Patient Positioning Aid: Project Proposal

Funded By the RERC

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Executive Summary:

The patient positioning aid will allow persons with disabilities access to medical imaging devices such as MRI and CAT scan. Patients with disorders such as Parkinson’s disease, diabetes, renal failure, and heart failure will benefit from use of this device in clinical settings. Such a device is needed because current positioning aids do not meet the needs of most patients and medical personnel. The patient positioning aid will allow for patients to imaged in various positions using various medical imaging platforms. The optimal design of the positioning aid will be low-cost and easy to use for patients and medical staff alike. It will also be easy to store with the limited amounts of storage area most hospitals have.

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Statement of Need:

Many people, especially people with disabilities such as diabetes and Parkinson’s disease require the use of medical imaging technologies such as MRI, x-ray, and CT scan. However, patients with disabilities lack a great deal of access to imaging devices due to problems with the positioning of the patients during the process of imaging. Static positioning devices such as foam wedges and coils that are available today are not very effective in alleviating this problem. A device is needed that will allow for patients with such disabilities to access imaging devices allowing for various positions to be obtained. The device needs to be versatile, low-cost, easy to use, and easy to store, as well as compatible with many different imaging devices.

Market Research:

Our research shows that there are positioning aids on the market that are designed for use with patients. These devices consist mainly of foam wedges, wraparound coils, and table mounted arm and leg positioners. Most common are the wedges, which come in sets and range in price from around $150 to $400. Wraparound coils are not very commonly used and few were found in research. Arm and leg positioners were also found on the market by various companies but were still not as popular as the foam wedges. None of the products on the market were found to provide the versatility needed for patient positioning during imaging.

Table 1: Market Research Data

<table>
<thead>
<tr>
<th>Maker</th>
<th>Model</th>
<th>Price</th>
<th>Product Name</th>
<th>Type of aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>BizChair</td>
<td>3004-HAUS</td>
<td>$331.99</td>
<td>Positioning Wedge system</td>
<td>Wedge system</td>
</tr>
<tr>
<td>MedTek</td>
<td>MT-KC-01</td>
<td>Not listed</td>
<td>Knee crutch positioner</td>
<td>Positioner</td>
</tr>
<tr>
<td>MedTek</td>
<td>MT-AP-01</td>
<td>Not listed</td>
<td>Arm Positioner</td>
<td>Positioner</td>
</tr>
<tr>
<td>Fornar</td>
<td>N/A</td>
<td>Not listed</td>
<td>Solenoid coils</td>
<td>Wraparound coil</td>
</tr>
<tr>
<td>Newmatic Sound Systems</td>
<td>FSWG</td>
<td>$319.99</td>
<td>Standard wedge group</td>
<td>Wedge</td>
</tr>
<tr>
<td>Newmatic Sound Systems</td>
<td>FRXG</td>
<td>$159.99</td>
<td>Routine X-ray group</td>
<td>Wedge</td>
</tr>
<tr>
<td>MedTek</td>
<td>MT-VL-FBB-01</td>
<td>$150</td>
<td>Vac-Lok</td>
<td>Wedge</td>
</tr>
</tbody>
</table>

Project Description:

Objectives:

The objectives are to design a low-cost, versatile, easy-to-store, and easy-to-adjust patient positioning aid. With this positioning aid there will be no need for hospital staff members to purchase multiple components in order to provide a variety of positions and meet the needs of various patients. This device will incorporate multiple attachments that can be positioned and set in the desired location in order to adjust the patient in numerous positions. The positioning aid will be able to meet the needs of patients with disabilities. It will be strong so that the segment weight of overweight patients weighing up to 500lbs can be supported. The device will better immobilize patients so that patients with diseases such as Parkinson’s can have an accurate image taken without having to worry about tremors. It will be thin so once it is put on top of the imaging table patients with limited movement will not have to climb up very high. The positioning aid will be compatible with various imaging technologies including but not limited to MRI, CT, and x-rays. It will be durable so that a new doesn’t need to purchase often saving the hospital money.

Methods:

The patient positioning aid is composed of four main elements, each element having its own special function which aids in making the patient positioning aid both versatile and able to work with a range of examination tables and imaging platforms. In talking about the design it is very important to make note and give a quick introductory description of the imaging platforms the patient positioning aid will be used in – these include: x-ray, CT scan, and MRI. Both x-ray and CT scan use very small and controlled amounts of x-ray radiation which is passed through the body and different tissues absorb the radiation at different rates. CT stands for computed
tomography and is sometimes also called CAT scan, and it uses special x-ray equipment to obtain image data from different angles around the body and then uses computer processing of the information to show a cross-section of body tissues and organs. The CT scanner itself is a large, square machine with a hole in the center and the patient lies still on a table which can move up or down and slide into and out from the center of the hole. MRI scan stands for magnetic resonance imaging and it makes use of magnetic and radio waves which when sent through the body affects the body’s atoms, forcing the nuclei into a different position. As they move back into place they send out radio waves of their own which the scanner picks up and a computer turns these signals into a picture. The MRI scanner is a rather large apparatus and the patient lies down on a bed which is then slid into a large, cylinder-shaped magnet, and with an MRI scan it is possible to take pictures from almost every angle, whereas a CT scan only shows pictures horizontally.

The three major base elements of the patient positioning aid are the support board, the foam padding, and the four attachment arms. These three major elements are depicted in the diagram labeled Figure 1.
Starting from the base of the design and working upwards, the first major element is the support board. The support board is a very important aspect of the design for not only is it the base of the patient positioning aid but it is also a major component required for making the design versatile. The support board has to be strong enough in order to withstand transport and storage, but also made out of a non-ferrous material so that it will not interfere with the scanning and imaging technologies. The first material chosen for the board was carbon fiber, for its strength to weight ratio is extremely high – that is carbon fiber is a surprisingly strong material based on its weight. However, carbon fiber is also extremely expensive, thus the material of choice for our design is polyethylene. The polyethylene board will not interfere with the scanning and imaging technologies and it is lightweight so it can be transported easily. The dimensions of the board are 72” x 22” x 3/16” and it will consist of two halves which are...
connected together by aluminum hinges. The design of the support board makes it versatile because it is lightweight as well as six feet long which will be sufficient for a person of any height, and the hinged-aspect of the board makes it able to fold which will aid in storage of the device. Also adding to the versatility of the design, the support board can be placed upon any of the beds of the scanners as well as secured to the scanning bed by special fasteners and all other elements of the design will then either be attached to or placed upon the board.

The next major element of the design is the foam padding which will be placed on top of the support board. This element of the design serves two major functions: the foam greatly increases the comfort of the design for when a patient lies on it, and also aids in the static positioning of the patient. Based upon the need for each patient the foam padding could be just simply a foam pad or could also consist of the types of foam wedges which are already on the market. The actual foam pad will be a type of memory foam which will actually slightly mold around the patient as they lay upon it. This type of foam padding will greatly increase the comfort of the apparatus as well as serving as a way to reduce slight involuntary movements of the patient such as small twitches because the foam will be molding around the patients limbs and torso. Also, at this point the scanning technician can put in other foam supports such as head and neck wrests, or small wedges all based upon the comfort needs of the patient as well as according to which area of the patient is to be scanned.

Also depicted on the diagram of the design in Figure 1 are the four support arms. These four supports arms will be made out of a non-ferrous material such as aluminum in order to not interfere with the imaging and scanning technologies as well as be able to support the loads of patient’s limbs. In order to greatly add to the versatility of the design the use of four attachment arms was decided upon. If the need arises for all four of any one patient’s limbs to be scanned or
imaged at once this design supports that need – greatly adding to the versatility of the design. This part of the design of this patient positioning aid is also designed with the thought of the highly real possibility of having patients of various heights. With this in mind the four attachment arms are designed to be able to be slid along the length of the board along a track system, made out of a non-ferrous material, which is secured to both sides of the support board. Each of the four attachment arms will also have adjustable heights, with a maximum height of up to eighteen inches which will accommodate a patient of any size. In order to increase the load-bearing safety of the attachment arms, clamps will be attached to the base of the supports arms. With this design the scanning technician is able to adjust the position of the support arms according to the location of each patient’s limbs. Once the support arms are in the correct position the clamps will be clamped down onto the support board making them much more secure for supporting the weight of the patient’s limbs.

The patient positioning aid will also come with a plethora of different shaped and sized attachments which are to be attached to the four attachment arms – again aiding in the versatility of the design. The attachments will consist of arm grips, arm boards and leg boards, and knee crutches. Arm grips are extremely useful in scanning and imaging technologies because they greatly aid in the static positioning of a patient’s arm. For example, with an arm grip attachment the scanning technician is able to have the patient lay with their arm(s) straight up and the patient can hold onto the arm grip which aids in having the position static. The arm and leg boards can be attached to any of the four attachment arms and the patient will lay their arms or legs straight across them. Arm and leg boards greatly increase the quality of the images taken by both CT and MRI scanners. The CT scan only takes horizontal images, thus having the arm or leg in a static horizontal position will greatly improve the quality of the image. The quality of the MRI image
will also be improved because the arm or leg will be more secluded from other body tissues which will make the image of the arm or leg much more crisp. The final attachment is the knee crutch which is shaped like an upside-down U. This attachment allows for more accurate images of the knee for both the CT scanner and MRI scanner can take images of the knee away from the rest of the patient’s body tissues. Having both a leg board and the knee crutch also allows for the scanning technician to take images of the leg or knee in various positions. Each position can show something different on the image; for the tissues within the leg or knee are being affected differently in each different position.

**Professional Components:**

Every medical device needs to be analyzed for potential hazards that may arise with the failure of any component. A reliability analyses can identify the possibilities of failure. The designers of the medical device need a thorough understanding of all the components of the device and have to account for malfunctions and limitations that may arise during testing and usage. In the positioning aid there are only mechanical hazards that may arise.

The FDA classifies medical devices in three classes depending on the potential risk to the user it possess. The positioning aid will be classified as a Class II device since it has some potential risk to the patient if improperly used or in case of malfunction. In addition the FDA utilizes a risk assessment program which assigns a level of concern according to the potential injury the device could impose on the user. Then according to the level of concern the pre-market evaluation time is determined. There are three levels of concern, major for death or serious injury, moderate for non-severe injuries, and minor for devices that will not lead to injury even if they malfunction. Hazards that are reviewed during risk analysis and classification are biological for allergic reactions, chemical for toxins, electrical for possible shocks, mechanical,
radiation, and thermal hazards. The patient positioning aid would most likely be classified somewhere in between minor and moderate since there is not a huge potential for injury. The positioning aid will only need to consider mechanical hazards. The worst thing that can happen is a clamp breaking off and causing injury only if it strikes the patient after breaking off. Other than that there is really no big concern since the patient will be lying down on a solid object that will be securely attached to the operation table.

**Timeline:**

Written Project Proposal: October 14\textsuperscript{th}, 2005  
Design One: October 19\textsuperscript{th}, 2005  
Design Two: October 26\textsuperscript{th}, 2005  
Design Three: November 2\textsuperscript{nd}, 2005  
Analysis of Optimal Design: November 9\textsuperscript{th}, 2005  
Parts Order for Optimal Design: November 16\textsuperscript{th}, 2005  
Construct Optimal Design: January-April 2006  
Final Product: April 2006  
Final Report and Oral Presentation: May 2006

**Budget:**

The budget for our Patient Positioning aid was set by the RERC competition committee, each team is allotted two thousand dollars to spend on their positioning aid device. However, the goal of each team is to develop a device that is both cost-effective and capable of performing in the ways specified by the client.
Components of our Design:

Patient Transfer Table:
- (Biodex Model #056-352)
- Dimensions: 72”x 22”x 3/16”
  $190.00

Foam Padding and Foam Head Rest:
- (Infab Model # 583480)
- Dimensions: 72”x 19”x 1”
  $160.00

Attachments:
- 2 arm boards $400.00
- 2 knee supports $300.00

4 Aluminum Rods to hold Attachments: $100.00

Tracks for Attachments: $100.00

Other: $50.00

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Total Design Cost: $1200.00
Money left over: $800.00

Conclusion:

Patients need to undergo various medical examinations (i.e. CT scan, MRI, X-ray), which require them to remain static throughout the testing process. However, certain disabilities can lead to patient discomfort during the test or may even prevent the patient from partaking in the examination. These problems have created a need in the medical industry for a versatile, low-cost, easy-to-adjust patient positioning aid. The positioning aid will also be made of all non-ferrous materials, since it will be used in the MRI imaging system. It must be relatively lightweight and the hospital staff should not have any problem lifting the device onto the examination table or imaging platform. The design will fold in half in order to cut down the storage size of the device when it is not in use. The use of a track system for the hand, arm and knee attachments will allow for an easier and faster patient set-up time for the lab technician. All
of these modifications to the current patient positioning aids will greatly benefit both the patient and the lab technician. In addition to fulfilling all of the patients needs, this device will also be cost-effective for the hospital and their number one choice when selecting a patient positioning aid.