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Hand rehabilitation device for patients during acute phase of stroke

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Capstone Design

BME 400

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Abstract

Stroke affects approximately 700 000 people each year, one quarter of which sustain a long term disability. Rehabilitation is an effective method employed to combat these long-term effects. A contemporary form of rehabilitation, robot- aided therapy, has proved effective in improving motor functioning of patients. This type of therapy utilizes a mechanical means to assist the patient in performing the motion that was lost. We have developed a device that facilitates the supination/pronation of the wrist and flexion/extension of the hand. The device consists of a wrist rotator and an incorporated hand grasper, each powered by its own motor and ultimately controlled by a microprocessor. The microprocessor makes it feasible to adjust the speed and degree of rotation based on the patient's progress.

Background

Each year, an average of 700,000 Americans suffer from stroke (American Stroke Association, 2007). A stroke occurs when there is a blockage or a rupture of a blood vessel in the brain ultimately resulting in damage that hinders the brain from functioning properly. Males over the age of 55, with African-American, Hispanic, Asian/Pacific Islander backgrounds, or those with a family history of stroke are at the greatest risk. Of the 700 000 stroke victims each year, 72% are above the age of 65 (The American Heart Association, 2007). Strokes in women are more likely to end in a fatality than strokes in men. Even though it is rare, the incidence of stroke in children occurs three in every 100,000 (National Stroke Association, 2007).

Results of stroke

Depending on the location in the brain, the damage caused by stroke can affect speech and muscle control. A common result of stroke is hemiplegia, which is a partial paralysis that affects one of the sides - down the sagittal plane - of the body. Loss of motor functioning is a common result of hemiplegia. Stroke is the biggest cause of long-term disabilities in adults with more than two-thirds of survivors sustaining a disability (National Stroke Association, 2007). However, rehabilitation following a stroke can reduce the number of chronic impairments..

Rehabilitation methods

The field of rehabilitation following stroke continues to expand. Typically, muscle control is not recovered in impaired limbs if no motion has returned within the first few weeks following the stroke, leaving the patient with a chronic impairment (personal communication, Jill Johnson, MCOW). Even though recent studies are challenging that fact, rehabilitation during the acute phase of stroke, which refers to the first three months following the stroke, is still extremely important time during which patients regain muscle control.

The traditional method of rehabilitation for patients after stroke is physical and occupational therapy. These methods focus on activities of daily living (ADLs) and methods to compensate for the loss of motor functioning. However, newer methods of rehabilitation are being developed to improve the quality of rehabilitation patients receive. -A drawback of PT and OT are that they are labor intensive and require the patient to work one-on-one with a therapist. One-on-one time with a therapist can be difficult with staffing-to-patient ratios. These newer methods strive to decrease the time that the patient spends with the therapist and increases the time the patient spends performing rehabilitation exercises.

Some of these new methods are constraint induced motor therapy (CIMT), electrical stimulation, and robot-aided therapy. CIMT restrains the patient's non-impaired limb forcing the patient to use their impaired limb to perform daily tasks. The logic behind this type of therapy is that using the impaired arm will improve the patient's motor control. Electrical stimulation sends electrical pulses to innervate either muscle fibers or nerves. Electrodes are placed on the skin over muscles or nerves and the device sends current through the electrodes to the skin to excite muscle groups causing the limb to perform a basic movement. Bioness, Inc has several devices that patients can use to compensate for loss of functioning after stroke. Robot-aided therapy is method that uses

a computer interface to provide visual stimulation to keep the patient engaged during rehabilitation sessions and to track the abilities of the patient as they attempt to move the impaired limb in a specific motion. The computer is able to track the forces and the displacements that the patient is able to produce. If a patient is unable to complete the specific motion, the computer turns on a motor that will complete the motion for the patient.

Methods

Design criteria

We have designed a robot-aided therapy type device to be used for rehabilitation of the supination/pronation of the wrist and flexion/extension of the hand. Our client required that the device be used with patients in the acute phase after having a stroke. The device uses a mechanical method to facilitate the motions of the wrist and hand. It will be used in a hospital inpatient or outpatient clinic, and it must be portable for the therapist to move between patient's rooms. Therefore, we put a 25 lb. limit on the device, and it must be compact enough to fit on a table or wheelchair tray. The device will be used .5 – 2 hrs a day by each patient and could be used by as many as three patients a day. The device must be able to withstand that amount of use. The device should be as -aesthetically pleasing as possible to avoid intimidating patients.

Anthropometric considerations

The device also must accommodate a wide range of possible users. We chose to design the device to fit ±2 standard deviations from the average, which statistically includes 97.5% of the population. The anthropometric measurements that we took were: elbow to fist length, grip breadth, wrist diameter, hand length, hand thickness, hand breadth. Each measurement is shown below in Figure 1 besides wrist diameter.

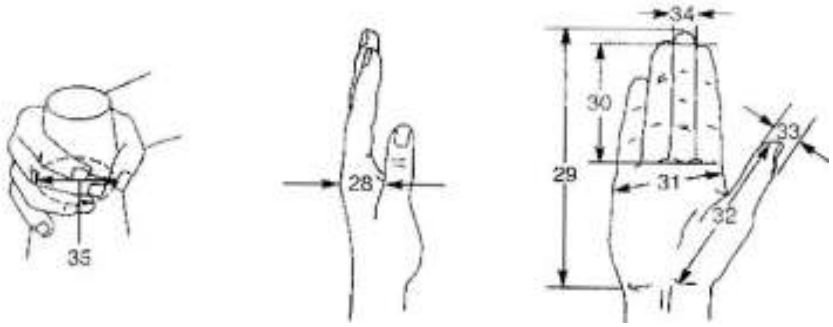


Figure 1a. *Pictorial representation of dimensions*. Hand dimensions that were considered

TABLE 1.5
(Continued)

Measurement	Males 50th percentile	Males ± 1 S.D	Females 50th percentile	Females ± 1 S.D	Population Percentiles, 50/50 Males/Females 5th	50th	95th
22. Elbow-to-fist length	38.5 (37.1)	2.1 (3.0)	34.8 (32.9)	2.3 (3.1)	31.9 (28.9)	36.7 (35.0)	41.1 (41.0)

HAND							
28. Hand thickness, metacarpal III	3.3	0.2	2.8	0.2	2.7	3.0	3.6
29. Hand length	19.0	1.0	18.4	1.0	17.0	18.7	20.4
30. Digit two length	7.5	0.7	6.9	0.8	5.8	7.2	8.5
31. Hand breadth	8.7	0.5	7.7	0.5	7.0	8.2	9.3
35. Grip breadth, inside diameter	4.9	0.6	4.3	0.3	3.8	4.5	5.7

Figure 1b. *Anthropometric dimensions: arns, hands*. Visual and data ranges in inches for the dimensions. (Champney 1975, 1977, 1979; Muller – Borer 1981, NASA 1979)

The wrist dimensions that were considered were a minimal to maximal range of 1.81" to 2.32" (Diffrient, Tilley & Bardagjy, 1981). Additional design criteria for the prototype are in Appendix 1.

Results

The current design has been an accumulation of work over the past three semesters. The idea for the motion of the wrist rotator has changed little over the past three semesters while the hand grasper has changed dramatically each semester. The wrist rotator has consisted of a padded cylinder that has been rotated by a motor connected by a gear system. The hand grasper has progressed from a joystick controller, to an inflatable bladder, to the present rotating bar.

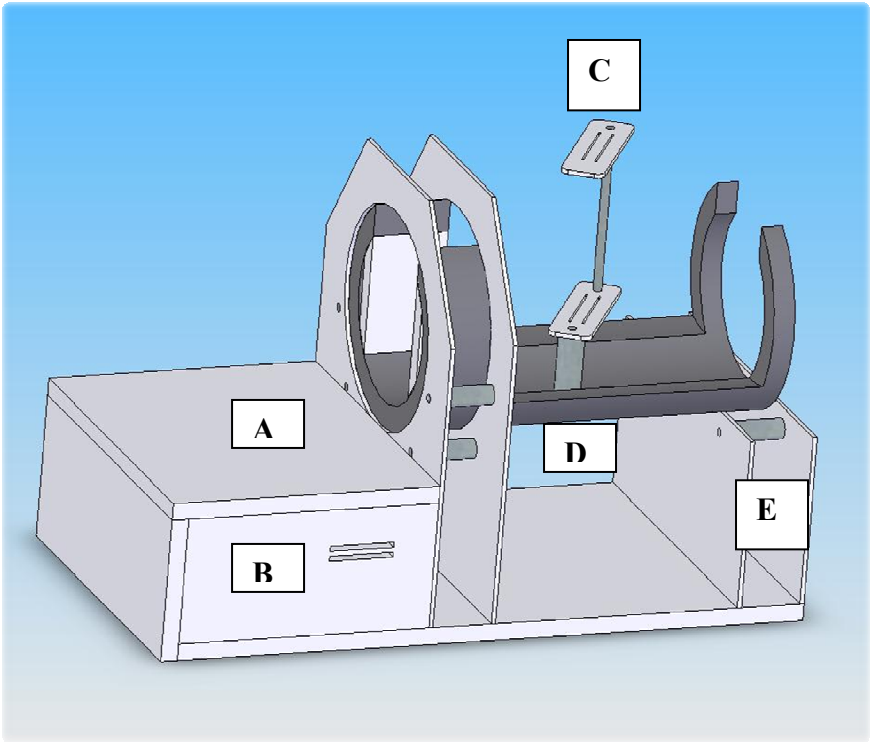
The wrist rotator began as a small cuff that only covered a 2" portion of the wrist. It had a hinged top to allow the wrist to be easily inserted into the cuff. The cuff was padded to reduce discomfort for the patient and to allow wrists of varying sizes to fit securely into it.

The hand grasper from the previous semester utilized an inflatable bladder to facilitate the opening of the hand. An external air compressor controlled the bladder. In order to continue this design for the hand grasper, a small, powerful air compressor would be needed to inflate the bladder. We, however, were unable to find a compressor that fit into the budget and met the size and weight requirements of the device. Therefore, the design was modified.

A control system also needed to be developed to control each of the devices and to monitor the movements of the patient.

Current design

The final design is shown in Figure 2. The dimensions of the device are shown in Appendix 2.



A. Elbow sits here and the wrist sits on the cylinder
B. 12V DC motor encased
C. Hand grasper, fingers attached by elastic banding
D. 3° stepper motor connected to cylinder to power hand grasper
E. Ball-bearing rollers for low-resistance rotation of the rotator, usually encased but open to show bearings

Figure 2. *Current prototype*. Parts labeled and described.

Wrist rotator

The main goal of the design for this semester was to incorporate both the supination/pronation and flexion/extension movements so that they could be performed simultaneously. This called for some major changes of the design while preserving the overall functionality of the wrist rotator. After last semester, we decided that the hand grasper portion of the device needed to be mechanical in order to increase controllability as well as decrease the overall cost, weight, and complexity of the device.

Our previous design had the patient inserting their arm into the machine so that the hand rested over the rotator motor. We reversed this process to allow elongation of the rotator to support the hand grasper device. The forearm now rests on the motor box and the hand is completely in the rotator. We extended the base-plate and built a stand on the other end to support the rotator/hand grasper device. The rotator was milled out of 6-inch diameter PVC cut to an 11-inch length. We retained the same dimensions and overall look at the end where the wrist is secured from our previous design, with the exception of vertical plates inserted to provide a more firm coupling with the wrist. The sides of the PVC tube were milled away to allow the hand grasper to rotate freely when attached to the rotator. The extended base-plate was made from ½ inch HDPE, as is the rest of the device frame.

A toothed gear strip runs around the outside of the rotator that is driven by the 12V DC high-torque, low rpm motor.

Hand grasper

The hand grasper portion of the device consists of two rectangular pieces of acrylic connected on one end by an aluminum rod. A motor's drive shaft is coupled to the

end opposite of the aluminum rod. The motor is mounted on the outside of the wrist rotator so that the drive shaft extends into the inner portion of the wrist rotator. Elastic spans the opening between the two pieces of acrylic and functions in supporting and positioning the patient's fingers. The patient's hand is placed between the two pieces of acrylic so that the longitudinal axis, extending from a person's wrist to finger tips while the hand is fully extended, coincides with the major axis of the rectangles. The patient's fingers are positioned so that the aluminum rod is gently pressed against the tips of the patient's fingers on the fingernail side of the hand. The elastic supports both the front and back of the fingers. As the drive shaft of the motor rotates, the aluminum rod of the hand grasper follows a circular arc, causing the fingers following this same arc.

To construct the hand grasper, two pieces of 1/8" acrylic were cut to 4" X 1 ½". Two 1/8"slits were cut along the long axis of the acrylic pieces, each 3/16" from the center. A 5/16" hole was drilled into one end of each of these pieces and a ¼" hole was drilled into the opposite end of one piece. A 5 1/2" X 3/8" aluminum rod was used to connect the two pieces of acrylic. The diameter of the rod was reduced to approximately 5/16," 1/8" in from both ends. Holes were drilled and tapped into each end of the rod. The 5/16"diameter ends of the aluminum rod were inserted into the 5/16" holes of the acrylic. Machined screws and washers were then used to fasten the acrylic to the rod. Another aluminum rod was used to couple the open end of the acrylic to the motor's drive shaft. A ¼" hole was drilled into one end of a 1" aluminum rod so that it could be placed over the drive shaft. A hole was drilled and tapped for a set screw to fasten the aluminum rod to the drive shaft. Another hole was drilled into the opposite end of the couple and tapped for an 8/-32" machine screw. A washer and machine screw were used to fasten the acrylic to the couple. Finally, elastic was wrapped through the slots between the two pieces of elastic. Epoxy was used to adhere the elastic to the acrylic.

Microprocessor

The microcontroller provides a series of benefits for controlling our system: autonomy of exercises; variable speed control with minimal work; safety mechanisms, and; digital feedback. The benefits greatly increase our projected efficacy of this device by increasing the possibilities for clinical usage. The microcontroller we used to begin automating the system is a Moto 1.0 brainstem module from Acroname, Inc. This microcontroller has three different forms of functioning, in Slave Mode, directly acting on inputs and outputs from a host computer; TEA mode, running tiny embedded application programs written in C/C++; Reflex mode, where one command or input triggers one or multiple other commands. A benefit of this microcontroller is the direct interface it has for a 3A Back EMF H-bridge (also sold by Acroname, Inc.). The 3A Back EMF H-bridge, shown in Figure 4, is based on the LMD18200, which is a 3A H-Bridge designed for motion control applications, this chip allows for motion control by reversing polarity and regulating current applied to the motor.

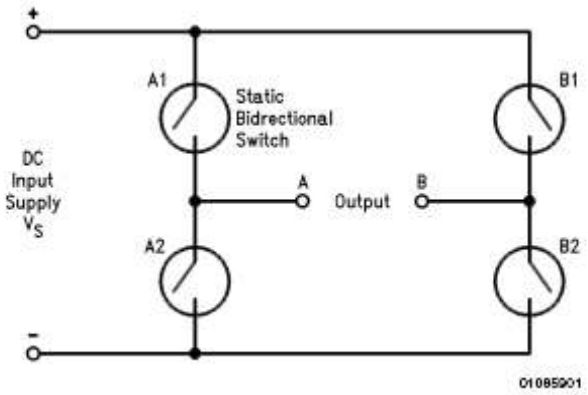


Figure 4. *Simplified H-Bridge schematic*. Shows the circuitry involved with controlling the polarity applied to the motor.

This specific component allows for three main forms of motor feedback: back-EMF; current sensing; quadrature encoder. Back-EMF is the default selection on the board and requires a specific timing sequence while it both operates a motor and takes feedback measurements simultaneously. The measurements are taken from the back-EMF by supplying current to the windings of the motor and running the motor for a given amount of time, the current is removed for the minimal amount of time it takes to read the voltage created from the motor's continuing motion. Current sensing mode allows the current being used by the motor to be read as an analog value with 1 Volt/Amp of voltage/current, this then allows the detection of power the motor is using and this can be adjusted to control speed or torque application by the motor. The third form of feedback is by using the quadrature encoder; this mode is independent of the other two modes and can be used simultaneously with either of the other modes. By using the quadrature encoder mode, you need a motor encoder connection. This mode allows for the most accurate feedback from the motor and consequently the best motor control. Our motor does not have an encoder. Therefore, we were not allowed to detect these multiple variables, and we were forced to use current sensing as the feedback mode and to control the motor's speed.

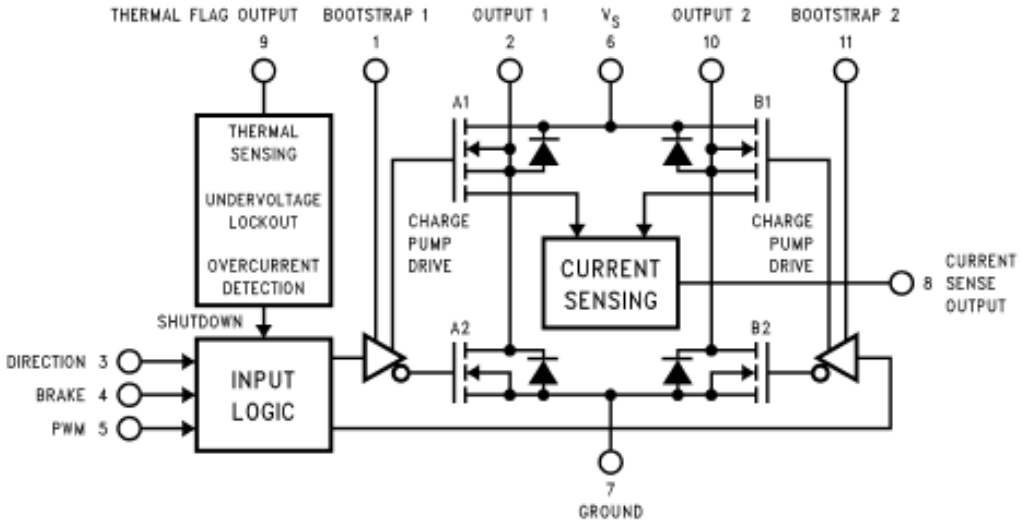


Figure 5. *Block Diagram of the LMD18200 H-bridge.* Demonstration of I/O pins for the H-Bridge.

The microcontroller once properly integrated, the pin connections are shown in Figure 5, will provide autonomy of exercises as the patient will be able to do perform the rehabilitation exercises with minimal therapist supervision. This may increase the time the patient can spend in physical therapy, as well as possibly increase the amount of rehabilitation exercises they can do while in in-patient care. Another benefit of the microcontroller is to have variable speed control; we did this by including a potentiometer or rheostat. This way an analog input can be read by the microcontroller through an analog I/O pin; this analog input can be dialed up and down such that we can have a variable speed depending on what the physical therapist deems appropriate for the specific patient.

In addition to variable speed adjustment for patients, we will need safety mechanisms for different patients. Our goal is to incorporate limiting switches into the system such that they will signal the microcontroller to stop the system from continuing motion in the initial direction. These limiting switches will trigger the microcontroller to receive a 1 into the digital input at an I/O pin. This digital input will result in the system stopping the current motion, a three-second timer being applied before the device starts motion again in the opposite direction. As a secondary safety mechanism, a second set of limit switches will be added behind the trigger limit switches, which will cut power to the mechanism because the machine has surpassed the tolerance limit of the patient.

The final benefit of the microcontroller is its potential ability to receive analog and digital inputs from the h-bridge to send data to a “host” computer or pc. This will allow a program to interpret the messages from the microcontroller and display a visual representation of the rehabilitation exercises. This visual representation will serve as informative feedback to the patient and could be designed to form a game. This will allow the patient to visualize their progress and be an engaging form of rehabilitation.

Additional work to be completed

Further work on the device needs to be completed before the testing phase can begin. The hand grasper will be modified so that it can accommodate hands of various sizes. This will be accomplished by designing a mechanism that allows the motor to translate towards and away from the wrist support. Additionally, the elastic of the hand grasper will be replaced with a single piece of material that can be cleaned and/ or replaced easily.

Limiting switch circuits will be incorporated into the microprocessor, and the limiting switches will be physically placed on the device to prevent over rotation of the wrist rotator and hand grasper. The limiting switches must be moveable to accommodate the different levels of functioning for each patient. A visual program will also be made and incorporated into the device to give the patient visual cues. The program will have points on the screen to where the patient has to move a cursor. The rotation of the wrist and the opening/closing of the hand will correspond to different directions on the screen. This will give the patient visual stimulation while they perform each motion.

The system will also be taken to a product designer to make it more aesthetically pleasing and less intimidating. After aesthetic changes are made, a padded armrest will be added, and the wrist rotator will be padded as well.

We are also waiting to hear about the status of additional funds in order to get a Servo motor. This type of motor will allow the patient to do active motion. Our current motor is not back-drivable, which means that the patient cannot work against our motor. We were initially unable to get the Servo motor because it did not fit into our budget, and we received our current motor as a donation. However, to get the system to work as our clinic requires, a Servo motor is needed. The Servo motor also comes with an encoder so that the microprocessor can read the torque, forces and position of the motor. This will simplify the programming of the system.

Testing

We have submitted an IRB protocol to our client to be approved at the Medical College of Wisconsin – Milwaukee. Our IRB protocol has 3 phases: system testing, clinician testing and patient testing.

Phase 1: System testing

After the completion of the work on the device, the system will be tested. The programs for the microprocessor and the limiting switches will be tested to ensure the quality of the programs and effectiveness of the switches. The rotating components will also be tested to determine the force that it will put on the arm and hand. The forces will be compared to the maximal allowance of forces on those joints. The device should not cause additional strain in the joints of the patients.

Phase 2: Clinician testing

Five clinicians will be tested on their performance with the system and surveyed about their opinion of the device. Inclusion criteria for the clinicians are

- Physical or occupational therapist

- Must be currently working with patients in the acute phase of stroke
- Working with inpatient or outpatients

After consent has been given, two teammates will meet with a clinician. First, the teammates will give the clinician information about the purpose of the system and what the system hopes to accomplish. Teammate 1 will then set up the device on teammate 2. Teammate 1 will go through a step-by-step procedure on putting the patient into the device and how to set up the computer program interface. The clinician will then set up the device for both teammates. The two trials will be timed and the times will be analyzed to test for the learning curve of setting up the device. Finally, the clinician will be surveyed about their opinion of the efficacy of the device.

Phase 3: Patient testing

A comparative study between rehabilitation with our device compared to PT/OT therapy will be run. Six patients will be chosen based on the following inclusion criteria:

- Acute phase of stroke
- Stable health
- Reduced motor functioning in arm and hand
- Inpatient or outpatient
- Have to be able to sit up in bed or in the wheelchair for at least 60 minutes
- Be doing regular PT or OT therapy

After consent has been given, the patient will be tested for their functional abilities: active and passive supination/pronation of the wrist and flexion/extension of the hand. The passive wrist and hand motions will be tested with a goniometer to measure the amount of rotation or opening that the wrist and hand can perform. The active wrist action will be tested by our device by a measure of the force that it can put on our device. The active motion of the hand will be tested with a dynometer.

All patients will be participating in PT/OT therapy. The patients will be tracked over 10 sessions of therapy. The patients in the experimental group will then use our system for 15-minute sessions for 10 sessions. The patients will be tested again after the fifth and tenth sessions. The data will be collected and then analyzed to statistically test whether improvements are greater in the experimental group compared to the control group.

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Appendix 1

Device for Acute Rehabilitation of the Paretic Hand After Stroke

Carly Brown
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Nathan Kleinhans

2/9/07

This device will assist in hand rehabilitation in stroke victims in the first three months after stroke.

Stroke is the leading cause of long-term disability in the United States. Hand impairment is prevalent in stroke patients and is particularly debilitating since it limits independence and the ability to use the hand to do real tasks like eating and drinking. The goal is to design a device to facilitate hand rehabilitation in the acute phase, first 3 months, after stroke.

Design requirements:

- easily to attach to the impaired arm
- comfortable to wear
- accommodates various sized hands and forearms
- attach to either the left or the right arm
- portable and mobile to be used while seated in a wheelchair
- active, mechanical mechanism for rotation of wrist and grasping of the hand
- separate motion of wrist and hand
- 90 degree rotation from neutral for wrist

1. Physical and Operational Characteristics

a. *Performance Requirements*- The device will be used during physical therapy sessions. The sessions will be 3 times a week, for a maximum use time of 2 hours per sessions, and the sessions will continue for 6 weeks. Also, no more than 3 patients will use one device within a therapy session. So, the device will be used on an average of 18 hours a week. Loading and unloading of the device onto the wheelchair will be done by a physical therapist. The device should be able to be used on either arm and be used with a wide range of arm sizes. The motions of supination and pronation of the wrist and flexion and extension of the hand will be focused on.

b. *Safety*- The device should not cause physical discomfort of strain to the user. The device should be easy to use for sanitary reasons. Also, the device should not impede with the movement of the wheels of the wheelchair.

c. *Accuracy and Reliability*- The device should allow for 180° rotation. The device should be able to rotate repeatedly for the durations of the sessions without change in rotational resistance of the device.

d. *Life in Service*- The system should work for 3 years, after that time the system would be replaced with a new system. The battery life for an alkaline battery in use is 140 hours.

e. *Shelf Life*- The shelf life should be able to sit on a shelf for 10 years. The only component that would have a shorter shelf life would be the battery, which is easily replaced.
f. *Operating Environment*- The device will be used within a hospital, in a clinical setting. It will be used indoors.
g. *Ergonomics*- The range of sizes of our device will fall within 2 standard deviations of the average size arm. Be able to accommodate any size arm without causing discomfort, itching. Also should not debilitate arm function by being strapped into a fixed position. The device should also be allowed to be adjusted and released by their good arm.
h. *Size*- Work within the confines of a desktop for a wheelchair which is the size 24" x 20", and also attach our system to any part of the wheelchair. The maximum volume of our device will be 24"x 20"x 18".
i. *Weight*- Less than 15 lbs
j. *Materials*- Hypo-allergenic materials that are easily cleaned.
k. *Aesthetics*- Should not be intimidating, unimposing, and interactive.

2. Production Characteristics

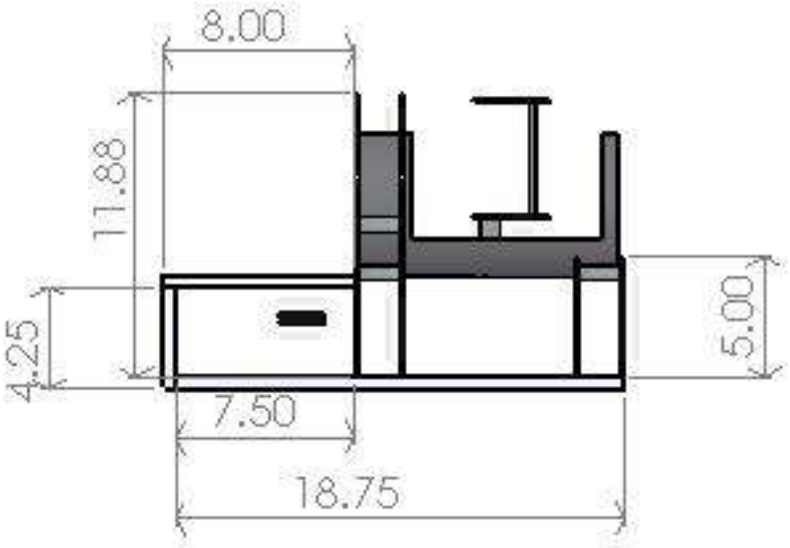
a. *Quantity*- 1
b. *Budget*- total: $750 this semester: $600

4. Miscellaneous

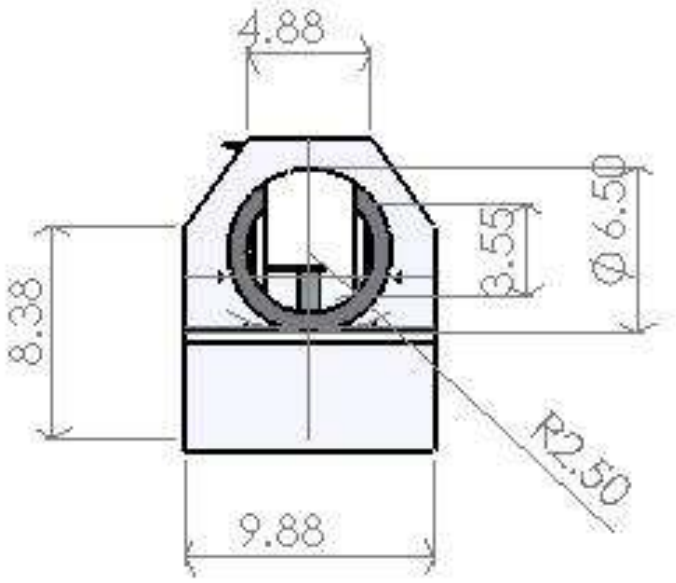
a. *Standards and Specifications*- Since our device will be in the prototype phase, there are no FDA regulations that govern our project.
b. *Customer*- The user of this device will be within the age range of 45-80, so the device should be geared toward that audience. Variations could be made to the system to accommodate other ages.
c. *Patient-related concerns*- sterilization
d. *Competition*- A BME design group from Marquette University.

Appendix 2

Side (Dimensions in inches)



Front (dimensions in inches)



Top (dimensions are in inches)