The Impact of the Internet of Things on Implanted Medical Devices including Pacemakers, and ICDs

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***Abstract*— The Internet of Things describes multiple distributed systems where all (or most) everyday items include embedded systems in order to connect to the internet. This paradigm has the potential to revolutionize global industry and daily life. Healthcare is once such industry where the Internet of Things may provide great advantages to patients, care givers, and medical institutions. As the number of radio frequency emitters increases under this new paradigm public health and safety must also be taken into account. This paper explores the electromagnetic interference on implantable cardiac rhythm management devices caused by RFID interrogators. A standard electromagnetic compatibility test framework is proposed in order to diagnose the possibility of interference. Also, a mitigation method is proposed and tested. It is shown that the proposed method can reduce the incidence of clinically significant interference by nearly 60%.**

Keywords—Pacemaker; Defibrillator; RFID; electromagnetic interference

I. INTRODUCTION

A. Background

The Internet of Things (IoT) is a ubiquitous application of radio frequency (RF) technology which will affect all individuals around the world in a direct manner [1]. Currently, Radio Frequency Identification (RFID) and Near Field Communication (NFC) are two embodiments representing what IoT is all about [1], [2].

In one scenario, every item sold commercially will contain an RFID tag. Based on the major suppliers of commodities and items to WalMart and other super stores, this will mean one trillion (10^{12}) items/tags per year. In the 48 contiguous United States, there are 7.6+ million square kilometers of land. This is 7.6+ x 10^{12} square meters, which gives an RFID tag for every 7.6 square meters. Roughly speaking, accounting for roads, vacant land and apartment buildings, this is at least one tag per room per year. Thus, in a few years, we could expect at least several tags per room.

B. The Critical Health Care Issue

As the tags begin to communicate with each other, the IoT scenario implies there will be at least one reader per room. This is where the situation becomes problematic. While we can expect some RFID or NFC reader activity within a room, the public spaces of buildings will be more a more dense reader environment. It is known that RFID and NFC readers can be a problem when operated in the near vicinity of persons with pacemakers and implantable cardioverter-defibrillators (ICDs). While NFC devices typically require a shorter read range, they operate at a frequency that typically causes more problems with implanted cardiac rhythmic management devices (CRMDs) [2], [3].

In public spaces for non-secure information gathering, one can expect the rate at which reading can be done must increase. This presents a drawback as the primary issue causing problems with CRMDs is the rate at which the power is turned on as the reader performs its interrogation.

II. THE INTERNET OF THINGS

Healthcare is likely the most complicated and life critical area of the IoT [4]. The things include the traditional items that can be found in any company or organization, such as personnel tracking or electronic article surveillance systems. Some of the things have short lives such as smart sponges in operating rooms and others live for years as in implantables such as pacemakers, which have lifetimes of a decade or more.

Things may be passively connected to the internet where existence, location and condition are important, which are essentially the same as in other areas [5]. The more interesting applications revolve about those things which are both active and interactive. These devices may be implanted or wearable. The ability to collect longitudinal data has opened new opportunities for healthcare which reinforces the usage of more internet connected devices.

Current medical developments have essentially moved the patient monitoring devices typically found in a critical care room such as EKG, pulse oximeter, blood pressure, temperature, etc., into a discharged patient's home, with the

nurses' station being a computing device connected to a broadband communication link. The primary limiting factor is the cost of this collection of devices.

Current research and development is now reducing the cost of each of these elements thus lowering overall cost while requiring the same bandwidth, although the connection may go from wired broadband to wireless Wi-Fi or broadband [5]. Decreasing the cost thus increases the bandwidth requirements due to more extensive usage. More recent research involves implanting the devices directly into the body which eventually will lead to multiple connected devices within the body.

As wireless connectivity has gone from facilities in a critical care hospital, to the home of a recently discharged patient, and ultimately to the body of the individual, the primary connectivity device has gone from the nurses' station, to a personal computer, to a server located within the body. Multiple server concepts are being developed including commercial body area networks to facilitate this transition.

The understanding of the structure of this type of internet, where readers/servers are mobile while maintaining a cloud structure for the ultimate data repository, is the basis for research in degrees of connectivity. This structure is one of things within things.

The data gathering in these medical systems is related to the problem of sampled data systems and digital control of electrical engineering where data must be consistently sampled with fixed intervals with very tight time deviations. Such conditions are not currently possible with the connectivity mechanisms of the current internet of things, leading to new research topics.

The interesting uniqueness of the thing in the healthcare environment includes an identification number (MAC Address), a local database, a position with dynamics in three dimensions and a "pulse" (biomarkers or vital signs). For the more general things, there has been identification of high end (implants of all types) and low end surgical sponges whose detection is much more valuable than the intrinsic value of the thing itself.

III. Interference of RFID Devices on CRMDs

A number of studies have been conducted investigating electromagnetic interference (EMI) on CRMD systems. Many have explored the EMI caused by cellular telephones [6]-[8]. According to the findings in these studies, sophisticated filtering techniques have all but eliminated the risk of EMI due to cellular telephones in modern CRMDs. Other studies have implicated various medical procedures such as electrocautery and magnetic resonance imaging as being possible sources of EMI [9]-[11]. These procedures have the capacity to cause clinically significant interference and should be avoided by the CRMD patient. A number of studies have also indicated RFID as a possible source of clinically significant interference [12]-[15]. The upward trend that is expected in RF emitters due technologies such as the IoT highlights the necessity of comprehensive EMI testing involving RFID interrogators and CRMDs. The sections that follow describe our effort to provide such a testing methodology.

A. Methodology

When conducting EMI testing on CRMDs, it is necessary to either simulate real-world conditions where a patient with an implanted CRMD comes into close proximity with an RF emitter. This can be achieved by conducting in-vivo experiments where a pacemaker patient agrees to subject their pacemaker to various RF sources. While this approach may more closely approximate real world scenarios, it would be more costly, time consuming, and possibly hazardous to the patient's health [3]. The in-vitro approach, taken here, has the advantages of being much more flexible in terms of the number and types of CRMDs that can be tested, as well as being standardizable. Three in-vitro human tissue simulators were utilized in this testing. The first simulator, developed at Hokkaido University [12], is an upright saline tank in which the CRMD can be placed. The Hokkaido torso, shown in Figure 1, is made of a clear acrylic and measures 360x340x25mm. The concentration of saline solution, 1.8 g/l NaCl, was chosen to closely match the electrical properties of the human body when exposed to RF radiation.

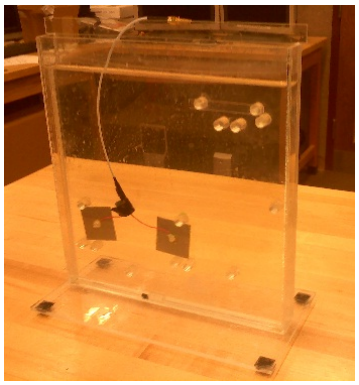

Figure 1 - Hokkaido Torso Simulator

The second tissue simulator, developed by the FDA [3], is also a clear acrylic, saline tank. This torso simulator, however, is oriented in the horizontal direction and measures 585x425x152mm. Shown in Figure 2, the FDA torso contains a plastic grid on which the device under test (DUT) rests. The height of the grid within the saline is adjustable in order to simulate different tissue depths.

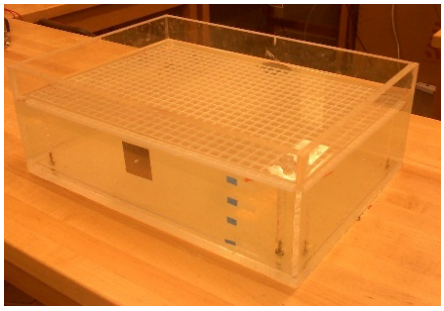

Figure 2 - FDA Tissue Simulator

The last tissue simulator utilized in this testing was a tissue interface circuit (TIC). Developed in ANSI/AAMI PC69 as an American National Standard for electromagnetic compatibility (EMC) testing of CRMDs [16], the TIC is simply a circuit designed to approximate the electrical characteristics of the human body. Figure 3 shows a picture of the fabricated TIC along with a circuit diagram. Unlike the other two simulators, which allow for over-the-air EMC testing, the TIC directly interfaces between an RF generator and the DUT through end-launch SMA connectors.

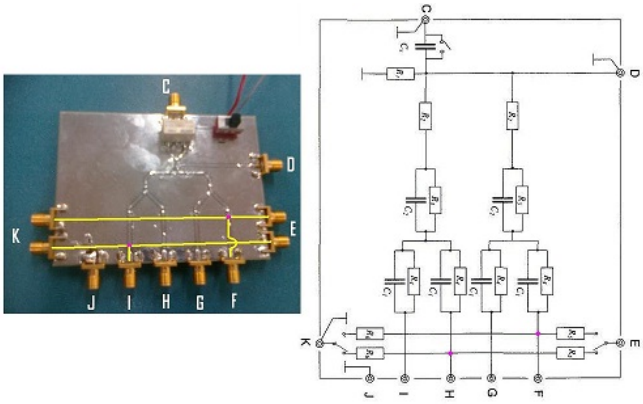

Figure 3 - Tissue Interface Circuit - Fabrication and Design

In order to fully characterize the EMC of tested CRMDs, three different types of off-the-shelf RFID interrogators were utilized. The interrogators were chosen to cover the most often used RFID frequencies; 143 kHz (LF), 13.56 MHz (HF), 915 MHz (UHF). These interrogators were operated both over-the-air via an antenna (Hokkaido, FDA), and directly connected via SMA connections (Hokkaido, FDA, TIC). The pacing output of the DUT was monitored for any anomalies on an oscilloscope.

There are many different manifestations of EMI in CRMDs noted in the literature. These include pacing inhibition, asynchronous pacing, noise reversion, tracking, and mode switching [6], [8]. The testing described here focuses on pacing inhibition and asynchronous pacing. Inhibition is a scenario in which the CRMD should be stimulating the heart muscle due to the lack of a normal heart rhythm; however, due to the presence of RF, the CRMD does not produce a pacing output. Figure 4 shows an oscilloscope screenshot depicting pacing inhibition.

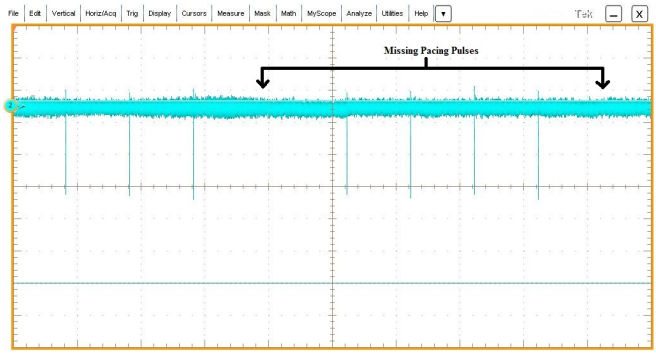

Figure 4 - Example of Pacing Inhibition

Asynchronous pacing is the opposite situation of pacing inhibition; in the presence of an RF emitter the CRMD produces a pacing output when it should be inhibited due to a normal heart rhythm. In order to test for asynchronous pacing an artificial ECG signal was generated and introduced into the tissue simulator. An example of an asynchronous pace is shown in Figure 5.

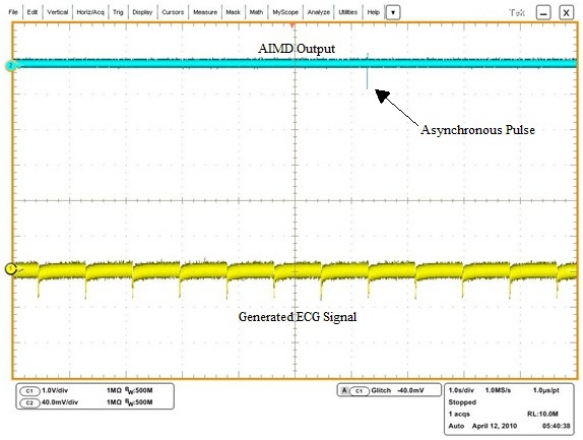

Figure 5 - Example of Asynchronous Pacing Signal

B. Results

A total of 887 tests were performed on six different CRMDs; 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 in ICDs, at 5.76%. Additionally, consistent with other findings, lower frequency carrier waves were shown to cause greater rates of interference. LF signals resulted in interference in 23.7% of the trials. This figure was 3% for HF signals and there were no incidents of interference recorded for UHF signals. These results are detailed in Figures 6-8.

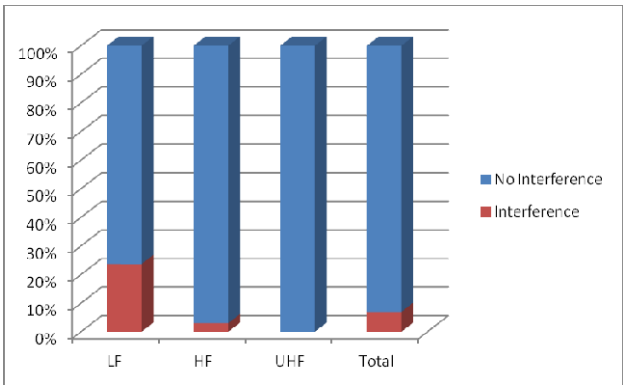

Figure 6 - Overall Test Results

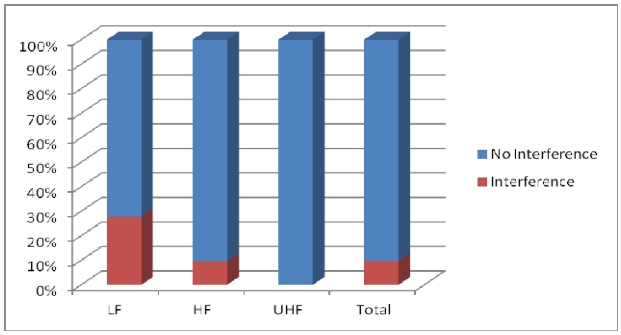

Figure 7 - Test Results for Pacemakers

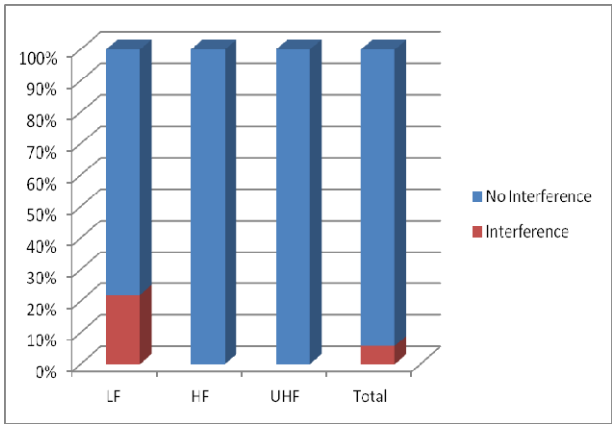

Figure 8 - Test Results for ICDs

IV. Certain Mitigation Possibilities of RFID Interference

With the marked increase in RF emitters in people's everyday lives, as predicted by the emergence of the IoT, it also becomes increasingly important to mitigate the possibility of EMI on implanted CRMDs. The default mitigation method most commonly employed today is the use of proximity guidelines [12]. Many devices that emit RF energy have warning labels affixed to them in order to warn CRMD patients to keep their distance. This mitigation method, however, is unrealistic in an environment with the density of emitters that would be required for the IoT. More sophisticated mitigation methods must be researched and employed in order to assure the safety of CRMD patients. One of the main advantages of the general, in-vitro testing methodologies proposed in this paper is that it provides a standard framework through which mitigation techniques can be tested.

It has been shown that modulated RF fields have a much higher incidence of EMI in CRMDs and it is believed that the mechanism of this interference is inductive coupling caused by alternating magnetic fields [12], [17]. The mitigation method investigated here seeks to reduce the level of the voltage induced in the CRMD system. As is shown by Faraday's Law of Induction, the induced voltage 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 surrounding tissue [12], [17]. The proposed method, rather than utilizing the common on-off keying modulation technique, utilizes a ramping amplitude for the carrier wave bursts. Figure 9 shows the difference between these two scenarios. 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 burst is effectively decreased, which should lead to a decreased voltage in the CRMD.

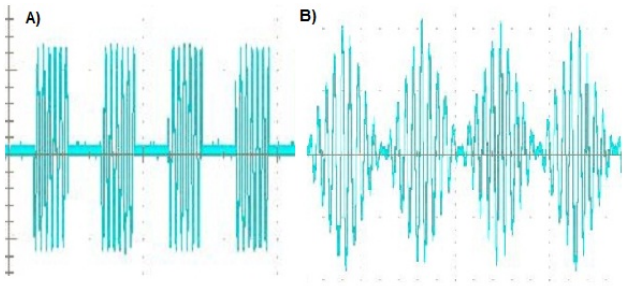

Figure 9 - A) On-Off Keying, B) Proposed Ramped Amplitude Modulation

In order to test the ramped amplitude modulation technique, a National Instruments PXI-1044 signal generator was used. Labview 8.2 software was utilized in generating the ramped amplitude signal from the signal generator as well as an on-off keying signal. Both signals operated at a carrier frequency of 13.56 MHz (HF), and a maximum power of 40 dBm was generated.

Two pacemakers and one ICD were tested and initial results, shown in Figure 10, were promising. For the purposes of this experiment, the definition of interference was split into two categories of clinical significance as defined by Hayes et al. [6]. Type 1 interference is any inhibition lasting three seconds or longer 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 on-off keying type 1 interference was recorded in 83.33% of the cases and no type 2 interference was recorded. In contrast, the ramped amplitude modulation technique resulted in type 1 interference in 14.58% of the cases, and type 2 accounted for 23.61% for an overall incidence of 38.19%.

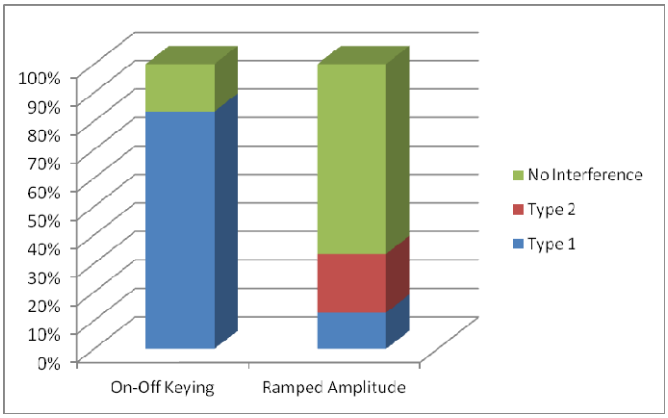

Figure 10 - Mitigation Experimental Results

V. Expected Scenarios

A. Background

The current RFID and NFC scenarios for the IoT are governed by functionality and security. This is in part a result of the FDA taking a slow pace with regard to CRMDs interference. In recent years, both the FDA and FCC have considered the issues but have not yet enacted any on-point legislation.

The fact that IoT is a relatively new field results in most of the effort dealing with applications and "gee whiz" scenarios of a futuristic world such as the refrigerator talking with the foods therein and, in case the milk is beyond its "pill" date, automatically ordering more, or at a minimum sending a text message for the shopping list to include milk.

In the authors' opinion, health issues will become more relevant as the IoT roll out accelerates. It is the authors' further opinion that there are alternative functionality methodologies that will likely enhance rather than inhibit IoT implementation.

It has been demonstrated that certain orientations of RFID tags with respect to readers and certain frequency bands have an effect on performance [18], [19]. In addition, the many reading devices have affects on performance of other devices [20].

In other cases, it has been demonstrated that RFID and NFC need not communicate over the air but rather communication can be effected by a simple touch [21].

B. Expected Outcomes

One of the apparent reasons health administrators have been slow to act is that to date there are no reported deaths due to RFID exposure. This is contrasted with the cell phone usage recommendations which are based on the heating of the tissue, Specific Absorption Rate (SAR), as opposed to an electrical episode within CRMDs [22].

The failure of a pacemaker to produce a heart beat due to what it sees from the sensor is not a recordable incident thus whether there is or is not an interference problem is not currently detectable. The demonstration of this phenomenon is on the schedule for the RFID Center at the University of Pittsburgh.

VI. Conclusion

Many emerging technologies are converging at an ever increasing rate to realize systems such as the IoT. The IoT holds overwhelming promise to transform and improve the lives of billions of people worldwide. However, as we approach the full realization of the IoT, we must be cognizant of the potential harm such systems may cause to the general public. One very real and potentially hazardous situation that we have explored here is the electromagnetic interference on implanted CRMDs. Through a massive, in-vitro study we have shown that RF emitters do indeed have the capacity to cause clinically significant interference in implanted CRMDs. We have proposed standard test equipment and procedures that may be used in future EMC studies. Finally, we have shown how this comprehensive testing framework may be utilized to investigate possible methods to mitigate the EMI effects of RF emitters on CRMDs. The mitigation method proposed here, ramped amplitude modulation, shows real promise in mitigating EMI on CRMDs, and may be of benefit to millions of cardiac patients the world over.

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