**Engineering 498**

**Active Assist Elbow Orthosis**

System Requirements Document





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**1.0 Scope**

### 1.1 Background / History

Orthotic devices have been essential in correcting deformities and stabilizing post-operative limbs and joints for many years. For post-operative orthoses, the exact method of rehabilitation has been the doctor’s conclusion. Lower limb orthoses have been widely more popular than upper limb orthoses, and the method for rehabilitating both are quite different. While the existing products on the market for an upper limb orthotic brace consists of rigid, locked device, there are other recent tools used to passively move the elbow joint.

The device on the market for elbow rehabilitation is called a CPM, also known as a continuous passive movement device. The idea is that the device will passively flex and extend the arm without the patient using their muscles to create this movement. The goal of the CPM is to move the synovial fluid, and avoid scar tissue and cartilage buildup. The most necessary component of the CPM that will be integrated with the Active Elbow Orthosis is the controlled range of motion parameter. The doctor programs the device to move the joint within a range of angles, and slowly increases this range throughout the healing process. This concept will be integrated with the elbow brace to allow the patient to move their joint a certain amount while wearing the device. The downside to the CPM is the fact that the patient is not actively moving their limb – the device performs this movement passively. To improve this device for the elbow joint, the option to move the elbow actively would greatly facilitate the healing process by virtue of stimulating the muscles to move. The new system for the elbow would carry out the motor traits that the CPM contains, only the motor will not be able to entirely move the limb alone; the brace requires movement from the patient.

Another device on the market that is currently being implemented by many orthopedic surgeons after surgery is called the Dynasplint. While this device is offered as a lower limb orthosis and an upper limb orthosis, the elbow flexion device is most similar to the improved Active Elbow Orthosis. The Dynasplint is responsible for restoring the patient’s range of motion in their arm by immobilizing it for the duration of the wear in order to reduce inflammation. The idea of the splint is to provide a low-load extended stretch while it is fastened to the arm. The benefit of the Dynasplint is that is allows the stiff joint to be engaged in a deep stretch while the patient is inactive. Similarly to the CPM, the patient is not required to assist in the healing of the joint until he/she begins physical therapy. The only drawback to this form of healing is the fact that the patient is not actively moving the joint while it is being stretched. This will not achieve the desired scar tissue breakdown like the Active Elbow Orthosis. The new system would be an improvement from the Dynasplint because it would allow the doctor to program how long the patient will be stretching the joint, as well as the parameters the patient should be moving the elbow after it has been stretched. The new device will also assist the patient in these movements by guiding the joint using a motor, but it will still require the patient to put in at least half the effort to achieve the movement.

While there is an endless list of post-operative elbow orthoses, the last product similar to the Active Elbow Orthosis is called the UltraFlex Custom for Bi-Directional EO. This device is specifically designed to treat a triceps or a biceps rupture, but the goal is to hinder the movement of the arm by implementing a variety of locking devices. The doctor is able to control the angle at which the brace can lock, providing the patient with the ability to move his/her arm, but only to a specific angle before the lock becomes effective. The benefits of this device include the fact that there are two hinges on either side of the elbow, which assist in the movement of the joint; however, the joint is still being controlled because of the locking system. The doctors or physicians are responsible for changing the different locks on the device that correspond with the patient’s healing process. Unfortunately, this brace is designed to improve the muscles after surgery or trauma instead of the elbow joint. Focusing on the elbow joint will be the first improvement made on the UltraFlex elbow orthosis. The next improvement that will be made to this device is the addition of the Bluetooth/iOS interface. This will allow the doctor or physician to alter the range of motion that the patient should be achieving through the app on the computer or phone. Rather than changing the locking system every 10-20 days until the full range of motion is achieved, the iOS interface will allow continuous communication between the doctor and the patient on the rehabilitation process.

With the Active Elbow Orthosis, the many benefits that are offered through the three devices stated above will be harmonized together. While minimizing the doctor/patient visits, this brace will maximize the possible rehabilitation necessary to achieve the full range of motion that is desired.

### 1.2 Need Statement

Elbow stiffness after surgery is a common and debilitating problem. It is caused by the accumulation of fibrous tissue in the joint and surrounding structures during the healing process and can occur after many types of elbow surgery. It is made worse by the rigid post-operative bracing that is used to stabilize the elbow after surgery. It is commonly treated with range of motion exercises performed daily, but the exercises can be painful and are often ineffective. Thus, there exists an unmet need for a brace that simultaneously stabilizes the elbow after surgery and provides frequent motion to prevent the buildup of scar tissue and maintain the range of motion of the elbow joint.

The goal of this project is to design and create a motor-hinged elbow orthosis that will maintain as much range of motion in the joint throughout the six-month healing process while also breaking down the scar tissue in the joint. This device should aid recovery after surgery, having the advantage over physical therapy of being wearable and user controllable. While performing the flexion/extension movement in the arm, the orthotic will actively assist the patient into moving the arm to a predetermined angle per doctor’s orders. This elbow orthosis will be a staple in the orthopedic surgical department.

### 1.3 Concept of Operations

**System Boundaries**

There will be a number of different interfaces that must be accounted for in the final product. The frame of the elbow brace will interface with the sensor, such as an IP Motion Sensor, to detect the angle of the arm. This interface is critical as proper detection of the arm angle will determine the effectiveness of the device. To be effective, the angle measurement must be within 2.5o either way of the actual angle of the arm. The sensor will then interface with the iOS application via Bluetooth connection. The iOS application will then relay the measurements and determine whether the brace should continue its movement of reverse its motion.

To continue the motion of the brace or reverse its motion, the iOS application must interface with the motor. If the maximum arm angle is reached, which is determined by the range of motion parameters, the iOS application will signal to the motor to stop and reverse its motion guiding the arm to stop extending and begin flexing. The motor then interfaces with the actual brace as it controls the action of the device. The motor will deliver the torque necessary to extend the brace and fold it.

**System Environment**

While the Active Elbow Orthosis is a wearable and user controllable device, there are still limits on the exact environment where maximum performance is attained. First of all, the brace is designed using a motor to assist the movement of the elbow, so any extreme hot or cold conditions would decrease the performance of the motor and the sensors that are integrated into the system. Ideally, the patient should be using the brace indoors while in an area free of recreation to prevent the brace from performing incorrectly or breaking. But realistically the brace can be worn indoors and outdoors in an environment free of water. The brace is designed for the patient to use for a few hours a day to prevent the power in the motor from depleting. The device should be operated in an environment where the smartphone is nearby to access the app that controls the brace. The brace should not be operated in a densely populated area, or an area where the brace could potentially break. The brace should not be near water or exposed to water which could cause damage to the motor and the batteries that operate it. This device should also be removed while the patient sleeps.

**System Constraints**

Based on the market research and previous devices, the manufacturing costs of this device should be under $300. Current elbow brace devices cost approximately $300, thus, to be competitive on the market and generate a profit, the device must be able to be manufactured for under $300, so it can be sold for a similar price or less. The iOS application will be written in Xcode using an objective c language. Using Xcode will be the easiest and most efficient way to create the application, despite other potential methods of creating it.

The life expectancy of the device should be a full day. The potential for a full day of use will allow the consumer to recharge it while he or she is not using it at night, and if it is only used for a brief time during the day, then the battery may last for several days. The battery should have a way that it can be recharged and not need to be replaced every time it dies. The device shall fit around a person’s arm, which means that it will be able to be adjusted in length and cuffs around the arm will be able to be adjusted as well. The device should not weigh more than 5 pounds. The consumer will be placing this device on their arm as part of a therapeutic recovery, thus, it should be lightweight and not very strenuous on the arm. The device shall not deliver more than 30 Newton-centimeters of torque. The device is intended to be an active assist device, which means the force of the device should not be able to move the arm against a resistance. Rather the device should simply assist the motion of the arm.

**System Use**

The Active Elbow Orthosis will be ultimately designed for both adults and children, however the initial design will be for adult users. The most ideal scenario for the brace to be used is as follows:

Immediately post operation, the Active Elbow Orthosis is placed on the patient.

The patient will be given a 10-day healing process where he/she will immobilize the elbow to prevent the stitches and staples from tearing. Once the 10-day healing process is complete, the doctor will program the device with the corresponding app, and enter in the rehabilitation process he/she sees fit for the next three-six months. The app will be communicating to the motor and the sensors inside the brace via Bluetooth, and the doctor’s exercises will be viewable to the patient on their app on their smartphone. The user will turn the motor on through the app, and the Bluetooth will connect to the app on the interface. The doctor will have inputted the range of angles he/she feels the elbow should be exercised, and how many repetitions will be necessary. The patient will begin his/her exercising by slowly extending the elbow with assistance from the motor until the desired angle is reached. Once the desired angle is reached, the device will communicate that information to the app, the motor will stop, and the system will lock. The motor will reverse allowing the elbow to flex and move back to the starting angle. Flexing and extending the arm will continue until the number of reps the doctor orders has been achieved. The patient will then lock the device in the proper immobile position to encourage the prolonged stretch, and then he/she will power down the system. If the patient feels that the exercise was simply unbearable, he/she will input that into the app which will alert the doctor of the circumstances. The doctor will then be able to write a new rehab schedule with a smaller range of motion acquired on the app which will be immediately viewable to the patient.

In the event that the user attempts to move the brace past the programmed angle, the device will alert the user through a beeping noise, or an automatic locking followed by a beeping noise. By using this locking system, the user will not be able to put an extensive amount of force on the brace that would inevitably break the motor.

A slip clutch may be able to solve the motion problem for most medical equipment.This method is at a lower cost and lasts longer than alternative methods. Slip-clutch capacity is dependent on torque, rpm, and duty cycle. For overload protection, a slip clutch can be anything from a simple shear pin, to a ball detent, to a more complex device with friction pads.

In case that the motor stops working unexpectedly, or the app stops communicating with the device, the user will be instructed to power down the device through the app and restart it. This will prevent the possibility of the motor overheating. The app will also let the user know when the battery on the device is running low, and it will immediately shut the device off when the battery dies.

**Expected Output**

The expected function of this device is an elbow brace that will provide active assistance to the person wearing it while they are flexing or extending the arm. In particular, there will be a sensor to detect the angle of the arm and Bluetooth system that will communicate with an iOS application. The sensor on the device will be able to detect the angle of the arm and the direction the arm is currently moving. The sensor will also communicate with the motor to indicate the direction it should be moving and the Bluetooth system to determine the range of motion it should allow the arm to move.

The Bluetooth system will communicate with the iOS application, where the range of motion is set by the user. Once the range of motion is set by the user, it is expected that the device will move within that range and there will be no more than an error of plus or minus 2.5o either way. On the iOS application, there will be an option for the physician/technician to set limits for the possible range of motion a patient can choose, alerts to remind the patient to do their exercises, and an option to set the amount of time a patient will use the device. Once the patient has finished using the device, he or she will be able to give feedback on their daily exercises via the iOS application.

### 1.4 Stakeholders

In the design and production of a new device, it is important to keep in mind all those who have a vested interest in the success of the product. To get the project started, there must be organization, a clear process, and an achievable goal. These are put into place by a sponsor, for this project Dr. Daniel Latt, who invests time and oversees operations. Dr. Latt is one of the main stakeholders on this project due to his invested time and resources, and he would like to see measurable results. In terms of those working on the project, all team members would be stakeholders in the device as their name would potentially be listed on any patent that would come as a result of the work on the project.

Other stakeholders in the project would be patients suffering from a stiff elbow joint and scar tissue buildup after elbow surgery. This device has the potential to help a patient regain normal function and mobility in the elbow during their recovery from an elbow injury. Any patient seeking the best possible treatment during their recovery would be a stakeholder in this device. Along those similar lines, physical therapy companies are always looking for the most effective means of treatment to help current patients and attract new ones. These companies would certainly be stakeholders in a device that could potentially benefit their business.

## 2.0 Applicable Documents

### 2.1 Sponsor Furnished Documents

### Dr. Daniel Latt has provided the following documents located in Appendix A.

### 2.2. Sponsor Furnished Equipment

### Dr. Daniel Latt has agreed to donate an elbow brace for the team to use in the building portion of the design process. Other equipment that will be available to use is the cadaver lab and a CPM machine.

### 2.3 Pertinent Engineering Documents

* Patent EP 1410774 A1
* Patent CN204106501U
* Patent US8679040 B2
* Orthopedic Elbow Surgeries: Background Research
* Additional Background Research
* Donjoy X-Act ROM Elbow brace instructions manual - http://www.djoglobal.com/sites/default/files/XAct%20ROM%20Elbow%20IFU.pdf
* Any other instruction manuals that we will use for our motor/sensor/brace

## 3.0 Requirements

### 3.1 Required System States and/or Modes

**3.1.1** AEO Lock**:** The device shall be passively locked in a fixed position with max 30 and 50

lbs of force applied.

**3.1.2**Release Mechanism**:** The device shall contain a release mechanism allowing it to free

swing from 0 to 180 degrees.

**3.1.3** Range**:** The device shall lock within a range of elbow angles determined by the doctor.

That range will be inputted into the system through the iOS application.

### 3.2 System Capability Requirements

**3.2.1** AEO Activation**:** The AEO shall be powered on/off via the iOS application and a wireless connection. The AEO user will control when the iOS application sends a wireless signal that powers the device either on or off.

**3.2.2** AEO Measurement**:** The elbow angle measurements shall span the whole range of

motion for a healthy individual.

**3.2.3** Motor Torque**:** Motor shall have a maximal torque force of 30 N cm acting on the elbow joint to assist in the patient’s elbow flexion and extension.

**3.2.4**Position Tolerance**:** Motor shall have a rotary actuator able to positionate at an angular position ± 2.5° from the desired position.

**3.2.5**Motor Response**:** Motor shall have a receiver function, following instructions from the iOS app that activates motor motion.

**3.2.6**Removal of Motor**:** Motor should be capable of being removed from the device.

**3.2.7** AEO Sensor**:** The AEO shall utilize a sensor to measure the angle of the elbow.

### 3.3 System External Interface Requirements

**3.3.1**Battery Life**:** The battery shall power the Active Elbow Orthosis for 5-10 minutes.

**3.3.2** Battery Recharge**:** The battery should recharge for 3-5 hours.

**3.3.3** Battery Communication**:** The battery shall power on through instruction from a wireless

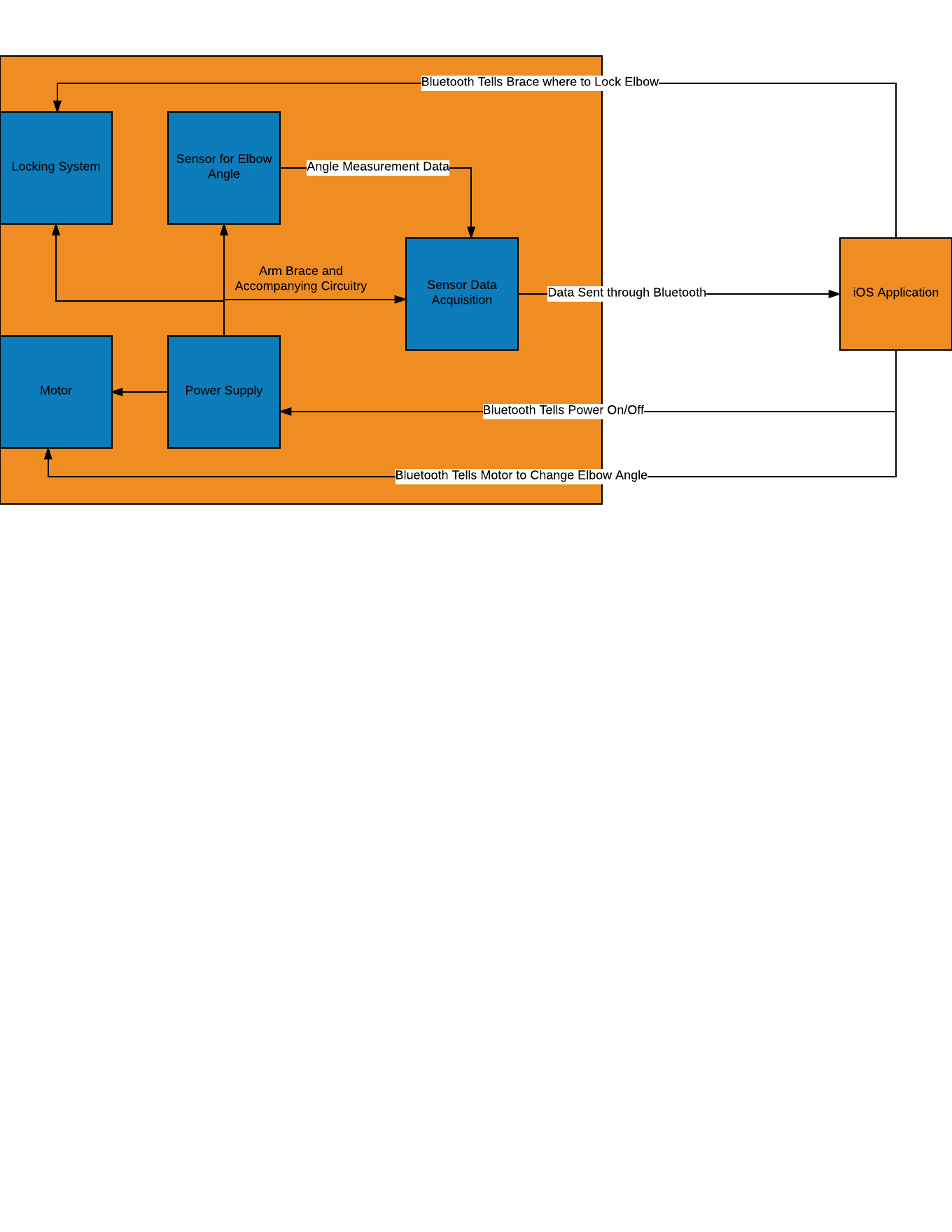
connection from the iOS application.

**3.3.4** Angular Velocity Feedback**:** The AEO shall give feedback to the patient if the angular

velocity of their elbow joint is below the minimum angular velocity.

**3.3.5**Feedback**:** The AEO feedback shall be given through the iOS application.

### 3.3.1 Interface Identification and Diagrams



### 3.4 System Internal Interface Requirements

**3.4.1** Angular Velocity**:** The AEO shall have a minimum angular velocity of 10 degrees per

second in flexion and extension.

**3.4.2** Communication Distance**:** The device shall function within 5 feet of the phone

containing the iOS application.

### 3.5 System Internal Data Requirements

**3.5.1** Sample Rate**:** The angle measurement data shall be sent to a phone application through a wireless connection at a rate no less than 1 Hz.

**3.5.2** Sensor Accuracy**:** The sensor shall work within 2.5 degrees of the actual angle.

### 3.6 Safety Requirements

**3.6.1** Emergency Shut Down**:** The AEO shall have an emergency shut off mechanism. When

the emergency shut off mechanism is engaged, the motor will quit working and the device will be able to swing freely.

**3.6.2** Water Safety**:** The AEO shall have waterproof coverings for the battery and the wires.

**3.6.3** Communication Error**:** The AEO shall prohibit the motor from running when there is no

wireless connection or when no elbow angle data has been sent to the application for 5 seconds.

### 3.7 Security and Privacy Requirements

**3.7.1** User Input**:** Range of motion, speed, and duration of use parameters shall be able to be

adjusted on the iOS application by a physician or technician only.

### 3.8 System Environment Requirements

**3.8.1** Temperature Range**:** The system shall be functional in temperatures as hot as 120

degrees and as cold as 20 degrees.

**3.8.2** Weather**:** The system minus the motor shall be functional when lightly splashed with

water to mimic light rain, but not submerged in water.

### 3.9 Computer Resource Requirements

### 3.9.1 Computer Hardware Requirements

**3.9.1.1** Device and App Communication**:** The AEO shall have a single-board computer to

communicate between the device and the iOS application.

**3.9.1.2** Motor Communication**:** The AEO shall have a microprocessor to control the motor of

the device.

### 3.9.2 Computer Software Requirements

**3.9.2.1** iOS Compatibility**:** The AEO shall have an accompanying iOS application.

### 3.9.3 Computer Communications Requirements

**3.9.3.1** Data Transfer: The sensor system on the device shall be able to send elbow angle data to the iOS application wirelessly. The elbow angle will be measured by the sensor, calculated by a computer processor on the device, and sent to the iOS application wirelessly.

### 3.10 System Quality Factors

**3.10.1** Functioning**:** The system shall perform all required functions the first time they are

inputted.

**3.10.2** Battery Life**:** The system battery shall work throughout the duration of an exercise

lasting 10-20 minutes.

**3.10.3** Durability**:** The system shall function properly after 6 months of the patient wearing the

brace. The brace shall display no signs of physical deterioration.

**3.10.4** Removable Parts**:** The system shall have removable parts including the motor, battery,

and sensor that are easily replaceable and installable.

**3.10.5** Accessibility**:** The system shall always be accessible. The device will be able to be

powered on at any time of the day or night and the system will function properly.

**3.10.6** Reusability**:** The device shall be reusable for multiple patients. After recharging the

battery and adjusting the brace to fit another patient, the device should still function normally.

**3.10.7** Usability**:** The system shall be easy to use for patients ranging from 10 years old to 80

years old

### 3.11 Design and Construction Constraints

**3.11.1** Weight**:** The Active Elbow Orthosis shall weigh less than ten pounds.

**3.11.2**Fastening Mechanism**:** The Active Elbow Orthosis shall include an attachment

mechanism that will fasten to the upper arm and lower arm of the patient.

**3.11.3** Comfortability**:** The attachment mechanism shall have soft tissue and skin-friendly pads

for comfort.

**3.11.4**Size Adjustment**:** The attachment mechanism shall include a method for changing size

to fit the patient.

**3.11.5** Motor/Battery Detachment**:** The attachment mechanism shall include a modular with a

detachable motor and battery.

**3.11.6**Pronation/Supination**:** The attachment mechanism shall control the forearm in the

action of pronation or supination.

**3.11.7** Battery Placement**:** The battery shall be placed on the upper arm of the Active Elbow

Orthosis.

**3.11.8**Motor Placement: Motor shall have maximum dimension limitation that fits within 4 cm

from brace.

### 3.12 Personnel Related Requirements

**3.12.1** Usage Time: The Active Elbow Orthosis shall be able to be worn 24 hours a day

post-surgery.

**3.12.2** Device Instructions**:** The device instructions shall be read by the user.

**3.12.3** Instructions Language: The device instructions shall be in English.

**3.13 Logistics Related Requirements**

**3.13.1** Battery and Motor Maintenance: The battery and the motor shall both be replaceable.

## 4.0 System Requirements Verification

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Systems Requirements Verification Matrix** | | | |  | | | | | | |
| **Project Number** | **16051** |  | | | | | | | | |
| **Project Name** | **Active Assist Elbow Orthosis** |
| **Project Sponsor** | **Dr Latt** |  | | | | **Verification Method** | | | |  |
| ID | System Requirement  Level 1 | Subsystem Requirement  Level 2 | Element Requirement  Level 3 | Specification | Status | Test | Analysis | Inspection | Demonstration | Additional Comments |
| **3.1** | **Required System States and/or Modes** |  |  |  |  | - | - | - | - |  |
| **3.1.1** | **AEO Lock** |  |  | < 30-50 lbs |  | x |  |  |  |  |
| **3.1.2** | **Release Mechanism** |  |  |  |  |  |  |  | x |  |
| **3.1.3** | **Range** |  |  |  |  |  |  |  | x |  |
| **3.2** | **System Capability Requirements** |  |  |  |  | - | - | - | - |  |
| **3.2.1** | **AEO Activation** |  |  |  |  |  |  |  | x |  |
| **3.2.2** | **AEO Measurement** |  |  |  |  |  |  |  | x |  |
| **3.2.3** | **Motor Torque** |  |  | <35 N cm |  | x |  |  |  |  |
| **3.2.4** | **Position Tolerance** |  |  | <2.5˚ |  | x |  |  |  |  |
| **3.2.5** | **Motor Response** |  |  |  |  |  |  |  | x |  |
| **3.2.6** | **Removal of Motor** |  |  |  |  | x |  |  |  |  |
| **3.2.7** | **AEO Sensor** |  |  |  |  | x |  |  |  |  |
| **3.3** | **System External Interface Requirements** |  |  |  |  | - | - | - | - |  |
| **3.3.1** | **Battery Life** |  |  | 5-10 min |  |  |  |  | x |  |
| **3.3.2** | **Battery Recharge** |  |  | 3-5 hours |  |  |  |  | x |  |
| **3.3.3** | **Battery Communication** |  |  |  |  | x |  |  |  |  |
| **3.3.4** | **Angular Velocity Feedback** |  |  | <10˚ / sec |  |  |  |  |  |  |
| **3.3.5** | **Feedback** |  |  |  |  |  |  |  | x |  |
| **3.4** | **System Internal Interface Requirements** |  |  |  |  | - | - | - | - |  |
| **3.4.1** | **Angular Velocity** |  |  | <5˚ / sec |  | x |  |  |  |  |
| **3.4.2** | **Communication Distance** |  |  | <5 ft |  |  |  |  | x |  |
| **3.5** | **System Internal Data Requirements** |  |  |  |  | - | - | - | - |  |
| **3.5.1** | **Sample Rate** |  |  |  |  |  |  |  | x |  |
| **3.5.2** | **Sensor Accuracy** |  |  | <2.5˚ |  | x |  |  |  |  |
| **3.6** | **Safety Requirements** |  |  |  |  | - | - | - | - |  |
| **3.6.1** | **Emergency Shutdown** |  |  |  |  | x |  |  |  |  |
| **3.6.2** | **Water Safety** |  |  |  |  |  |  | x | x |  |
| **3.6.3** | **Communication Error** |  |  |  |  |  |  |  | x |  |
| **3.7** | **Security and Privacy Requirements** |  |  |  |  | - | - | - | - |  |
| **3.7.1** | **User Input** |  |  |  |  |  |  |  | x |  |
| **3.8** | **System Environment Requirements** |  |  |  |  | - | - | - | - |  |
| **3.8.1** | **Temperature Range** |  |  | 20˚-120˚ |  |  |  |  |  |  |
| **3.8.2** | **Weather** |  |  | rain |  |  |  |  |  |  |
| **3.9** | **Computer Resource Requirements** |  |  |  |  | - | - | - | - |  |
| **3.9.1.1** | **Device and App Communication** | Computer Hardware Requirements |  |  |  |  |  | x |  |  |
| **3.9.1.2** | **Motor Communication** | Computer Hardware Requirements |  |  |  |  |  | x |  |  |
| **3.9.2.1** | **iOS Compatibility** | Computer Software Requirements |  |  |  |  |  | x |  |  |
| **3.9.3.1** | **Data Transfer** | Computer Communication Requirements |  |  |  |  |  |  | x |  |
| **3.10** | **System Quality Factors** |  |  |  |  | - | - | - | - |  |
| **3.10.1** | **Functioning** |  |  |  |  |  |  |  | x |  |
| **3.10.2** | **Battery Life** |  |  |  |  |  |  |  | x |  |
| **3.10.3** | **Durability** |  |  |  |  |  |  | x | x | hypothetically |
| **3.10.4** | **Removable Parts** |  |  |  |  |  |  |  | x |  |
| **3.10.5** | **Accessibility** |  |  |  |  |  |  |  | x |  |
| **3.10.6** | **Reusability** |  |  |  |  |  |  |  | x |  |
| **3.10.7** | **Usability** |  |  |  |  |  |  |  | x |  |
| **3.11** | **Design and Construction Constraints** |  |  |  |  | - | - | - | - |  |
| **3.11.1** | **Weight** |  |  | <10 lbs |  |  |  | x |  |  |
| **3.11.2** | **Fastening Mechanism** |  |  |  |  |  |  |  | x |  |
| **3.11.3** | **Comfortability** |  |  |  |  |  |  | x |  |  |
| **3.11.4** | **Size Adjustment** |  |  |  |  |  |  |  | x |  |
| **3.11.5** | **Motor/Battery Detachment** |  |  |  |  |  |  |  | x |  |
| **3.11.6** | **Pronation/Supination** |  |  |  |  | x |  |  |  |  |
| **3.11.7** | **Battery Placement** |  |  |  |  |  |  |  | x |  |
| **3.11.8** | **Motor Placement** |  |  | < 4 cm |  |  |  | x |  |  |
| **3.12** | **Personnel Related Requirements** |  |  |  |  | - | - | - | - |  |
| **3.12.1** | **Usage Time** |  |  | 24 hours / day |  |  |  |  | x |  |
| **3.12.2** | **Device Instructions** |  |  |  |  |  |  | x |  |  |
| **3.12.3** | **Instructions Language** |  |  |  |  |  |  |  | x |  |
| **3.13** | **Logistics Related Requirements** |  |  |  |  | - | - | - | - |  |
| **3.13.1** | **Battery and Motor Maintenance** |  |  |  |  |  |  |  | x |  |

* **Demonstration:** The operation of the system, or a part of the system, that relies on observable functional operation not requiring the use of instrumentation, special test equipment, or subsequent analysis.
* **Test:** The operation of the system, or a part of the system, using instrumentation or other special test equipment to collect data for later analysis.
* **Analysis:** The processing of accumulated data obtained from other qualification methods. Examples are reduction, interpolation, or extrapolation of test results.
* **Inspection:** The visual examination of system components, documentation, etc.

**4.1.1** Requirement will be verified by a **test**. The device shall either be worn or tightly secured

so that the arm attachment is vertical and the forearm attachment is horizontal. The brace will be locked in a fixed position, and a 30 pound weight will be suspended from the forearm attachment 6 inches from the hinge. The brace will withstand this amount of weight for 15 seconds. A 50 pound weight will be applied next and the same test will be used. The brace shall withstand this amount of weight being applied without breaking.

**4.1.2** Requirement will be verified by a **demonstration**. The device shall be locked at 180

degrees, and the release mechanism will be manually applied. The forearm attachment

of the brace shall swing from 180 to 0 degrees. The release mechanism should also be

accessed through the iOS app.

**4.1.3** Requirement will be verified by a **demonstration**. The device shall be manually

programmed to lock within a 0-180 degree range by every 10 degrees. The device will

be locked from 180-170 degrees, and the ROM and resistance will be verified. The

device will then be relocked from 180-160 degrees, then 180-150 degrees and so forth.

**4.2.1** Requirement will be verified by **demonstration**. When the device is powered on via the

iOS application, the motor will begin to move the device.

**4.2.2** Requirement will be verified by **demonstration**. The iOS application will display the

elbow angle of the AEO. Then the elbow angle of the AEO will be changed and the iOS

application should display the new elbow angle after a reasonable amount of time.

**4.2.3** Requirement will be verified by a **test**. Device should be able to create motion when force less than 35 N cm is applied. If force exceeds the limit, motor should not be able to create any movement.

**4.2.4**Requirement will be verified by a **test**. The AEO, with no individual wearing it to avoid external forces being applied, will be instructed to go to a specific degree with the iOS application. The device will pass the test if the iOS application shows an angle ± 2° from the desired position.

**4.2.5**Requirement will be verified by **demonstration**. The AEO should begin its motion when it is instructed by the iOS application.

**4.2.6**Requirement will be verified by a **test**. AEO features (sensor, motor motion, power, interface) should be working. Motor will be detached, and attached again. The device will pass the test if it is still able to complete all the features.

**4.2.7**Requirement will be verified by a **test**. The test subject will instruct the AEO to go to a determined angle, eg. 0°, 45°, 90°, 130°. iOS application should be giving the accurate reading, comparing the angle given by the application and a physical measurement with an exacta goniometer.

**4.3.1** Requirement will be verified by a **demonstration**. A human subject shall wear the AEO

and perform the required 10 minute exercise and the battery power should remain consistent throughout.

**4.3.2** Requirement will be verified by **demonstration**. The battery component of the AEO

shall detach and be hooked up to the corresponding charging outlet and should be fully

charged after 3-5 hours.

**4.3.3** Requirement will be verified by a **test**. The battery component will be attached to the

AEO and must turn on when the iOS application instructs it to. This shall work through a wireless connection that both the iOS application and the battery component will have.

**4.3.4** Requirement will be verified by **demonstration**. A human subject shall wear the AEO

and flex or extend their forearm at a rate below the minimum angular velocity. The AEO

should provide visual or auditory feedback to the subject and observers.

**4.3.5**Requirement will be verified by **demonstration**. A human subject shall wear the AEO

and flex or extend their forearm at a rate below the minimum angular velocity. The AEO

should provide visual or auditory feedback to the subject and observers. The feedback

should come through the iOS application.

**4.4.1** Requirement will be verified by a **test**. A human subject shall wear the AEO and flex or

extend their forearm at a rate below the minimum angular velocity. The angular velocity

of the human subject’s elbow joint will be controlled by having the subject extend or flex

their elbow 90 degrees at a constant rate in about 18 seconds, which is half the

minimum angular velocity of the AEO. The AEO should provide visual or auditory

feedback to the subject and observers.

**4.4.2** Requirement will be verified by a **demonstration**. The device will be powered on and

the motor will be assisting a person in the movements of extension and flexion. Meanwhile, the subject will be walking further from the phone until they reach 5 feet away. The device shall still function normally.

**4.5.1** Requirement will be verified by **demonstration**.The iOS application will display the

elbow angle of the AEO. Then the elbow angle of the AEO will be changed by +/- 90

degrees and the iOS application should display the new elbow angle after a reasonable amount of time.

**4.5.2** The requirement will be verified by a **test**. A healthy individual will use the brace for

angle measurements at maximum extension and flexion. Firstly, the individual test

subject will fully extend their elbow while wearing the AEO. The device will pass the test

if the iOS application shows the correct angle of the elbow within 2.5 degrees of the

actual angle. Secondly, the individual test subject will fully flex their elbow while wearing

the AEO. The device will pass the test if the iOS application shows the correct angle of

the elbow within 2.5 degrees of the actual angle.

**4.6.1** Requirement will be verified by a **test**. The AEO shall be placed on a human subject.

While active assist is taking place the emergency shut off mechanism will be pushed

and the motor should automatically shut off.

**4.6.2** Requirement will be verified through an **inspection** and a **demonstration**. The AEO

shall have a case that will not let any water through.

**4.6.3** Requirement will be verified through a **demonstration**. The iOS wireless connection will be turned off and the AEO will not function.

**4.7.1** Requirement will be verified by **demonstration**. On the iOS application, the user will not

be able to change the device parameters. A technician or physician will be able to

change the parameters.

**4.8.1** Requirement will be verified by a **test**. The device shall be placed in the refrigerator at

20 degrees for 30 minutes and tested by the motor assisting the motion from 0-180

degrees immediately after removal. The device shall then be placed in an oven at 120

degrees for 30 minutes and tested immediately after removal. The device shall work as

long as the motor can withstand the temperatures ranging from 20 degrees to 120

degrees.

**4.8.2** Requirement will be verified by a **test**. The device minus the motor shall be splashed

lightly with water to mimic rain drops and then tested manually to verify the range of

motion from 0 to 180 degrees occurs.

**4.9.1.1** The requirement shall be verified by **inspection**. The single-board computer’s

presence will be shown on the device.

**4.9.1.2** The requirement shall be verified by **inspection**. The microprocessor’s presence will

be shown on the device.

**4.9.2.1** The requirement shall be verified by **inspection**. The iOS application’s existence will

be shown on an iPhone.

**4.9.3.1** The requirement shall be verified by **demonstration**. The iOS application will display

the angle of the AEO brace.

**4.10.1** Requirement will be verified by a **demonstration**. The patient will be given a random

angle to be inputted into the iOS app, and the device shall adjust to this angle range

and perform correctly during the first try. This test will be administered with 5 different

people acting as patients.

**4.10.2** Requirement will be verified by a **demonstration**. The device shall be powered on, and

a mock 10 minute exercise will be performed. The patient wearing the device will

provide the least amount of muscle force required to move the elbow, lengthening the duration of the exercise, and requiring the motor to work at full capacity.

**4.10.3** Requirement will hypothetically be verified by an **inspection** and a **test**. The team will

not have 6 months to wait to inspect and test the device.

**4.10.4** Requirement will be verified by a **demonstration**. The device shall contain a removable

motor, battery, and sensor. The motor, battery, and sensor will be detached and

reattached one at a time, and then the device will be powered on.

**4.10.5** Requirement will be verified by a **demonstration**. The device will be powered on and

off at midnight, 6 in the morning, noon, and 6 at night to verify that it works at all hours of the day and night

**4.10.6** Requirement will be verified by a **demonstration**. The device will be powered on and a

mock exercise will be performed by one person. Once the battery has been recharged,

the brace will be resized and fit to another person, and the same procedure will be executed. This process will be repeated for 5 different people to demonstrate how the brace is reusable.

**4.10.7** Requirement will be verified by **demonstration**. The device shall be worn by a child

(~10 years old) and function comfortably. The child should be able to program the

device on his/her own without assistance. The device shall then be worn by an elderly adult (~ 80 years old) and function comfortably. The adult should be able to program the device on his/her own without assistance.

**4.11.1** Requirement will be verified by **inspection**. The device shall be set on a scale and

weigh less than ten pounds.

**4.11.2** Requirement will be verified by **demonstration**. The AEO shall be placed in the arm of

a human subject and be strapped in place securely.

**4.11.3** Requirement will be verified by **demonstration**. The device shall be worn with the

padding resting comfortably on the skin without any discomfort or irritation.

**4.11.4** Requirement will be verified by **demonstration**. The AEO shall be placed on multiple

human subjects with it being adjusted each time to their specific size.

**4.11.5** Requirement will be verified by **demonstration**. The motor and battery shall both

detach from the device when the user desires.

**4.11.6** Requirement shall be verified by a **test.** The AEO shall be placed on a human subject

with a set angle of supination or pronation. The subject will then try to change that angle of supination or pronation and not be able to do so.

**4.11.7** Requirement will be verified by **demonstration**. The AEO shall be placed on a human

subject and when set in place, the battery component will be at the location of the upper arm.

**4.11.8**Requirement will be verified by **demonstration**. AEO should be measured from the different surfaces and shall have maximum dimension limitation that fits within 4 cm.

**4.12.1** Requirement will be verified by **demonstration**. The AEO shall be worn for 24 hours a

day after surgery while still maintaining correct functionality and comfortability.

**4.12.2** Requirement will be verified by **inspection**. Physician have to instruct the patient on the usage of the AEO.

**4.12.3** Requirement will be verified by **inspection.** The instructions shall be verified that they are in English.

**4.13.1** Requirement will be verified by **demonstration**. The user shall be able to replace both

the battery and motor with a new battery and motor; functionality shall be the same.

## 

## 5.0 Acronyms

**A.E.O.** stands for active elbow orthosis, which is the device that the project intends to build.

## Appendices

**Appendix A:**

