THE USE OF RADIO FREQUENCY IDENTIFICATION (RFID) IN TRACKING SURGICAL SPONGES AND REDUCING WRONG-SITE SURGERIES

A Thesis presented to the Faculty of the Graduate School

at the University of Missouri-Columbia

In Partial Fulfillment of the Requirements for the Degree

Master of Science

Ву

KYLE WILLIAMS

Dr. Luis Occeña, Thesis Supervisor

DECEMBER 2008

The undersigned, appointed by the dean of the Graduate School, have examined the thesis entitled

THE USE OF RADIO FREQUENCY IDENTIFICATION (RFID) IN TRACKING SURGICAL SPONGES AND REDUCING WRONG-SITE SURGERIES

resented by Kyle Williams,						
a candidate for the degre	e of master of science,					
and hereby certify that, ir	n their opinion, it is worthy of acceptance.					
	Professor Luis Occeña					
	Professor James Noble					
	Professor Daniel Turban					

ACKNOWLEDGEMENTS

I would like to acknowledge the following people for their assistance: Luis Occeña, Mike Klote, Susan Hankins, Dr. Paul Dale, Amy Tinsley, Gao RFID Inc., byshipping.com, Damon Dageenakis from HID Global, The University of Missouri Food Science Department, Rick Disselhorst, and the University of Missouri Industrial Engineering Department.

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	ii
LIST OF TABLES	iv
LIST OF FIGURES	v
ABSTRACT	vii
CHAPTER 1: INTRODUCTION	1
CHAPTER 2: LITERATURE REVIEW/NEED OF THE RESEARCH	3
Current Medical Procedures for the Prevention of Retained Foreign Objects	3
Current Medical Procedures for the Prevention of Wrong-Site Surgeries	4
RFID overview	5
Bar-coding in Hospitals	8
RFID in Hospitals	8
CHAPTER 3: METHODOLOGY	11
CHAPTER 4: RESULTS & DELIVERABLES	18
Continuous RFID Detection System	18
Wrong-Site Surgery Prevention Program	29
CHAPTER 5: FUTURE RESEARCH	32
BIBLIOGRAPHY	34
Appendix A: Read Ranges for HF and LF RFID Tags	38
Appendix B: Ballistics Gelatin	45
Appendix C: Visual Basic Code	46

LIST OF TABLES

Table 1: RFID Systems Characteristics	13
Table 2: Tag Performance in Saline Solution	2 3
Table 3: Tag Performance in Ballistics Gelatin	24
Table 4: Tag Performance in Boneless Pork	25
Table 5: Tag Performance in Pig Carcass	28
Table 6: Performance of 82x49 Tags in Different Mediums Tested	28

LIST OF FIGURES

Figure 1: HF Tags	18
Figure 2: Read Ranges for HF 82x49 Paper Inlay	19
Figure 3: Read Ranges for HF 82x49 Paper Inlay	19
Figure 4: Saline Solution	20
Figure 5: LF Tags	21
Figure 6: Read Ranges for LF Tag with Longer Distance	22
Figure 7: Read Ranges for LF Tag with Longer Distance	22
Figure 8: LF Tag Test in Ballistics Gelatin	23
Figure 9: 3.36 lb Boneless Pork Roast Test	24
Figure 10: Initial Proposed Setup	26
Figure 11: Initial Setup with Carcass	26
Figure 12: Second Setup with Carcass	26
Figure 13: Insertion of Tag into Cavity	27
Figure 14: GUI for Wrong-Site Surgery Prevention Computer Program	29
Figure 15: Microsoft Excel File for Wrong-Site Prevention Computer Program	30
Figure 16: Read Ranges for HF Circle	39
Figure 17: Read Ranges for HF Cirlce	39
Figure 18: Read Ranges for HF Square	40
Figure 19: Read Ranges for HF Square	40
Figure 20: Read Ranges for HF Paper Inlay	41
Figure 21: Read Ranges for HF Paper Inlay	41
Figure 22: Read Ranges for HF Plastic Inlay	42
Figure 23: Read ranges for HF Plastic Inlay	42
Figure 24: Read Ranges for 23 inch Rated LF Tag	/13

Figure 25: Read Ranges for 23 inch Rated LF Tag	. 43
Figure 26: Read Ranges for 13 inch Rated Tag	. 44
Figure 27: Read Rages for 13 inch Rated Tag	. 44

ABSTRACT

Even with the process of manually counting medical instruments and sponges used in open cavity surgeries, a Massachusetts' insurer estimated that 1 in 10,000 open cavity surgeries have claims of retained instruments and sponges. The major danger comes from any sponges that remain within a patient. These sponges can cause further complications including sepsis, obstruction, and death. While there have been developments in using radio frequency identification (RFID) technology to identify any remaining sponges within a cavity, the methods are still prone to human error. These errors might seem easily preventable since it does not seem all that difficult to have an accurate count of the number of instruments and sponges that have been used in a surgical procedure; however, there are continuously cases of retained foreign objects reported.

There has been some promising research in the use of RFID technology to ensure that medical sponges are not mistakenly left in surgical patients. The basic concept is that each sponge used in a surgery has an RFID tag attached to it. Before the patient is closed up after the surgery is completed, a handheld reader is passed over the patient to detect if there are any sponges that were not removed from the cavity. The initial trials were very successful, with 100% detection of tags remaining in the cavity, and no false readings (the reader detecting a tag not within the cavity). The issues of human error and retained sponges were raised during trials. For example, if the scan is performed incorrectly—the wand is too far away from the body—this could cause tags not to be read. Another concern is that any sponges used after the scan has been performed have a chance of not being removed.

I propose to research the possibility of having a continuously scanning RFID system. This system would eliminate the human interaction of the current handheld scanning devices. With the human interaction no longer a factor in the process, scanning the cavity too early to detect all of the sponges used or scanning at a distance too great for the tags to be read will no longer be of any concern. An additional advantage to a continuously scanning system is that a monitor can be placed in view of the surgeons that will display the number of sponges currently on the table. The surgeon can know the number of sponges in the patient at any point in the surgery. In addition to the detection of sponges, tags could be placed on surgical instruments to ensure that there are no retained instruments in the cavity.

In addition to the detection of RFID tagged sponges, RFID tags have the possibility to assist in decreasing the number of wrong-site surgery occurrences. It is estimated that one wrong-site surgery will occur in every 112,994 operations. Based on this statistic, it is estimated that a single large hospital will see an occurrence serious enough to be reported to risk managers or result in a lawsuit once every five to ten years. While the number of occurrences is small, 84% of wrong-site surgery claims lead to payment to the plaintiff. One study had a median payout of \$12,000 with an average of \$1,528 in legal fees.

The proposed use of RFID technology to assist in the reduction of wrong-site surgery will not replace the Association of Perioperative Registered Nurses (AORN) guidelines to follow the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) protocols. Instead, the proposed use of the technology will assist in making the procedures to be performed and information on surgical sites more readily available during surgery. To do this, the procedure(s) to be performed and at what location(s) can be stored as information in a computer database. This information can then correspond to an identification number on an RFID tag that is placed

on the patient. When the patient is then on the surgical table, the tag identification number read by RFID reader will be cross-referenced with the tag numbers in the database in order to display any information pertaining to the procedure. A written description of the procedure, in addition to radiographs and patient history, can be displayed on a monitor in the operating room.

The research performed shows promising findings that it is possible to have a continuously scanning RFID system used in the detection of surgical sponges within a surgical cavity. The tests performed on a freshly slaughtered pig carcass show that multiple tags could be identified while in the surgical cavity. Several more developments need to be made to the continuously reading system before clinical trials can be performed.

The paper also describes the development of a software program that utilizes RFID tags to increase the availability of information in the operating room to decrease the chances of wrong-site surgeries. This system needs to be integrated with a hospital database system before any clinical trials can be performed.

With possible benefits coming from using RFID technology in both identifying surgical sponges and instruments within a surgical cavity and increasing the ease of communicating information about the procedures that are to be performed, it is easy to see the attraction of further development of RFID in the surgical process.

CHAPTER 1: INTRODUCTION

A Massachusetts' insurer estimated that 1 in 10,000 open cavity surgeries have a claim of a retained object after the cavity has been closed. The major danger comes from the retention of surgical sponges. The complications can include sepsis, obstruction, and death [12]. With the seriousness of the complications caused by retained objects, it is obviously imperative that the objects are not retained in the cavity. If an object is located in the body after the surgical cavity has been closed, an additional surgery must be performed to remove the object, increasing the cost for the hospital. Thus, it would benefit the hospital to ensure that there are no objects retained in the cavity before the cavity is closed. The current method is to manually count instruments and sponges before and after the surgery. If there is a discrepancy in the counts, the cavity and surrounding area are search. An X-ray is then performed if the missing item cannot be found [1].

In an effort to reduce the number of retained sponges, radio frequency identification technology (RFID) has been applied to assist in the detection of sponges within the cavity. The preliminary clinical study of one system was successful in correctly detecting 100% of the RFID tagged sponges with no false readings. The study presented some concerns with the possibility of human error in the process. These were reading the tags too early and performing the process incorrectly [12].

Another area that has recently had growing concern in the medical field is wrong-site and wrong-patient surgeries. As the names imply, this would be when the procedures is performed on the incorrect site on the patient—mainly occurring on the incorrect side of the

body—and when a procedure is performed on a patient that it is not meant for. It is estimated that one wrong-site surgery will occur in every 112,994 operations. A hospital would see an occurrence every five to ten years [11]. While this number is small, 84% of wrong-site surgery claims lead to payment to the plaintiff [13].

The current practices to help prevent wrong-site surgeries involve having the surgeon marking the surgical site while the patient is still lucid. Additionally, a nurse signs a "boarding pass" that identifies the side and site of the surgery. In the operating room, a "time out" is taken, where the entire staff actively participates to identify the patient, correct surgical site, and that the planned procedure is correct [5]. While these procedures are decreasing wrong-site surgeries, there are several factors that can still result in a wrong-site surgery such as multiple surgeons, multiple operations, and a lack of access to information pertaining to the operation.

One objective of this research will be to further develop the use of RFID technology to decrease the human error in the detection of sponges and medical instruments within surgical cavities in order to reduce the occurrences of retained objects. Another objective will be to develop the use of RFID technology for reducing the occurrences of wrong-site and wrong-patient surgeries.

The scope of the research will include a proof of each proposed concept—the continuous detection of sponges, along with the increased communication and verification of the surgical procedure(s). An additional goal of this project is to develop a relationship between the Industrial and Manufacturing Systems Engineering department at the University of Missouri with one or more of the regional hospitals in hopes that further research opportunities will be made.

CHAPTER 2: LITERATURE REVIEW/NEED OF THE RESEARCH

Current Medical Procedures for the Prevention of Retained Foreign Objects

The current method to help ensure that foreign objects are not retained in the surgical cavity is to manually count the instruments and sponges before and after the surgeries and compare the counts. These protocols are based on the Association of Perioperative Registered Nurses (AORN) recommended practices for sponge, sharps, and instrument counts. If a discrepancy occurs, a search of the cavity and surgical room is performed to locate the missing object. In discussions with nurses familiar with the operating room and findings in literature, most missing sponges are found in the waste buckets, on the floor, or unused on the back table [7]. If the object cannot be located, an X-ray is performed of the cavity area. The medical instruments are made of stainless steel and will therefore show up on the X-ray. The sponges have an X-ray detectable strip added to the sponge so that detection is possible. While performing the X-ray should ensure that there are not instrument or sponges remaining in the cavity, the X-ray is an additional cost for the hospital and exposes the patient to additional radiation. The protocols can account for up to 14% of operative time [9]. In some hospitals, patients that are considered higher risk of having a possible retained object are required to have an X-ray performed before the surgical cavity is closed. These patients include the morbidly obese, trauma patients involving two or more surgical teams, lengthy procedures involving three or more teams, and patients who have had the wound packed initially and are returning for possible primary closure [19].

It has been estimated that a foreign object is retained anywhere between 1 in 9,000 operations to 2.4 per 10,000 [9] with one study involving 47 claims resulting in an average cost

of \$52,581 in compensation and legal expenses. This study showed that in cases where a foreign object is retained, more than two-thirds of the time a surgical sponge is the item retained. Also, the detection of the retained object can take anywhere from a day to several years. Removal of the retained objects and treatment for complications caused by the object were required in sixty-nine percent of the patients. One of the patients died due to the retained object [7].

There are several reasons for the retention of surgical sponges and instruments. Some include emergency situations, unplanned changes in the procedure, obese patients, carelessness, and human error [8]. Other reasons include the redundancy associated with the counting procedure, along with interruptions and distractions. A disturbing reason for retained objects given in the AORN Journal is the case where there is a hostile response to the questioning of careless practices and where team members feel distress about approaching colleagues regarding count discrepancies [2].

Current Medical Procedures for the Prevention of Wrong-Site Surgeries

The current practices to prevent wrong-site surgeries have the surgeon consult with the patient and mark the spot of the operation. The nurse will sign a "boarding pass" that identifies the site and side of the operation. When the patient is in the operating room, the entire surgical staff will take what is known as a "time out" and stop what they are doing. During this "time out", the operating room staff is required to actively participate in identifying that the correct patient is in the room, the surgical site is correct, and the planned procedure is correct. Additionally, during the "time out", if appropriate, it must be confirmed that the patient's

radiographs are in the OR. Surgeons must also confirm that all of the instruments, devices, and supplies that may be required are available [5].

A major cause of wrong-site surgeries is that the original diagnosis was inadvertently altered at some point between the doctor's diagnosis and the scheduling of the operating room [19]. One study found that there were no crosschecks to ensure that the consent form and the schedule request matched the physician's note or radiologic report [17]. The consultation with the patient to mark the operation site would ideally identify this mistake. However, a study of 100 patients in a private practice setting showed that when asked to comply with explicit preoperative instructions for the prevention of wrong-site surgery, 37% did not mark the surgical site and 7% did not comply with the instructions [5]. Additionally, environmental or cognitive problems—such as, a noisy environment, anxiety, confusion, or the patient being a passive recipient of care—can cause a patient or family members to incorrectly identify the surgical site [17]. The following are some of the factors that have been identified by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to contribute to wrongsite surgeries: multiple surgeons, multiple operations, unmarked site, not requiring verification in the operating room (OR), a lack of access to pertinent information, and problems in organizational culture. Communication errors involving the surgical teams, the patient, or patient family members can be identified in the majority of wrong-site cases [5].

RFID overview

Radio frequency identification (RFID) was first used in a commercial setting in the 1970s as a theft prevention system. The tags were either in the set or unset position. If the tags went through the readers in the set position, an alarm in the store would sound. In the 1980s, RFID technology was beginning to be used as a faster method to pay for tolls on roads. Recently, this

easier payment method has been applied to several other payment processes, such as gasoline cards and ski passes [10].

An RFID system consists of three components; the interrogator, the antennas, and the tags. The interrogator, or reader, sends out an electromagnetic wave through its antenna. The tag's antenna is tuned specifically to receive these waves. After the tag's antenna has received the wave the tag then modulates these waves to convey information back to the reader. The interrogator then converts the waves into a digital signal in order to communicate with a digital system such as a computer [3].

There are three types of RFID tags—passive, active, and semi-active. Passive tags are essentially "read only" tags that contain no internal power source [15]. When an electromagnetic field is sent by a reader, inductive coupling occurs, allowing the passive tag to become energized. Active tags do have an internal power source and data on the tags can be written, erased, and rewritten. Active tags are continuously sending out electro-magnetic waves. Semi-active tags have an internal power source; however, the tag does not use this power source until it has received an electro-magnetic wave from a reader. Tags with an internal power source have the ability to be read from a greater distance, they are generally more expensive and larger than passive tags.

RFID tags are typically made up of three components—the chip, antenna, and inlay. The chip stores the data that is sent to the RFID reader. The antenna picks up the radio frequency signal produced by the reader and then transmits the data stored in the chip to the reader. This is all protected in packaging called the enclosure or inlay [18]. For active and semi-active tags, the power source is the fourth required component [10]. The size of the tags can range from less than a millimeter to the size of a book. The size is dependent upon the application of the

tag [10]. The antenna is the main component that determines the size of the tag. By using a larger antenna, the tags can be read from a greater distance from the interrogator. The interrogator antenna size can also increase the read range.

It is also important to understand that certain materials can affect how well an interrogator can read a tag. There are three main issues that are attributed to the reduction of performance due to different mediums. The first is absorption. This is when the material absorbs the energy transmitted from the antenna. This can cause the reduction in the wave strength. Another issue is when the material around the tag reflects or refracts the waves, resulting in a distortion of the original signal. Dielectrics, insulators, also affect RF signals by resisting the flow of electrical current, which can result in a detuning effect on the tag's antenna [3]. These are all issues that can be seen in the surgical room with absorption and resistance from the body tissue and distortion from metal surgical tables.

Depending on the application of an RFID system, different operation frequencies can be used. The three main frequencies that will be considered for this research are low frequency (LF), high frequency (HF), and ultrahigh frequency (UHF). Each frequency has benefits and drawbacks. Low frequency systems operate between 125 and 134 kHz. One major drawback to a LF system is that it has slow read rates. In general, LF systems have a shorter read range than higher frequency systems. A major benefit is that LF systems are able to operate well around water and metals. High frequency systems—operating around 13.56 MHz—have a slightly larger read range than LF, but require a higher power source. The UHF can have a read range of up to three meters and have faster read rates. However, the UHF systems operating at 860-930 MHz frequencies do not operate well around water or metals [3].

Bar-coding in Hospitals

There has been some research using surgical sponges with bar codes attached to perform a computer-assisted sponge count. One of the benefits of the computer assisted counting system is that the computer alerts the staff member counting the sponges if a sponge is being counted multiple times. The system also improves the ability to detect discrepancies in the sponge counts. However, it does not change the time required to resolve the discrepancy. Additional difficulties with the system include scanning unintended sponges and attempting to scan sponges out of the field while the system was still in the "scan in" mode [9].

RFID in Hospitals

There has been some promising research in the use of RFID technology to ensure that medical gauze is not mistakenly left in surgical patients [12]. The basic concept is that each piece of gauze used in a surgery has an RFID tag attached to it. Before the patient is closed up after the surgery is completed, a handheld reader is passed over the patient to detect if there is any gauze that was not removed from the cavity. The initial trials were very successful, with 100% detection of tags remaining in the cavity and no false readings—the reader detecting a tag not within the cavity. The issues of human error and retained gauze were raised during trials. For example, if the scan is performed incorrectly—the wand is too far away from the body—this could cause tags not to be read. Another concern is that any gauze used after the scan has been performed has a chance of not being removed.

RF Surgical Systems Inc. is one company that has developed a wand system for detecting RFID tagged surgical sponges. The system uses LF passive tags that are low cost. The tags operate in such manner that there is no signal interference from pacemakers or other medical devices. This particular application is used to assist in ensuring that no sponges have been

retain within the surgical cavity, even if there are no discrepancies in the manual counts. The wand is moved over the surgical cavity. If a sponge is detected, the detection console will have a visual and audible alarm that will notify the staff that a sponge has been located [16]. The system has the ability to read 24 inches above and below the wand, but does not keep track of the number of sponges within the surgical cavity.

One company that uses the RFID wand to scan for retained surgical sponges has developed a counting system as well. Before the operation begins, sponges are placed in a bin that detects their presence using the RFID tags that are imbedded in them. When a sponge is needed in the operation, it is removed from the bin. After the sponge has been removed from the surgical cavity, it is placed back in the bin. The number of sponges that are out of the bin and the number of sponges are in the bin are tracked on a display screen. If a discrepancy occurs, then the RFID wand can be used to scan the patient cavity for the missing sponge [14].

The continuous system proposed in this thesis would encompass the RFID wand method along with the ability to keep track of sponges using a counting method. Once a tag entered the interrogation zone it would be identified as entering the surgical cavity and added to a running count of the number of tags within the cavity. This has the possibility of eliminating the manual counting if the system is proven to be error free in the detection of the sponges. Since the system would be continuously monitoring the surgical cavity for tagged sponges, it also acts similarly to the wand in detecting any sponges retained within the cavity.

An RFID system is also proposed to help decrease wrong-site surgeries by increasing the access of information within the surgical room. The system would allow the surgical team to display information pertaining to the patient, such as radiographs and prior medical history, within the OR. This would permit crosschecks of the patient's consent form, the OR schedule,

and the radiograph to ensure the correct operation site. This would be extremely beneficial if there are multiple surgeons or operations with one patient. The additional surgeons have the advantage of being able to instantly access information about the patient before and during the operation. With the increased instant access to patient information, if there is any confusion pertaining to an operation, it can be resolved quickly within the OR.

CHAPTER 3: METHODOLOGY

While the bar code and RFID systems provide additional assistance for ensuring that no surgical sponges are retained within the surgical cavity, there are still downfalls for each system. A downfall for the bar code system is that each of the sponges must be scanned individually by the system before and after the surgery. If a sponge is not accurately scanned by the system, this could result in a discrepancy in the count. Additionally, bar code systems require a line-of-sight to read the bar code. If the bar code is covered in a substance that makes it difficult to be read, this could cause a miscount in the process. The RFID wand system has the downfall of human errors mentioned in chapter two. The benefit of an RFID counting system over a bar code system is that RFID technology allows for multiple tags to be read simultaneously in an interrogation zone without worrying about a line-of-sight. Thus, the system should eliminate the need for a manual count. A downfall for the system would be if a sponge was introduced to the sterile field without being first introduced within the RFID's interrogation zone.

This research proposes to eliminate these current concerns by using an RFID system that will continuously scan the surgical cavity for RFID-tagged surgical sponges. The use of an RFID system would eliminate the need for line-of-sight that is required by a bar code system. The proposed system would identify any tagged sponges that enter and leave the surgical cavity. By having an RFID system continuously scanning the surgical cavity, this will eliminate the possibility of an RFID-tagged sponge entering the body cavity without being counted by the system. Additionally, a continuous scanning system would eliminate the possibility of human

errors occurring because a wand scan was performed too early or a scan performed at an incorrect distance from the surgical cavity.

In developing the continuous detection system, the first stage is to procure an appropriate RFID system. Since the body cavities have an effect on the radio waves, it is important that the RFID system that is chosen has the capability to read tags through a body. This would suggest that the system be either be low (LF) or high frequency (HF) (125 kHz – 13.56 MHz). While LF systems are reported to work extremely well around water and metals, literature that gave a definite specification about the effects of water and metal on HF systems was difficult to find. In a phone conversation with a representative from Clear Count Medical Solutions, we learned that the company's RFID system actually uses high frequency. Therefore, it is reasonable to expect that HF may have an acceptable performance for this research.

RFID systems have different read ranges based on the operation frequency and antennas being used. It is therefore important that the system has a read range that is large enough to detect tags throughout the entire surgical cavity. In addition, the reader should allow for the data from the reader to be used in a middleware program that displays the information in the context needed by the project—counting the number of tags within the interrogation zone, displaying information about the operation(s), and determining if the correct components are in the operating room.

Another important characteristic that the system should contain are anti-collision protocols. This allows for multiple tags in the interrogation zone to be read. If there are no anti-collision protocols and multiple tags are within a zone, none of the tags will be read. Table 1 shows the RFID systems we looked at towards that end of the decision process.

		Read	Anti-		
RFID Systems	Frequency	Range	Collision	PC Interface	Cost
Alien 9650	UHF (902.75 MHz)	~10'	YES	Java, .NET	\$1,028.49
Moby D	HF (13.56 MHz)	25.5"	YES	C, Visual Basic	-
GAO 233004	HF (13.56 MHz)	12"	YES	Visual Basic, RS-232	\$499.00
HID 5375	LF (125 kHz)	13" - 6'	NO	Wiegand, RS-232	\$369.00
GAO 211005	LF (125 kHz)	35"	NO	Wiegand, RS-232	\$599.00

Table 1: RFID Systems Characteristics

Since the literature suggests that UHF waves do not travel well through liquids, the Alien system would not be suitable. While the LF readers have long read ranges, neither of the systems have the ability to read multiple tags within an interrogation zone. The high frequency readers have both the ability to read multiple tags within the interrogation zone and a maximum read range of one foot or over. There were difficulties reaching a sales representative who had an extensive knowledge of the Moby D system. It was therefore felt that if any problems were to arise with the system, it might be difficult to get them resolved in a timely fashion. This left the Gao 233004 system. While the read range is shorter than some of the other systems, it was felt that the anti-collision ability was a more important characteristic than the read range since the research deals with reading multiple tags within the cavity at a single time.

The first step after the RFID system has been acquired is to map the interrogation zones of the reader for different tag sizes when there are no other materials that could reduce the read ranges of the tags. This gives a baseline for the ability of the tags and will give a general idea of the tags capabilities before testing in different materials. Additionally, the ability of the system to read multiple tags simultaneously should be checked to ensure its capability.

Once the interrogation zones have been mapped, tests will be performed on the ability of the tags to read through different materials that may simulate a human body cavity. The test materials will begin with roughly a nine percent saline solution. Dr. Paul Dale suggested this as an initial simulation of the human body composition [6]. Heating distilled water to a temperature under the boiling point is the first step to creating the solution. Salt is slowly stirred into the water until the granules no longer dissolve. The remaining salt granules are filtered out. The water is now a 100% saline solution.

To create a solution that is roughly nine percent saline, the 100% solution is mixed with distilled water with nine parts to 91 parts, respectively. The saline solution will be placed in a plastic jar. Then tags will be placed within the jar and an attempt to read those tags will be performed. The tags that do not have plastic inlays should be placed in a watertight plastic bag to ensure that the circuitry does not get wet, causing the tag to not operate.

Since the body is not totally composed of water, the performance of tags that are placed between blocks of ballistics gelatin will be tested. The mixture is similar to ballistics gelatin that the FBI uses to simulate the effect of firearms ammunition on human and animal muscle tissue. The instructions for the mixture can be found in Appendix B. For this experiment, the gelatin is poured into plastic containers to create roughly 7.5"x7.5"x1.5" blocks. Three blocks are made and placed on top of the RFID antennas. The RFID tags are put in plastic sandwich bags—to reduce the amount of gelatin residue retained on the tags—and then placed between and on top of the blocks to test to see if they can be read.

Once the tags have been tested in the ballistics gelatin, the performance will be tested in a piece of meat purchased at a grocery store. This test is a natural progression from the ballistics gelatin, showing if the tags can work in actual body tissue versus just a simulation of

tissue with the gelatin. If the tags cannot be read through this size sample of tissue, then it is highly unlikely that the tags could be read while in a human cavity. The tags should be placed in plastic sandwich bags and the antenna should be covered in plastic wrap for sanitary reasons. The tags will then be place within the piece of meat and then placed within the interrogation zone of the antenna.

If the tags can be read while in the two to four pound piece of meat, the next test will be to place the tags within a pig carcass. Using a carcass of 150 pounds or more, this would closely simulate the ability to detect tags within a human body. Not only is it important to determine if the tags are detected while in the cavity, but it is important to ensure that all of the tags are being detected simultaneously and that they are detected as soon as they are within the interrogation zone. Again, for sanitary reasons, the tags should be placed in sandwich bags and the reader should be covered with plastic wrap. The tags should be read before being placed in the cavity to ensure the system is working properly. The antenna should be placed in such a position that the interrogation zone will encompass the cavity. If the antenna is placed on a metal table, a material that does not interfere with the reader's signal should be placed between the antenna and the table. This "buffer" should be no less than 2.5 inches thick. This dimension was determined by placing different sized "buffers" on the top of a sheet of metal and attempting to read a tag placed on top of the "buffer". The tags should then be placed within the cavity at different locations. While this is occurring, the detection of the tags should be monitored to ensure that new tags are being read once they enter the cavity and that existing tags remain being identified as within the field.

Parallel to this research is to investigate the use of RFID to help ensure that the correct operation is performed on the correct patient. With the lack of cross-checking the

documentation pertaining to surgery, having all of this documentation easily accessible in the operating room for everyone to see would be extremely beneficial. A system that utilizes RFID technology to access a patient database is proposed. All of the patient information critical to the operation would be stored in a database along with a unique identification number that corresponds to an RFID tag that is located on the patient's body. When the patient enters the operating room, the tag is scanned and information pertaining to the surgery is then displayed on monitors within the room. This will not only allow for cross-checking the initial diagnosis with the subsequent documentation, but also allow for the entire surgical staff to have instant access to pertinent information, especially if there are multiple surgeons, multiple operations, or the surgical site is not marked.

For this research an example program will be developed to show how a patient's RFID tag could be scanned and the information pertinent for the operation is then displayed on a monitor in the surgical room. The program will be developed using Microsoft Visual Basic 2008 Express Edition. The first objective is to establish communication between the program and the RFID reader using the computer's serial port. This will be accomplished by using the serial port controller available in Visual Basic. Once this link is established, the RFID tag's identification number should be able to be read and displayed by the program.

The next step is to have the program reference a database file and display the data corresponding to the tag that was scanned. Since this is an example program, a Microsoft Excel file will be used as the database file. The program should display the tag identification number, the patient's name, the operation to be performed, and any documents that are needed—such as radiographs and consent forms.

The results and conclusions of the continuously scanning RFID system that was proposed in this chapter can be found in Chapter 4: Results and Deliverables. Additionally, Chapter 4 will discuss the development of the program proposed to help prevent wrong-site surgeries.

CHAPTER 4: RESULTS & DELIVERABLES

Continuous RFID Detection System

Once the RFID system had been acquired, the interrogation zones of the reader for the different tag sizes were mapped. The HF tag shapes can be seen in Figure 1. Figure 2 and Figure 3 show the read range of the 82x49 paper inlay. The read ranges for the entire set of tag types can be found in Appendix A.

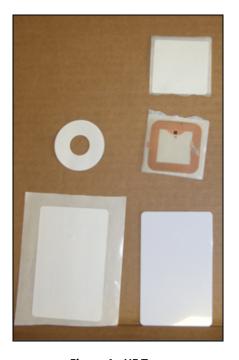


Figure 1: HF Tags

In Figure 2, the gray area represents the reader antenna. The first number represents the maximum read distance—in inches—at the specific location. It is important to note that two of the tags will not read directly over the antenna, but must be a minimum height above the antenna to be read—this is the distance denoted by the second number. It is unclear why these two tags will not read directly over the antenna while the other tags will. For the 82x49 paper

inlay, the tag can be read directly on the antenna; therefore the minimum read distance is zero. The type of tag used can drastically change the maximum read range because of the shape of the antenna. The 82x49 tags have the longest read ranges of 11.5 and 13 inches. The circle tag has the shortest maximum read range at six inches.

				0/0				
		0/0	1/0	2/0	1/0	0/0		
0/0	1/0	2/0	10/0	10/0	10/0	2/0	1/0	0/0
3.5/0	3.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	3.5/0	3.5/0
•								
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
5.5,5	0.0,0	_0.0,0					0.0,0	0.0,0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
3.5/0	5.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	3.3/0	3.3/0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
0.5/0	2.5/0	10.5/0	40.5/0	44.5/0	10.5/0	40.5/0	2.5/0	2.5/0
3.5/0	3.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	3.5/0	3.5/0
0/0	1/0	2/0	10/0	10/0	10/0	2/0	1/0	0/0
		0/0	1/0	2/0	1/0	0/0		
				0/0				

Figure 2: Read Ranges for HF 82x49 Paper Inlay

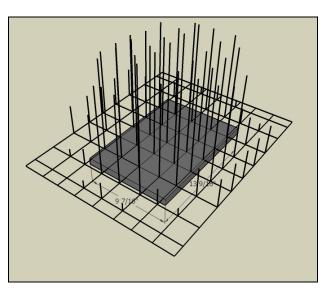


Figure 3: Read Ranges for HF 82x49 Paper Inlay

In addition to mapping the interrogation zones for each tag type, the demonstration software that came with the system was used to ensure that the tags were being read continuously and accurately while in the interrogation zone. The software also showed that multiple tags in the interrogation zone were being read simultaneously. Not only does the software show the identification numbers of each of the tags within the interrogation zone, but it also displays the aggregate number of tags that are being detected. This shows that it is possible to develop a program with the capability of displaying the number of sponges within an interrogation zone and, therefore, if time does not permit the development of a program displaying the aggregate count, then this program could be used to demonstrate that application.

After mapping the interrogation zone of the HF tags without any materials that could obstruct the read distances, the tags were tested in different materials. The tags were tested in a plastic jar containing a nine percent saline solution—seen in Figure 4 (Note that food coloring was added to the solution to increase visibility in the photograph). Only the larger plastic tags could be read while in the solution. The tags were read at a maximum height of eight inches at the center of the antenna. Table 2 shows these read ranges. This creates the possibility of a HF RFID system not being appropriate to read through a surgical cavity as proposed in this research.



Figure 4: Saline Solution

Since the HF tags had a poor performance in the saline obstruction, a low frequency RFID system was purchased. The LF system was bought from www.byshipping.com via an Ebay auction. Due to the funding constraints of the project, it was important to find a LF system that had a longer read distance and yet at a suitable cost. It is important to note that the LF system that was purchased does not have the capability to read tags when more than one tag is in the interrogation zone. However, after correspondence with a member of the HID Global engineering department, it was confirmed that LF RFID systems have the capability to read multiple tags within an interrogation zone [4]. Thus, LF systems should have the capability to read multiple tags simultaneously through water. The system that was purchased has two different types of RFID tags used. The supplier rated one of the tags to have a read distance of 13 inches, while the other tag was rated at 23 inches. The tags can be seen in Figure 5.



Figure 5: LF Tags

Similarly to the HF system, the interrogation zones for the two types of tags were mapped. The interrogation zones for the tag with the longer read range can be seen in figures 6 & 7. It can be seen that the tags could be detected at a greater distance than their ratings. For example, the longer tag was rated at 23 inches and was able to be detected at 25 inches. The read range for the other tag can be seen in Appendix A.

6/0 16/0 19/0 21/0 21/0 21/0 19/0 16/0 6/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0									
17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5/0 20.5 19/0 6/0	6/0	16/0	19/0	21/0	21/0	21/0	19/0	16/0	6/0
20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5/0 20.5 19/0 6/0	6/0	19/0	20.5	22.5/0	22.5/0	22.5/0	20.5	19/0	6/0
20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0	17.5/0	20.5/0	21/0	24/0	24/0	24/0	21/0	20.5/0	17.5/0
20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0	20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5/0 20.5 19/0 6/0	20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0 22/0 24/0 25/0 25/0 25/0 24/0 22/0 20.5/0 17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0	20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
17.5/0 20.5/0 21/0 24/0 24/0 24/0 21/0 20.5/0 17.5/0 6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0	20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
6/0 19/0 20.5 22.5/0 22.5/0 22.5/0 20.5 19/0 6/0	20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
	17.5/0	20.5/0	21/0	24/0	24/0	24/0	21/0	20.5/0	17.5/0
6/0 16/0 19/0 21/0 21/0 19/0 16/0 6/0	6/0	19/0	20.5	22.5/0	22.5/0	22.5/0	20.5	19/0	6/0
	6/0	16/0	19/0	21/0	21/0	21/0	19/0	16/0	6/0

Figure 6: Read Ranges for LF Tag with Longer Distance

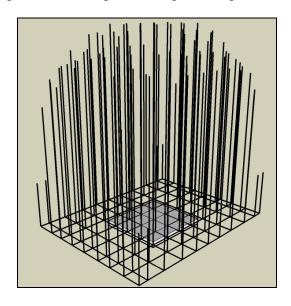


Figure 7: Read Ranges for LF Tag with Longer Distance

Next, the ability of the LF tags to be detected in the saline solution was tested. The saline solution reduced the read distance of the tag with the longer read distance from 25 inches to 22 inches. The tag with a shorter range continued to read at the same distance as if it was not in the solution. Table 2 shows the read range for each HF and LF tag in the saline solution.

Tag Type	Read Range
Circle (HF)	No Read
Square (HF)	No Read
82x49 Paper (HF)	No Read
82x49 Plastic (HF)	8 inches
82x49 13 inch Rating (LF)	15 inches
82x49 23 inch Rating (LF)	22 inches

Table 2: Tag Performance in Saline Solution

Additionally, both the HF and LF tags were then tested in the gelatin blocks to have a controlled simulation of human muscle tissue. The setup for the LF reader can be seen in Figure 8 (Note that food coloring was added to the gelatin to increase visibility in the photograph). Table 3 shows the read ranges of the tags within the gelatin. The gelatin blocks had no adverse effects on the read distance of any of the tags. This suggests that the HF tags may still perform well within muscle tissue since the water has been absorbed into the tissue and not free standing.



Figure 8: LF Tag Test in Ballistics Gelatin

Tag Type	Read Range
Circle (HF)	6.5 inches
Square (HF)	12 inches
82x49 Paper (HF)	11.5 inches
82x49 Plastic (HF)	12 inches
82x49 13 inch Rating (LF)	15 inches
82x49 23 inch Rating (LF)	25 inches

Table 3: Tag Performance in Ballistics Gelatin

An initial test to determine if it is possible to read tags through meat was performed to simulate reading tags through human tissue. The 82x49 paper and plastic HF tags were placed in a 3.36-pound boneless pork roast for the test. The tags were placed in the center of the roast, with 8.5 cm of meat on one side and 6 cm on the other. The placement of the tags in the meat can be seen in Figure 9. The meat was then placed over the RFID antenna to determine in the antenna the tags could be read. The test was performed on the LF tags as well. The read ranges of each tag can be seen in Table 4. There were no changes in the read distances of the tags. It is important to note that the plastic wrap used to cover the antennas for sanitation reasons created inconsistent read distances for the smaller HF tags and therefore these tags were not tested within the pork roast.

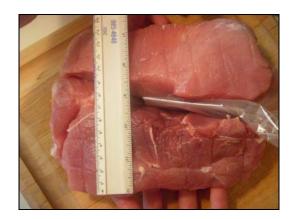


Figure 9: 3.36 lb Boneless Pork Roast Test

Tag Type	Read Range
Circle (HF)	Not Tested
Square (HF)	Not Tested
82x49 Paper (HF)	11.5 inches
82x49 Plastic (HF)	12 inches
82x49 13 inch Rating (LF)	15 inches
82x49 23 inch Rating (LF)	22 inches

Table 4: Tag Performance in Boneless Pork

With the successful testing of the tags in the pork roast, the next step was to test the tags within a freshly slaughtered pig. The University of Missouri Food Science department and Rick Disselhorst provided a testing area and pig for the experiment. The specimen that was used for the experiments was scheduled for slaughtering by the Food Science department. The pig that was used was a smaller pig with a thickness of around 11 ½ inches at the chest. It was felt that this size would simulate a human body cavity better than the larger specimens that were available. The pig was killed, cleaned, and beheaded. The breastplate was then cut open to allow for the insertion of the RFID tags. The initial placement of the RFID antenna was underneath the carcass and on top of a buffer to eliminate interference from the metal table (See Figure 11). The buffer was a foam pad that was roughly three inches thick and can be seen in Figure 10. The weight of the pig caused the pad's thickness to decrease and, as a result, the metal table caused the tags to not read properly. Therefore, the antenna was placed on the top of the pig as seen in Figure 12.

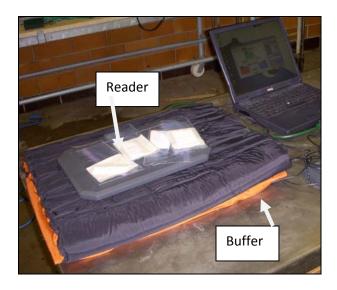


Figure 10: Initial Proposed Setup



Figure 11: Initial Setup with Carcass



Figure 12: Second Setup with Carcass

Once the antenna was in place, the HF tags were placed within the cavity. The cut that was made to open the breastplate did not allow for much access into the cavity. Therefore, the tags were only placed a few inches inside of the cavity. The antenna was able to read the tags that were in the cavity. It was also able to read multiple tags within the cavity. It is important to note that the read range for the tags was decreased to roughly half the thickness of the pig carcass. Because of the size of the cavity, it was difficult to place more than two tags far enough apart within the cavity that they could be read easily. It was also observed that the antenna seemed to need to be placed perfectly parallel to the cavity opening to obtain consistent readings of the tags. Table 5 shows the read ranges of the different tags.

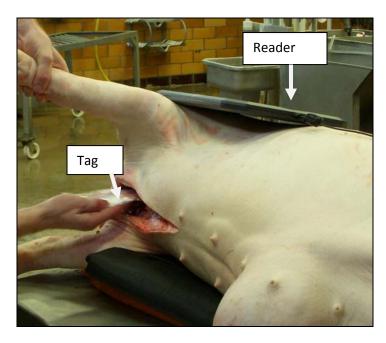


Figure 13: Insertion of Tag into Cavity

Tag Type	Read Range
Circle (HF)	Not Read
Square (HF)	Not Read
82x49 Paper (HF)	5.25 inches
82x49 Plastic (HF)	5.25 inches
82x49 13 inch Rating (LF)	Malfunction
82x49 23 inch Rating (LF)	Malfunction

Table 5: Tag Performance in Pig Carcass

It is important to note that the LF reader was not used with this experiment because in testing the thickness needed for the buffer, either the antenna or the tags were manipulated in such a way that the read ranges of the tags decreased to only a few inches. It would have not been beneficial to test the LF system with these subpar performances. We considered this condition to be a malfunction. Additionally, since the smaller HF tags were not tested in the boneless pork, they were not tested in the pig carcass. Table 6 shows the results of the larger tags, both HF and LF, in the different mediums that were tested.

Tag Type	No Medium	Saline Solution	Gelatin	Meat Sample	Pig Carcass
HF (Paper inlay)	11.5 inches	No Reading	11.5 inches	11.5 inches	5.25 inches
LF (13 inch rated)	15 inches	15 inches	15 inches	15 inches	N/A
LF (23 inch rated)	25 inches	22 inches	25 inches	25 inches	N/A

Table 6: Performance of 82x49 Tags in Different Mediums Tested

With this initial testing of the HF RFID system, it seems that a continuously scanning system is possible. The tests show that not only were tags detected accurately while located inside of a freshly slaughtered pig carcass, but also multiple tags could be detected within the cavity. It was also important to show that the tags were not detected until placed within the interrogation zone, which coincided with the cavity. This interrogation zone was smaller than that of the interrogation zone when the HF reader was tested with other mediums, however, it is promising that the zone was still large enough to encompass the cavity. While additional testing should be performed to further develop the system, this initial testing shows that a continuous detection system is possible.

Wrong-Site Surgery Prevention Program

In developing the program to help prevent wrong-site surgeries, the LF RFID system was used since there are no anti-collision protocols for the system. This would allow only one tag to be read by the reader at a single time, avoiding the possibility of having the program attempt to display two sets of information simultaneously. The Visual Basic source code can be found in Appendix C. The Graphical User Interface (GUI) developed can be seen in Figure 14.



Figure 14: GUI for Wrong-Site Surgery Prevention Computer Program

To begin, the "Start" button is clicked. The "Start" button then changes to the "Open COM" button. Clicking this will open the serial port that has been defined within the program. When a tag has been placed within the interrogation zone of the LF reader, the reader will make an audio and visual indication that it is being detected. Clicking the "Get Info" button in the GUI will have the program access its corresponding Excel file—an example can be seen in Figure 15. The program will write the tag's identification number into cell A1. Cells B1 through F1 use the Index and Match functions (Corresponding to the code in cell B1 in Figure 15) to display the correct column information corresponding to the tag identification number written into cell A1. The program will then display the information from cells B1 through D1 on the GUI. Clicking Image 2 and Image 3 can display the images that are found in cells E1 and F1, respectively.

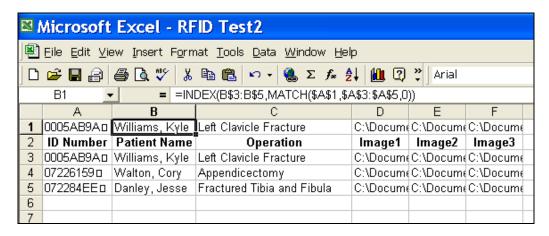


Figure 15: Microsoft Excel File for Wrong-Site Prevention Computer Program

The major benefit of a program such as this is that all of the patient's information can be displayed in the operating room by clicking the appropriate button in the GUI. This creates the ability to check patient history, radiographs, or other information directly from the operating room if there are any concerns by the surgical staff. While there were no tests of the program performed within an operating room environment, this is only a preliminary program that

represents a proof-of-concept for a methodology that can be a possible solution for wrong-site surgeries caused by confusion and a lack of information.

This concept of using RFID tags to tie into the patient database for instant access to patient information in the surgical room, along with the continuously scanning RFID system, can act as the ground work for the future development in the prevention of wrong-site surgeries and retained foreign objects. Some possible extensions for these topics can be seen in the following chapter.

CHAPTER 5: FUTURE RESEARCH

With developments in any medical technology, there are rigorous regulations and concerns that must be overcome in order to bring the technology to the market. The development of the proposed continuously scanning RFID system used to detect retained surgical sponges may have a more difficult time overcoming these regulations and concerns since the retention of sponges is such a serious condition. Understandably, the medical community will be reluctant to rely solely on a system that has no human checking component. The RFID systems that are currently being used in the practice of the detection of sponges are used as an additional "safety net" to the traditional counting procedure. Therefore, it is vital that the system become failsafe before implemented without a human aspect to check the count as well. It is foreseeable that RFID technology could advance to the stage where the counting procedure is no longer needed and the RFID system is only used in the detection of sponges.

The extensions of this research will first include the development of an RFID system specifically developed for this application. The system should include the criteria used in choosing the RFID system used in this research—multiple tag reading, a long read range, and the ability to operate near water and metal. One of the major problems in the tests performed with the pig carcass was the interference from the metal table. While there may be surgical tables that are made of materials other than metal, my research did not find any such tables. Thus, the system will either need to be able to operate with one side directly touching a metal surface or a buffer system will need to be developed for the antenna. Additionally, a system should be

utilized that uses smaller RFID tags that can be sewn into the surgical sponges, similar to the current wand systems. This allows for the sponges to be more flexible and easier to use.

Once the new RFID system has been developed, additional tests should be performed on pig carcasses. If this proves successful, the next step would be to perform clinical studies with human subjects. With the concerns for the human safety and the reliability of the system that might be raised in the medical field, several studies may be needed to show the capabilities of the system.

There is also further development needed on the computer program proposed for the assistance in preventing wrong-site surgeries. Integration into the hospital's database will be needed in order to access the patient information, such as the radiographs, consent forms, and schedule. Additionally, concerns about security and patient privacy will need to be addressed. The interface that displays the patient's information will most likely be redesigned to better meet the needs of the surgical team.

While there are still concerns that need to be overcome, the use of radio frequency identification in surgical rooms seems extremely plausible. The ability to track items similar to the way barcodes work, but with out having to have a clear line-of-sight, can increase efficiency in operating rooms. In addition, the ability to have patient information on hand without having to manually collect and transport the information will allow for a safer, more efficient operating room.

BIBLIOGRAPHY

[1] Association of Perioperative Registered Nurses, 2006 Standards, Recommended Practices,
and Guidelines. 2006.
[2] "Past Practices for Proventing a Potained Foreign Pody." AOPN Journal Vol. 94/2006): 520
[2] "Best Practices for Preventing a Retained Foreign Body." <u>AORN Journal</u> Vol. 84(2006): S30-
S36.
[2] Cooney, Elaine M RFID+ The Complete Review of Radio Frequency Identification. Thomson
Delmar Learning, 2006.
[4] Dageenakis, Damon. "Re: Low Frequency RFID Question." E-mail to author.06 July 2008.
[5] Dagi, T., R . Berguer , S . Moore , H . Reines. "Preventable Errors in the Operating Room - Part
2: Retained Foreign Objects, Sharps Injuries, and Wrong Site Surgery." <u>Current Problems in</u>
<u>Surgery</u> Vol. 44(2007): 352-381.
[6] Dale, Paul. Associate Professor of Clinical Surgery at the University of Missouri. Personal
interview. 25 June 2008.

[7] Gawande, Atul A., David M. Studdert, E. John Orav, Troyen A. Brennan, Michael J. Zinner. "Factors for Retained Instruments and Sponges After Surgery." . New England Journal of Medicine 348(2003): 229-235.

[8] Girard, Nancy J., RN. "The Countdown to Safety." AORN Journal Vol. 79(2004): 575-576.

[9] Greenberg, Caprice C., Rafael Diaz-Flores, Stuart R. Lipsitz, Scott E. Regenbogan, Lynn Mulholland, Francine Mearn, Shilpa Rao, Tamara Toidze, Atul A. Gawande. "Bar-coding Surgical Sponges To Improve Safety: A Randomized Controlled Trial." <u>Annals of Surgery</u> Volume 247, Number 4(2008): 612-616.

[10] Jechlitschek, Christoph. "Radio Frequency IDentification - RFID." <u>CSE574S: Advanced Topics in Networking: Wireless and Mobile Networking (Spring 2006)</u>. 24 APR 2006. Washington University in St. Louis. 23 Jul 2008 http://www.cse.wustl.edu/~jain/cse574-06/ftp/rfid/index.html.

[11] Kwaan, Mary R., MD, MPH, David M. Studdert, LLB, ScD, Michael J. Zinner, MD, Atul A. Gawande, MD, MPH. "Incidence, Patterns, and Prevention of Wrong-Site Surgery." <u>Archives of Surgery Vol 141(2006)</u>: 353-357.

[12] Macario, Alex, MD, MBA, Dean Morris, MBA, Sharon Morris, RN, BSN, CNOR. "Initial Clinical Evaluation of a Handheld Device for Detecting Retained Surgical Gauze Sponges Using Radiofrequency Identification Technology." <u>American Medical Association Archives of Surgery</u>
141(2006): 659-662.

[13] Meinberg, Eric G., MD, Peter J. Stern, MD. "Incidence of Wrong-Site Surgery Among Hand Surgeons." The Journal of Bone and Joint Surgery, Incorporated Vol 85(2003): 193-197.

[14] "Product Overview." <u>ClearCount Medical Solutions</u>. 01 APR 2008. Clear Count Medical Solutions. 15 APR 2008 http://www.clearcount.com/>.

[15] "Radio-frequency identification." <u>Wikipedia.com</u>. Wikimedia Foundation, Inc.. 23 APR 2007 http://en.wikipedia.org/wiki/RFID.

[16] "RF Surgical Sponge Detection - Product Overview." <u>RF Surgical Systems, Inc.</u>. 2008. RF Surgical Systems, Inc.. 21 Jul 2008 http://www.rfsurg.com/.

[17] Rogers, Michelle L., Richard I. Cook, Robert Bower, Mark Molloy, Marta L. Render. "Barriers to Implementing Wrong Site Surgery Guidelines: A Cognitive Work Analysis." <u>IEEE Transactions</u> on Systems, Man, and Cybernetics - Part A: Systems and Humans Vol. 34(2004): 757-763.

[18] Smith, Roger. "RFID: A Brief Technology Analysis ." <u>RFIDConsultation.eu</u>. 2004. CTOnet. 24 APR 2007 http://www.rfidconsultation.eu/docs/ficheiros/RFID_analysis.pdf.

[19] Tinsley, Amy. Manager for Surgery Services at the University of Missouri Health Care's University Hospital. Personal interview. 26 June 2008.

Appendix A: Read Ranges for HF and LF RFID Tags

In the figures that have numerical representation, the gray area represents the reader antenna. The first number represents the maximum read distance—in inches—at the specific location. Two of the tags will not read directly over the antenna, but must be a minimum height above the antenna to be read—this is the distance denoted by the second number. There is also a three-dimensional representation of the interrogation zone. The numerical values in the first figure correspond to the heights of the lines in the three dimensional representation.

Circle (HF)

				х				
		х	х	x	х	х		
x	х	0.5/0	0.5/0	0.5/0	0.5/0	0.5/0	х	х
х	0.5/0	2.5/0	4/0	4/0	4/0	2.5/0	0.5/0	х
x	0.5/0	4/0	5.5/0	6/0	5.5/0	4/0	0.5/0	х
х	0.5/0	4/0	5.5/0	6.5/0	5.5/0	4/0	0.5/0	x
x	0.5/0	4/0	5.5/0	6/0	5.5/0	4/0	0.5/0	х
x	0.5/0	2.5/0	4/0	4/0	4/0	2.5/0	0.5/0	х
х	х	0.5/0	0.5/0	0.5/0	0.5/0	0.5/0	х	х
		х	х	х	х	х		
				x				

Figure 16: Read Ranges for HF Circle

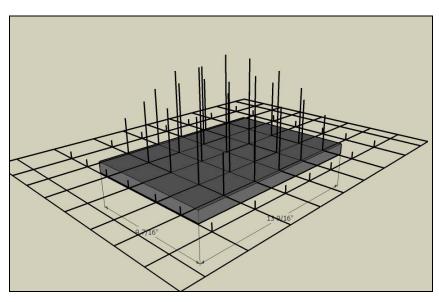


Figure 17: Read Ranges for HF Cirlce

Square (HF)

				2/0				
		2/0	2/0	2/0	2/0	2/0		
х	2/0	5/0	7.5/1	7.5/1	7.5/1	5/0	2/0	Х
1.5/0	2/0	9.5/0	11/1	11/1	11/1	9.5/0	2/0	1.5/0
1.5/0	7/0	10.5/0	12/1	12/1	12/1	10.5/0	7/0	1.5/0
1.5/0	9/0	10.5/0	12/1	12/1	12/1	10.5/0	9/0	1.5/0
1.5/0	7/0	10.5/0	12/1	12/1	12/1	10.5/0	7/0	1.5/0
1.5/0	2/0	9.5/0	11/1	11/1	11/1	9.5/0	2/0	1.5/0
x	2/0	5/0	7.5/1	7.5/1	7.5/1	5/0	2/0	х
		2/0	2/0	2/0	2/0	2/0		
				2/0				

Figure 18: Read Ranges for HF Square

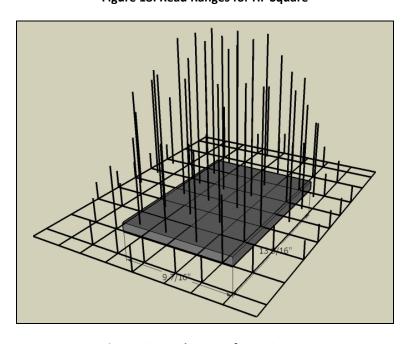


Figure 19: Read Ranges for HF Square

82x49 Paper Inlay (HF)

				0/0				
		0/0	1/0	2/0	1/0	0/0		
0/0	1/0	2/0	10/0	10/0	10/0	2/0	1/0	0/0
3.5/0	3.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	3.5/0	3.5/0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
3.5/0	9.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	9.5/0	3.5/0
3.5/0	3.5/0	10.5/0	10.5/0	11.5/0	10.5/0	10.5/0	3.5/0	3.5/0
0/0	1/0	2/0	10/0	10/0	10/0	2/0	1/0	0/0
		0/0	1/0	2/0	1/0	0/0		
				0/0				

Figure 20: Read Ranges for HF Paper Inlay

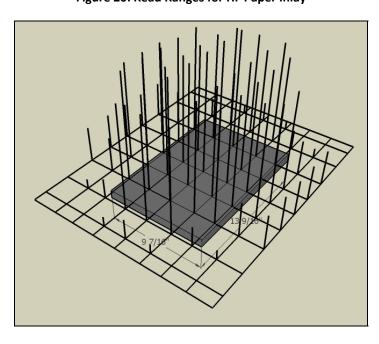


Figure 21: Read Ranges for HF Paper Inlay

82x49 Plastic Inlay (HF)

				2/0				
		1/0	2/0	2/0	2/0	1/0		
4/1	3/1	6.5/1	9/1	9/1	9/1	6.5/1	3/1	4/1
4.5/1	7.5/1	10.5/1	11/1	11/1	11/1	10.5/1	7.5/1	4.5/1
6.5/1	10/1	11/1	11.5/1	12/1	11.5/1	11/1	10/1	6.5/1
6.5/1	8/1	11.5/1	11.5/1	12/1	11.5/1	11.5/1	8/1	6.5/1
6.5/1	10/1	11/1	11.5/1	12/1	11.5/1	11/1	10/1	6.5/1
4.5/1	7.5/1	10.5/1	11/1	11/1	12/1	10.5/1	7.5/1	4.5/1
4/1	3/1	6.5/1	9/1	9/1	9/1	6.5/1	3/1	4/1
		1/0	2/0	2/0	2/0	1/0		
				2/0				

Figure 22: Read Ranges for HF Plastic Inlay

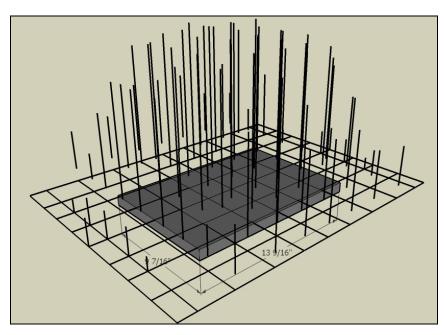


Figure 23: Read ranges for HF Plastic Inlay

Tag with Longer Read Range (LF)

6/0	16/0	19/0	21/0	21/0	21/0	19/0	16/0	6/0
6/0	19/0	20.5	22.5/0	22.5/0	22.5/0	20.5	19/0	6/0
17.5/0	20.5/0	21/0	24/0	24/0	24/0	21/0	20.5/0	17.5/0
20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
20.5/0	22/0	24/0	25/0	25/0	25/0	24/0	22/0	20.5/0
17.5/0	20.5/0	21/0	24/0	24/0	24/0	21/0	20.5/0	17.5/0
6/0	19/0	20.5	22.5/0	22.5/0	22.5/0	20.5	19/0	6/0
6/0	16/0	19/0	21/0	21/0	21/0	19/0	16/0	6/0

Figure 24: Read Ranges for 23 inch Rated LF Tag

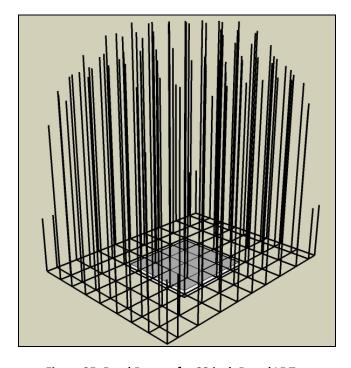


Figure 25: Read Ranges for 23 inch Rated LF Tag

Tag with Shorter Read Range (LF)

0/0	2.5/0	3/0	4/0	4/0	4/0	3/0	2.5/0	0/0
2.5/0	3.5/0	3.5/0	4.5/0	4.5/0	4.5/0	3.5/0	3.5/0	2.5/0
4/0	3.5/0	10.5/0	13/0	13/0	13/0	10.5/0	3.5/0	4/0
4.5/0	10.5/0	14/0	14.5/0	14.5/0	14.5/0	14/0	10.5/0	4.5/0
4.5/0	12/0	14.5/0	15/0	15/0	15/0	14.5/0	12/0	4.5/0
4.5/0	12/0	14.5/0	15/0	15/0	15/0	14.5/0	12/0	4.5/0
4.5/0	12/0	14.5/0	15/0	15/0	15/0	14.5/0	12/0	4.5/0
4.5/0	10.5/0	14/0	14.5/0	14.5/0	14.5/0	14/0	10.5/0	4.5/0
4/0	3.5/0	10.5/0	13/0	13/0	13/0	10.5/0	3.5/0	4/0
2.5/0	3.5/0	3.5/0	4.5/0	4.5/0	4.5/0	3.5/0	3.5/0	2.5/0
0/0	2.5/0	3/0	4/0	4/0	4/0	3/0	2.5/0	0/0

Figure 26: Read Ranges for 13 inch Rated Tag

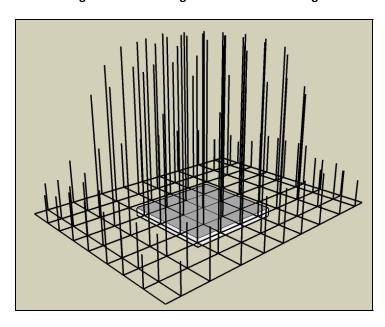


Figure 27: Read Rages for 13 inch Rated Tag

Appendix B: Ballistics Gelatin

The following are the instructions on how to make the ballistics gelatin that was used in this research. These instructions were taken, and slightly modified, from http://www.myscienceproject.org/gelatin.html

- 1. Slowly mix four ounces of plain Knox gelatin with one quart of water in a metal pan, ensuring that the gelatin dissolves completely in the water.
- 2. Refrigerate the mixture for two hours.
- 3. Heat the gelatin over a pan of heated water. The temperature of the gelatin should not get about 130 degrees Fahrenheit.
- 4. Once the mixture has melted completely, slowly pour into a plastic container sprayed with nonstick cooking oil.
- 5. Refrigerate for 36 hours.

Appendix C: Visual Basic Code

```
'Any reference names need to be declared using DIM or CONST
Public Class Form1
  Dim objExcel As New Excel. Application
 Dim objWrkBk As Excel.Workbook
 Dim objSht As Excel.Worksheet
 Dim patientname As String
 Dim operation As String
  Dim picture1 As String
 Dim picture 2 As String
 Dim picture3 As String
 Const ButtonTextOpenPort As String = "Open COM Port"
 Const ButtonTextClosePort As String = "Close COM Port"
 Dim ReceivedData As String
  'This stores the data obtained from the serial port as the user declared "ReceivedData"
 Private Sub DataReceived(ByVal sender As System.Object, ByVal e As
 System.IO.Ports.SerialDataReceivedEventArgs) Handles SerialPort1.DataReceived
    ReceivedData = SerialPort1.ReadLine
  End Sub
  'This opens the communication with the serial port. The button needs to be clicked twice.
  Private Sub opencom1_Click(ByVal sender As System.Object, ByVal e As System.EventArgs) Handles
  opencom1.Click
    Button1.Enabled = True
    If (opencom1.Text Is ButtonTextOpenPort) Then
      SerialPort1.Open()
      If SerialPort1.IsOpen Then
        opencom1.Text = ButtonTextClosePort
      End If
    Else
      SerialPort1.Close()
      If Not SerialPort1.IsOpen Then
        opencom1.Text = ButtonTextOpenPort
      End If
    End If
  End Sub
'By clicking Button1, TextBox2 displays the data from the serial port, the program accesses the Excel file
  "RFID Test.xls" and writes the data from the serial port into cell A1. The program then stores the values
 from cells B1, C1, D1, E1, & F1 as user defined values. Some of these values are displayed on the form
  using RichTextBox2, RichTextBox1, and PictureBox1. NOTE: In order to have the Excel file recongnize
```

TextBox2.Text = ReceivedData

Button1.Click

Private Sub Button1 Click(ByVal sender As System.Object, ByVal e As System.EventArgs) Handles

the tag ID number, the number must be written into Excel cell using a VB program.

```
objWrkBk = GetObject("C:\Documents and Settings\Kyle Williams\Desktop\RFID Test.xls")
    objSht = objWrkBk.Worksheets(1)
    objSht.Range("A1").Value = ReceivedData
    patientname = objSht.Range("B1").Value.ToString()
    operation = objSht.Range("c1").Value.ToString()
    picture1 = objSht.Range("F1").Value.ToString
    picture2 = objSht.Range("D1").Value.ToString
    picture3 = objSht.Range("E1").Value.ToString
    RichTextBox2.Text = patientname
    RichTextBox1.Text = operation
    PictureBox1.Image = Image.FromFile(picture1)
    Button2.Enabled = True
    Button3.Enabled = True
    Button4.Enabled = True
 End Sub
 'When this button is clicked, PictureBox1 displays the file declared as picture1
 Private Sub Button2 Click(ByVal sender As System.Object, ByVal e As System.EventArgs) Handles
 Button2.Click
    PictureBox1.Image = Image.FromFile(picture1)
  End Sub
  'When this button is clicked, PictureBox1 displays the file declared as picture1
 Private Sub Button3_Click(ByVal sender As System.Object, ByVal e As System.EventArgs) Handles
  Button3.Click
    PictureBox1.Image = Image.FromFile(picture2)
  End Sub
  'When this button is clicked, PictureBox1 displays the file declared as picture1
  Private Sub Button4_Click(ByVal sender As System.Object, ByVal e As System.EventArgs) Handles
 Button4.Click
    PictureBox1.Image = Image.FromFile(picture3)
 End Sub
End Class
```