Arm Rehabilitation Medical Device
Design Report—Volume I

Team Members
Anne Halverson       Brandon Peterson
Bruce Weldon          Lawrence Formosa
Ludong Sun            Yashovardhan Sand

Industry Sponsor
Sister Kenny Rehabilitation Institute/Sister Kenny Research Center
EXECUTIVE SUMMARY

Stroke patients currently lack an affordable and effective device to assist in shoulder rehabilitation. With the help of Sister Kenney Rehabilitation Institute, a new device employing a modified 4-bar mechanism with counterweight aims to fill this void. The figure below shows the main components of the device that sit underneath the table and provide the necessary assistance. This design was chosen because of its ability to create an energy input profile very near zero to move the device.

The device is split into 2 main sections, the blue coupler for the arm to rest, and the moving counterweight links. The moving parts were placed underneath the table to keep them away from the patient and therapist to increase safety. A piece of aluminum sheet metal completely hides the moving links. The device also cleanly hangs on a table and has screw levelers to hold it in place for different table shapes. This allows for the device to be easily placed on or taken off the table and tightened appropriately ensuring the device does not fall off the table.

One of the main design requirements was to provide assistance for shoulder flexion since many stroke patients lose some or most mobility in the arms. By providing the necessary assistance the patient can rebuild the damaged neural connections to regain full function of their arm through neuroplasticity. This device successfully unloads the arm onto the coupler in the figure shown, and the counterweight helps move the arm. At the worst case, the patient only needs to apply 2.5 lbs. of force to move their arm and the device forward, which they should be able to generate.

We used ANSYS to analyze stress concentrations across the entire device, and the device was determined to be structurally sound and stable. There were high safety factors (4 or more) at many points and stresses due to bending, creep and shearing were not large enough to cause failure. An extra link was added and the coupler was placed close to the frame to reduce excessive bending in the device.

Safety and comfort is very important for patients using this device. Six subjects of variable sizes and arm weights were asked to use the device and fill out a questionnaire about safety and comfort. All participants indicated that the device appeared safe and was comfortable while using the device. Variability between participant to participant did not negatively affect the device in any way.

The final design requirement of importance was repeatability of the device. Users, both familiar and unfamiliar with the device, were asked to perform 200 repetitions. This amount was chosen because it is far larger than the repetitions that will be completed during a single therapy session. None of the users reported the device locking up, and many commented that the motion was easy to complete. Therefore, this device will definitely be able to handle any amount of therapy sessions for stroke patients.
TEAM CONTRIBUTIONS

ANNE HALVERSON

- Did Solidworks modeling of the device frame, hanging mechanism, end links, counterweight assembly, and the device assembly.
- Assisted in background research.
- Wrote the original manufacturing plan and updated for changes to the design.
- Created the evaluation plan.
- Wrote 4 evaluation abstracts.
- Assisted team in developing concept alternatives and design ideas.
- Spent approximately 25 hours machining parts for the prototype.
- Spent approximately 15 hours assembling the parts.
- Wrote the Alternative Designs section.
- Wrote the Strengths and Weaknesses section.
- Helped the group with writing the Technical Review.
- Compiled Volume 2 for uploaded of final draft.
- Performed variability study and wrote evaluation report.
- Performed repeatability study and wrote evaluation report.
- Assisted with force evaluation.
- Compiled the Product Design Specifications.
- Developed the User Needs Table.
- Helped to determine metrics for the PDS.
- Put together the concept selection table and evaluated alternative designs.
- Put together original bill of materials (before changes to prototype).
- Determined stock parts to be ordered and put order through on McMaster.
- Worked on troubleshooting the prototype for approximately 12 hours.

BRANDON PETERSON

- Researched medical terms and background information critical to the project.
- Reviewed the pros and cons of the design of the team from the previous semester.
- Assisted the team in collecting user needs and determining design requirements.
- Experimented with four bar linkages while trying to find one that creates proper arm motion.
- Created four cardboard prototypes of four bar linkages to communicate idea to others.
- Discovered a four bar linkage that created correct arm motion and was used in final design.
- Investigated four configurations of the fifth bar and counterweight locations.
- Designed the initial 2-dimensional model from which the 3-dimensional CAD model was created.
- Created “Project Energy Analysis” spreadsheet to predict the performance of the design.
- Assisted the team in manufacturing the prototype.
- Wrote the analysis of the previous team’s design, the Summary of the Design, the Functional Description, the Overview Drawing, the Assistive Force evaluation, the Environmental Impact Statement, and the Four Bar Mechanism alternative concept.
BRUCE WELDON

- Researched alternative devices available
- General patent searches
- Assisted the team in collecting user needs and determining design requirements
- Explored alternative design concepts (not used)
- General device concept refinement (Example: moving the device under table)
- Assisted the team in manufacturing the prototype
- Entirety of the ANSYS analysis of device
- Documentation Revision and Updating of all documents
- Gantt Chart
- Determined additional uses for the device

LAWRENCE FORMOSA

- Created the CAD model of the links
- Created the CAD model part drawings
- Wrote the executive summary for the project
- Assisted in machining the prototype parts
- Performed the necessary background research for the project
- Assisted in compiling volume 1
- Assisted in creating the manufacturing procedure along with the associated drawings
- Spearheaded device selection and acquisition
- Wrote the cost analysis for the device
- Assisted in the construction of the PDS and WBS
- Generated an alternative concept and discussed with team and advisors

LUDONG SUN

- Construction of ARM Google site
- Did final check and edited assignment one and two right before submission
- Searched Background information, which includes medical terms, previous patent and existing device
- Generated an alternative concept and discussed with team and advisors
- Assisted team with writing PDS and WBS
- Helped team in making prototype in machine shop
- Assisted with evaluation (force analysis)
- Wrote the annotated Bibliography, patent search, Functional Block Diagram, evaluation plan of design report.
- Designed and created a poster for design show
YASHOVARDHAN SAND

- Researched required terms and information regarding the project
- Assisted team in reviewing the pros and cons of the design of the team from the previous semester
- Assisted in writing the project executive summary
- Assisted the team in collecting user needs and determining design requirements.
- Generated an alternative concept and discussed with team and advisors (not used)
- Created the device implementation procedure
- Compiled the regulatory and safety considerations
- Assisted team in machining parts for the prototype
- Assisted in device evaluation
- Compiled and completed volume 1 and volume 2
- Created the safety and repeatability evaluation for patients
- Constructed an evaluation questionnaire for device testing
- Assisted in the construction of the PDS and WBS
Table of Contents

1. PROBLEM DEFINITION .............................................................................................................. 6
   1.1 PROBLEM SCOPE .............................................................................................................. 6
   1.2 TECHNICAL REVIEW ......................................................................................................... 6
      1.2.1 PRIOR ART ............................................................................................................... 6
   1.3 DESIGN REQUIREMENTS ................................................................................................. 9

2. DESIGN DESCRIPTION ............................................................................................................ 11
   2.1 SUMMARY OF THE DESIGN ............................................................................................ 11
   2.2 DETAILED DESIGN ......................................................................................................... 12
      2.2.1 FUNCTIONAL BLOCK DIAGRAM .............................................................................. 12
      2.2.2 FUNCTIONAL DESCRIPTION ..................................................................................... 13
      2.2.3 OVERVIEW DRAWING ............................................................................................. 18
   2.3 ADDITIONAL USES .......................................................................................................... 19

3. EVALUATION .......................................................................................................................... 19
   3.1 EVALUATION PLAN .......................................................................................................... 19
   3.2 EVALUATION RESULTS .................................................................................................... 20
      3.2.1 SAFETY ..................................................................................................................... 20
      3.2.2 STRUCTURAL INTEGRITY .......................................................................................... 20
      3.2.3 REPEATABILITY ........................................................................................................ 21
      3.2.4 ASSISTIVE FORCE .................................................................................................... 21
      3.2.5 VARIABILITY EFFECT .............................................................................................. 21
   3.3 DISCUSSION ...................................................................................................................... 22
      3.3.1 STRENGTHS AND WEAKNESSES .......................................................................... 22
      3.3.2 NEXT STEPS ............................................................................................................. 22

4. REFERENCES .......................................................................................................................... 23
1. PROBLEM DEFINITION

1.1 PROBLEM SCOPE
After suffering a stroke, patients often lose strength and/or coordination in various parts of the body. Stroke victims then go through rehabilitation therapy to help them recover as much motion as possible and hopefully regain the ability to perform everyday tasks such as walking or reaching. Arm rehab devices are available to practice the reaching motion, but the devices currently on the market are too expensive for most patients to buy for at home use. In order to improve the rate of recovery, at home therapy is crucial and it needs to be possible for more to afford. This project aims to design a device that provides stroke patients with the same benefits of rehabilitation devices already available, while keeping cost affordable. The therapy done on this device is passive assistance, which allows the patient to initiate motion but also provides an adjustable assistant force throughout the motion.

1.2 TECHNICAL REVIEW

1.2.1 PRIOR ART
The Animated Dissection of Anatomy for Medicine (A.D.A.M.) Encyclopedia describes a stroke as the rapid loss of brain function due to interruption of blood supply to the brain [1]. This can be caused by a clot blocking an artery or a blood vessel breaking. Lack of a blood supply causes two million brain cells to die per minute, which shows the urgency of immediate treatment of stroke patients. Depending on the part of the brain affected, symptoms can include muscle weakness on one side of the body, loss of hearing or memory, trouble walking or speaking plus many more. Strokes also vary widely in severity and recovery rates. Some patients may experience only minor problems such as weakness of an arm or leg. People who have larger strokes may be paralyzed on one side or lose their ability to speak. Some people recover completely from strokes, but more than 2/3 of survivors will have some type of disability [2]. The National Security Agency (NSA) also puts stroke as the 4th leading cause of death in the US, with over 7,000,000 stroke survivors estimated in the country over age 20. There are many ways to prevent stroke, which include maintaining a healthy lifestyle, keeping track of blood pressure and cholesterol levels, and watching for atrial fibrillation.

Following a stroke, it is very important that the patient attend occupational physical therapy and begin to retrain their brain. Repetitive motion exercises are often used by therapists to begin this brain recovery. There are various types of arm rehab devices, each with the goal of repairing the connections of the brain that initiate arm movement. In arm rehabilitation, the goal is to engage the anterior deltoids, which assist the pectorals in shoulder flexion and elbow extension. These motions are important in stroke rehab because often the arm develops spasticity, which is an increase in muscle tightness that ends up pulling the arm tightly towards the body. The shoulder flexion/elbow extension motion strengthens the muscles that have become weak, while not engaging those that are stiff. The real-life benefit of this motion in occupational therapy is for reaching or grabbing applications, a very important part of everyday life.
There are products for arm rehabilitation already on the market, and they often include a sophisticated control system in order to provide all levels of assistance. Robotic systems are used in most of these devices, because they can be programmed for many different applications. An example of this is the inMotion Arm [3], a product of Interactive Motion Technologies. This device is “assist-as-needed”, meaning that the robot reacts to patient feedback and adjusts resistance to constantly challenge and engage the patient with individualized therapy. This ensures that all movements will be completed, because the computer can sense when motion slows and patients requires additional assistance. The computer also tracks performance as therapy progresses and can provide the patient and therapist with this, guiding future therapy. While this device can accomplish the same rehabilitation as our design, it also contains a wide variety of other types of exercises, not just the simple reaching motion. It would be an ideal way for all patients to exercise, but it is infeasible for each stroke victim, or even rehabilitation clinic, to buy a $7,000 device just for one part of their rehabilitation. Other than the cost, this device is an effective product and has clinical rehabilitation trials to back its effectiveness.

Another currently available competing product is the Tailwind by Encore Path, Inc. [4] The Tailwind takes a very customizable approach that provides a linear, forward motion of the hand to produce the desired shoulder flexion. The design emphasizes customizability, both to patient-by-patient needs like physical body-size constraints, and to the desired motion difficulty and direction. This is accomplished with handles that the patients grasps, mounted to adjustable bars with forward motion barriers, all connected to a mounting bar to create the most desirable body alignment, as shown in Figure 2.
Though this device provides rehabilitation benefits, it has some drawbacks. First, the device is prohibitively expensive for most patients, at roughly $2000, which often is not covered under any form of insurance. Second, the patient must be able to grip the handles to operate the device. This could be mitigated with straps, but is an issue regardless, as many stroke patients have very limited ability to use their arms or even their fingers, making the device virtually useless to patients early in the rehabilitation process when the arm can’t naturally perform the needed exercise. Third, because it is so customizable, an assistant of some sort is almost a necessity to set up the device and ensure the patient is performing the correct motion, mitigating the main goal of the product to lessen the need for therapists to be present. Finally, as with the second point, the patient must be far into the rehabilitation process to use the device, and so must have the strength to freely move their arm themselves. Again, in early stroke victims, even limited motion of fingers can be exceedingly difficult, so without assisting forces, the device is inoperable.

Figure 3- A photo of the design created by ME 4054 students in Fall 2012.
Another design was created by ME 4054 students last fall. Their design, shown in Figure 3, was an interesting concept, but ultimately did not meet many of our necessary requirements. This product sits on top of a table. To use it, the patient sits at the table and rests their arm on the white arm pad. A torsional spring provides assistance as the arm is moved forward (towards the center of the table). Once the arm is fully extended, the mechanism allows the patient to twist the arm inwards toward the patient’s body while the arm is being pulled back toward the starting position. The idea is that during retraction, a smaller force is needed to recompress the torsional spring because the arm actually travels a longer distance than it did during extension.

A few key problems with this design have prevented it from being used. The friction in the joints of the mechanism makes the arm very difficult to move and essentially counteracts the extension assistance provided by the spring. Safety is another concern with this design, as it contains pinch points and tends to “shoot” the arm pad towards the center of the table if released with no weight on the pad.

1.3 DESIGN REQUIREMENTS

<table>
<thead>
<tr>
<th>DESIGN SPECIFICATION</th>
<th>EVALUATION PLAN</th>
<th>EVALUATION METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device is Safe</td>
<td>Have many people try the device, and analyze locations of pinch points, other safety hazards.</td>
<td>Prototype Testing</td>
</tr>
<tr>
<td>Device is Structurally Sound</td>
<td>Place the device under maximum stress states and confirm that no stress exceeds safety factor.</td>
<td>ANSYS Analysis</td>
</tr>
<tr>
<td>Device is Repeatable</td>
<td>Have many people try the device, and monitor whether there are catching points or other factors affecting repeatability.</td>
<td>Prototype Testing</td>
</tr>
<tr>
<td>Device Provides Assistance Force</td>
<td>Measure the force necessary for a patient to move the device throughout the entire motion.</td>
<td>Force Gauges</td>
</tr>
<tr>
<td>Device can be used by any Patient</td>
<td>Measure the magnitude of the change in input force when different variables are changed (arm weight, patient height, velocity of motion, etc.)</td>
<td>Prototype Testing</td>
</tr>
</tbody>
</table>

There are many important design requirements for this rehabilitation device, all of which can be found in Volume II of the design report. One design requirement that is especially important is the need for assistance during shoulder flexion. Many stroke patients lose some or all mobility for shoulder flexion, thus, it is necessary to assist this motion to retrain the brain through repetition. To meet this requirement the machine will use some form of energy input to drive the drive shoulder flexion with about 5lbs of force. The force data was calculated using data from supplied from our advisors. By providing the necessary assistance, the patient will be able to reconstruct neural pathways to regain movement.
This rehab device must follow a set path to ensure the correct muscles and motions are being rehabilitated. The deltoids are a major muscle responsible for shoulder flexion and will be targeted [13]. From conversations with physical therapists, patients can overcompensate with different muscles groups to make up for lost shoulder flexion. This can lead to incorrect muscle groups being strengthened, while the desired muscles remain weak. This motion will constrain the path of the device to follow only shoulder flexion until the arm is fully extended. The path of motion will be verified by a physical therapist to ensure the desired range is met. The only acceptable motion is that where only the deltoids are used no biceps or other upper body muscles since this device is meant to isolate those groups of muscles.

This device must allow for continuous repetitive use, because many repetitions are needed to regain arm movement. One goal of this device is to be used with minimum therapist intervention and within a patient’s own home. The device cannot be reset after every repetition because that would be too time consuming and inefficient. It needs to provide at least 50 repetitions before being reset; however, 200 repetitions is the ideal number. This requirement for continuous repetitions was determined with the help of our project advisors and through multiple group discussions. By allowing many repetitions to be completed before resetting the device, the patient will be able to work under minimum supervision from the therapist.

All medical devices that eventually make it to the market are subject to FDA inspection and placed in one of three different classes based on safety and how it is used. This device will need to be a class 1 medical device. Class 1 medical devices do not require detailed FDA inspection, are not intended for sustaining life, and pose no serious threat of injury or illness [12]. This device will solely use mechanical parts to operate and will operate with very low relative forces. By eliminating electronics and high forces, the process to get the device to the market and amount of pre-market testing will be greatly reduced. The cost of manufacturing a device that does not use electronics will also keep the market price of the device low. This will keep the device very safe and efficient for patients; our advisors determined this to be a significant requirement for the device.

The cost of this rehab device in the market must also be significantly lower than competing devices. Current shoulder flexion rehab devices are very expensive and sell for thousands of dollars. For instance, the TailWind costs around $2,000, and the InMotion devices cost around $7,000 [4,3]. The aim of this new device is to be under $50 in manufacturing costs. The market price is tough to gage since many parts would be cheaper when bought in bulk, but the entire device would be marked up due to general low demand of such devices compared to other manufactured devices. This will provide significant cost savings for patients, their families, and therapists. Material choice, manufacturing, and concept selection will need to be completed to keep this device as low cost as possible. By reducing the cost of the device it will be affordable for everyday households, rather than only being available at rehabilitation centers.
2. DESIGN DESCRIPTION

2.1 SUMMARY OF THE DESIGN
The design has two main components, both of which are illustrated in Figure 4a and Figure 4b. The first component is a four bar mechanism that will allow the arm to achieve the correct path of motion. This mechanism will clamp on the side of a table and hang lower than height of the table, with an armrest attached to a rigid structure that is part of the coupler of the linkage. The rigid structure will allow the armrest to be slightly higher than the height of the table. When using this device, the patient will be sitting next to and parallel to the edge of the table.

The second component of the design is a fifth bar that is attached to the linkage and uses a counterweight that will assist the motion of the user’s arm. The counterweight will provide a load when the patient’s arm is moving downwards and will provide assistance when the patient’s arm must be lifted. This will reduce the force required to move the arm by making the potential energy of the system as close to zero as possible at all times during the motion. The idea is that with the assistance of the counterweight, the patient will only need to input a minimal amount of energy into the system while extending the arm outwards.

A CAD model of the full mechanism is shown in Figure 4a and Figure 4b, and the details of the design will be explained further in the following sections.

![Figure 4a- A rear view of the linkage as seen from under the table.](image-url)
2.2 DETAILED DESIGN

2.2.1 FUNCTIONAL BLOCK DIAGRAM

Figure 5- A functional block diagram of the system.

Figure 4b- A front view of the linkage.
2.2.2 FUNCTIONAL DESCRIPTION

Four Bar Linkage and Armrest

To achieve the desired motion, a four bar linkage was designed to mimic the natural motion of the arm. This linkage will clamp to the side of a table to allow it to be used at home as well as in the clinic. Figure 6 shows how the initial and final positions of the arm were defined. In Figure 6, Link 1 (shown in red) is anchored to the table and acts similar to the user’s upper arm. Link 1’s length is equal to that of the average person’s upper arm and the mechanism is designed so that Link 1 will be at the same angle as the upper arm at any given time. Link 2 (shown in blue) acts similar to the lower arm and will be at the same angle as the lower arm at any given time.

![Diagram of four bar linkage and armrest](image)

Figure 6- A diagram of the defined initial and final link positions

Next, another link was needed to guide Link 2 through the correct path. The process through which the length and position of this link were found is known as Two-Position Motion Synthesis. This method states that the anchored end of the final link must be an equal distance from the unattached end of Link 2 at the initial and final positions. In other words, the anchor point could have been chosen to be anywhere on the green dotted line in Figure 6. For convenience, the anchor point was chosen to be at the height of the table.

The complete four bar mechanism is shown in Figure 7. Notice that additional members have been added to Link 2 (blue) to translate its motion to a location that is above the table. These members make up one rigid structure on which the armrest is placed.
Fifth Bar and Counter Weight

Although the mechanism shown in Figure 7 does create the desired arm motion, it does not offer the user any type of assistance in moving the arm. To assist in moving the arm, Link 5 (shown in brown) and a counterweight has been added to the mechanism, as shown in Figure 8. The fifth link shares one end point with that of the Link 2 and Link 3, while another pin on the black link moves up and down the sliding joint (shown in purple). The purpose of the sliding joint is to allow the counter weight to follow the correct path and be at the desired height at any given point in time. The counterweight is located on the end of the Link 5 and moves in a path similar to the path shown by the dotted black line. The idea is that the weight is lifted initially by the weight of the patient’s arm moving downwards, and then the weight falls in the latter part of the movement in order to assist in lifting the arm upwards.
Figure 8- A diagram that demonstrates the approximate motion of the counter weight.

For further clarification, Figure 9a and Figure 9b show the entire mechanism at the initial and final positions, respectively.

Figure 9a- A diagram of the entire mechanism at the initial position.  
Figure 9b- A diagram of the entire mechanism at the final position.
Three Dimensional Design

The mechanism shown in Figure 9a and Figure 9b is a two-dimensional linkage in which links and joints must pass through each other. To make the design work in three dimensions, each link must move on a different vertical plane, as shown in Figure 10.

![Diagram of three-dimensional design](image)

**Figure 10- A top view of the system showing the vertical plane in which each component moves.**

As shown in Figure 10, the entire mechanism except for the armrest will be tucked away under the table. This can also be seen in Figure 4b, in which all links except for the blue coupler are hidden behind a steel plate. Locating the moving links of the mechanism under the table serves a few key functions. First, it will help to reduce the clamping force necessary to hold the device in place by balancing the weight of the arm and armrest with the weight of the counter weight. It will also make the device much more convenient to use, as the majority of the mechanism will be below the table, out of the way of the user, and for the most part out of sight. Finally, having a majority of the moving parts beneath the table will make the product much safer to use, as the pinch points created by its motion will not be exposed to the user.
Clamping System

The mechanism will be clamped to the table using a steel plate and four screws. A side view of the device showing the steel piece and two of the four clamping screws is shown in Figure 11. The two remaining screws are not visible because they are directly in line with the two screws shown in Figure 11. For further clarification, one can refer back to Figure 4a, in which all four clamping screws are clearly visible.

The four clamping screws are adjustable and allow the mechanism to fit on tables of different sizes. They are tightened to provide an upwards force into the table. Each screw has rubber padding on the end to help prevent the device from sliding around on the table. Finally, a steel mount supports the weight of the entire device while providing a downward force into the table.

Figure 11- A side view that illustrates the method of attaching the mechanism to a standard table.
2.2.3 OVERVIEW DRAWING

Figure 12-Overview Drawing

- **Armrest**: Provides support and stability for the patient’s arm while they perform the exercise.
- **Device Frame**: This provides structural stability for the entire mechanism, and also prevents the patient from coming into contact with any pinch points.
- **Counterweight Mount**: The weights will be attached to this rod allowing assistance to be altered for patient requirements.
- **Counterweight Link**: This link provides assistance through the change in energy of the counterweight.
- **Clamping Screws**: These screws tighten to provide an upwards force into the table to hold the device in place on tables of varying sizes.
- **Steel Table Mount**: Supports the entire weight of the mechanism and helps clamp the mechanism to the table.
- **Slider Carriage/Track**: This slider mechanism allows the counterweight link to move vertically at its axis of rotation.
- **Theses bars** shift the motion of the coupler to the top of the mechanism so that a person can comfortably use the device at table height.
- **Four Bar Mechanism**: (fourth link is ground link) These links and joints provide motion which is desired for this exercise. Force is transferred from counterweight link through mechanism into arm.
2.3 ADDITIONAL USES

Because of the simple nature of the motion the mechanism provides, it should be able to scale to larger applications without trouble, until material, weight, and frictional inefficiency limits are reached. Therefore this mechanism could be applied as an intermediate step between other sections of assembly lines, serving to allow horizontal motion of loads with minimal force input, even under high weight impositions, and tip the loads onto a track with the natural rocking motion of the device. To meet these higher weight impositions though, the materials would likely have to be altered to steel or stronger candidates, and the beams composing the mechanism could be altered to support even larger loads without functionally changing the motion achieved and the energy balance reached overall. But, as the loading on the system increased, the amount of force would also likely have to be increased for motion slightly. This also could be reduced though by replacing all pin joints with appropriate bearings.

This all comes with the caveat that the overall goals imposed on this project’s specific application would have to reevaluated, as any scaling would also affect the material costs and change weight balances. In any case, the design would have to be re-optimized for the scenario being considered.

Other potential uses with less dramatic alterations required would be things like rocking chairs, keyboard trays, disk trays, and potentially any other use where small motion is required. Again, in every case though, the design would have to be re-optimized, as this project is meeting very stringent goals under the current design requirements.

3. EVALUATION

3.1 EVALUATION PLAN

The purpose of this evaluation plan is to determine if the design satisfies the five design requirements specified in Section 3.3. These criteria have been restated in Table 1, along with a brief summary of their evaluation plans. The evaluation plan procedure and results for each specification are discussed further in Section 5.2. The first design specification, Device is Safe, is binary, while the other four are quantitative. These design specifications were chosen for their importance along with the ability to measure them.

<table>
<thead>
<tr>
<th>DESIGN SPECIFICATION</th>
<th>EVALUATION PLAN</th>
<th>EVALUATION METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device is Safe</td>
<td>Have many people try the device, and analyze locations of pinch points, other safety hazards.</td>
<td>Prototype Testing</td>
</tr>
<tr>
<td>Device is Structurally Sound</td>
<td>Place the device under maximum stress states and confirm that no stress exceeds safety factor.</td>
<td>ANSYS Analysis</td>
</tr>
<tr>
<td>Device is Repeatable</td>
<td>Have many people try the device, and monitor whether there are catching points or other factors affecting repeatability.</td>
<td>Prototype Testing</td>
</tr>
</tbody>
</table>

Table 2- Design Specifications with Evaluation Methods.
### Device Provides Assistance

<table>
<thead>
<tr>
<th>Force</th>
<th>Measure the force necessary for a patient to move the device throughout the entire motion.</th>
<th>Force Gauges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device can be used by any Patient</td>
<td>Measure the magnitude of the change in input force when different variables are changed (arm weight, patient height, velocity of motion, etc.)</td>
<td>Prototype Testing</td>
</tr>
</tbody>
</table>

### 3.2 EVALUATION RESULTS

#### 3.2.1 SAFETY

An analysis of the safety of all aspects of this device is essential. As a Class 1 medical device it is important that the device does not introduce any additional risk of harm to the patient from use of the device. A full evaluation of the pinch points, sharp edges, and possible safety issues was performed on a working prototype. There were six test subjects used to test this device.

The final device does not impose additional risk on the patient. The device has very low stored energy input that can provide high force pinching. The weight of the device is relatively low (<30 lbs). The device was computer stimulated for structural stability under high load conditions, in order to assure that if a patient places their weight on the device they will not fall over. These types of considerations are described in Volume II, section 3.1.1 in further detail for review.

#### 3.2.2 STRUCTURAL INTEGRITY

The structural integrity of this device is important for many obvious reasons. This rehabilitation device is going to be used as an exercise device, and patients must be able to trust that the device will not give out under their weight, or fail after a year of use.

In order to evaluate the structural integrity of the device, ANSYS was used in order to run a stress analysis of the device. This analysis was then used to find the points of maximum stress in each assembly component, safety factors were then computed by comparing the stress state with the maximum yield stress of the appropriate material. This method is described in further detail in Volume II, section 3.1.2.

After analyzing the stress state of the device under an “extreme-load” situation where it is assumed that a patient of 200 pounds is placing his full weight on the device arm rest, it was determined that the device would not fail under these circumstances. The stress state at its worst point was still a safety factor of 4 above yield limit. Considering this, the device will be structurally sound under normal loading conditions.
3.2.3 REPEATABILITY
This device is designed to provide very repeatable function to patients. Repeatability is one of the most important design criteria, and in order to facilitate the repair of the damaged connections between the brain and body, numerous repetitions of the exercises are crucial. As a mechanical device, the main concerns in this area were catching of the mechanical parts, friction, and the smoothness of the repetitions.

In Volume II, section 3.1.3, results of a repeatability study are shown. This study involved user trials in which six (both with and without prior knowledge of this device) attempt to operate the device for a designated number of repetitions. The test subjects were asked to do 200 repetitions because it is unlikely that patients will be doing more repetitions than this in one session. The results indicate that the device is very reliable in its ability to perform for 200 repetitions, and it is thus reasonable to assume that there are not any major repeatability concerns.

3.2.4 ASSISTIVE FORCE
The assistive force provided to the user of the device is one of the most important design specifications, since the entire purpose of the device is to allow patients with limited physical strength to practice arm flexion.

The assistive force is provided to the user by the counterweight. The force was measured at twelve locations throughout the motion of the arm. To measure this force, a spring was first used to hold the mechanism in a static position. The displacement of the spring was then measured and related to the force through the spring. The data in Figure 21 of Volume 2 was measured by repeating this process for each position. For each plot in Figure 21, a different amount of weight was added to two links of the mechanism to simulate the arm weights of patients of varying sizes.

As the results in Figure 6 show, the input force which was necessary to perform the exercise is within the range of reasonable values. Refer to the report Volume II, section 3.1.4 for a detailed report on this evaluation.

3.2.5 VARIABILITY EFFECT
As a medical device, this product would need to perform well for any patient. This was a very important design consideration, as anyone can suffer a stroke. The variable patient’s approximate arm weight and patient arm length were considered for their significance on the input force.

In order to measure the effect of each variable, a range of patients used the device while it measured the input force. After finding a relationship between the arm weight and input force, it will be possible to see if the arm weight is significant enough to change the required force of the patient. If the change in force is not statistically significant, then it is possible to consider placing a constant counterweight and not having a variable counterweight setup.
Similarly, a relationship is found between patient arm length and the input force required throughout the motion. If this relationship shows that the patient’s arm length does not play a statistically significant role in the input force, then there would not have to be further consideration into altering link lengths of the device to accommodate patients of different sizes. There should also be an exchange with the test users who do not match up with the size person we designed the prototype for to make sure that the path of motion is still comfortable and natural feeling.

3.3 DISCUSSION

3.3.1 STRENGTHS AND WEAKNESSES
A major strength of this device is that it is an assistive device that does not require any electronic or energy input. The lack of electronics ensures a low product cost. A lower cost of the device versus its competitors would allow many more patients to purchase an exercise device for home rehabilitation which greatly reduces rehabilitation time. The device provides enough force to counteract the weight of the arm, thus allowing the patient to move their arm with very low input force. The device requires the patient to initiate motion, an important design consideration, as initiation of the motion is necessary for the brain to actually make new neural connections, without which the device is rendered useless.

An additional strength of the device is its ability to be mounted to any tabletop. This adds to the versatility of the device and makes it easier for at home use. By designing the device to sit under the table, it also provides space saving. The under-table design also removes the device from the tabletop or floor, thus lowering its impact on the patient’s on daily life.

The absence of an energy storage element is another benefit in regards to safety concerns. It eliminates the potential for a large energy release at the wrong time, causing harm. It also means that there is no need for electronic maintenance or replacement of a battery or spring.

There are some weaknesses to this device that could be improved upon with further design improvement. First, the design does not easily adjust for arm rest height, which could be easily corrected with sliding links. Also, the device requires additional force on elbow extension, which was not desired. Another weakness is the large weight of the device. This can be reduced by choosing different materials with similar properties but less density.

3.3.2 NEXT STEPS
When the device enters the market, physical therapists will need to be trained on its use and familiarized with the varying counterweight system. There will be an accompanying chart to help identify the counterweight that should be used based on a patient’s weight. Multiple trials with stroke patients for typical rehabilitation periods should be conducted to quantify any increase or decrease in rehabilitation time. Since this team has not conducted any experiments with patients, this will be crucial to proving that the device works and will be useful to patients.
Once the device is completed, the FDA approval process for medical devices will need to be completed. The goal of this project was to create a class 1 medical device, thus the required paperwork and possible search for a 510(k) device will be needed to legally market the device. Sales forecasts, vendor selection, and a delivery plan will need to be completed in addition to the manufacturing plan the team has laid out before the approval process.

Some future design teams may wish to look into making the arm rest and support adjustable to different patient chair heights. One possible way this can be done is through holes at various heights on the cylindrical rods for a small push button attached to an inner rod that adjusts the length of the rods. This solution is very similar to other devices in today’s market. The final change to be made to the device is to eliminate the force required elbow extension and this is done by optimizing the counterweight ratio, and will lead to more effective therapy.

4. REFERENCES


