COMPUTED TOMOGRAPHY ORIENTATION DETECTION SYSTEM

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EXECUTIVE SUMMARY

Every year, patients at medical institutions experience wrong-site surgery, a surgery that occurs at the wrong location in or on the body. In fact, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reported 450 cases of "wrong-site surgery" from 1995-2005. Such improper operations lead to lawsuits and stained reputations for medical institutions. As a result, there has been a strong push for the improvement of patient safety throughout all medical operations and disciplines.

One area of concern is the accurate labeling of computed tomography (CT) images. A CT scanner is an x-ray device that builds a three-dimensional representation of a subject by compiling and organizing a series of two-dimensional x-ray images. The current protocol dictates that one technologist input the patient's orientation into a computer, and this is the only input used to label the CT image. Without a double check in place, the system is vulnerable to errors that could lead to wrong site surgery.

We have been asked to develop a system that ensures the accurate labeling of patient orientation in CT images. In conjunction with our sponsor, Dr. Caroline Blane of the University of Michigan Health System, we defined the customer requirements and engineering specifications needed to produce the most desirable solution for this problem. Dr. Blane ranked all of the pertinent customer requirements while our team devised a list of relevant engineering specifications based upon research and engineering intuition. The most critical design considerations are listed below:

Customer Requirements	Engineering Specifications
1. Be highly reliable	• Material
2. Take little time	• Easy implementation
3. Be unobtrusive to patient	• Time added to procedure
4. Implement in current system	• Radiation exposure
5. Minimize radiation exposure	• Number of Components
6. Minimize image streaking	• Fatigue lifetime

Following these guidelines, we developed two viable solutions: the Second Technologist Double-Check System (STDC) and the Bed Insert Sensor System (BIS). The STDC system uses the orientation input of the CT room technologist and compares it to the orientation input of the control room technologist via a console in the CT room. The computer compares the two inputs, and if they match one scan is allowed to initialize. If they do not match, the technologists are required to re-input the orientations until they match. An application of basic statistics implies than if one technologist rarely makes an error, the chances that two will make the same error on the same scan are orders of magnitude less.

The BIS system determines a patient's orientation based upon which headrest or footrest is inserted into the CT bed. The current CT scan process utilizes several different headrest and footrest inserts for patient comfort and support. Each insert is designed to cater to one distinct patient orientation and contains one sensor that is uniquely identified by a receiver in the CT room. Each signal therefore corresponds to exactly one patient orientation. The orientation signal coming from the insert is compared to the computer input from the control room technologist. If the orientations agree, the CT process is allowed to continue and the scan commences. If the orientations disagree, the process is halted and the technologist is required to repeat the process until the orientations match. This automated double check aims to eliminate problems at the source.

In preliminary testing, the engineering success of both systems looks promising, but their different strengths and weaknesses relate strongly to their potential market success. We determined that the less expensive STDC system is the best solution for the UMHS and other institutions that commonly staff two technologists per CT scanner. However, the more expensive BIS system is better suited to serve the industry as a whole, particularly private practices and institutions that

staff one technologist per CT scanner. The relative cost of each system compared to the $1.5 million cost of a typical CT scanner is minute. Thus, cost is not significant when either system is included in the price of a new CT scanner, but becomes more important when retroactively installing either system on an existing CT scanner.

Our future plans are to approach CT manufacturers with these systems. We plan to approach General Electric (GE) first because the bulk of our research and design is based upon GE CT scanners. It is important to note that the implementation of either system requires access to the confidential corporate software that operates the CT system. While this could complicate business endeavors, this sacrifice was made in accordance with the customer's primary concern: reliability. The system loses it robustness and becomes far less reliable when the enforced computerized stop is replaced with a by-passable, human protocol step.

We have filed for patent protection on the ideas and designs contained in this report. Over the next weeks and months, it will be necessary to complete the patent process to gain intellectual property rights. During this time, we will make contact with the proper personnel at the UMHS in an effort to build support in marketing and selling our ideas to industry.

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1. ABSTRACT

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reported that 450 patients in the last 10 years have had "wrong site surgery", a surgery that occurs at the wrong location in or on the body [1]. A prime source of this error is due to incorrect marking of the left and right side of the body on the computed tomography (CT) scan image. The current CT scan process at the University of Michigan Health System (UMHS) requires that only one person input patient orientation and past precedent shows this system is not reliable enough. The ultimate goal of this project is to develop a system that is highly reliable and will ensure that the patient orientation (left, right, anterior and posterior) is properly marked on the CT scan.

2. PROBLEM STATEMENT

Every year, some patients have surgery on the wrong side of their body. While this happens relatively infrequently (on average 45 times every year for the past ten years), it can occasionally result from the incorrect marking of the CT image [1]. The current CT scan process relies on one technologist to note the patient's orientation in the computer and this single-person interaction is where the error occurs. The University of Michigan Department of Radiology has asked our group to create a process that virtually eliminates the chance that the wrong orientation is noted on the CT scan image.

3. INFORMATION SOURCES

Information for a problem of this nature is not heavily documented but rather lies in the insight of the technologists and radiologists who carry out these procedures on a daily basis. Some attempts at solving the problem exist. Two systems we found that seek to resolve this problem are the external marker currently used at UMHS and the CheckSite system developed by CheckSite Medical.

During a meeting with Dr. Caroline Blane and CT technologist Barry Crawford from the UMHS, we were provided with invaluable insight into the CT process. Dr. Blane recommended a "double-check" system during the CT process to reduce error as well as introducing our team to the CT field and team. Mr. Crawford guided our team through the CT process, provided first-hand information and small technical details about the process that has been outlined in the customer requirements section of this report.

Patent research shows that very few solutions exist for this problem. The only prominent solution comes in the form of labeled markers that are placed on the body before the CT scan occurs [2]. These markers are made of dense material that appears on tomography images, allowing identification of the patient's physical orientation to be translated to a CT or MRI image. However, this system provides no safeguards to ensure the labels are properly placed on the patient; it only improves the probability that the patient's orientation is properly interpreted by radiologists and surgeons.

Another solution implements a safeguard analogous to a department store anti-theft system. Developed by CheckSite Medical, the CheckSite system outfits each patient with a wristband containing an activated microchip that alerts a sentry gate outside the operating room [1]. Nurses and technologists are required to verify the patient's surgical information before the wristband can be deactivated. If the wristband has been deactivated, the gates remain silent while the patient is wheeled through. However, if the wristband is active while passing through the gates, the gates sound an alarm and the nurses and technologists are required to go back and recheck the

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information. This system is effective but has no automated or computerized "double check" which allows for the same human error and disregard for procedure that we are trying to eliminate. Finding a solution to a problem of this type requires gradual, continual feedback from CT technologists and radiologists. The missing information to this problem will continue to flow between the engineering and the medical teams as advancements and ideas are brought forth from each side.

4. CUSTOMER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

The UMHS has come up with a set of requirements for the system that is to be designed. First and foremost, the new system must be able to correctly mark the left, right, anterior, and posterior sides of the body on a radiological image. This new system must be more reliable than the existing system and should serve as a reliable "double check." It should also be relatively easy to implement and add only a minimal amount of time to the existing process. With regards to the patient, the new system should be unobtrusive and minimize any additional radiation exposure. Should a design be chosen that requires an external marker to be placed on the body, that marker material should produce minimal radiological interference.

In terms of quantifying the engineering specifications, any new system that is developed should be integrated into the current CT scan process and technology. We are aiming to create a design that doesn't require a complete change of the current process. Creating a reliable double check means that any new design would prevent the CT scan from occurring when a technologist and any double check system disagrees on patient orientation. In terms of minimizing time that is added to the process, we are aiming for additional time to be on the order of seconds instead of minutes or hours. In terms of minimizing radiation exposure, the exposure is the dosage of radiation per x-ray.

5. DESIGN CONCEPTS

Throughout the brainstorming process we developed many design concepts. Each initial design concept was then analyzed based on its pros and cons to determine how feasible it would be in terms of production and implementation. The design concepts that were generated are outlined and discussed at length in Appendix A. We will further discuss our Alpha Design Concepts in the following section.

6. ALPHA DESIGN CONCEPTS

In order to select the optimal design, we weighed our customer requirements (as determined by the customer) and engineering specifications (as interpreted by our team) in the QFD chart seen in Appendix B. The strength of the relationship between the customer requirement and the engineering characteristic was judged on a 1-5 scale. A "one" indicated no significant relationship and a "five" indicated a very strong relationship. The final rank of the customer requirements is determined by summing up the total value of relevancy with the engineering characteristics adjusted for the importance of the customer requirement. This ranking tells us which of the customer requirements demanded the bulk of attention throughout the design process. The details of this process can be seen in Appendix B. The results of this process showed that two systems stood out above the rest. These systems are the Second Technologist Double Check system and the Bed Insert Sensor System (BIS). Due to our customer's interest in both systems, as well as our judgment that these systems could cater to different institutions, we decided to pursue both of these design concepts. An algorithm for both systems is outlined in Appendix C.

6.1 Second Technologist Double-Check System

The STDC system takes into account an additional technologist's input before accepting an orientation and proceeding with the CT scan. Technologist A in the control room continues his or her role of inputting the patient's orientation into the control room computer. Technologist B inputs the patient orientation by pushing a button on a console corresponding to that particular orientation. This console contains descriptions of each of the six possible patient orientations next to each button. Before the CT pre-scan (scout) begins, the computer checks that both inputs match. If correct, the CT scan is allowed to commence. If incorrect, the system stops and requires that both technologists re-enter the orientation information until they match.

6.1.1 Engineering Design Parameter Analysis

By introducing an additional, highly trained technologists' input into the process, the STDC system greatly reduces the likelihood of error in CT image marking. As stated previously, this system is easily implemented into the existing process, is unobtrusive to the patient, and adds no additional radiation exposure. From a mechanical standpoint, the actual design for this system is straight-forward: to create an interactive console that compares the second technologist's input to the original technologist's input and halts the process if the inputs do not match. The main factors to consider for the STDC system are longevity, implementation in the CT operating room, dimensions, and overall user-friendliness and safeguard effectiveness.

The longevity of the double check console is broadly governed by how long the orientation buttons last. Therefore, highly durable push buttons will be used to ensure long life and to minimize the chance the machine breaking down. The buttons will be similar to gasoline octane selection buttons that you would find on a gas pump, but instead will have pictures of different patient orientations printed on them. The console will be made of durable, inexpensive, injection-molded plastic.

The console will be placed in the CT operating room on a wall nearby the CT machine. This allows the operating room technologist easy access without interfering with the procedure. A key override system will be installed to accommodate for situations when only one technologist is available. When the override is activated, the double check is skipped and the process reverts to that of the existing system. Proper placement of the console in the CT room is vital to serving as a reliable double check. While our customer suggested placing it near the door separating the safe room from the CT room, we recommend placing it near the CT room technologist's workspace. This would decrease temptation for the safe room technologist to bypass the system.

The entire console will measure at maximum twelve inches square by three inches deep. This allows plenty of room for two rows of three buttons, each a maximum of three inches square with 1 inch above and below for spacing and labeling. Four inches of depth allows for enough room for heavy-duty buttons and circuitry, and the console can be built into the wall if desired.

6.1.2 Final Design Description

The STDC console will be approximately twelve inches square by three inches deep. Six buttons will display different patient orientations and will be built into the front panel. The console will be placed near the secondary technologist's workplace in the CT room and can be built into the wall if desired. The information from the console can be transmitted wirelessly or through hard-wiring. The console will include a key override that disables the system for instances where only one technologist is available, such as off-shifts.

6.1.3 Prototype Description

A prototype of the console has been produced for the Design Exposition. It is a low-budget mock-up of the console that functions similarly. Six toggle switches light up four different light emitting diodes (LEDs) that illustrate which orientation is entered by the technologist. These LEDs were affixed to a console representing the computer.

6.1.4 Prototype and Initial Manufacturing Plan

The prototype is a smaller, less expensive version of the actual console. It was constructed by our team and others with knowledge in electronics. Because the goal of the prototype was to display the system's functionality, the prototype is as elaborate as the actual console would be. In contrast, the actual console will be made of injection molded plastics for both the housing and the button covers. The electrical components will be purchased from a distributor and the console will be assembled professionally

6.1.5 Validation Plan

To ensure the STDC system works properly, we plan to do several things. We have the general behavior of CT technologists in order to implement proper additional safeguards (i.e. the strategic room placement of the console). We propose testing of our prototype at the UMHS to conduct studies on the use of the STDC system. Additionally, we strongly recommend protocol training that enforces the control room technologist and secondary technologist both input the patient's orientation into their respective terminals for each and every scan.

6.2 Bed Insert Sensor System

The bed insert sensor (BIS) system determines a patient's orientation based upon which headrest or footrest is inserted into the CT bed. The current CT scan process utilizes several different headrest and footrest inserts for patient comfort and support. Each insert is designed to cater to one distinct patient orientation and contains one sensor that is uniquely identified by a receptor in the CT room. Therefore, each signal corresponds to exactly one patient orientation. The orientation signal coming from the insert is compared to the computer input from the primary technologist. If the orientations agree, the CT process is allowed to continue and the scan commences. If the orientations disagree, the process is halted and the technologist is required to repeat the process until the orientations match. This automated double check aims to eliminate problems at the source.

6.2.1 Engineering Design Parameter Analysis

When planning the Headrest BIS system, the most crucial elements are choosing an effective sensor system, determining the necessary number of inserts, the physical design of each insert, and properly implementing the RFID system. All new components need to have minimal metal content to function properly in the CT process and need to remain unobtrusive to the patient and the process. These considerations are held at the forefront when selecting the sensors and designing the headrests for the system.

Sensor Selection: We decided to implement radio frequency identification (RFID) sensors into the BIS system because of their small size, low metal content, and how well they can be integrated into the existing system. Because RFID technology communicates through radio waves, the x-rays emitted by the CT machine are not obstructed in any way.

Selecting the optimal RFID system is important as there are a wide variety of RFID chips available on the market. There are many things to consider when it comes to choosing the appropriate system: how much information can be stored on each chip; which frequency is relevant for our use; sensor range and accuracy; and powering the chip.

We decided to utilize ultra-high-frequency (UHF), passive, read-only RFID chips. The UHF chips fit the system needs very well because of their exceptional range (up to 30 feet) and fast data transfer rate. However, UHF waves experience difficulty passing through materials, so the chip may need to be placed on the outside of the headrest to guarantee signal reception. A passive sensor system, which turns off once the sensor signal is obtained by the receptor, has been selected because the passive headrest sensors do not require batteries and therefore do not

interfere with the CT imaging process. Lastly, we selected read-only chips so the information on the chip cannot be overwritten at any time. [3]

Insert Design: The BIS system requires careful headrest and footrest insert design. Each insert will be designed specifically for the orientation which it is intended to be used. They will be designed in an obvious, unambiguous way such that the patient and technologist will notice if the wrong insert is in place because it will not fit the patient properly or comfortably. In addition, the inserts will be color-coded to further ensure the proper use of the correct insert, thus reducing the number of system interruptions.

We determined that five inserts are necessary to account for the six patient orientations. The proposed inserts and their corresponding orientation usages are listed below:

- Headrest 1: Face up
- Headrest 2: Supine Coronal
- Headrest 3: Face down; prone
- Footrest 1: Face down
- Footrest 2: Face up

Three headrests are needed for the insert system to function properly; the two headrests that are currently in use are shown below. Figure 1 shows the current headrest used for both the face up, head first position and the face down, head first position. Under the new system, this headrest only will be used for the face up, head first orientation, therefore functioning as Headrest 1. Figure 2 on p. 6 shows the headrest currently used only for the supine coronal position (face up-head first, with the head tilted back at a 90 degree angle); its conditions of use will not change, and will function as Headrest 2. Both of these headrests are needed based solely upon physical patient limitations. However, since the left and right side of the patient is the same for both, each of these headrests will be equipped with identical RFID chips indicating that the patient is in the face up, head first orientation.

Figure 1*: Current Headrest for Both Face Up and Face Down Orientations*

Figure 2: Current Headrest for Supine Coronal Orientation

Because the headrest shown in Figure 1 on p. 5 is no longer going to be used for face down, head first patient orientations, a new headrest must be designed to account for the face down, head first and prone positions. A preliminary Headrest 3 design is shown in Figure 3. Headrest 3 is contoured to the natural shape of a human face when the patient is lying face down. To reduce the necessary number of headrests, a durable chin support will rotate up for prone position sinus scans. Headrest 3 will be equipped with an RFID chip identifying the patient's orientation as face down, head first.
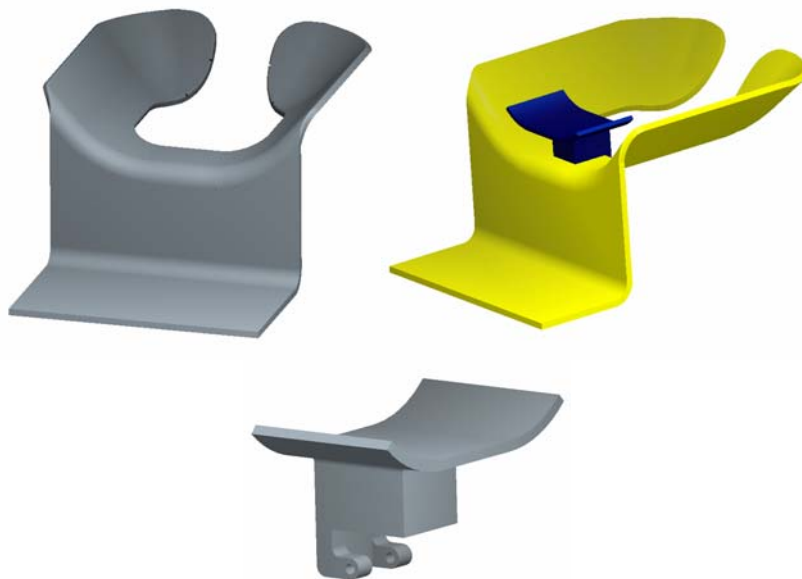

Figure 3: Preliminary Headrest 3 Design for Face Down and Prone Orientations

The current footrest is shown in Figure 4 on p. 7. This footrest is currently used for both the face up and face down orientations. In the new system, the current footrest will be titled Footrest 1 and used only for a face down-feet first patient orientation. It will be equipped with an RFID chip identifying the patient to be in the face down orientation.

Figure 4: Current Footrest for Both Face Up and Face Down Orientation

Footrest 2 has been designed to distinguish between face up and face down orientations. It is critical that Footrest 2 is designed in such a way that it is clear to the patient and technologist that the footrest is only used for the face-up orientation. We have modified the existing footrest cushion to include intuitive stitching as to where the patient's heels are to go. This is a visual cue to both the patient and the technologist that the patient should be in the feet first, face up orientation. An RFID tag will be placed in Footrest 2 that identifies it as the face up, feet first position. The engineering drawings for the newly designed inserts can be found in Appendix D.

RFID Implementation: Our idea is to place the RFID sensor at the base of the CT machine below the RFID chip location on the insert. This minimizes the distance the signal must travel before being received by the sensor. This placement is out of the way of high-trafficked areas of the CT scan room, out of the scan region, yet relatively close to the location of the RFID chips themselves.

The RFID chips will be placed at the furthest end of each headrest/footrest insert away from the bed. This location is optimal for two reasons. First, locating the chip at the end of the inserts places it out of the scan region, thus eliminating any streaking that might appear on the CT image. When CT scans are taken, the technologist can identify which region the machine scans. The end of each headrest and footrest would almost always be located outside of this scan region. If for some reason the end of the headrest was included in the scan region, the chip would be far enough from the patient that any scatter that occurred would not affect the readability of the CT image. If needed, the inserts can be lengthened.

6.2.2 Final Design Description
The BIS system uses three headrests and two footrests coupled with RFID chips to determine the patient's orientation. The five inserts will be designed to cater to one distinct patient orientation and are listed below.

- Headrest 1: Face up
- Headrest 2: Supine Coronal
- Headrest 3: Face down; prone
- Footrest 1: Face down
- Footrest 2: Face up

We decided to implement passive, UHF, read-only RFID chips because of the negligible radiological interference and exceptional read range of the chips. Each insert contains one RFID chip that is uniquely identified by a receiver in the CT room. The RFID chips will be placed at the very end of each insert furthest away from the bed to minimize the chance of CT interference and to optimize sensor-receiver communication. Once the computer has received the signal from the RFID receiver, that signal is compared to the input from the primary technologist. If the orientations agree, the CT process is allowed to continue and the scan commences. If the orientations disagree, the process is halted and the technologist is required to repeat the process until the orientations match.

6.2.3 Prototype Description

We were unable to obtain an RFID receiver for our prototype due to budget constraints. To demonstrate our design at the Design Expo, we built a mini mock-up of a CT bed and. We also created two small inserts, one headrest and one footrest, using a Rapid Prototyping 3D Printer. We placed two electromechanical switches underneath the bed and wired them to the LED box ("computer") described in the STDC prototype section 6.1.3 on p. 3. Each electromechanical switch was positioned such that notching the two inserts on opposite sides would trigger only one switch at a time. The positioning of the switches can be seen in Figure 5.
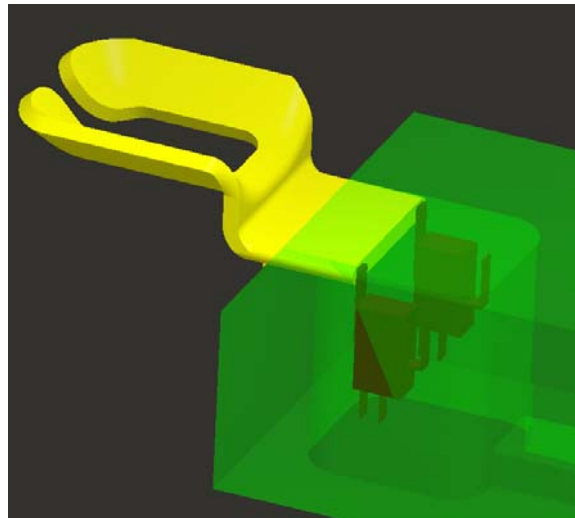

Figure 5. Position of electromechanical switches beneath CT bed prototype.

6.2.4 Initial Manufacturing Plan

With the help of the 3D Laboratory in the Duderstadt Center, we were able to print mini mock-ups of the newly designed headrest and existing footrest. We purchased LED lights of differing colors to use with each of the different mini-inserts were print. The CT bed was machined from Delran plastic. This manufacturing plan differs from our final design manufacturing plan. We created drawings to-scale of headrests and footrests to be used with this sensor design.

6.2.5 Validation

The most crucial step in validation of the BIS system is to quantify the amount of material interference the RFID chips cause in a CT scan. To determine the amount of interference, testing was completed at the UMHS. The exposed chip was placed in the center of a footrest and several scans were completed. The chip produced a one centimeter sphere of interference. Therefore, if the chip is placed more than five centimeters away from the patient, the radiological scatter produced by the RFID would be sufficiently unobtrusive.

To this end, we plan on placing the chip at the end of the insert furthest away from the CT bed. The benefits to this are two-fold. The first benefit of this location is that it maximizes the distance away from the patient. The second reason is that the end of the insert is seldom included in the scan field. This means that only in rare cases will x-rays be transmitted through the chip, which further reduces the chance of radiological interference. For these reasons, we believe that our design has been validated, and implementing RFID technology will not adversely affect the ability to read a CT scan image.

7. COST ANALYSIS

The estimated cost of production for a new STDC system is approximately $400. Included in this number are the cost of injection molding the console and buttons, labor, and assembly of the console. Retroactively adding the STDC to an existing CT scanner requires more labor, so the cost is inflated to $1000. Labor dominates the production cost of this system.

The estimated cost of production of the BIS system is approximately $15,000. Included in this number are material, labor, and assembly of the new bed inserts. We also incorporated the cost of purchasing an RFID receiver from an outside distributor ($1000-$5000). Currently, each carbon fiber GE insert has a retail price of $700-$1000. The RFID microchips cost pennies to purchase and are negligible. The material cost of the inserts and the cost of the RFID receiver dominate the production cost of this system.

There is considerable fluidity in the estimated cost of our systems. However, the retail price of each system is orders of magnitude smaller than the retail price of the GE Lightspeed CT scanner. It's clear that the fluidity in production costs and retail price are small enough to affect very few, if any, sales. This reduces the importance of detailed cost analysis and as such we have quoted conservative estimates of the production costs of our systems.

8. RECOMMENDATIONS

After completing an engineering analysis of both the BIS and STDC systems, we believe that the next step is a clinical trial. First and foremost, more data is needed on the number of images that are incorrectly marked. There are no official statistics regarding this number, although through conversation with personnel familiar with this issue, it is believed to be roughly one in every 235 scans. For there to be a verification of the system's functionality in terms of reducing the number of incorrectly marked images, there needs to be a comparison point. Once data on the number of improperly marked images using the current procedure is obtained over a three month period, either system can be implemented. The number of incorrectly marked images during the clinical trial will then be compared to the number of incorrectly marked images under the old procedure to fully assess any new system's reliability.

Before any implementation of the BIS system can occur, several complete systems must be manufactured. If a clinical trial were to be conducted by the University of Michigan Health System, nine complete sensor systems would need to be installed. To this end, it is necessary to obtain nine RFID receivers and nine complete sets of headrest and footrest inserts equipped with the proper RFID chips. A computer code would also have to be developed and installed into the existing GE Lightspeed machines that are currently in use at the UMHS. The computer code will need to link the new system into the existing computer network and can be developed from the algorithm described in Appendix C. It should be noted that this algorithm can be used to develop the code for either the BIS or STDC system. For the STDC system, nine complete consoles will need to be installed on the current machines. This will also require a computer code that will link it to the machines and computer network currently in use.

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We have filed for patent protection on the ideas and designs contained in this report. Over the next weeks and months, it will be necessary to complete the patent process to gain intellectual property rights. During this time, we will make contact with the proper personnel at the UMHS in an effort to build support in marketing and selling our ideas to industry.

9. CONCLUSION

There is a need for safeguards against incorrectly marking patient orientation on CT images. Due to this problem, we have developed two systems that we are confident will show, upon further testing, a large reduction in the number of wrong-site surgeries that occur each year. This will greatly impact the medical community as a whole.

To develop these two systems we used knowledge gained from classes and real world experience. We used what we learned about materials, statistics, analysis, and design and manufacturing. As a group we generated design concepts, performed research on existing technologies, and fabricated two different prototypes to convey our final designs. We became proficient in each area discussed in this report and our prior presentations so if the need arose, any one of us could give the entire presentation ourselves.

In order to translate the prototype of the STDC system into a manufactured model, we would like to implement push buttons instead of toggle switches to further ease the effort put forth by the CT room technologist in inputting the patient's orientation. This system will be best suited for the UMHS and other institutions that staff two technologists for each CT scanner. In the instance that there are not two technologists on hand for each CT scanner (i.e. off-shifts), we will have an override key, available only to the supervisor on duty, to lock out this system.

We recommend the BIS System for private practices or institutions that don't have the luxury of having two technologists on staff for each CT scanner. This would allow for an automated double check.

If and when clinical trials prove the systems effective as a safeguard, they can be modified to fit the needs of other radiological imagine machines such as x-rays and Magnetic Resonance Imagine (MRI) machines.

Both systems have the capability of being manufactured. They are both highly innovative and have received great support from the University of Michigan Department of Radiology.

10. ACKNOWLEDGEMENTS

11. REFERENCES

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APPENDIX A: DESCRIPTIONS TO THE VARIOUS DESIGN CONCEPTS GENERATED

A.1 Bracelet Detection System

The bracelet detection system was the first design idea proposed, initially brought to us by Dr. Blane. The idea behind the bracelet detection system is that every patient who receives a CT scan wears a bracelet containing a small amount of metal on their right wrist. When the scan is performed, the bracelet is detected on the CT image, thus indicating the left and right side of the CT image.

While it would be a relatively simple, physical concept, we found there to be a number of reasons why we dismissed it from our alpha design concept plans. First, it would require human interaction. Moreover, this design would require interaction from the patient themselves. This is an undesirable trait as far as our customer requirements are concerned. Another reason we deemed this concept inappropriate for our use is for cases such as abdominal CTs. When a patient has an abdominal CT, frequently their arms are raised above their head; therefore the bracelet would not be able to be detected during either the scout or the scan itself. Another downfall of this concept is that the bracelet would be in the (relatively) same location for the feet-first, face-up and the face-first, face-down orientations. Therefore, it would be hard to distinguish the exact orientation of the patient. From here, we were able to develop a wider range of ideas, as can be read below.

A.2 Pre-Scan to Identify Patient's Orientation

The idea of using a pre-scanned image came about after we talked with Barry Crawford, one of the CT technologists at the University of Michigan hospital. Barry described to us that the current CT scan process includes a pre-scan, or what's commonly known as a scout. From the scout image, we would identify a landmark organ or body part to determine the orientation of the patient.

We initially liked this idea a lot for a variety of reasons: it is automated, therefore reducing human interaction (and the probability of a misidentified orientation); it is easy to implement alongside the current system; it doesn't require any extra physical devices; and it adds little-to-no time to the process. The more we thought about this design concept, however, the more we realized some potentially harmful downsides: it would require additional radiation exposure to the patient; the design requires computer science programming and, moreover, an interface with General Electric's software; and it would be difficult to classify a physical anchor common in every person's body.

A.3 Ceiling-Mounted Digital and Thermal Cameras

The patient is photographed using automated digital and thermal cameras. The resulting images are interpreted by a computer to identify the patient's orientation by searching for landmarks on the human body. The computer will search the thermal image for the human head, defining whether the patient is oriented head first or feet first into the CT scanner. Next, the computer will search the "head" portion of the digital image for facial features like the eyes and the nose. The presence of these features indicates the patient is lying face up, and the absence indicates the patient is lying on his or her stomach. This information is translated to left-right, anterior-posterior information, which is compared to the technologist's inputted patient orientation. If the technologist and computer agree, the procedure continues uninterrupted. If the technologist and computer disagree, the process comes to a halt until a supervisor logs into the computer program

to manually fix the orientation information. Also, a copy of the digital image can be saved with the CT image for an additional double check by the radiologists who analyze the images.

These ceiling mounted cameras act as an automated double check, are easy to integrate into the existing procedure, add little-to-no time or radiation to the procedure, and add no additional human interaction to the procedure (except in the error correctional procedure). However, the cameras are expensive and potentially inaccurate. In event of incorrect orientation identification by the computer, unnecessary time and hassle will be added to the procedure.

A.4 Weight Sensors

A system of weight sensors is installed in the CT bed to define the patient's orientation based on his or her weight distribution.   The patient's orientation could easily be read as being oriented as "feet first" or "head first" based on where the majority of the person's weight is located relative to their height and midpoint. However, an unsolved problem lies in distinguishing between face-up and face-down orientations.

There are some concerns with this system, such as the fact that a humans' weight distributions vary greatly due to, for example, sex, height, and weight. There is also the possibility that oversized patients could be misidentified depending on if they were larger on the bottom half of their body as opposed to the top half. Also, some of the patient could be off the bed entirely, causing the sensors to misinterpret the orientation.   The major drawback to this design is the inability to determine whether a patient was oriented "face up" or "face down".   Weight distribution would be read as approximately equal regardless of whether the patient was face up or face down; therefore, this system is unlikely to work on its own. Thus, the system fails to accurately identify the L/R, A/P sides of a patient – the most crucial customer requirement. Also, the system needs to implement new beds with carbon fiber weight sensors, greatly increasing the cost.

A.5 Combination of Systems

All of the systems presented thus far have flaws that could reduce the likelihood that they would be able to work on their own.   Each concept was analyzed and compared to the others.   We began trying to assess whether or not combining two concepts would cover each one of the individual concept's flaws.   Should no concept individually work on its own, elements of several systems will be combined to form a better solution.

APPENDIX B: DETAILS TO THE ALPHA DESIGN CONCEPT PROCESS

Figure 1: QFD for concept generation

1	Not related
2	Weakly related
3	Neutral
4	Moderately related
5	Strongly Related

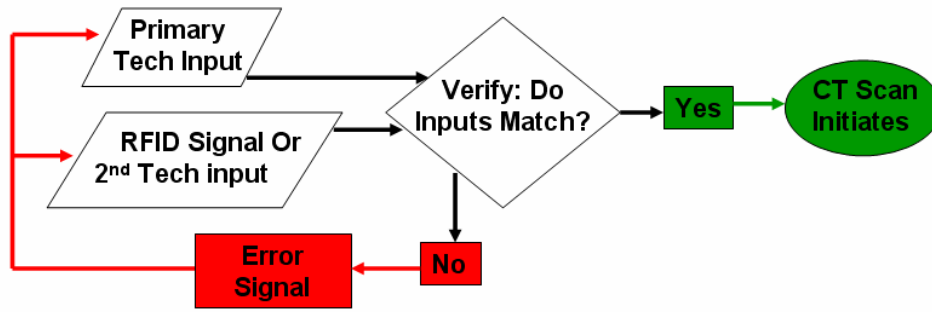| Customer Requirements	Normalized Importance to Customer (Relative Weight)	Material	Time	Minimize Radiation Exposure	Number of Components	Fatigue Lifetime	Location in Scan Room	Reliability (Double Check)	Volume	Mass	Easily implimented	TOTAL - CUSTOMER REQUIREMENTS	RANK
Highly Reliable	1.00	3	1	1	3	4	3	5	1	1	1	23	1
Easy to Use	0.50	1	3	1	3	1	3	2	2	2	3	10.5	7
Takes little time	0.80	1	5	4	3	1	4	1	1	2	2	19.2	2
Unubtrusive	0.70	2	3	4	3	1	4	1	3	3	2	18.2	3
Minimize Additional Radiation Exposure	0.60	3	3	5	1	1	1	1	1	1	1	10.8	6
Work with MRI & CT	0.10	5	1	1	2	1	1	1	1	1	4	1.8	11
Durable	0.35	4	2	1	5	5	2	2	2	2	3	9.8	8
Inexpensive to Implement	0.40	4	3	2	4	4	1	3	2	3	4	12	5
Compact Size	0.30	2	1	1	3	1	3	1	5	3	3	6.9	10
Works with Current System	0.70	4	2	3	3	1	3	3	1	1	5	18.2	3
Reduce Scatter	0.40	5	1	1	1	1	3	2	3	3	1	8.4	9

By analyzing all of our options based on pros and cons and comparing them to the QFD we quickly eliminated quite a few concepts. However, our customers were equally satisfied with two of our design concepts: the Second Technologist Double-Check system and the Bed Insert Sensor System). Because these ideas were so closely matched as far as customer requirements are concerned, the QFD shown above was used to aid in a final decision. Figure 2 on the following page illustrates a simple chart that was used to help us more accurately analyze the two remaining design concepts. In this chart the design concept that best met the customer requirement was awarded a point value determined from the QFD. The most important customer requirement had a point value of 11, the next important had a point value of 10, and so on. After completing this chart we discovered that the Second Technologist Double check Touch Screen Sensor system had a narrow edge over the Headrest Sensor System, but neither system was

clearly better than the other.   After discussion of our results with our customer we have decided to further pursue both design concepts.

Fig. 2: Analysis of Touch Screen and Sensor System based on customer requirements

| Customer Requirement	Rank	Touch Screen		Sensor System	
Highly Reliable	1	×	11		
Takes Little Time	2			×	10
Works with Current System	3 (tie)			×	9
Unobtrusive to Patient	3 (tie)	×	9	×	9
Inexpensive to Implement	5	×	8		
Minimize Additional Radiation Exposure	6	×	7	×	7
Easy to Use	7			×	6
Durable	8	×	5		
Reduce Scatter	9	×	4	×	4
Compact Size	10	×	3	×	3
Works with MRI & CT	11	×	2		
			49		**48**

APPENDIX C: ALGORITHM

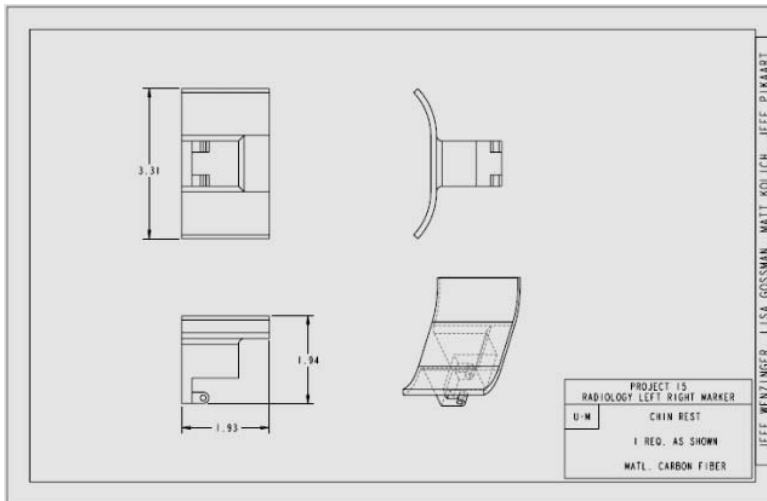*Flowchart Algorithm for Both Designs*

APPENDIX D: ENGINEERING DRAWINGS
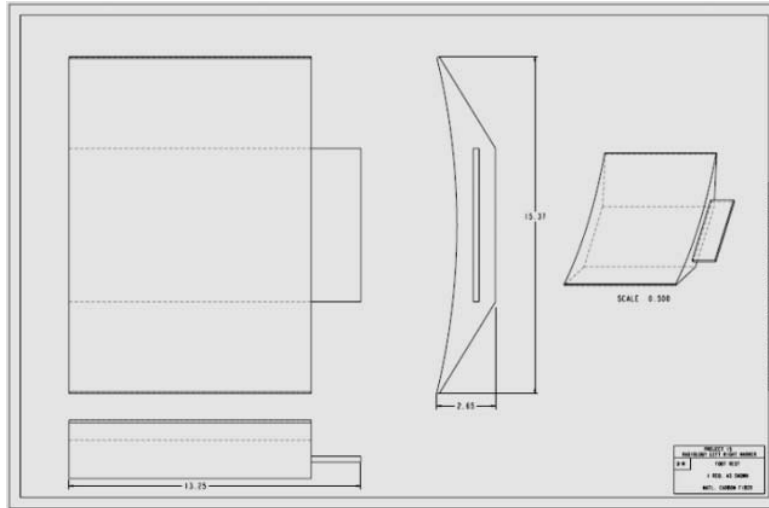
Newly Designed Footrest Insert
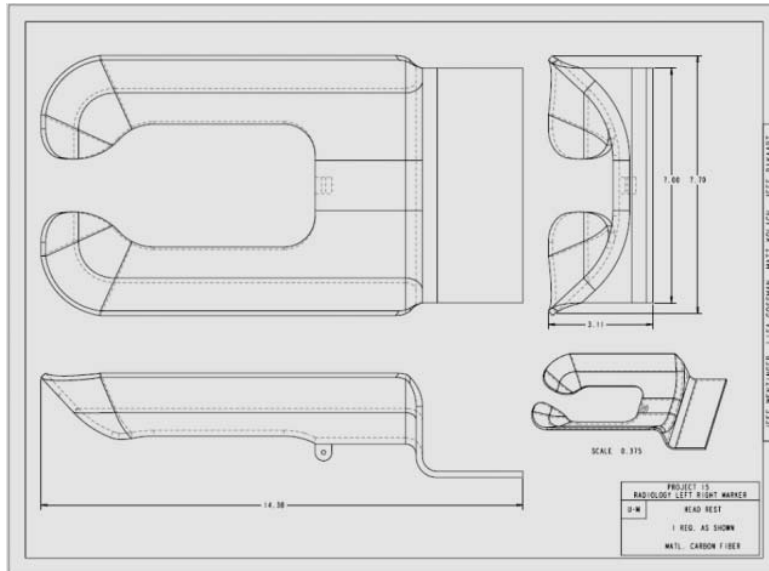
Headrest Insert for Face Down, Head First Position (incl. Prone Position)

Chinrest for Face Down, Head First Insert (used for Prone Position)