Patient Positioning Aid:

A Project Proposal and Guideline for Completion

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Design Client and Competition Director:
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Introduction

The following document outlines a step-by-step procedure for completion of a patient positioning aid device that interfaces with various medical imaging technologies. This document will ultimately serve as a guideline throughout the fall and spring semesters aiding the design team to develop a prototype for the Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC on AMI) 2005-2006 National Student Design Competition. The following sections specifically describe the project's problem statement and function, resources, schedule, deliverables, and goals. These descriptions and outlines will serve as a reminder of the project's scope and deadlines as the team moves toward May 2006 and the submission of a functional, certified positioning aid prototype to Dr. Enderle and the RERC on AMI's design competition.

Problem Statement / Prototype Function

Patient positioning limitations onto and within medical imaging devices, which may include the initial patient transfer and/or maintaining static positioning during data acquisition and measurement, have rendered many individuals with disabilities unable to reap the benefits of imaging technologies. Often times, medical personnel have difficulty transferring patients onto the bed of an imaging modality because the patient is either too fragile or too obese. Once the patient is on the bed, the task of keeping a patient still is also difficult. To date, foam wedges and/or wrap-around "coils" are used for static positioning within CT and MRI scanning systems. However, more versatile and effective means are required to meet the wide range of disabilities and imaging systems that are encountered by physicians and medical technicians on a daily basis.

Resources

The design team is comprised of four undergraduate engineers specializing in various disciplines, a faculty advisor, and a competition director, also serving as the design team's client. Additionally, the team has several resources provided both by the University of Wisconsin – Madison and surrounding healthcare industries. Each member of the design team has been given a team role to ensure the success and effectiveness of the four-member system. These individuals and roles, along with additional team resources and time commitments, are outlined and described below.

Team Leader: Joseph Grudzinski

Joseph Grudzinski's primary responsibilities as team leader include maintaining the project schedule, keeping the team focused on the project's scope and purpose, and distributing responsibilities among the four-member team. Additionally, Joe will be responsible for updating the team's academic advisor and competition director every Thursday afternoon with the team's weekly progress report. This report will outline the team's successes and difficulties from the previous week in addition to the goals for the week to come. Joe can be reached at grudzinski@wisc.edu and by telephone at (414) 628-4497.

Team Communiator: Joshua Anders

Joshua Anders will be responsible for the logistics behind team meetings. In addition, Josh will serve as the communication link between the design team and the project's faculty advisor, competition director, and industry contacts. Josh can be reached at anders@wisc.edu and by telephone at (608) 628-6696.

Biomedical Website Implementation Group (BWIG) Representative: Megan Buroker

Megan Buroker's primary responsibility will be to maintain a user-friendly and widely accessible website consisting of the project's problem statement, current status, photographs, progress reports, deliverables, and contact information. In May of 2006, the website will be completed with the addition of a videotape demonstrating the functionality of the final prototype in action with a human subject. This website is a primary concern of the team as it will serve as a reflection of the quality of the prototype and a source of review for the competition board when selecting contest winners. Megan can be reached at mkburoker@wisc.edu and by telephone at (608) 444-3152.

Biomedical Student Advisory Committee (BSAC) Chair and Representative: Alyssa Walsworth

In addition to organizing and facilitating bimonthly BSAC meetings, Alyssa will be responsible for conveying the team's comments and concerns regarding the department's design sequence to the faculty advisors and design student peers. Alyssa will learn of successes and failures of other teams described during the open forum construction of these biweekly meetings. Her duties will then entail implementing these ideas into the patient positioning team's design strategies. Alyssa can be reached at aswalsworth@wisc.edu and by telephone at (612) 961-7034.

Faculty Advisor: Professor Mitchell Tyler

Professor Tyler has been actively involved in the design sequence at the University of Wisconsin – Madison for several years. Additionally, he teaches a course in Biomechanics (BME 315) and actively researches and designs in the field of Rehabilitative Engineering. The

team will meet with Professor Tyler on a weekly basis for progress updates and discussions of future tasks to be completed. Professor Tyler will evaluate the team's deliverables, consider the progress of the prototype, and serve as an information source. Professor Tyler can be reached at metyler1@facstaff.wisc.edu and by telephone at (608) 262-5112.

Design Client and Competition Director: Dr. John D. Enderle

Dr. Enderle, the director of the 2005-2006 National Student Design Competition, will receive and, along with the competition board, evaluate the project's final prototype, deliverables, and website. Through the course of the year, Dr. Enderle will be used as a resource with his background in rehabilitation and medical instrumentation in the field of Biomedical Engineering. Dr. Enderle can be reached at jenderle@bme.uconn.edu and by telephone at (860) 486-5521.

Additional University of Wisconsin Resources

The University of Wisconsin's Engineering Centers Building (ECB) will be used extensively as a place for team meetings and prototype construction. The ECB holds a tool crib, a student mechanical engineering shop, and a student electronics lab, all accessible and regularly used by BME design students. Engineering Hall will serve as a meeting place with the team's faculty advisor, Professor Tyler. Additionally, the countless computer labs in Engineering Hall will be used to complete the deliverables associated with the design process. The University of Wisconsin's Waisman Center as well as the University of Wisconsin Hospital and Clinics have been and will continue to be a valuable source of hands-on design as it is home to the university's research MRI, PET, microPET, and CT scanners.

Additional Resources in Local Healthcare Industries

General Electric (GE) Healthcare is headquartered in Waukesha, Wisconsin. The team has already secured a verbal commitment to tour the imaging facilities and discuss previously attempted design prototypes from the Director of PET Scanning, Mr. Michael Peters. GE has, for several years, dominated the foreign and U.S. markets in the field of imaging technologies. Their most popular products include PET, CT, MRI, PET/CT, and mammography imaging systems. GE's commitment to imaging excellent will likely be a valuable aid in the team's design process.

TomoTherapy Incorporated is located in Madison. Dr. Thomas Mackie, a professor in Biomedical Engineering and Medical Physics, is the co-founder and serves as a key University of Wisconsin connection for students interested in Medical Imaging design projects. The company makes a radiation cancer treatment machine that is becoming more available to the public around the United States. TomoTherapy's system uses CT scanning as a part of the treatment. By designing a new aid, more patients could have access to this treatment. They can aid in identifying the needs of a positioning device in CT scanning and are familiar with the product approval process. A contact will be made in late September of 2005 to request permission to visit the site and discuss potential design avenues.

Time Commitments

Such a demanding design will necessitate many hours throughout the course of both the fall and spring semesters. Each week there is a mandatory group and advisor meeting on Friday lasting two hours. This time is spent recapping the week for the advisor and delegating the next

week's tasks. In a normal week, each person spends approximately four hours doing research which is independent from the three additional hours per week that is spent participating in team meetings. After the proposed prototype design is finalized, team members will spend upwards of 20 hours per week constructing the prototype. The number of hours will increase near deadlines when deliverables are due. During winter break though, the time commitment will decrease considerably because the team members reside in different cities. The time commitment will be contingent upon how much time each member wants to contribute to individual work. As the spring semester starts up again, the team regroups and the increased time commitment resumes. It should also be noted that a person's time commitment also depends on his/her course load.

Project Timeline

Schedule

To complete this project, the team will need to remain on a precise schedule throughout the next year. At the beginning of the fall semester the team created a working document outlining the Product Design Specifications (PDS). The PDS specifies the problem, client requirements and design requirements such as physical and operational characteristics and production characteristics. Also, regulatory standards and guidances were included so that, in the case of a successful prototype, FDA approval may be pursued. Existing patented devices that could be used for this application were researched to prevent possible infringement. As the design process continues, the PDS will be updated frequently.

The actual construction of the design will not start right away. Once the client requirements are specified, preliminary background and literary searches are conducted, and brainstorming will take place; three preliminary design ideas will then be decided upon. Each of the ideas will be analyzed further in a design matrix format, and one design will be chosen by the end of September. Material selection and ordering will begin the first week of October to allow for lengthy lead times on products since back orders can range from two to six weeks. Beginning the acquisition of materials at this time will still allow for any delays arising from construction or material selection. Construction can last two to four weeks depending on the complexity of the design and the availability of the aforementioned resources. The product should be finished by mid-November so that preliminary tests can be conducted and any necessary changes can be made.

The goal of the second semester is to fine tune the design and to get the prototype the approval of the Institutional Review Board (IRB). Once the changes are finalized, a list of sequential tasks must be completed to start the approval process. First off, because the system is a Class II medical device we need to do human trials. In order to do human trials, we must draft a Human Subject Protocol that will be reviewed by a committee. The committee makes revisions that must be changed in the document before any human trials can be conducted. A patient consent form will be drafted for the Human Subject Protocol approval. This consent form will outline the use of the device and any potential risks. Only after a patient signs the form will he/she be tested with the device. The last but most crucial step is finding patient subjects. Our group has projected that five patients will most likely be sufficient. However, more may be needed to test the weight limits.

A graphical representation of the aforementioned schedule can be found in the Appendix of this document.

Deliverables

Additionally throughout the semester, the team will work on completing a variety of deliverables to display progress on the project. These deliverables include reports, presentations, a poster, a web page and a video. On October 14th a mid-semester written report and presentation will be given to faculty advisors and fellow undergrads, detailing the background research, preliminary designs, a design analysis, and future work for the chosen design. On December 2nd a final report will be completed as well as a final poster presentation. The final presentation will build on the mid-semester presentation, adding problems encountered and a cost analysis. A similar schedule will be followed in the spring semester. Each week the web site will be updated to display the weekly progress report, pictures of our progress, and a video which will display the final design and how it works; the mid-semester and final reports and presentations will also be included.

Conclusions

Ultimately, our patient transferring and positioning system will allow disabled people to access to the benefits of many imaging modalities. In the past, if a patient weighed too much it was impossible for medical personnel to transfer him/her to the imaging bed. With our system, a physician or technician with minimal strength and flexibility will be able to safely and quickly transfer obese patients. Once the patient is transferred, the second part of the system, the patient positioning element, comes into effect. By effectively positioning a patient and keeping them still, better diagnostics can be made and the time on the bed can reduced. Overall, our system will aim towards granting every person access to technology and treatment options that are otherwise unfeasible due to size or other physical disabilities.

Appendix

Task	September					October				November				December
	2	9	16	23	30	7	14	21	28	4	11	18	25	2
Deliverables														
Progress Reports														
PDS														
Midsemester Design Report														
Final Poster Presentation														
Design Notebooks														
Final Report														
Meetings														
Client														
Final Meeting with Advisor														
Research														
Background - Patient Transfer Systems														
Current Patents														
Materials														
FDA Regulations														
Design														
Brainstorming														
Preliminary Designs														
Finalize Design														
Prototype														
Order Parts														
Machine Parts														
Assemble														
Test														
Website Updating														
BSAC Meeting														

Joe
Josh
Alyssa
Megan
All