**Functional Requirement Document for:**

**Active Elbow Orthosis**

**Project 16051**

Author: Adriana Barreda and Michael Sveiven

Date: 9/10/2016

# TABLE OF CONTENTS

TABLE OF CONTENTS

Overview…………………………………………………..……………………...3

Stakeholders…………………………………………..………………………….4

Applications………………………………………………..……………………...5

Assumptions/Constraints……………………………….……………………….5

Risks………………………………………………….……………………...........5

Related Documents……………………………….……………………………...5

Functional Requirements………………………………………………………..6-7

# 

# Overview

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. The elbow joint 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.

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.

# Stakeholders

|  |  |  |
| --- | --- | --- |
| Stakeholder Name | Organization | Role |
| Dr. Daniel Latt | Department of Orthopaedic Surgery | Sponsor |
| Dr. Joseph Sheppard | Department of Orthopaedic Surgery | Sponsor |
| Dr. John A. Szivek | Department of Orthopaedic Surgery | Sponsor |
| David Gonzales | Department of Orthopaedic Surgery | Technical mentor |
| Steve Larimore | University of Arizona | Mentor |
| Michael Sveiven | BME/ECE | Team leader |
| Adriana Barreda | BME | Strategic planner |
| Blakeley Koziol | BME | Secretary |
| Justin Hsieh | ABE | Safety officer |
| Timothy Shimon | BME | Outreach officer |
| Carissa Grijalva | BME | Procurement officer |

## 

## Applications

The following applications are in scope:

* The Active Elbow Orthosis shall focus only on extension and flexion motion.
* The Active Elbow Orthosis shall be designed for adult patients, (should be scalable to children and must be able to accommodate different sized adults)
* The Active Elbow Orthosis will interface with an iOS application through Bluetooth.
* The data acquisition for The Active Elbow Orthosis will focus on the measurement of elbow flexion angle.

The following applications are out of scope:

* The Active Elbow Orthosis will not include pronation and supination motion.

## Constraints

* Constraints on the success of the project will include: cost, access to technologies, sponsor schedule, and schedule of students.

## Risks

* A failure in the device might induce an overwork of the motor, which could cause the device to reposition itself out of the angle limits of safety for the patient.
* A failure could include overload of the motor which would cause it to burn out or catch fire.

## Related Documents

1. Kyrylova, Anastasiia, "Development of a Wearable Mechatronic Elbow Brace for Postoperative Motion Rehabilitation" (2015). Electronic Thesis and Dissertation Repository. Paper 3019.

## Shawn W. O'Driscoll, “Continuous passive motion (CPM): Theory and principles of clinical application” (2000). Journal of Rehabilitation Research & Development.

# Functional Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| Requirement ID | Requirement Statement | Must/Want | Comments |
| FR001 | The Active Elbow Orthosis shall be wearable by patients throughout the day.  C | Must |  |
| FR002 | The Active Elbow Orthosis shall be portable with a battery.  C | Must | Rechargeable |
| FR003 | The Active Elbow Orthosis shall interface with an iOS application through Bluetooth.  T | Must | Maybe other interface (wireless) |
| FR004 | The Active Elbow Orthosis shall have a motor controlled by an iOS application that assists the patient in flexion.  A | Must |  |
| FR005 | The Active Elbow Orthosis shall have a motor controlled by an iOS application that assists the patient in extension.  A | Must |  |
| FR006 | The Active Elbow Orthosis shall measure the angle of the elbow.  M | Must |  |
| FR007 | The Active Elbow Orthosis shall send elbow angle data to the iOS application.  T | Must |  |
| FR008 | The Active Elbow Orthosis shall have a progressive, personalized, and adjustable schedule for increasing or maintaining the range of motion of elbow joint.  B | Must |  |
| FR009 | The Active Elbow Orthosis shall have locking system for maintaining angle  B | Want | Locked in a range and locked to a position |
| FR010 | The Active Elbow Orthosis shall have a feedback system for when the patient is resisting motion during an exercise or if the patient is resting.  M | Must |  |
| FR011 | The Active Elbow Orthosis shall have a shut off command triggered from the iOS app, at any moment the patient is in pain.  J | Want | Emergency shutoff on the AEO |
| FR012 | The Active Elbow Orthosis shall be scalable to fit on an adult or a child.  J | Want |  |