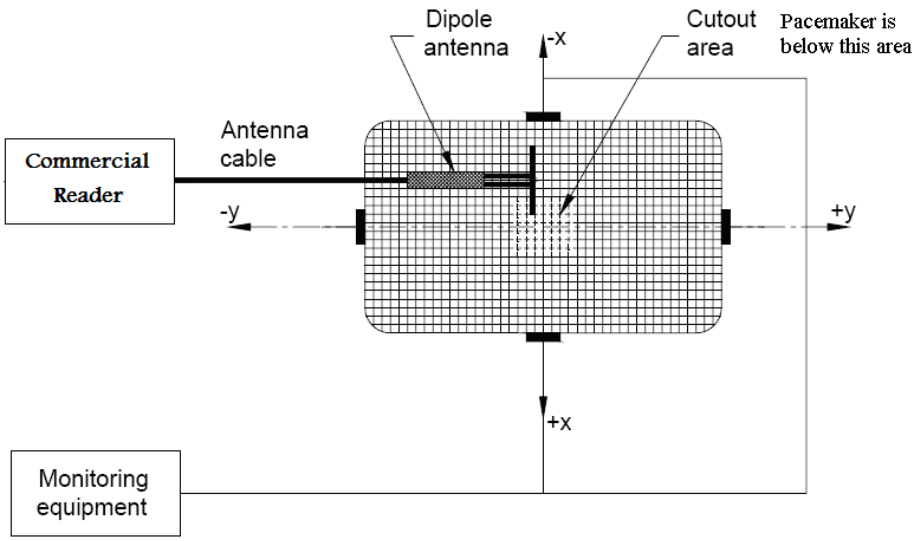


Figure 18. Over-the-air test setup for FDA torso

Direct injection tests are also performed on the FDA torso. In these tests, the output of the RFID interrogator is connected via an SMA cable to the two stainless steel electrodes mounted on the long sides of the FDA torso model. The RF signal is then introduced and device performance is monitored and recorded. Figure 19 shows a depiction of a direct injection test using the FDA torso simulator.

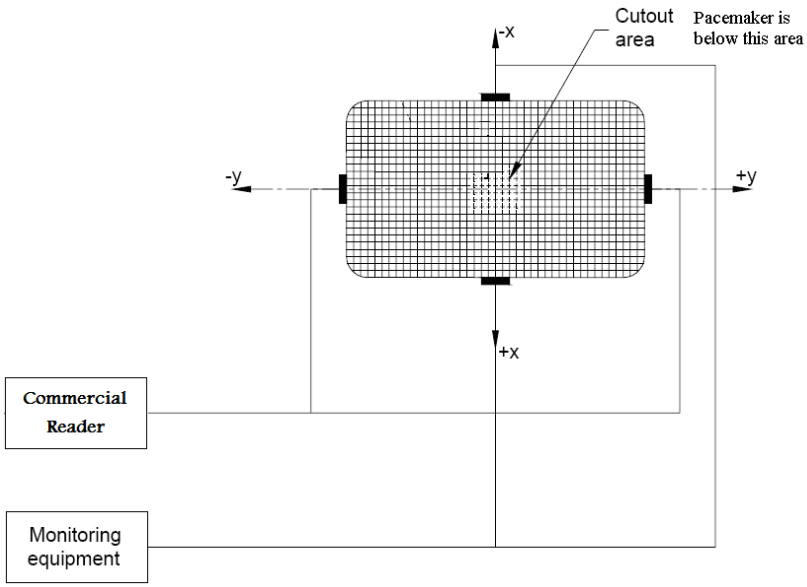


Figure 19. Direct Injection test setup for FDA torso

5.3 TISSUE INTERFACE CIRCUIT

The tissue interface circuit (TIC) is a tissue equivalent RC circuit designed to mimic the electrical properties of human tissue when RF signals are passed through [3]. A schematic of the TIC along with a depiction of the constructed circuit are shown in Figure 20. In this circuit, the AIMD terminal being tested is connected to the ports H and I while the metal housing of the AIMD is grounded to the J terminal. The advantages of the TIC include a small design and easy-to-reproduce test scenarios. However, the TIC does not leave any possibility for over-the-air interaction between AIMD and RFID interrogator. Instead, the RF signal is directly injected at the C terminal and sent through the TIC to the AIMD being tested at the J, I, and H terminals.

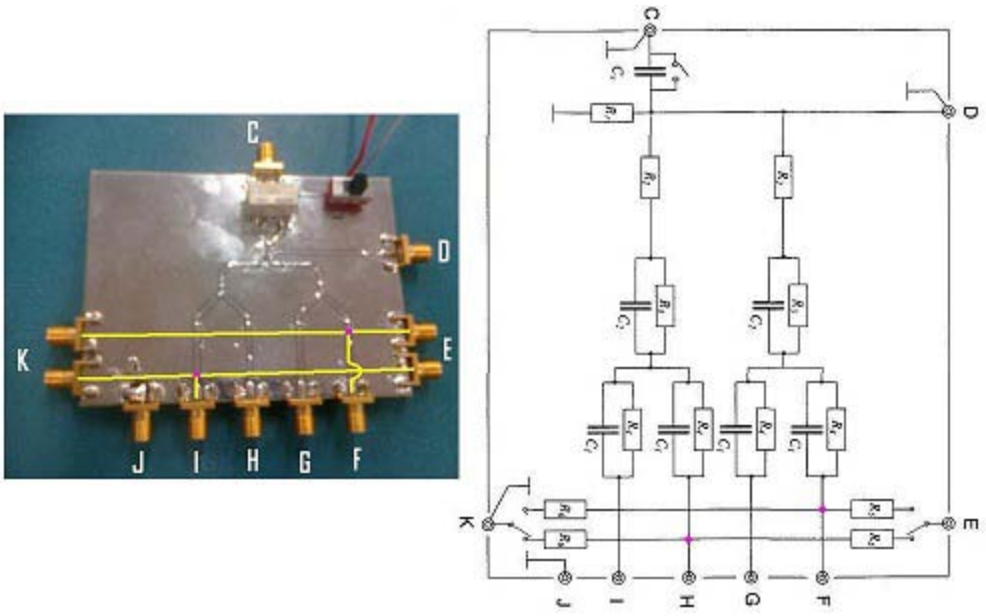


Figure 20. Picture and schematic of TIC

5.3.1 Construction

The TIC is an RC circuit fabricated on a printed circuit board utilizing coplanar waveguides. The incorporation of end-launch female SMA interfaces provides channels to inject the RF signal of interest, connect the AIMD being tested and to monitor system output. Table 3 contains the resistive and capacitive values for each circuit element detailed in the schematic above.

Table 3. TIC RC circuit element values

Circuit Element	Value
R1	68 Ω
R2	82 Ω
R3	120 Ω
R4	560 Ω
R5	56 kΩ
R6	1 MΩ
C1	15 nf
C2	180 pf
Cx	0.1 uf

5.3.2 Test Procedure

The TIC test setup is shown in Figure 21. For inhibition testing, ports D and K are connected to the oscilloscope to monitor system output. In testing for asynchronous pacing the generated ECG signal is injected on port K. The channel of the AIMD under test is connected to terminals H and I. The metal housing of the AIMD is connected to terminal J. Terminal E is grounded and terminals F and G are terminated with 50 Ω terminators. The RF signal from the RFID reader is then injected onto port C. Once all these connections have been made, the RF signal is passed through the TIC and device performance is monitored on the oscilloscope.

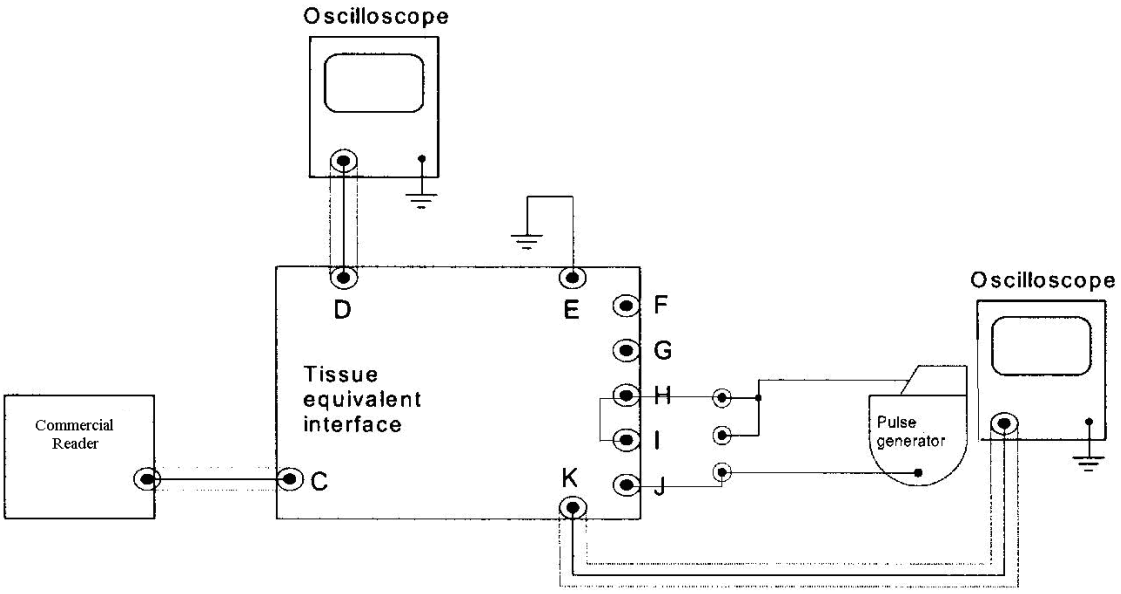


Figure 21. TIC test setup

6.0 SUMMARY OF EXPERIMENTS

Each AIMD was tested for inhibition and asynchronous pacing in each in vitro model. When testing for inhibition, the device under test (DUT) is placed in the in vitro model being used without incorporating a simulated heart beat signal. When testing for asynchronous pacing however, a simulated heart signal was injected into the in vitro model in order to inhibit pacing. The DUT output was monitored before the introduction of the RF signal in order to determine a baseline performance. The RF signal from the interrogator being tested would then be introduced and the test would be conducted according to the guidelines for the in vitro model being used as discussed in the previous section. Device performance to the test is recorded. Then the RF signal was removed, and the DUT output was again monitored for a return to baseline performance. In the case that the DUT is a dual chamber device each channel would be tested independently.

6.1 ARTIFICIAL ECG SIGNAL GENERATION

In order to simulate a heartbeat, a Hewlett Packard 33120A Arbitrary Waveform Generator was used to produce a signal with a frequency slightly higher than the pacing frequency of the DUT. The signal was injected into the in vitro model being tested according to the guidelines for that model discussed in section 5. The purpose of this artificial ECG signal was to inhibit the output

of the AIMD by making it sense a “normal” heart rhythm. In this case, interference is characterized as the inappropriate discharge of a pacing signal. Figure 22 shows the baseline performance of an AIMD with an injected ECG signal.

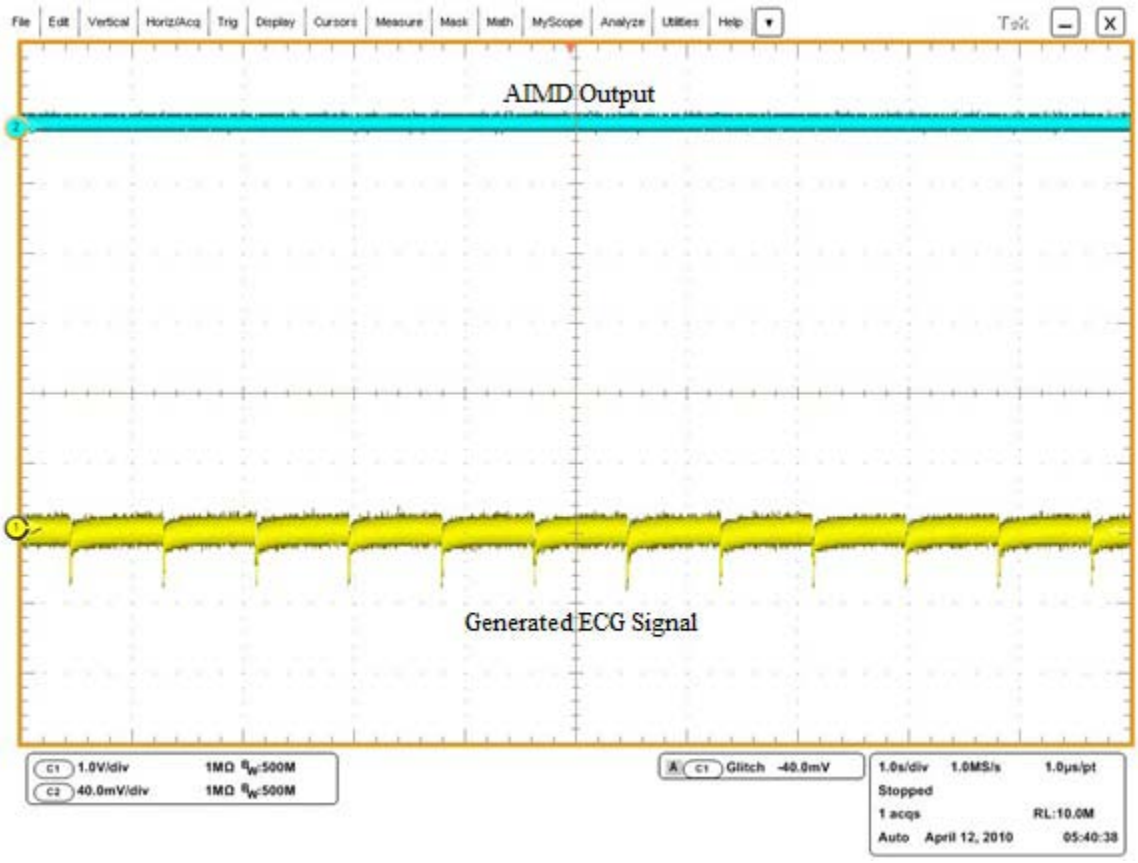


Figure 22. Baseline performance for Asynchronous tests

6.2 GENERAL TEST CONFIGURATION

In general, the testing setup consisted of the DUT, the in vitro model being tested, the RFID interrogator and antenna, an oscilloscope to monitor the DUT output, a signal generator to inject

an artificial ECG signal (if testing for asynchronous pacing), and a computer (if needed to run commercial RFID reader). Figure 23, Figure 24, and Figure 25 show the general test setup for each in vitro model. The channel of the AIMD being tested (either atrial or ventricular) was probed and monitored on the oscilloscope through the use of a BNC cable. The RF signal is then transmitted through an antenna to the in vitro model or directly injected through an SMA cable.

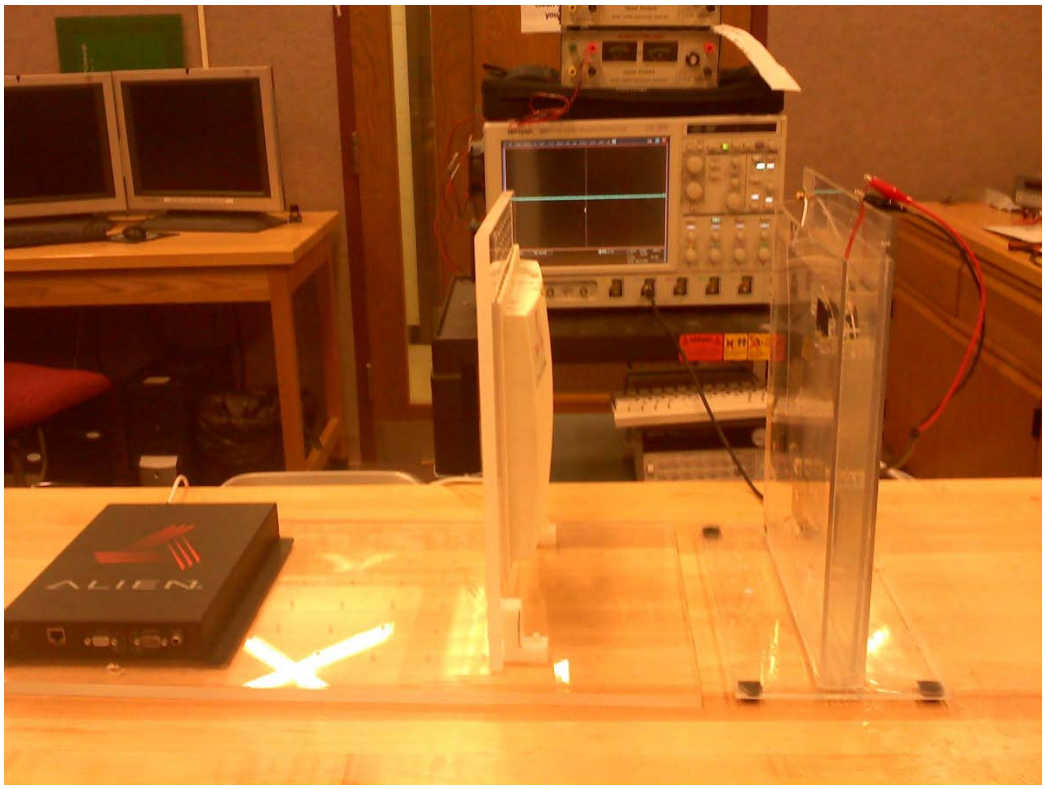


Figure 23. Example test setup for Hokkaido torso

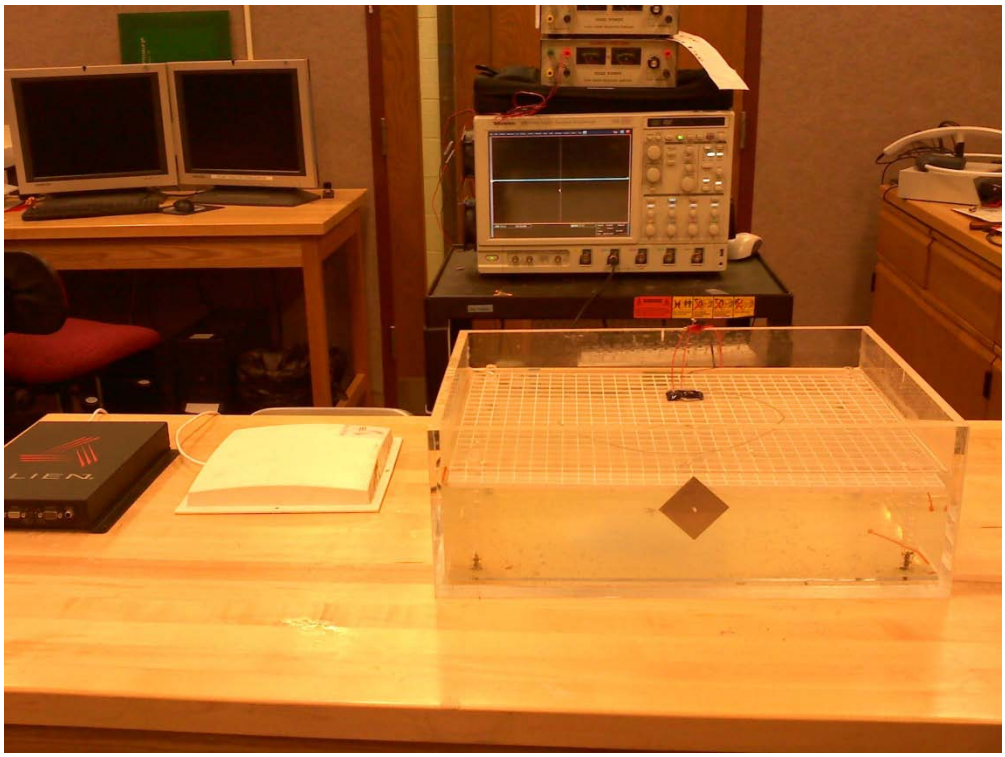


Figure 24. Example test setup for FDA torso

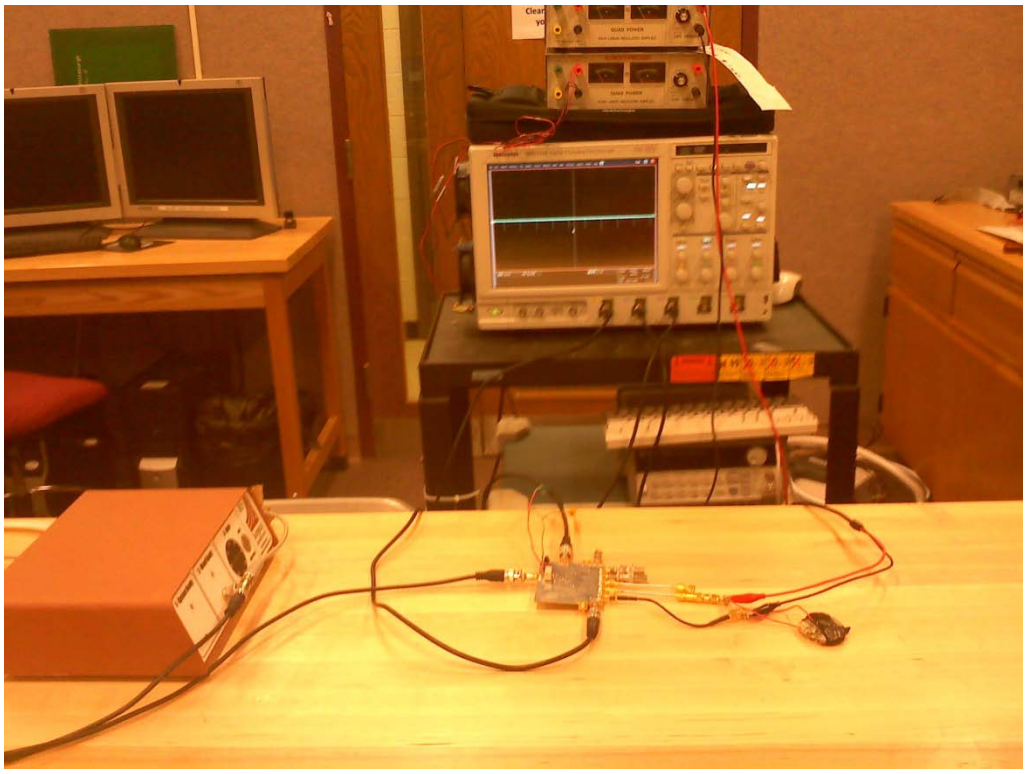


Figure 25. Test setup for Tissue Interface Circuit

7.0 RESULTS

A total of 887 tests were performed on six different AIMDs, four pacemakers and two ICDs. The overall incidence of interference was 6.99%. The incidence of interference in pacemakers was slightly higher, at 9.68%, than that in ICDs at 5.76%. Additionally, consistent with other findings, AIMD EMI immunity against HF signals was found to be significantly greater than that of LF signals with 3% and 23.7% incidence of EMI respectively. No occurrences of interference were recorded while testing with UHF readers. These results are detailed in Figure 26, Figure 27, and Figure 28.

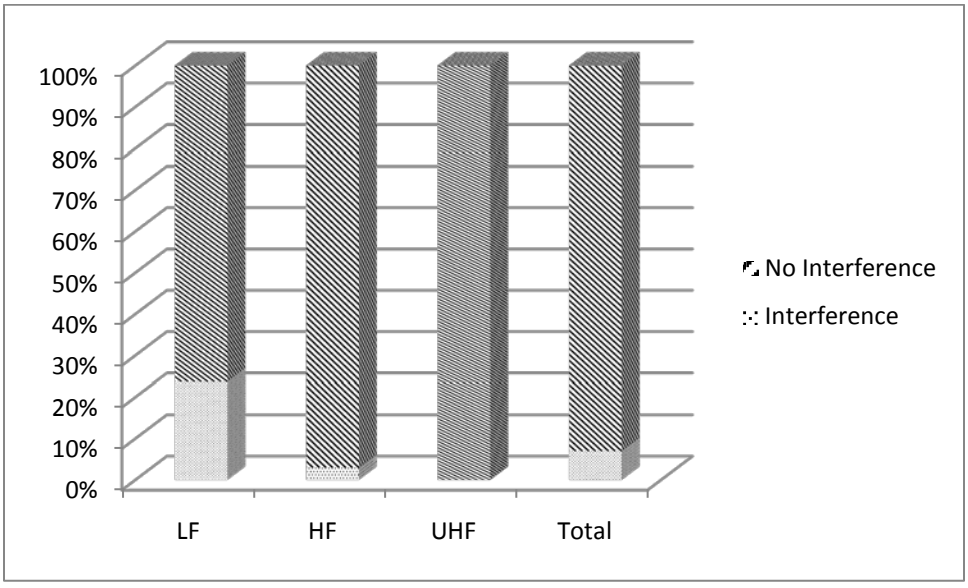


Figure 26. Overall Test Results

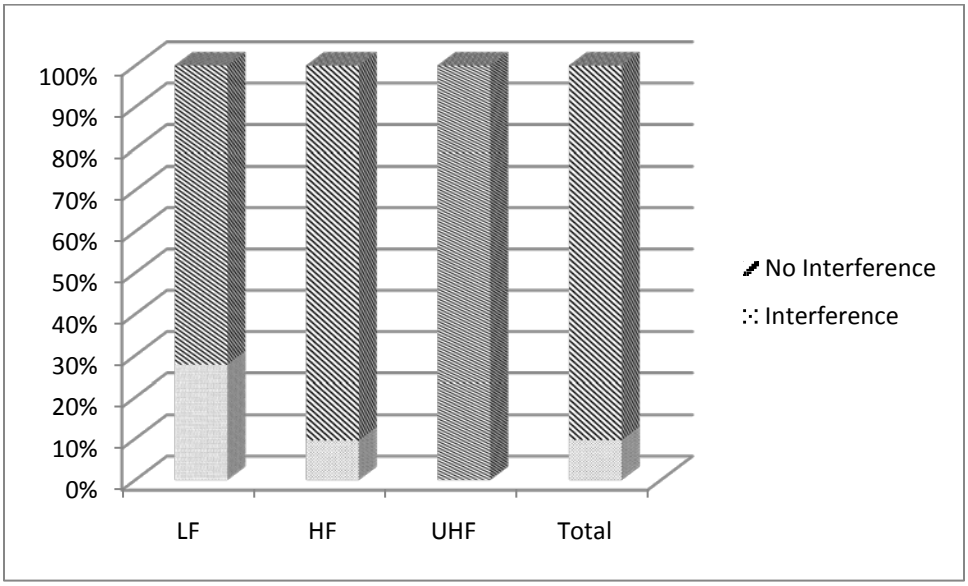


Figure 27. Overall test results for pacemakers

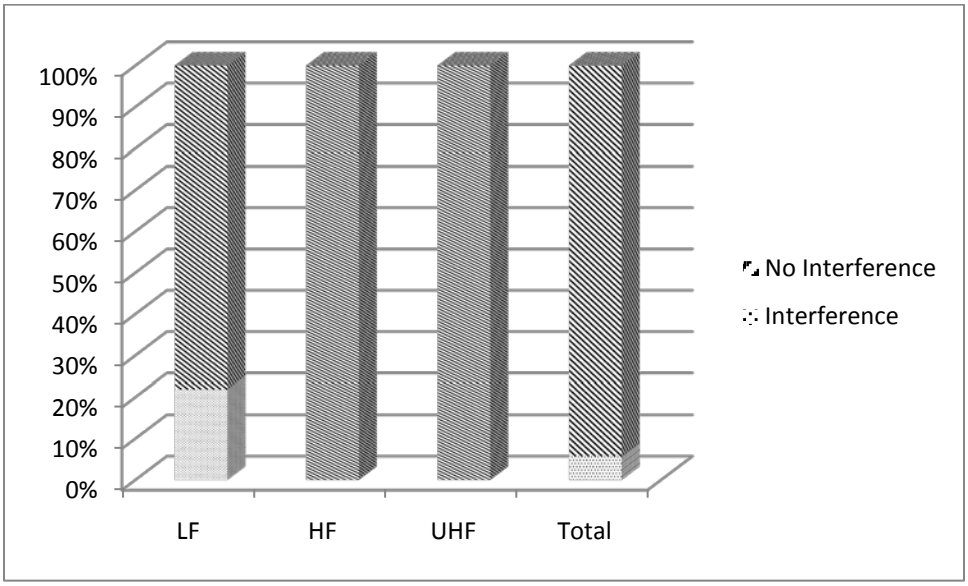


Figure 28. Overall test results for ICDs

7.1 HOKKAIDO TORSO

With the Hokkaido tank torso simulator, the overall incidence of interference was 8.85%. Pacemaker testing resulted in a 9.23% occurrence of EMI while 8.68% of ICDs were affected. These results can be seen in Figure 29, Figure 30, and Figure 31 respectively. Additionally, one of the goals of testing with the Hokkaido torso was to determine the maximum interference distance (MID) of the various AIMDs tested. The highest MID recorded was 33cm, the smallest was 2cm, and the average MID was 12cm. This data can be found in Figure 32.

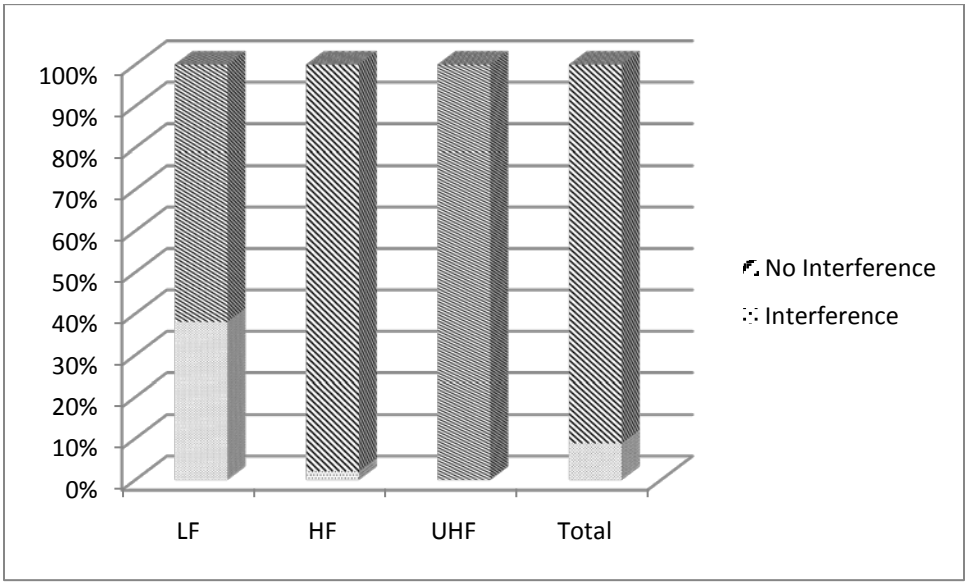


Figure 29. Overall test results for Hokkaido Torso

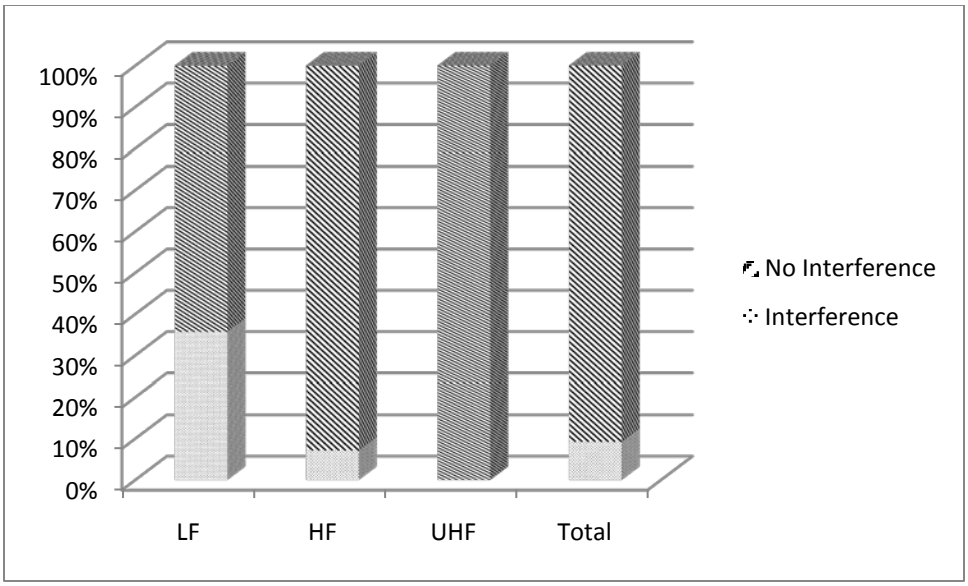


Figure 30. Test results for pacemakers in Hokkaido Torso

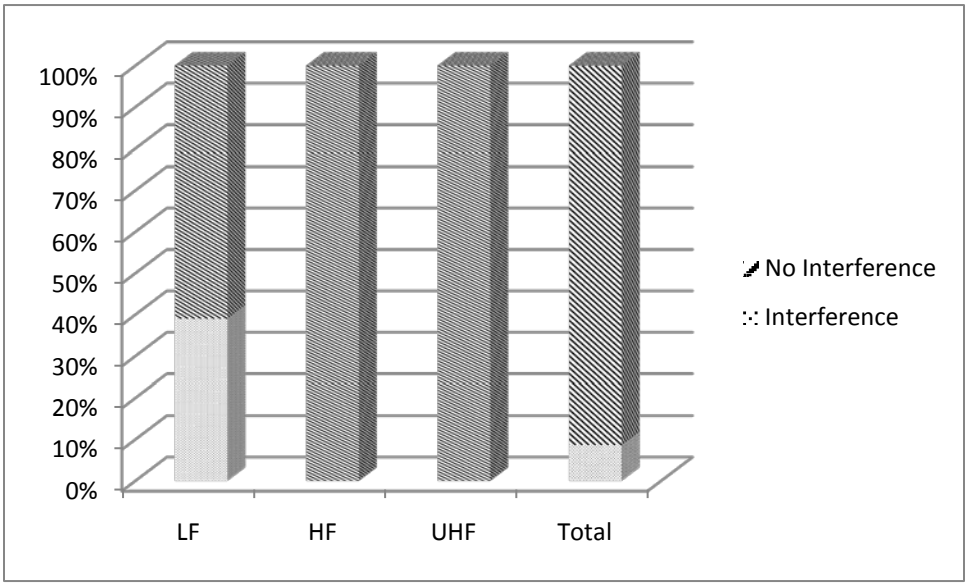


Figure 31. Test results for ICDs in Hokkaido Torso

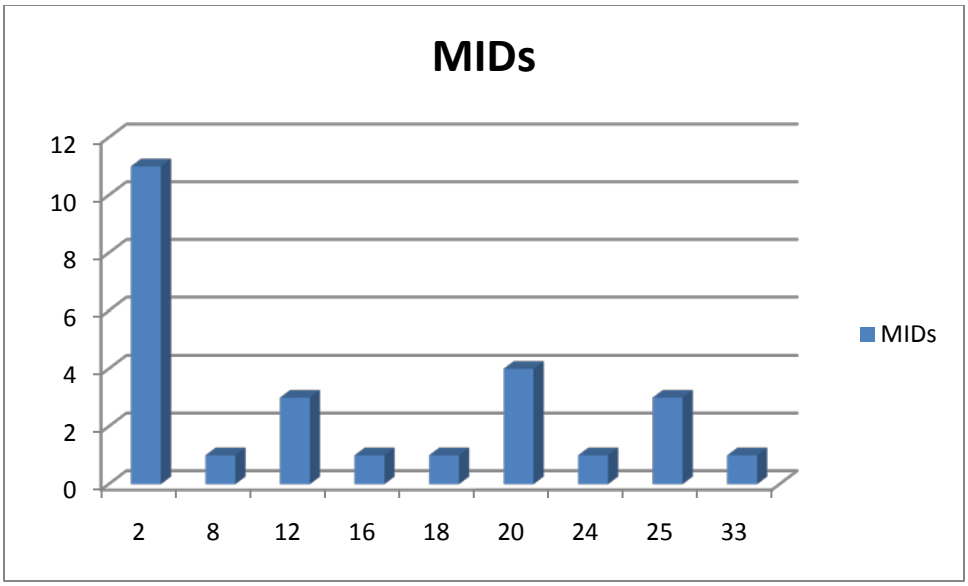


Figure 32. MID estimation results for Hokkaido torso

7.2 FDA TORSO

Tests conducted with the FDA torso simulator resulted in a lower incidence of interference than those conducted with the Hokkaido torso. The overall incidence of interference was 6.4% with pacemakers and ICDs experiencing EMI occurrences in 10.58% and 4.46% of the tests respectively. FDA torso test results are shown in Figure 33, Figure 34, and Figure 35.

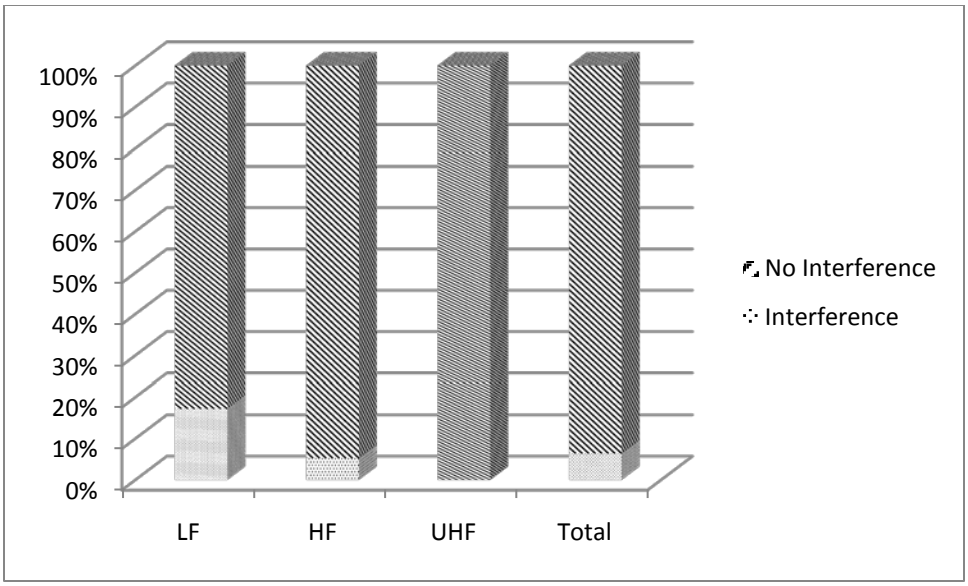


Figure 33. Overall test results for FDA Torso

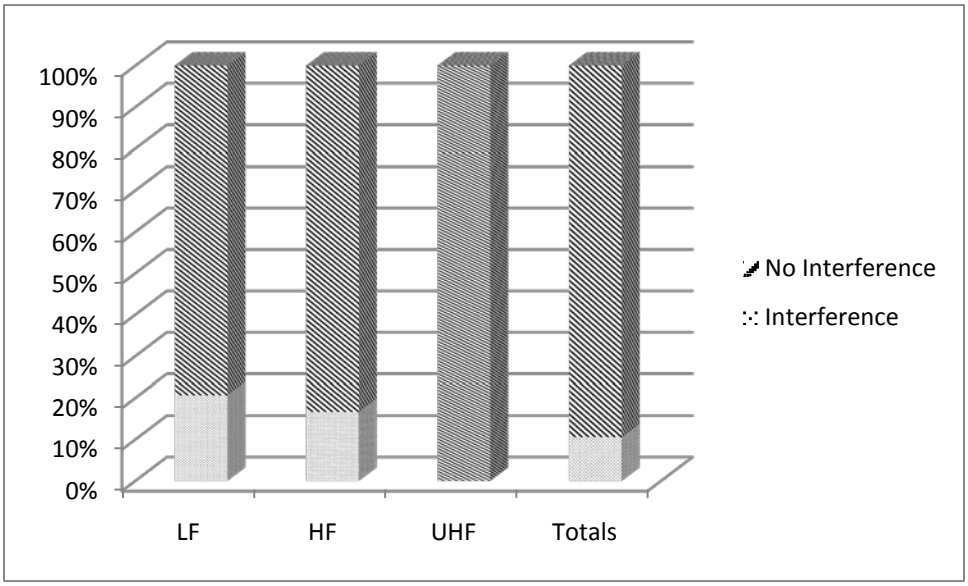


Figure 34. Test results for pacemakers in FDA torso

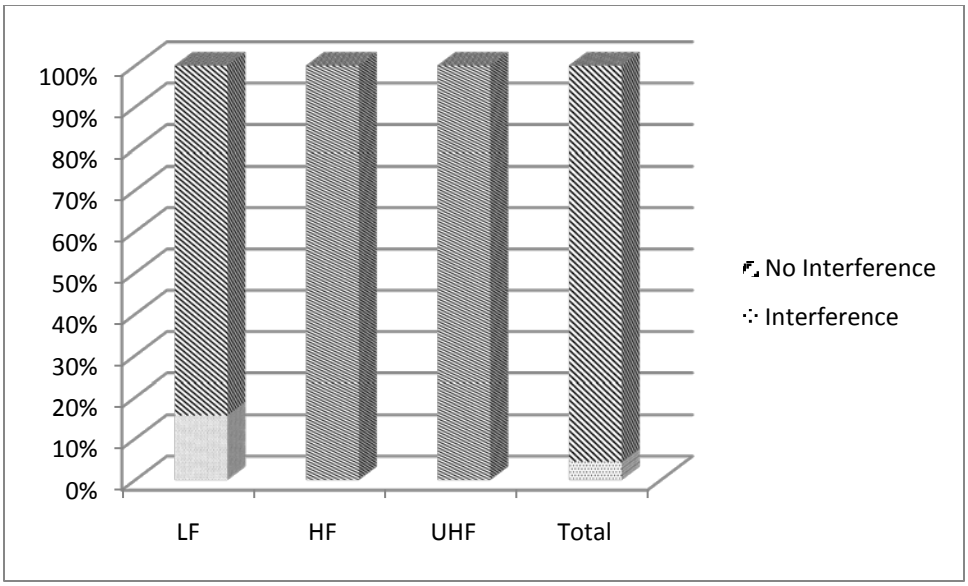


Figure 35. Test results for ICDs in FDA torso

7.3 TISSUE INTERFACE CIRCUIT

Overall incidence of interference observed while using the TIC was 2.84%. Pacemaker EMI occurrence was found to be 8.89% while no EMI interactions were observed with ICDs. These results are detailed in Figure 36, and Figure 37.

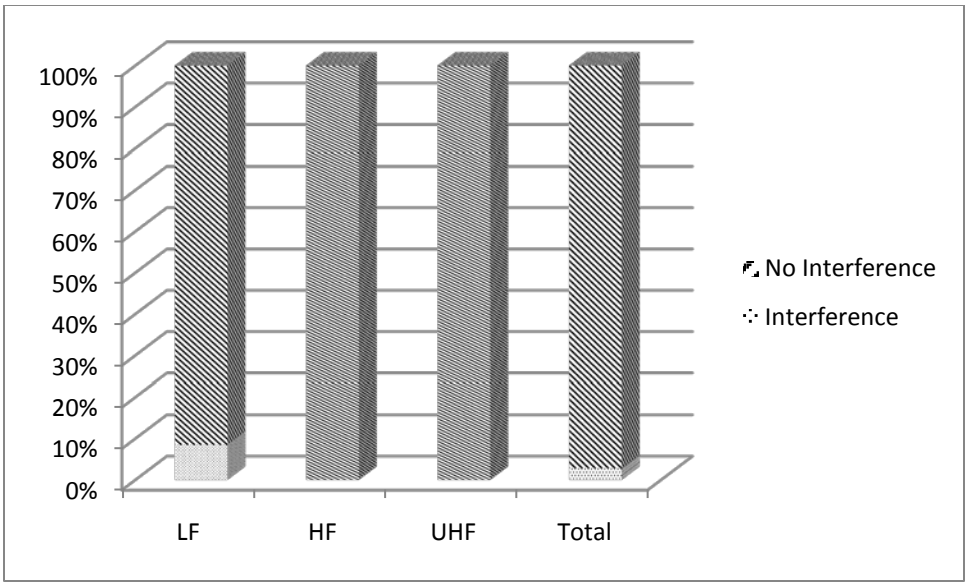


Figure 36. Overall test results for TIC tests

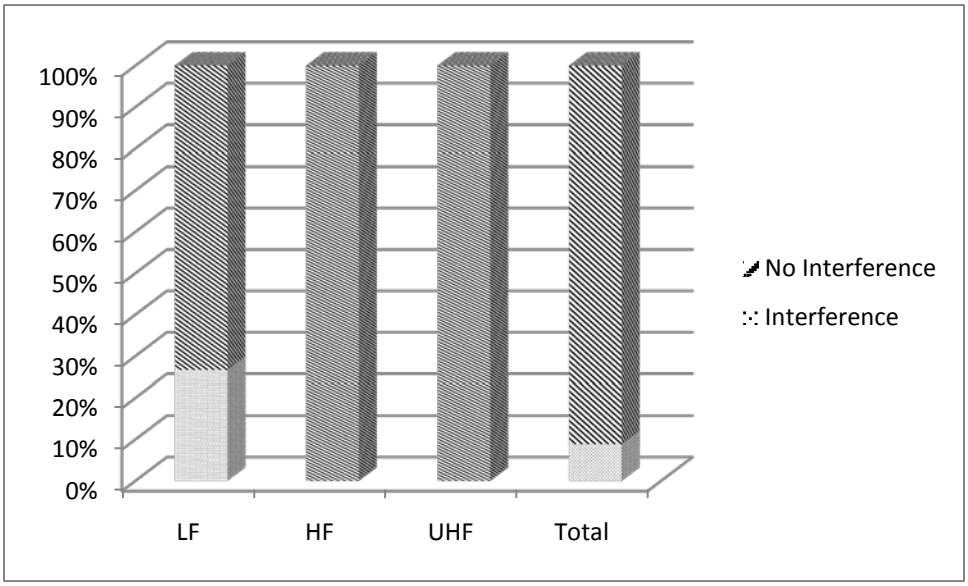


Figure 37. Pacemaker test results for TIC test

7.4 SENSING MODES

The literature suggests sensing mode (unipolar or bipolar) has an effect on the rate of EMI occurrences. Specifically, unipolar pacing configurations have been shown to be more susceptible to EMI than bipolar configurations. The data collected in this research corroborates these findings with unipolar configurations experiencing EMI in 12.68% of the test cases while bipolar configurations resulted in EMI 10.53% of the time. These results can be seen in Figure 38.

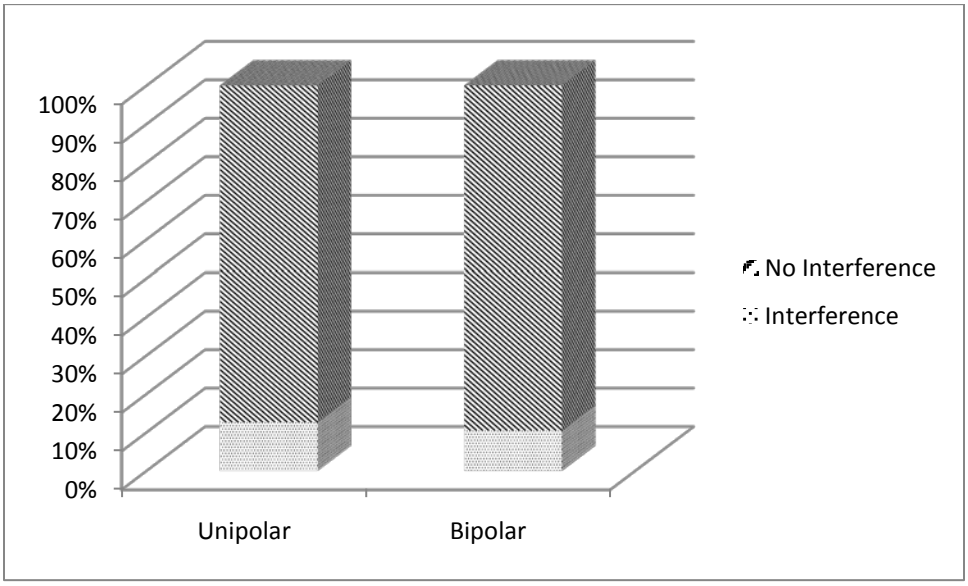


Figure 38. Test results for Unipolar mode vs. Bipolar mode

8.0 MITIGATION

In general, the default mitigation method most commonly used is a set of proximity guidelines [1]. Many devices that emit RF signals have warning labels affixed to them warning AIMD patients to keep their distance from these devices due to their capacity to interfere with their devices.

Other proposed mitigation methods focus on modulated RF fields because it has been shown that unmodulated, continuous wave fields have a much lower incidence of interference [1][11]. One study proposed (not tested) that moving the pulse repetition rate (PRR) outside of the range of a physiological frequency might cause the AIMD filters to filter out this noise [2]. Another proposed mitigation method is a radio filler method in which the gaps in the carrier wave would be filled by a signal of the same amplitude and frequency [1]. This method has been shown to be promising in the mitigation of EMI; however, it does have limitations. First, in the United States it is illegal to transmit on a single frequency indefinitely, a problem which frequency hopping or on-off keying modulation would solve. Also, it is unclear whether the radio filler technique will cause errors in tag readings.

The mitigation method proposed here does not seek to approximate a continuous wave from a modulated wave. Instead, this method seeks to reduce the voltage induced in the AIMD by the alternating magnetic fields of the RFID interrogator. As is shown by Faraday's law of induction, equation 4.1, the induced voltage, V_i, is directly proportional to the time rate of change

of the magnetic flux density perpendicular to the “one turn coil” made by the pacing lead system and the human body. The proposed method, rather than using on-off keying modulation, utilizes a ramping amplitude for the carrier wave bursts. Figure 39 and Figure 40 show on-off keying modulation and the proposed ramped amplitude modulation technique. By ramping the amplitude of the carrier wave burst, the time rate of change of the magnetic flux density seen at the edges of the carrier wave bursts is effectively decreased, which should lead to a decrease in induced voltage in the AIMD.

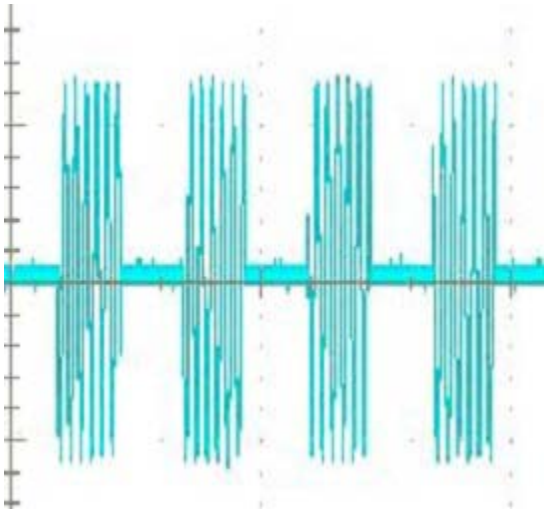


Figure 39. Waveform utilizing on-off keying modulation

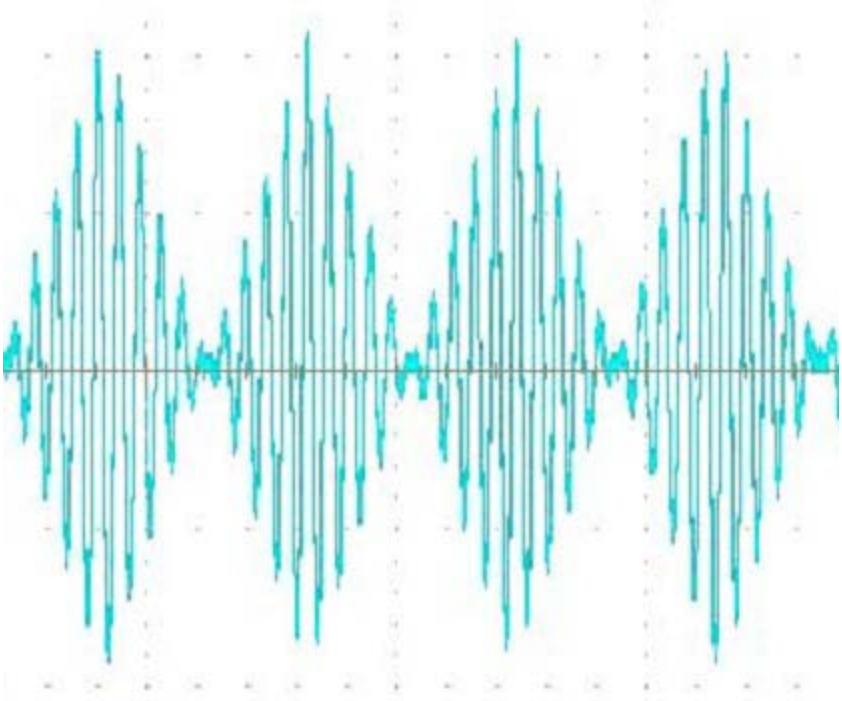


Figure 40. Waveform showing ramping amplitude mitigation technique

8.1 EXPERIMENTATION

In order to test the ramped amplitude modulation technique, a National Instruments PXI-1044 signal generator is used. Labview 8.2 software is utilized in generating the ramped amplitude signal from the signal generator as well as an on-off keying modulation signal. Both signals had a frequency of 13.56 MHz (HF), a maximum power of 40 dBm and were output through an antenna. For this experiment, the DUT was placed in the Hokkaido torso for testing due to the fact that it is the in vitro model that yields the most conservative results (most likely to allow interference). The DUT was then tested for interference caused by both RF signals over-the-air and directly injected following the procedures in section 5.1.2.

In testing of the DUT using the on-off keying modulation, the length of the burst was held constant at 250ms while the off time between pulses was varied between 10 and 250ms. In testing the DUT using the ramped amplitude modulation technique, the off-time was also varied between 10 and 250ms. The ramp time was varied from 125 to 500ms for each rising and falling ramp in order to ensure the same amount of power over the period was reaching the DUT as with the on-off keying method.

8.2 RESULTS

Two pacemakers and one ICD were tested. Initial results are promising and are shown in Figure 41. For the purposes of this experiment, the definition of interference was split into two categories of clinical significance as defined by Hayes et al [5]. Type 1 interference is any inhibition lasting three seconds or more and is definitely clinically significant. Type 2 interference is any interference that persists less than three seconds and is less likely than type 1 to be clinically significant. In the case of the on-off keying method, type 1 interference was seen in 83.33% of the cases, no type 2 interference was observed. The average MID observed in over-the-air testing of the on-off keying method was 21.05cm. By contrast, the ramped amplitude method resulted in type 1 interference in 14.58% of the test cases, and type 2 interference accounted for 23.61% of the cases, for an overall incidence of interference of 38.19%. The average MID observed in these tests were significantly shorter at 4.37cm, resulting in an average MID reduction of 79.24%, normalized over AIMD manufacturer. MID results can be seen in Table 4.

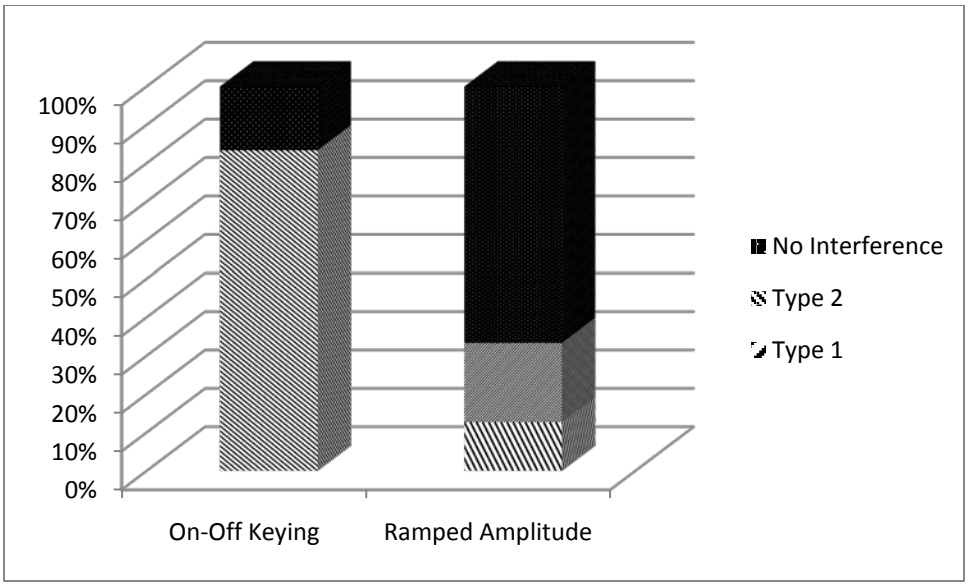


Figure 41. Mitigation experimental results

Table 4. MID results for mitigation experiments

	Average MID (cm)		
AIMD	**On-off keying**	**Ramped Amplitude**	**Percent Reduction**
St. Jude pacemaker	10.15	No Interference	100
Boston Scientific pacemaker	31.7	9.12	71.23028391
Medtronic ICD	21.3	3.99	81.26760563
Totals	26.5	6.555	75.26415094

9.0 CONTRIBUTIONS

In this thesis, a general testing framework for EMC testing of AIMDs exposed to electromagnetic fields produced by RFID interrogators is proposed and evaluated. Additionally, a novel EMI mitigation technique, modifying on-off keying modulation methods commonly used in RFID interrogator systems is evaluated.

If current trends continue as expected, over the next few years the number of patients requiring some form of cardiac pacing as well as the proliferation of RFID technology into everyday life will increase sharply [18]. In light of these upward escalating trends, the need for electromagnetic compatibility testing, as well as reliable EMI mitigation techniques, will also rise considerably in order to ensure safe environments for millions of people. The research presented here offers a robust and reliable testing framework through which EMC testing of AIMDs and RFID interrogators can be accomplished. This testing was realized through the use of multiple different *in vitro* models of the human torso into which an AIMD would be implanted. The use of multiple torso simulators provides a more complete assessment of the EM interaction between AIMDs and RFID interrogators.

Additionally, this thesis proposes a novel EMI mitigation technique aimed at reducing the magnitude of the voltage induced in the AIMD lead system caused by alternating magnetic fields emitted by RFID interrogators. This method is based on ramping the amplitude of modulated carrier wave signals so as to reduce the time rate of change of the magnetic flux density in the

EMF. Initial test results indicate this technique is a significant improvement over standard on-off keying modulation techniques commonly used in RFID systems in the mitigation of EMI caused in AIMDs.

9.1 LIMITATIONS

There are a few limitations to this research. First, only the pacing functions of the ICDs were tested. The defibrillation functions were not considered. Also, minimal testing of the proposed mitigation technique was performed as an introduction. Not every AIMD tested was converted from unipolar to bipolar pacing modes. In order to obtain more reliable results concerning the different rates of EMI occurring in each sensing mode, all AIMDs should be tested in both modes.

9.2 FUTURE WORK

Possible areas for future work include testing the proposed mitigation method more thoroughly. This could include testing more AIMD models, testing the AIMDs in the FDA torso and TIC, and testing the mitigation method using other carrier wave frequencies such as LF and UHF frequencies. The defibrillation and antitachycardia functions of the ICDs should be evaluated for EMI in order to more fully characterize their EMC with RFID readers.

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