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INSITU ASSESSMENT OF ELECTROMAGNETIC INTERFERENCE BETWEEN RFID SYSTEMS AND MEDICAL DEVICES

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ABSTRACT

The objective of the proposed work is to conduct in situ assessment of electromagnetic interference between radio frequency identification systems (RFID) and medical devices. Two RFID systems, one belongs to passive category working at 13.56 MHz and another belongs to active category operating at 2.5 GHz were considered. Ten medical devices including electrocardiogram monitor, ventilators, defibrillators and infusion pumps were tested. The tests were conducted in accordance to procedures specified in ANSI standard C63.18 for adhoc on site testing. Based on the results obtained, it was found that except distortion in the pulse oximeter by 2.5 GHz system at very close distance (5 cm), none of the devices affected by presence of two RFID systems tested.

Keywords: electromagnetic interference (EMI), electromagnetic susceptibility, patient safety, radio frequency identification.

INTRODUCTION

Patient safety is one of the most critical factors to measure the quality of the healthcare delivery in hospitals. Now days, occurrence of medical error is very common and various factors are attributed for its existence. According to the FDA study, the occurrence of medical error reaches 40% in paper based environments. Other factors contributing to the incidence of medical error are insufficient number of nursing staff (Pagliaro *et al*, 2006) fatigue and distraction of the healthcare staff (Dzik, 2006), and lack of attention of the doctors and nurses. The most common type of errors occurred in healthcare sector are, improper transfusion of blood (Dzik, 2006), in-correct identification of patients (Cheng- Yang *et al*, 2012), medication error (Miang Jiang *et al*, Wei Zhou *et al*, Edward Etchells *et al*, 2005, 2010, 2003) surgery at wrong site (Cheng- Yang *et al*, 2012), mislabeling of medical samples (Dzik, 2006), and errors by surgeon during surgical procedures (Edward Etchells *et al*, 2003). It is understandable that the nature of the health care service is complex and cumbersome, needs constant attention and becomes more vulnerable to incidents of medical error. It is compulsory for every hospital to keep system in a place so that it is impossible for errors to take place. Several studies pointed out that adoption of suitable information technology tools prevent the occurrence of medical errors (Kumkio Ohashi *et al*, 2010). Among the several technologies available, radio frequency identification (RFID) systems will prove to be superior in several aspects. RFID is a wireless technology equipped with reader, tags (transponders) and back end database system. Equipment or person to be tracked is tagged with RFID tags and whenever tags come into electromagnetic zone of reader, they can transmit the data along with their ID. By exploiting the characteristics of RFID, the health care industry can offer improved service to the patients and customers and enhance the quality of medical service rendered, and making patient care more consistent, and being economical (Pablo Najera *et al*, 2011). The applications of RFID in health care are enumerated in several literatures and few of them are, patient identification, patient tracking, medical asset tracking, medication safety, anti-drug counterfeiting, monitoring and controlling of epidemic diseases such as SARS (Cheng- Ju Li *et al*, 2004), monitoring of mentally ill patients [10], labeling of blood samples, monitoring of strayed dementia patients (Shang- Wei Wang *et al*), verifying the correctness of blood transfusion and monitoring of doctors and medical staff (Deborah Macy *et al*, 2007). Since RFID has diverse applications in health care, it is termed as future technology of the health care. One of the possible risks associated with the implementation of RFID technology in healthcare applications is that, the electromagnetic waves emitted by RFID readers or tags may potentially affect the proper functioning of medical devices (Remko van der Togt et.al, Suraj Kapa *et al*, 2008, 2011). Studies [Nickolas J Lasorte *et al*, Oxana S Pantchenko *et al*, Yue Ying, Barbara Christe *et al*, Bryan Houliston et.al, Periyasamy *et al*, 2010, 2011, 2009, 2008, 2009, 2013) have shown that EMI from these RFID systems may potentially alter the functioning of medical devices such as ventilators, defibrillators, pacemakers, anesthesia machine, and ECG recorders. The EMI occurred in medical devices varying from distortion in monitors, noise in speakers, flickering in monitors to switching off or complete stoppage of devices. The risk of electromagnetic interference (EMI) depends on frequency of RFID system, distance between RFID and medical device and predominantly it is occurring with high frequency system (Suraj Kapa *et al*, 2011). Also, the nature and type of EMI occurrence is unpredictable since it depends on the several factors including shielding effectiveness of medical device, type of medical device, and power emitted by RFID reader antenna. According to literature, there are several reports of scientific studies illustrated the both in vitro as well as in vivo testing of EMI between RFID systems and medical devices. Both kinds of results provided the useful results of

characteristics of EMI to medical community and according they devise their plans to install new communication systems. Even though there are conflicting results are available with regard to EMI between RFID system and medical device, it is essential for every hospital authorities to test their new RFID system to be implanted with existing stock of medical devices with a view to protect medical equipment from malfunction and to avoid potential hazards to patient safety. The objectives of the proposed work is to conduct in situ test to analyze the EMI between two RFID systems belonging to passive and active categories and certain group of medical devices used for vital signal monitoring, defibrillators, infusion pumps, and ventilators. After conducting the test, we categorized the EMI incidents as hazardous, significant or light depending on the outcome.

MATERIALS AND METHODS

Medical devices

A total of ten medical devices were evaluated according to ANSI standard C63.18 [ANSI C63.18, 1997] as shown in Figure-1.

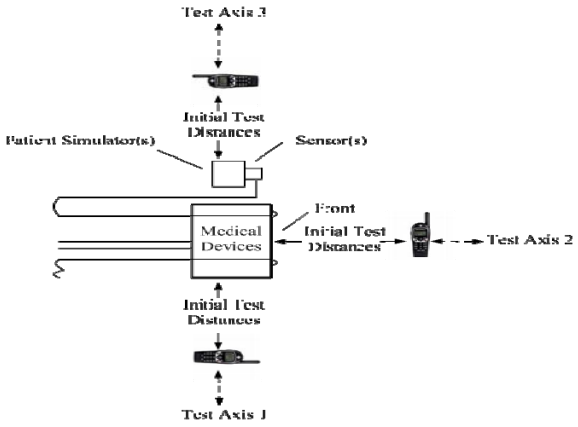

Figure-1. Test setup as described in ANSI C63.18.

They were 12 channel ECG recorder, treadmill or exercise test equipment, pulse oximeter, portable pulse oximeter, infusion pump, ultrasonic fetal heart meter, mechanical ventilator and two models of defibrillator. Selection of these devices for testing was based on inclination to include the representation of commonly used devices as well as equipment used in critical and emergency care. The tests were conducted in the rooms where the devices are usually kept. During the test, only one device was turned on and connected to a patient or not depending on the equipment tested. All the other devices in the room were kept switched off in order to reduce the undesirable surrounding noise.

RFID system

A typical RFID system composed of three main components: reader, receiver and tag (Suraj Kapa *et al*, 2011). In addition to this, it can have data network and management software. A general block diagram of RFID system is shown in Figure-2. Generally RFID tags are classified into two types: passive and active. Active tags have internal battery and passive tags have no internal battery. Passive tags receive their transmission power from the electromagnetic (EM) signal of a reader and scattered back to reader. Whenever tags entering an EM field zone of reader, they wake up and they start to broadcast their ID code along with the illuminator's ID code to a receiver.

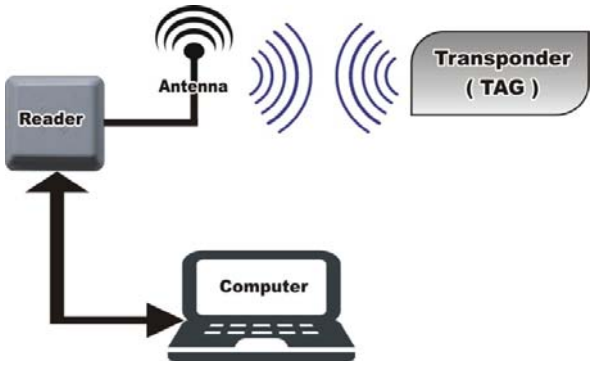

Figure-2. Block diagram of RFID system.

Passive tags can work in any of a number of different frequency bands. Low-Frequency tags, which work in the 124 KHz - 135 KHz range, have small read ranges up to half a meter. High-Frequency tags, working at 13.56 MHz, have ranges up to one meter or more. Ultra High - Frequency tags, which operate at frequencies of 860 MHz - 960 MHz and sometimes at 2.45GHz, have the greatest range - up to tens of meter. Active tags have read ranges of 100 m or more depending on the power input to the reader antenna. Similar to passive tags, various active tags in the market use many different transmitting frequencies and modes of operation, depending on the different national regulations.

There are two RFID systems used in this proposed work. One was passive RFID working at 13.56 MHz which is very popular for bulkier applications like in healthcare, since cost of the tags are cheap when compared to active tags. The read range of reader is only about 10 cm and sometimes the data can be read from tags by making physical contact with tags. The tags are available in different shapes such as ID cards and wristbands. Another RFID system used in this proposed work is an active system operating 2.5 GHz. It has a high read range of about 100 m in free space conditions and it is very useful for effective tracking of medical equipment at afaster speed. The technical details of both RFID readers and tags used in this work are given in Tables 1 and 2, respectively.

Table-1. Technical details of RFID readers used in this work.

Parameter	Specifications for passive 13.56 MHz RFID	Specifications for active 2.5 GHz RFID
Operating Frequency	13.56 MHz	2.4 -2.8 GHz
Maximum Simultaneous tag detection	No	200 tags
Communication Standard	USB	RS 232, Adaptive Ethernet Interface
Immunity to Noise and Interference	Yes	Yes
Reading Range	Up to 60mm	0- 100 m
Operating Temperature	-20°C to 50°C	-20°C to 60°C
Output Power	0.75 mW	+15 dbm

Table-2. Technical details of RFID readers used in this work.

Parameter	Specifications for passive 13.56 MHz RFID	Specifications for active 2.5 GHz RFID
UID(Unique Identification Number)	4 Bytes	4 Bytes
Memory	1 K Bytes	4 K Bytes

METHODS

The entire test was divided into three phases. One was involved in the assessment of EMI on medical devices if RFID system was implemented for tracking of devices or assets by tagging each medical device with tags and tracked by RFID readers placed at strategic points. Another one was coupled with evaluating EMI on medical devices if RFID system was installed for patient identification by tagging patients with wristband tags or ID cards. In such cases, patient with wrist band tags may disturb the functioning of medical devices if the RFID reader was in close proximity to them. The Third phase is to assess the EMI on medical devices if there is multiple number of RFID readers are located nearby. In this particular study, we carried out the test of assessing the EMI when two different RFID readers are positioned near to medical devices and observe the changes. These three phases were conducted one after another with careful evaluation of EMI incidents. Before conducting each test, a normal functioning of each device was evaluated. In case of device showing abnormal values or response during sample test, that particular device was excluded from the test. During the test, each device was kept on the non-conductive wooden table with power supply chord running besides the device. If the device is floor standing, then it was kept on the floor. The sensors in the monitoring device were connected to the human volunteer or sample circuit if needed. At the end of the test, once again each medical device was tested whether it was working properly or not.

Methodology for asset tracking

Initially each device was tagged with either passive 13.56 MHz tags or active 2.5 GHz active tags. Tagged medical devices were shown in Figure-3 and Figure-4. During tagging process, it was verified that whether any abnormality in occurred in devices or not. If it was occurred, then it was notified in spread sheet. Initially, the RFID reader was located at a distance of 100 cm from the medical device.

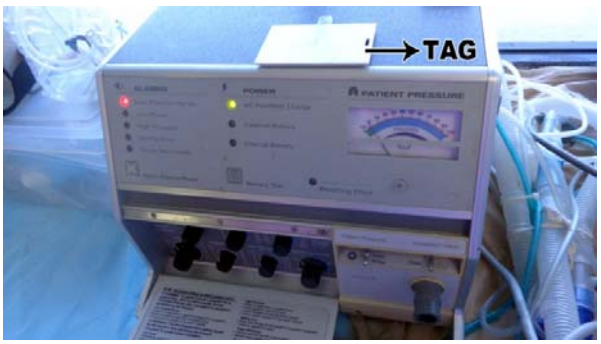

Figure-3. Defibrillator was tagged with RFID tag.

Figure-4. Infusion Pump was tagged with RFID tag.

Then the tagged device was tested for EMI when the RFID reader was activated. The device was tested for EMI another time with the RFID reader turned on. The distance between RFID reader and tagged medical device was decreased stepwise by 5 cm. At each step, EMI effects on medical device were notified. If the device demonstrated no incidents of EMI, then the distance will be further reduced stepwise till it make physical contact with concerned medical device. In case of EMI incidents appeared during stepwise decrement, then the distance between device and RFID reader was measured along with type of incident, orientation of the RFID reader antenna as well as distance at which the EMI effects were faded away was observed. The same set of steps will be followed for testing EMI for other medical devices concerned.

Methodology for patient monitoring

Every patient was provided with either passive 13.56 MHz tags or active 2.5 GHz while admitting them into hospital. To ensure accurate patient identification, RFID tag was attached on the wrist of patient and it should not be detached till they leave the hospital (Steffen *et al*, 2010). RFID tags were coded with details of patient and their past medical history. During hospitalization, they may require undergoing different diagnostic process in which either tags wrapped around wrists of the patient or RFID reader placed in the diagnostic room may alter the functionality of the device. This study was possible only with devices having physiological measuring sensors such as ECG monitors, pulse oximeters and treadmill. For other devices this could not possible because of human subject should not be connected to those devices. Patient with wrist band tags was rested in supine position or in standing posture depending on the measurement system. Measurement electrodes or sensors are connected to the patient with a view to avoid the direct contact with tags. Measurement of physiological parameters was performed without turning on RFID reader and verified that whether any disturbance occurring in the measurement or not. If no disturbance was observed, then RFID reader located at an initial distance of 100 cm was turned on and observed for any changes in the function of the medical device. If no changes were observed, then RFID reader was moved closer to the medical device by stepwise decrement of 5 cm. At each stepwise decrement, the function of medical device was verified for its abnormality. If no disturbances found, then RFID reader was moved further till it comes closer to tags wrapped around wrist of the patient. If any malfunction or changes in the measurement of physiological parameters were observed, then the distance between tag and reader was measured and type of malfunction as well as the distance at which malfunction or changes faded way was noted down. Similar set of procedures will be followed for testing EMI for other medical devices concerned.

Methodology for testing with multiple RFID systems

Similar kind of studies was already reported in (Bryan Houliston *et al*, 2009). Initially, each device was tagged with both 13.56 MHz tag as well as 2.4 GHz tag and finding out that if there is any change observed in the functionality of the medical device or not. If there was no change in the device's function, then both RFID readers separated by spacing of 1 foot are located at distance of one meter away from the medical device concerned. Both RFID readers turned on at that distance and verified that if there was any change in the functioning of the device or not. If there were no changes observed, then both readers were moved towards the medical device concerned till they made physical contact with tags attached on the device. In case of any significant events occurred during the test, then distance between RFID readers and device was measured as well type of event occurred was noted down. Also, the distance at which the adverse event disappeared was also noted down.

Methodology for testing with multiple RFID tags

This test was concerned with tagging of each medical device with multiple number of tags (maximum of five tags) of each RFID system concerned and finding out whether multiple tagging of device was affecting the functionality of the device or not. Each device was tagged with either 13.56 MHz or 2.4 GHZ tags one by one. During addition of each tag, each medical device was observed for any functional changes. If no events were occurred, then steps for finding out EMI between medical device and RFID system were followed. In case of any adverse events occurred during multiple tagging of devices, then further tagging of devices was stopped and noted down the EMI incidents occurred in spread sheet.

RESULTS

So far results are concerned; the implementation of passive 13.56 MHz RFID for patient identification as well as for asset tracking did not affect the proper functioning of all the devices tested. The devices were showing normal function even when RFID reader was made physical contact with the devices concerned. No flickering or distortion in monitors was observed. Similar results were obtained for implementation of active 2.4 GHz RFID for asset tracking except that distortion in monitor of pulse oximeter was observed when RFID reader was made close contact with RFID tag attached on pulse oximeter (shown in Figure-4). The distortion was disappeared when RFID reader was moved little farther away (more than 5 cm) from pulse oximeter. As far as patient identification is concerned, the working of 2.4 GHz RFID did not affect the functioning of all the medical devices tested. As far as testing of EMI with multiple readers are concerned, all the devices have shown immunity to combined electromagnetic radiations from both readers at all distances. But for the portable pulse oximeter, it did not exhibit any interference effects till both readers reach the distance of 5 cm from medical device. Once both readers reached the distance of 5 cm from pulse oximeter, distortion in the monitor was observed. The effect was continued till both readers have made physical contact with tags. Similarly, during the

process of multi-tagging of each device with 13.56 MHz tags, no effects of interference were observed. Similarly, none of the devices tested shown effects of interference during multi-tagging of each device with 2.4 GHz tags.

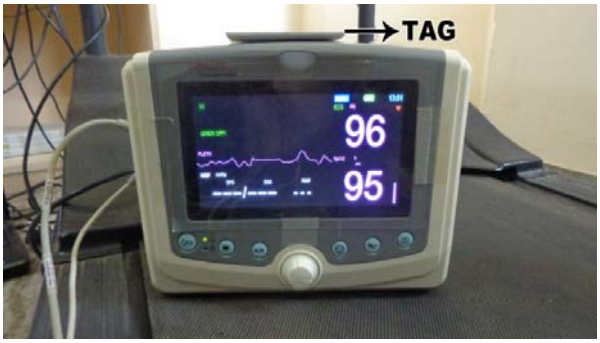

Figure-5. Distortion in pulse oximeter display.

DISCUSSIONS

Table-3 summarizes list of medical devices tested, RFID systems utilized and corresponding EMI incidents. The present work implemented the two RFID systems belonging to passive and active categories for patient identification as well as asset tracking in hospitals. These are major issues to be resolved in better way by implementation of appropriate information technology tools. The potential threat exists with RFID implementation in healthcare is that it will interfere with working of electronic devices located nearby. Several studies have proven this concept, so that it is imperative for hospital authorities to ensure that the new RFID technologies to be implemented will not interfere with their existing medical devices. This can be done by performing tests for assessing EMI in either controlled environment or in uncontrolled environment as specified in ANSI standard. The present work confirmed that, the deployment of passive 13.56 MHz RFID did not affect functioning of medical devices including ventilators, defibrillators and ECG monitors. This may be due to the following two reasons. One was the power emitted by passive RFID reader was very low and it can be further reduced in to a level in free space which is not enough to alter the functioning of the device. Second was that all the devices tested were manufactured in recent years; which have better shielding effectiveness. Similarly, medical devices tested were immune to electromagnetic radiation from active 2.4 GHz RFID system except pulse oximeter in which distorted waveform is displayed in monitor. During this event, RFID reader was made close contact with RFID tag attached on the pulse oximeter. At that juncture, both tag and RFID reader become sources of electromagnetic radiation and that could be possible reason for distortion in the monitor. According to EMI terminology, this event could be termed as 'light'. Except this, the results confirmed that these two RFID systems were safe to introduce in hospitals for patient identification and asset tracking. There could be possibility of multiple number of RFID readers placed nearby each medical device in hospital environments.

Table-3. List of devices tested and summary of EMI incidents.

Device name	Is this affected by passive 13.56 MHz RFID? If Yes Means during which methodology? Describe and classify incident. Also measure distance.	Is this affected by active 2.4 GHz RFID? If Yes Means during which methodology? Describe and classify incident. Also measure distance.	Is this affected by multiple number of readers? Describe and classify incident. Also measure distance.	Is this affected by multi-tagging of 13.56 MHz or 2.4 GHz?
ECG Recorder	No	No	No	No
Ventilator	No	No	No	No
Defibrillator (Two models)	No	No	No	No
Treadmill	No	No	No	No
Ultrasonic fetal heart meter	No	No	No	No
Infusion Pump	No	No	No	No
Pulse Oximeter	No	Yes Asset tracking. Distortion in monitor at 5cm distance. Termed as 'Light'	Yes Asset tracking. Distortion in monitor at 5cm distance. Termed as 'Light'	No
Portable Pulse Oximeter	Not Possible	Not Possible	Not Possible	Not Possible

In such cases, cumulative electromagnetic waves may interfere the functioning of medical devices significantly than by single reader itself. This proposed work included that situation by testing with two RFID readers. Results showed that the identical effects were observed when placing active 2.5 GHz reader closer to medical device. Also, multiple medical devices tagged with RFID tags may affect the functioning of another tagged medical device located nearby. This was simulated by multi-tagging of each device with both RFID tags and found that multi - tagging did not affect the functioning of medical devices concerned.

CONCLUSIONS

Based on the results obtained, the proposed work concludes that it is safe to introduce both passive 13. 56 MHz and active 2.5 GHz RFID systems for patient identification as well as for asset tracking in hospitals. They did not significantly interfere with working of medical devices tested except pulse oximeter wherein one light event was caused by active 2.5 GHz RFID system. Also it was confirmed that, working of multiple RFID readers did not affect the functioning of medical devices. Also muli-tagging of devices did not affect the performance of devices tested. The results are confined to two RFID systems, ten medical devices considered and testing protocol followed in this proposed work.

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