Device for acute hand rehabilitation after stroke

Preliminary Design Report

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BME 301

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Table of Contents

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Executive Summary

Stroke is the number one cause of adult disability in the United States. Rehabilitation centers throughout the United States utilize systems of varying degrees of sophistication to regain bodily function following the hemiplegia caused by stroke. The current rehabilitation systems range from squeezing a ball, to a robotic arm system that mirrors the movements between hands. The project is a continuation from last semester. Last semester, a conceptual model was constructed after midsemester design changes occurred with the design. The model was a mechanical wrist rotator and a hand grasper that allowed for transcutaneous electrical stimulation electrodes to activate the extension of the hand. The aim of the project this semester is to design a mechanical system of sophistication that falls between that of the systems previously mentioned. Another aim is to make this a comprehensive device, meaning that it should be universal, in regards to arm size and orientation, portable, and then also be mechanically driven to assist in the supination/pronation of the wrist, along with the extension/flexion of the hand. Our current design has a battery powered microprocessor that will send signals to a stepper motor and a pneumatic actuator. The stepper motor will power a wrist rotator for the supination/pronation of the wrist. The pneumatic actuator will inflate a rubber bladder that will be connected to the hand to simulate the gross motor action of hand extension. The microprocessor will also allow for varying signals to each of the components to allow for the variations of the conditions of patient.

Background Information

Since this project deals with patients after stroke, information about stroke, the people who are affected by stroke, the current rehabilitation methods used for these patients, and also the variation in the sizes of arms throughout the population in the United States is needed to give insight to this project.

Stroke

Stroke occurs in two instances. In the brain, a blood vessel can become blocked or a blood vessel can burst, which interrupts blood flow to the brain in both cases. When blood flow is interrupted, the brain cells in that area of the brain die and brain damage occurs. Effects of a stroke depend on which section of the brain the stroke occurred. Complete recovery is possible after stroke, but more than two-thirds of survivors will have some type of disability (National Stroke Association, 2006). Hemiplegia is a common disability that occurs from strokes. Where the affected side of the body is the opposite of the hemisphere of the brain where the blockage occurred.

Demographics

Stroke can happen to anyone. However, people over the age of 55, being a male, being African-American, Hispanic or Asian/Pacific Islander, or having a family history are at a greater risk of having a stroke. A stroke occurs on an average of once every 45 seconds in the United States. Of these stroke victims, 72% are above the age of 65 (The American Heart Association, 2006). Strokes in women are more likely than men to end in a fatality. Even though it is rare, the incidence of stroke in children occurs in three cases in every 100,000 (National Stroke Association, 2006).

Rehabilitation

Rehabilitation during the acute phase after stroke, three months post-stroke, is the most important time period after stroke. In most cases, if motion hasn't been regained within the first two weeks, motion is not recovered at all.

Rehabilitation methods range from basic movement methods to incorporating electrical stimulation to assist in movement to sophisticated robotic machines. Basic movement methods include squeezing tennis balls or cones and moving them between two points. These motions can be assisted by the incorporation of electrical stimulation. Electrical stimulation is used by activated muscles or nerves by sending current to them through electrodes placed on the skin. Electrical stimulation has advanced to where there are devices that can be placed on the arm to facilitate motions, such as hand grasping. The Bioness model is one of these devices and has a price of around $6000.

Studies on upper extremity rehabilitation have demonstrated that mimicry of the motions of the good arm have increased the recovered movement in the impaired hand. This mimicry method is used in the sophisticated robot-induced therapy machines. While the non-impaired hand does a movement, the device tracks that movement and mimics it in the impaired hand with a robotic arm.

Anthropomorphic Data

There is a great variance of sizes of arms and hands within the population; similarly, there is a difference between the sizes for men and women. The anthropomorphic data taken includes a range of ±2 standard deviations from the optimal for men and women, which statistically includes 97.5% of the population. The data that is pertinent for this project is the range of sizes of forearm length, handgrip, wrist diameter and dimensions of the hand. The following data was taken from Humanscale, by N. Diffrient, A. Tilley and J.Bardagjy.

The range of data that was recorded was the smallest value and the largest value from the ranges of the men and women. Forearm length, measured from the elbow to the wrist, was 5.8" - 11.2". Handgrip, measured from the wrist to the center of grip of the hand, had a range from 2" - 3.4". The minimum average wrist diameter was 1.81" to a maximum average diameter of 2.32". The length of the hand, wrist to finger tips, has a range of 6.3" – 8.3". For the width of the hand, measured the distance of thumb to pinky when the fingers were placed together, the range was 3.4" – 4.5". The height of the hand, measured as the height from a table to the top of the hand, varied from 1.7" – 2.8".

Design Requirements

Since this device will be used with patients who are three months post-stroke, most will be either in a wheelchair or still in bed. So, the device needs to be able to fit on a pre-existing wheelchair tray or a bedside table. The system also needs to be comfortable and non-imposing to the patients. Therefore, it must be lightweight to be moved from storage to the patient. The device should not exceed more than 25 lbs.

The device will be used during physical therapy within a hospital, so the ability to clean of the device between users is necessary. The device must be composed of materials that can be sterilized using alcohol or other anti-bacterial solutions between uses. Since the device will be used between patients, the device needs to withstand the use of at least three patients in a day. Each patient would last between 0.5-2 hours each day.

In addition, the device needs to be universal. It needs to be able to work on either the right or left hand as well as accommodate patients of different arm sizes, within two standard deviations of the average.

The complete product design specifications are in Appendix 1.

Previous work

The design from last semester began by focusing on the motion of supination/pronation of the wrist and incorporating a level of engagement for the patient. The first design that was decided upon was a device that incorporated an adjustable armrest that would restrain the forearm. This idea is shown in Figure 1.

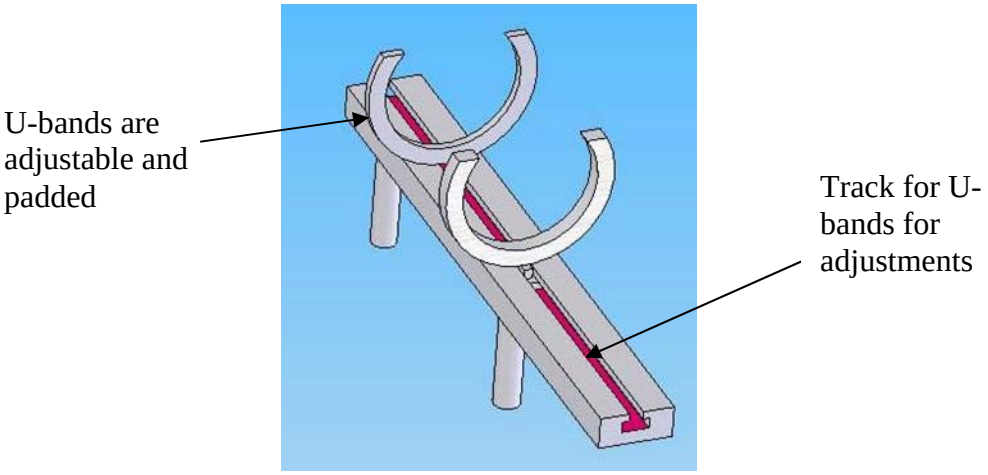

Figure 1. Arm rest

The supination/pronation of the wrist occurred in a 'Therapy Cylinder' which is shown in Figure 2. Originally the motion of the wrist was going to be facilitated by electrical stimulation through a Transcutaneous Electrical Stimulation (TENS) unit. However, a mechanical method was preferred by the client. So the base of the therapy cylinder was maintained, but the cylinder was connected to a torque motor. The motor needed to overcome a calculated 25 ft-lbs of force that could be generated by the wrist of the patient.

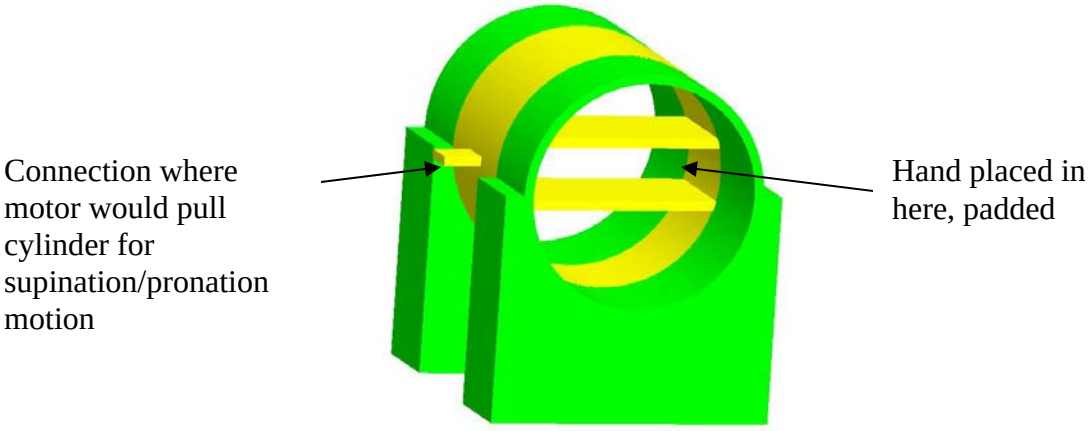

Figure 2. Therapy cylinder

The extension/flexion of the hand was also added after the initial design process. However, we choose to incorporate the TENS unit to assist in the flexion/extension of the hand. For the TENS unit to do this motion of the hand, the electrodes needed to be placed over the radial nerve that runs down the forearm. With the design that we had, the area on the arm that the electrodes needed to be placed were still accessible and not impeded by the device. The patient would then grasp a padded joystick. We used a pre-existing joystick so that the joystick could be interfaced with a computer program to engage the patient during the physical therapy session.

Design

The design changes for this semester are that there will be two systems, one for the supination / pronation of the wrist and flexion / extension of the hand. Also, both of the systems will be mechanically powered. The design will still have to be universal and portable for use in hospital physical therapy. The wrist rotator device that was decided upon was similar to the wrist rotator device from the previous semester.

For the mechanical mechanism of for the flexion / extension of the hand, there are two design choices. One choice emulates a hand with fingers that would have many moveable parts, and the other uses the premise of an inflatable bladder to extend the fingers.

Wrist Rotator

The wrist rotator component of the design will remain very similar to the design used last semester. It will consist of a horizontal cylinder that the patient can place their wrist into. The cylinder will be made of 5” diameter PVC that will be 2” long. The top will be cut off to allow the patient to place their wrist into the device. The PVC will be lined with padding to fit different sized wrist and make it comfortable. The padding will be lined with a covering that will be easily cleaned between users. The cylinder is supported by a bracket at each end that contains rollers to allow uniform rotation of the cylinder. A belt will connect to each side of the cylinder and run to a stepper motor controlled by a microprocessor. The design can be seen in Figure 3.

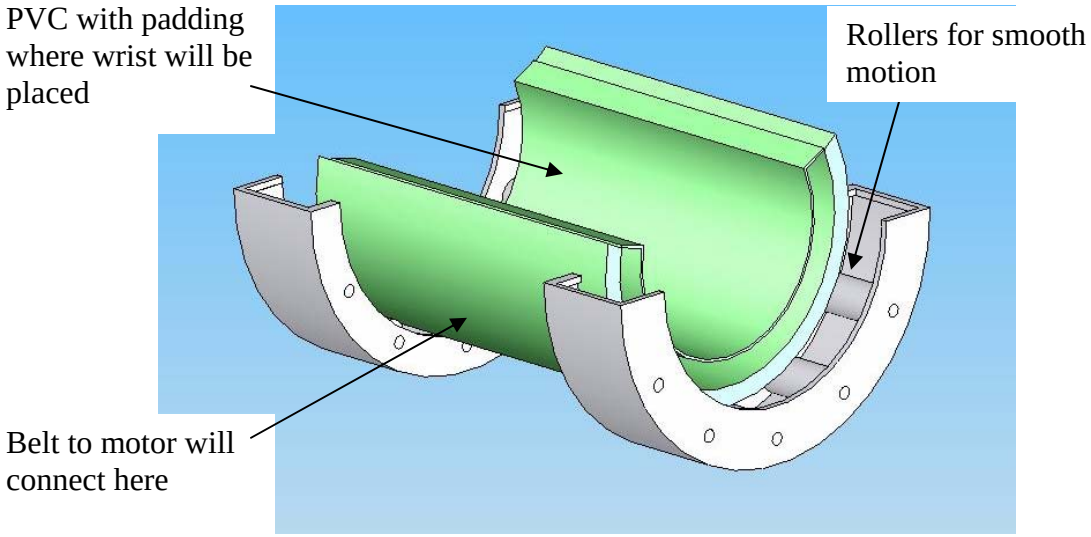

Figure 3. Wrist rotator

The microprocessor will be programmable to control the precise amount of rotation and speed of rotation of the wrist rotator. Different programs depending on a patients ability could be run. The programs would depend on the frequency of the rotations, the degrees per rotation, and the speed of the rotation. This allows it to be used on a wider range of patient depending on the level of dexterity possessed by each.

Hand Extension/Flexion

Mechanical Fingers

The mechanical fingers design of the hand grasper has individual "fingers" constructed out of aluminum tubing. The aluminum segments are hinged at the bottom and extended/flex similarly to actual fingers. Springs connect the segments on the underside and keep the segments in a constant flexed state. The segments will also have a hole running though them (drilled above center) with a cable through it. This cable runs from the first to the third segment and then out to another stepper motor. When the stepper motor retracts the cable, the fingers will open, or extend. The stepper motor will also be controlled by the microprocessor, allowing for a large amount of control in speed and degree of extension. This design is shown in Figure 4.

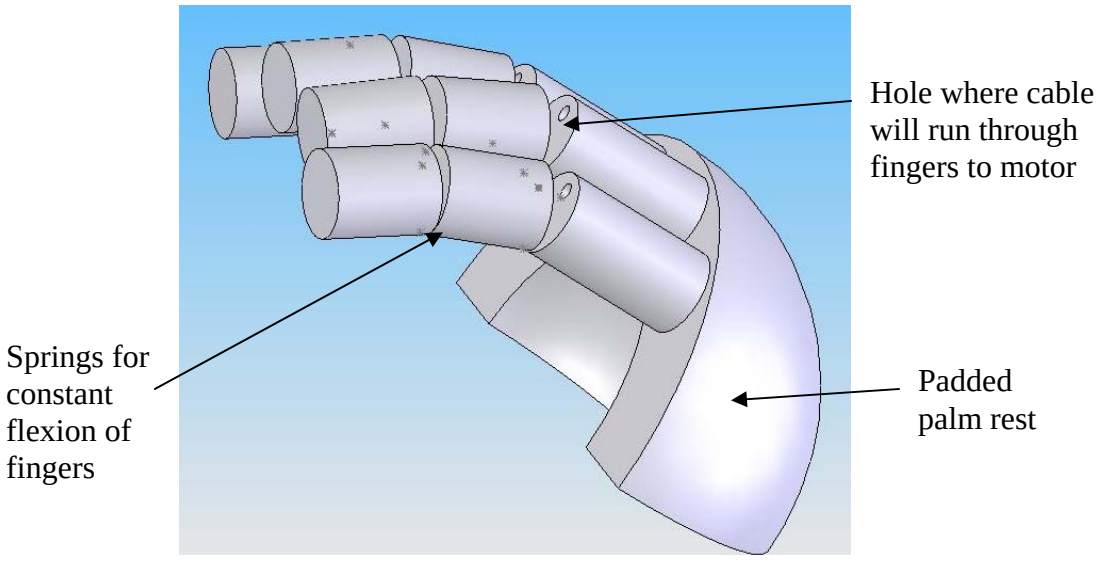

Figure 4. Mechanical fingers

Pneumatic Pump

The second design for the grasper is based on an air pump and bladder. A pneumatic actuator, once again controlled by the microprocessor, will fill a rubber bladder that the patient encloses his/her hand around. When the bladder is inflated, the fingers will be extended. A valve system will be incorporated to allow air to slowly escape from the bladder. Inflation is possible by simply pumping air in faster than it escapes, and pumping in air at the same rate at which the valves release it will maintain a constant pressure. Figure 5 shows the design of the pneumatic pump.

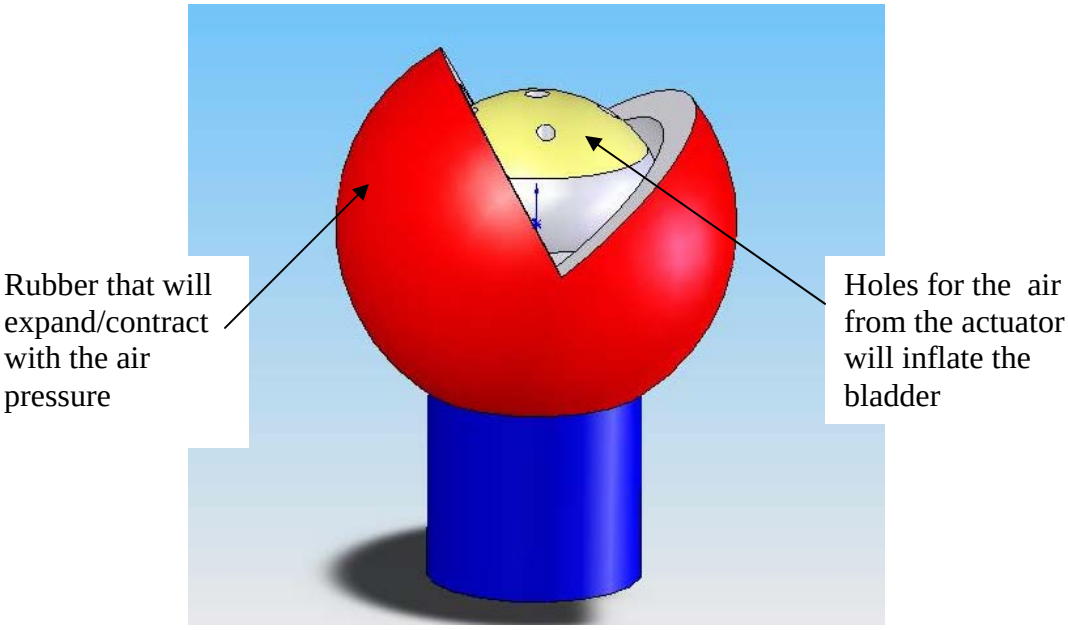

Figure 5. Pneumatic pump

Design Matrix

The two alternative designs for the hand extension/flexion component were evaluated using a design matrix. The design matrix is shown in Table 1. Each design was given a score of 1-5 in various categories with 5 being the highest possible score. A brief explanation of each of the categories is given below:

Cost: Amount of money needed to produce the design. A higher score indicates a less expensive manufacturing cost.

Manufacturing: Ease of constructing the design. A higher score indicates a relatively simpler design to manufacture than a lower score.

Universality: The ability of the design to accommodate various hand sizes as well as both left and right hands. A higher score indicates that the device has more ability.

PT-Friendly: How simple it is for the physical therapist to use, transport, clean, etc. A higher score indicates that a device is more PT-friendly than a device with a lower score.

Additional Movements: The ability to which each design is capable of simulating various types of grasps. A higher score would indicate that the device is capable of a variety of movements.

Weighted 1-5	Mechanical Fingers	Pneumatic Pump
Cost	2	3
Manufacturing	1	4
Universality	4	4
PT-friendly	4	4
Additional Movements	3	1
Total	**14**	**16**

Table 1: Design matrix used to evaluate the Mechanical Finger and Pneumatic Pump. Each design was given a score of 1-5 in the categories listed.

The two alternative designs for the extension/flexion component of the device scored equally in the Universality and PT-friendly categories. The projected costs for each design suggest that the Pneumatic Pump should be marginally less expensive to construct than the Mechanical Fingers design. The Pneumatic Pump scored much higher in the Manufacturing category because it is a much simpler design. The simplicity of the design should aid in avoiding complications and difficulty during construction as well as simplify the trouble shooting process during construction and use. The Mechanical Fingers model scored higher in the Additional Movements category because there is the possibility of controlling each finger separately allowing for different types of grasping whereas the Pneumatic Pump model, at this point, is only capable of simulating a spherical grasp. The total score of each design reveals that the Pneumatic Pump model is more feasible than the Mechanical Fingers model, based on these criteria.

For this design, a battery will be used to power a microprocessor, which will control the two wrist rotator and the pneumatic pump. The microprocessor will be able to have different programs for each system that will allow for a variability that can be changed depending on the patient. The layout of the device is seen in Figure 6.

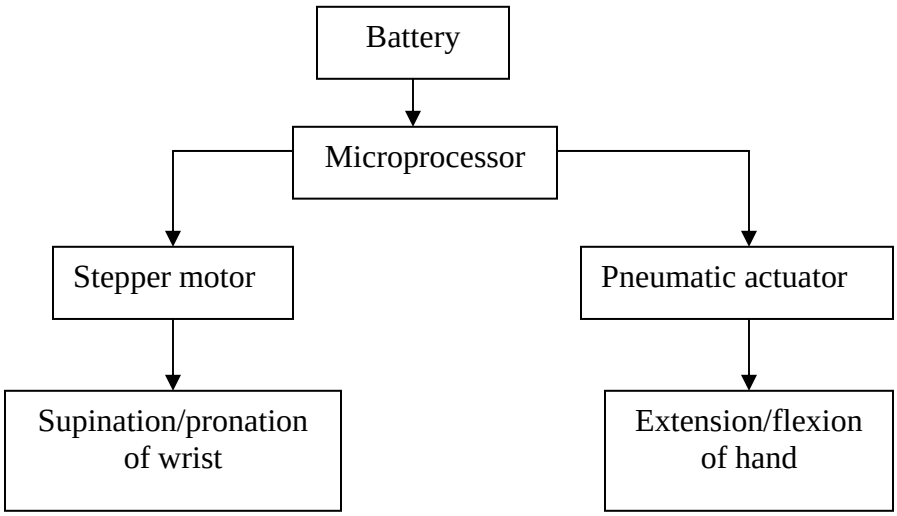

Figure 6. Layout of device

Budget

This device must be built for $600 or less. Projected costs indicate that the microprocessor and the hand grasper should cost approximately $150 each. The wrist rotator should cost approximately $200 to produce. This totals to $500 leaving $100 that can be used for miscellaneous materials that may not have been accounted for.

Future Work

By the end of this semester, construction of the Wrist Rotator and the Pneumatic Pump hand grasper are to be completed. These should be two independent mechanically functional systems. A timing circuit will control these functional systems, which will be in place of the microprocessor while it is being programmed. The device will be presented to Dr. Michelle Johnson of the Medical College of Wisconsin for feedback. The device will also be submitted to WARF in order for a possible patent on the design.

In future semesters, a microprocessor will be incorporated into the device allowing it to be more automated. Once the microprocessor has been successfully incorporated, the device will be tested for all of its mechanical aspects. Upon passing mechanical inspection, the device will be submitted for Institutional Review Board approval and possibly tested with human subjects.

Appendix 1

PRODUCT DESIGN SPECIFICATIONS

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.

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