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Memorandum

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From: MetaCapture

Subject: Final Design Report

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Executive Summary

Thousands of patients suffer severe brachial plexus injuries every year. Treatments which involve nerve reconstruction surgery are performed to restore arm and hand function. It's unclear whether these treatments, in particular, current surgery methods, effectively repair this injury and restore motor function. Patients may recover minimal metacarpophalangeal (MCP) joint motion, but there are currently no tools available to accurately and objectively measure restored hand function post surgery. MetaCapture has created a wearable device called the FlexiCapture that patients will wear for up to five days during daily life one year after surgery. This device is a research tool that monitors finger use and range of MCP joint motion. The FlexiCapture is durable and uses a flex sensor that is placed over the MCP joint to track finger movement. The FlexiCapture measures finger bend angles, records the time a person moves their fingers above a 5 degree threshold, and logs data continuously for up to five days. The chosen flex sensor, however, struggled with accurately and consistently measuring small angles. For future project development, we recommend using a higher fidelity sensor, implementing water resistance, injection molding parts, and testing the device on patients who suffer from brachial plexus injuries.

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1.0 Problem Definition, Market Analysis, and Design Requirements

1.1 Problem Definition

1.1.1 Background

The brachial plexus is a network of nerve fibers that runs from the spinal cord through the shoulder to the entire upper extremities. Its terminal branches transmit electrical impulses to different muscle groups of the upper extremities and are essential for limb control. A brachial plexus injury (BPI) results from the nerves being torn, stretched, compressed, or severed from the spinal cord and are typically caused by motor vehicle accidents. Many BPIs result in damage to the motor functions of the hand, and some injuries result in more severe loss of hand motor function than others. To treat severe injuries, patients undergo one of various surgical procedures that aim to restore nerve function to the injured region. These procedures include nerve grafting, nerve transfer and the transplantation of various structures.¹ There are around 5,000 brachial plexus surgeries per year which restore minimal function in the hand.² After rehabilitation, patients have limited movement at their metacarpophalangeal (MCP) joint and no movement at the wrist as the wrist is usually fixed during surgery. The goal of this project is to create a device that can quantitatively evaluate whether the surgical options for moderate to severe BPIs are beneficial for patients or if a new procedure needs to be explored.



Figure 1. Brachial plexus nerve fibers in the upper extremity²

There are various methods used currently to assess the success of surgery in a clinical setting. These include muscle stretching and joint rotation tests, measuring angles using a goniometer in order to evaluate their finger range of motion (ROM). The current quantitative measurement of goniometers has a 10° error. Patients are also given surveys regarding their outcomes of surgery, however, the results are often subjective and do not provide reliable data. Currently, there is a lack of statistics assessing hand use to determine the success of these surgeries.³

1.1.2 Problem & Need

The outcomes of brachial plexus nerve reconstruction surgery and patient recovery are difficult to measure especially in the hand and fingers. There is a need to determine whether sufficient functionality is restored in the MCP joint post surgery and 1-year rehabilitation. This solution is intended for use by young adult and adult patients, thus excluding children, who underwent brachial plexus trauma surgery in order to document and measure progress of post-op rehabilitation of motor functions in the fingers at home.

These patients have undergone a BPI resulting in decreased hand and sensory function. These patients have had brachial plexus reconstruction surgery and have been doing physical therapy for at least a year.⁴ After this surgery, these patients can only flex their fingers at the MCP joint in unison in order to close the hand. Their fingers return to the same resting position after flexion due to the elastic properties of the finger extensor tendons. BPI patients have their thumb and wrist fused to increase grip ability, which means they cannot consciously move their wrist or thumb. After the injury and surgery, these patients experience neuropathic pain, which is the experience of pain from normally non-painful stimuli. In addition, patients experience heightened sensitivity to pain stimuli due to their injury.⁵ These effects compound, and as a result these patients are very sensitive to touch in the hands and cannot tolerate skin contact that covers a large surface area.

1.1.3 Project Scope

1.1.3.1 Big Picture

The long term vision of this project is a waterproof device that has multiple tracking abilities and data output methods to provide a comprehensive evaluation of motor function in the fingers. Over time, this device would be able to track the motion and speed of individual digits. The device will fit comfortably on the hand or fingers and not interfere with daily activities. It needs to record data continuously from the fingers over 3-5 days and show how they moved during this time period. The data would depict the amount of time that each hand was used during the day so the clinician could determine how much the surgically repaired hand is being used compared to the healthy hand. This device would be used for research in determining the success rate of brachial plexus surgeries by comparing the usage rate of the surgically repaired hand to the healthy hand one year post operation and rehabilitation.

1.1.3.2 Team Objectives

The goal by the end of this semester was to present the client a functional device that continuously tracks the flexion of the fingers as a unit throughout a 3-5 day interval and clearly outputs amounts of finger use and range of finger motion. The clinician will be able to determine to what extent the surgically repaired hand is being used compared to the healthy hand and determine surgery success.

1.2 Market and Patentability Analysis

1.2.1 Market analysis

Wearable technology is a blossoming industry, with a market value of \$19.7 billion in 2017 and estimated growth to \$82.3 billion by 2023.⁶ This field includes smart watches, such as Fitbits and Apple watches, virtual reality glasses, GoPros, and healthcare and patient monitoring devices. Wearable medical devices, the total addressable market of the product, takes up \$4.8

billion of the wearable technology market and is expected to grow to \$19.5 billion by 2021.⁷ The served market of this device is the remote patient monitoring section of wearable medical devices, which is valued at \$1.4 billion and is expected to reach \$2.7 billion by 2023.⁸ Due to the lack of an existing market for this product, there is potential overlap with other markets such as the smartwatch market, which is currently \$10 billion.⁹ The target market is brachial plexus treatment and monitoring post-treatment outcomes. The cost for this surgery is on average \$80,000 with 4.96 brachial plexus cases per 100,000 people from traumatic injuries.¹⁰ With 100 million traumatic injuries from a population of 6.5 billion people every year, the total addressable market of patients that suffer from BPIs after traumatic injuries is \$410 million as of 2005.¹¹ With population growth forecasted to grow 1.1% per year until 2030 to 8.2 billion, the target market will grow to \$520 million by 2030.¹²

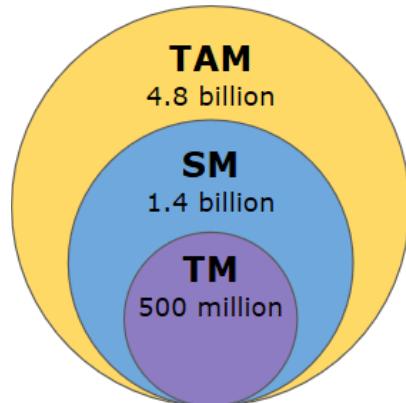


Figure 2. Diagram of total addressable market, served market, and target market.

Table 1 below includes other existing solutions and compares those to the FlexiCapture based on our design criteria. Our device meets all design criteria while other solutions fail to meet certain criteria, making our device a competitive product.

1.2.2 Patent Analysis

There are patents that are within the same market as the design, which is wearable monitoring of patients' medical problems. These products are mainly used for medical purposes, however, they cannot measure the motion of fingers in daily life. One of these wearable health monitors, US5964701A, is able to measure the health status of patients, such as heart rate and blood flow, and send that data to a health professional.¹³ The device includes a ring that monitors patient's health, sends information via electrical signals, and an accelerometer that removes the noise signal due to other finger movements. By using a smaller-size device and a wireless sensor, the device can be worn by patients daily without affecting their normal activities and living standards. However, this device is not intended to be used for precise finger motion tracking. The accelerometer built in the device can only eliminate the motion artifacts by body movements in the signal, instead of monitoring patients' daily finger motions.

Another patent, US9345424B2, represents a clinical force sensing glove and also has the same market/field as the design.¹⁴ The glove is able to quantitatively measure the force and displacement of the hand and fingers, using flexible applicators and sensors inside the gloves to measure the force and thus to detect the force and movement by the hand and fingers. However, this device is only available in a clinical setting, and needs to be used by a therapist. Patients cannot wear this device during daily activity. Therefore, although these patents are

within the same market as FlexiCapture, FlexiCapture is not affected. The table below (Table 2) compares the different patents discussed above to each other as well as to FlexiCapture and demonstrates our freedom to operate. The gap that FlexiCapture fills is that it will be a wearable medical device that can be used at home to monitor finger activity. None of these patents have all of these characteristics. (Note: The check mark, ✓, indicates that claim is included in the corresponding patent).

Table 1. Benchmark Analysis

Design Criteria	Actigra ph	Remote Health Monitor Patent	Clinical Force Sensing Glove Patent	Photographs of Rings	Magnetometer	FlexiCapture
Durable	✓	✓	✓	✓	✓	✓
Wearable	✓	✓		✓	✓	✓
Used at home	✓					✓
Used for Medical Application	✓	✓	✓			✓
Measures finger motion				✓	✓	✓

This table includes the benchmark analysis, comparing the current products to each other as well as to FlexiCapture. The check mark, ✓, indicates that design criterion is included in the corresponding product.

Table 2. Freedom to Operate

Claims	Remote Health Monitor	Clinical Force Sensing Glove	Photographs of 5 Rings	Magnetometer on Two Fingers	FlexiCapture
Wearable	✓		✓	✓	✓
Rings	✓		✓	✓	
Bracelet	✓		✓	✓	

Finger motion	✓	✓	✓	✓
Accelerometer	✓			
Magnetometer			✓	
Photograph		✓		
Wireless	✓		✓	✓
At Home				✓
Medical Device	✓	✓		✓

1.3 Design Requirements

Table 3 lists all critical and non-critical design requirements under the categories of device functionality, usability, and safety. The specifications for each design requirement is also listed.

Table 3. Design Requirements

Critical Design Requirement - Functionality		Design Specifications
Short Term	Measure range of motion of MCP joint during daily living activities	Measure joint angle from 0 to 90 degrees +/- 5 degrees
	Measure duration of MCP joint in flexion/extension motion during daily living activities	Measure motion longer than 25ms without a change in direction
	Measurements are accurate for at least 18 hours of use per day	Error ≤ 20% of daily activity recording repeatedly in conjunction with specification above
	Duration of use	Device power should be able to last 18 hours per day in a single use without charge
	Data storage	Storage at least 0.06 GB (18 hours a day for 5 days)
	Small (must not interfere with activities)	Hand length: 15.8cm < size > 17.9cm Wrist width: 5.4cm < size > 6.8cm Hand width: 6.9cm < size > 8.2cm Finger circ. 2.41cm
	Lightweight	Under 30g for the finger; under 80g for the wrist

	Shock resistant	After falling from 1 meter on hardwood the device is still accurate according to the specification above (3)
	Critical Design Requirement - Usability	Design Specifications
	Short patient training and initial setup of device time	Training: ≤ 5 min Setup: ≤ 10 min With error in tasks = 0%
	Short clinician/Researcher training time	Processing: ≤ 30min Training: ≤ 15min With error in tasks = 0%
	Non-Critical Design Requirement - Usability	Design Specification
	Efficient data extraction and processing	≤ 30 minutes
	Critical Design Requirement - Safety	Design Specifications
	Does not burn or have a lot of heat emission	Less than 93.2°F
	Does not electrocute	Current in contact with skin < 1/3mA
	Safely interface with hand and fingers	Biocompatible / no harm/irritation
Long Term	Critical Design Requirement - Functionality	Design Specification
	Water exposure	1 meter for 30 min
	Non-Critical Design Requirement - Functionality	Design Specifications
	Adjustable	Wrists between 13.7 - 19.3cm; length between 15.8 - 20.6 cm; finger circumference between 4.4 - 7.1 cm; hand width between 16.5-23.4 cm
	Wirelessly transfer data with external devices (monitoring devices and/or storage units)	No wires needed for communication between devices
	Duration of use	Continuous for 24 hours a day for 5 days

1.3.1 Functionality - Short Term Critical Device Requirements

Measure range of motion of MCP joint during daily living activities

This device must be capable of measuring the range of motion of the MCP joint during use. The complete range in which the device must be able to measure is from 0° to 90° with +/- 5° accuracy, where 0° is the max extension and 90° is the max flexion. This is because the MCP joint is only capable of a maximum of 90° of motion based on the anatomy of the joint.¹⁵ This range of error makes the device more accurate than the existing methods of measuring MCP joint angles using a goniometer, which has ± 10° of error.¹⁶ 5° error is acceptable in the effort to bridge the tradeoffs between high accuracy and difference in range of motion between patients. 5° is smaller than 10° to capture the smaller movements especially from patients with less MCP movement, but at the same time to be large enough to not capture subtle involuntary

movements. Measuring the range of MCP joint motion enables researchers to develop a more detailed picture of injured hand use during daily living activities.

Measure duration of MCP joint in flexion/extension motion during daily living activities

This device must be able to measure the duration of the MCP joint in flexion/extension motion during daily activities. These measurements need to be quantitative and monitor the amount of time that the MCP joint is in motion when longer than 25 ms without changing direction. 25 ms is the shortest amount of time it takes for a muscle to contract.¹⁷ The reason not changing direction is also specified is to avoid the possibility of multiple motions being counted as one motion.

Measurements are accurate for at least 18 hours of use per day

The device must accurately record finger motion duration by successfully recording when a finger moves with an error less than or equal to 20%. This specification is derived from the error that numerous motion tracking wearable devices encounter when measuring motion during “free-living” conditions which is 20%.¹⁸ Since FlexiCapture is supposed to be a device used solely to measure motion in daily activities, this level of error can be used as a requirement for MCP joint motion as well.

Store data for a minimum of 18 hours per day

In order to continuously record data and keep the data for clinical observation, the device needs a certain amount of storage. The specification for this design requirement is the device must contain at least 0.03 GB of storage. This was calculated by examining the amount of data it would take to store one line of code with all the necessary data values, and recording that code every 25 ms, as that is the fastest time a muscle can contract.¹⁹ Integers take up 4 bytes and decimals take up 8 bytes, which yields a total of 24 bytes per line. If data is recorded every 25 ms, 18 hours of data yields 0.06 GB of data storage needed.

Duration of use

The device needs to be able to stay on and continuously monitor hand movement during daily living activities for 18 hours without charging it. The device requires nightly charging, therefore the device needs to be able to be powered for 18 hours a day on one full charge. This specification is derived from people being awake for an average of 15.2 hours with a few hours of leeway.²⁰

Small - must not interfere with activities

The device must not interfere with daily activities, so the device should fit hand length sizes between 15.7 and 17.9 cm, wrist width sizes between 5.4cm and 6.8cm, hand width sizes between 6.9 and 8.2cm and finger circumference of 2.41cm.²¹ These measurements are the 95th percentile male hand sizes and the 5th percentile female sizes to encompass the majority of hand sizes

Lightweight

The device must be lightweight so as to ensure the device doesn't not interfere with hand movement and is comfortable to wear. The specification for this requirement is that the device must be under 30 g on the finger and 80 g on the wrist based on similar weights of rings and watches.²² These measurements are based on ring and watch weights that are worn daily on many people's hands.

Shock resistant

The device must withstand drops from three directions from 1 meter according IEC 60601-1:2005. This specification is appropriate due to the fact that patients put on and remove the device from the wrist, not above their head which is closer to two meters.

1.3.2 Usability - Short Term Critical Requirements

Short patient training and initial setup of device time

After analyzing intended users of the device and their usability needs, several usability requirements with measurable specifications were identified. One usability requirement is the device must be easy for patients to learn and time-efficient during the first device setup. This standard specifies that the device is user friendly and easy to adapt while maximizing the productive time ratio. Another specification is that the expected training time should at most 5 minutes and initial setup time should be at most 10 minutes. This is based on client interviews and the understanding that a patient appointment would be one hour.

Short clinician/Researcher training time

Another usability requirement is to have a short clinician training time. The specification for this is that the clinician training should be at most 15 minutes and at most 30 minutes for processing. This leaves a total of 45 minutes of training. This is based on similar specs from the Actigraph' training tutorials. The tasks associated with usage and data processing are in total about one hour, so our device takes less time to process the data.

1.3.3 Usability - Short Term Non-Critical Requirements

Efficient data extraction and processing

The device must allow for efficient data extraction and processing. The design specification is that the time required to obtain the information from the device should take at most 30 minutes. This time period was determined after meeting with the client as they were satisfied with a similar amount of time it takes to extract data from the Actigraph for gross arm movements. They expect to spend at most 10 minutes downloading the corresponding software, and at most 20 minutes to retrieve analyzed data from the device.

1.3.4 Safety - Short Term Critical Requirements

Does not burn or have a lot of heat emission

The device must not cause burn or generate a lot of heat emission. Skin burning from heat starts at 111°F.²³ Because these patients can't feel the exact sensation of burning, there is a maximum temperature specification 10% lower than the burning temperature. Another part of this design requirement is that the device does not cause discomfort from heat emission. Because skin is around 4 cm thick the temperature of the surface of the skin is 93.2°F.¹⁵ In order to ensure that there is no temperature discomfort to the patient, the specification for heat consistently generated by the device was set to be less than 93.2°F.

Does not cause electrical burn

Because the device is powered by a battery, the safety requirement of not experiencing electric burn ensures that the device can't harm the patient due to leaking current. The specification for this requirement is that leaking current doesn't exceed 10 mA. This specification is derived from the IEC 60601 family of standards.

Does not electrocute

Our device must not cause an electric shock to the patient. The specification for this is that the current in contact with the hand must be less than 1/3mA following the IEC standard 60601.²⁴

Safely interface with hand and fingers

Furthermore, the device must be biocompatible. This safety requirement indicates that the device should comply with the standard ANSI/AAMI/ISO 10993-10.⁵ The material of the device, which could be in contact with the skin, must not cause skin irritation or sensitization. During the period of use, the device should not induce adverse effects on skin, such as hypersensitivity, inflammatory response, skin corrosion, etc.

1.3.5 Functionality - Long Term Critical Requirements

Water exposure

The device must be water resistant so it can be worn during all daily living activities such as washing hands, cleaning dishes, and showering. The device must withstand water immersion at 1 meter for up to 30 minutes. This specification follows the rating IP67 from the IEC 60529 standard used to classify the protection level of electronic devices.²⁵

1.3.6 Functionality - Long Term Non-Critical Requirements

Adjustable

The device must be adjustable in size so it can be used by a variety of people with different hand and finger sizes. The device must be adjustable within the dimensions of 13.7-19.3 cm on the wrist, 15.8-20.6 cm long on the hand, 4.4-7.1 cm circumference on the finger and the width of the hand between 16.5-23.4 cm. These size ranges come from the 5th percentile women and 95th male hand dimensions.²⁷ This specification makes the assumption that the device is a wearable device on the hand.

Wirelessly transfer data with external devices

The device must be able to wirelessly transfer data with other devices such as additional monitoring devices and external storage units. The device can not have any wires that connect devices together. Clinicians are able to receive the data from the device wirelessly and monitor the movement of patient's fingers. Also, clinicians are able to get the data in real time without seeing the patients.

Duration of use

The device needs to be able to stay on and continuously monitor for 24 hours a day for 5 days. This long term design requirement is that the device would not have to be removed in order to charge during 3-5 days of wearing the device.

2.0 Detailed Design

2.1 Device Interface With the Environment

Based on the pugh matrix evaluation method, the flex sensor was chosen for the FlexiCapture device design. The design employs the SpectraSymbol 4.5 inch Flex Sensor that changes resistance upon bending, which changes the output voltage of the circuit. These changes in output voltage and resistance can be used to measure the duration of finger use, bend angle, and angular velocity of the MCP joint during daily activities. The sensor is overmolded with Dragonskin 10A, a type of silicone, and rests on the back of the hand with the sensor's midpoint

on the MCP joint of the middle finger (Figure 3). The distal edge of the sensor is fixed via a elastic band sewn together with a hook and loop fastener. Wires extend from the proximal end of the sensor to the circuitry on the wrist contained in the electrical housing. The housing is secured on top of the wrist via a similar method to the finger band. The device minimizes hand contact because the patients' hands are extremely sensitive to touch and too much circumferential skin contact can cause pain.

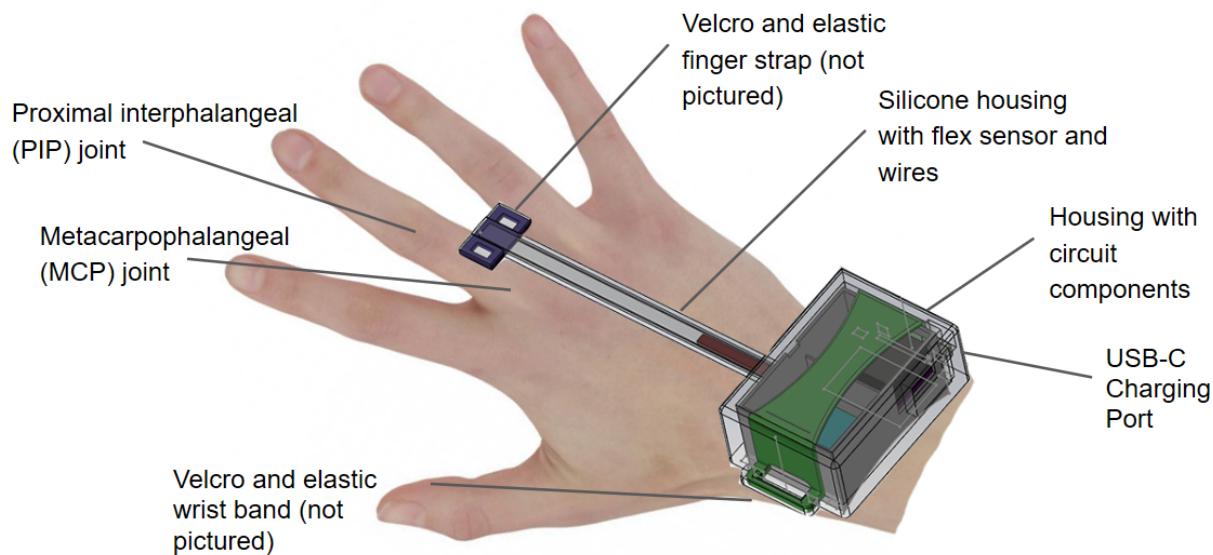


Figure 3. Device interface with the hand. The device rests over the middle finger and will bend at the MCP joint.

2.2 Solidworks Model

The device contains the SpectraSymbol Flex Sensor soldered to the circuitry. The sensor along with 3 PLA supports is overmolded with Dragonskin 10A. The Dragonskin allows for flexibility for the users to flex their hands without restriction and the inserts allow for stiffness for fixation to the arm or to protect the sensor. The Finger Band and Wristband supports provide stiff points for the finger and wristbands to grip onto so the silicone won't flop from the force. The Flex Sensor support blocks the housing and therefore the sensor bending at its base which could damage the sensor. The resulting part, the Top Half of Wrist Housing, slides onto the Bottom Half of Wrist Housing which is printed with PLA to protect the circuitry, which consists of the TinyZero system, the 3.7 VDC 500 mAh lithium ion polymer battery (LIPOB), and the soldered protoboards. The TinyZero system consists of the TinyZero Processor Board (TPB), MicroSD TinyShield (MTS), Real Time Clock (RTC), and the TinyShield Breakout Board, which all snap together and are fastened with M1.2 fasteners from the TinyDuino Mounting Kit. The Bottom of Wrist Housing is also curved to fit comfortably on the wrist. The Top Half of Wrist Housing and Bottom Half of Wrist Housing are held together by the force of the wristband and the support from the wrist. There is also a 1 cm colored portion on the flex sensor portion of the Top of Wrist Housing to align the device with MCP joint.

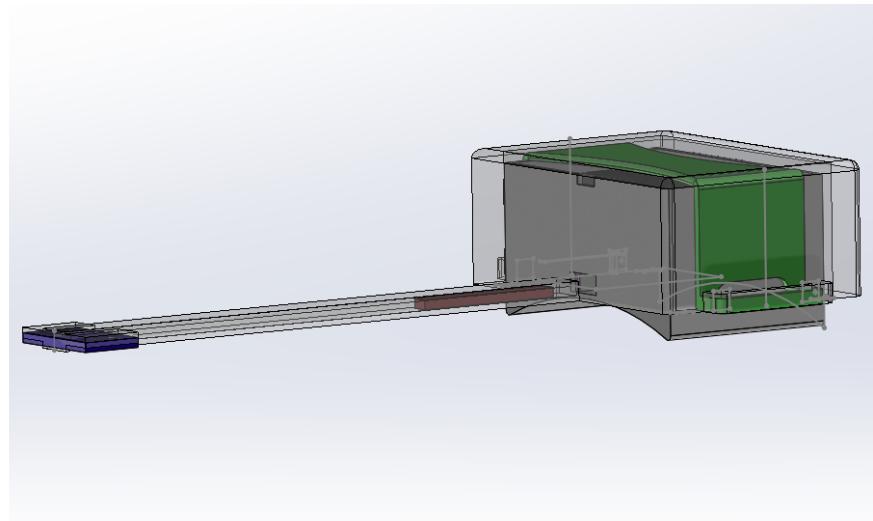


Figure 4. Assembled CAD model. The Top Half of Wrist Housing is a clear color to demonstrate Dragonskin 10A, with the PLA pieces overmolded inside of it.

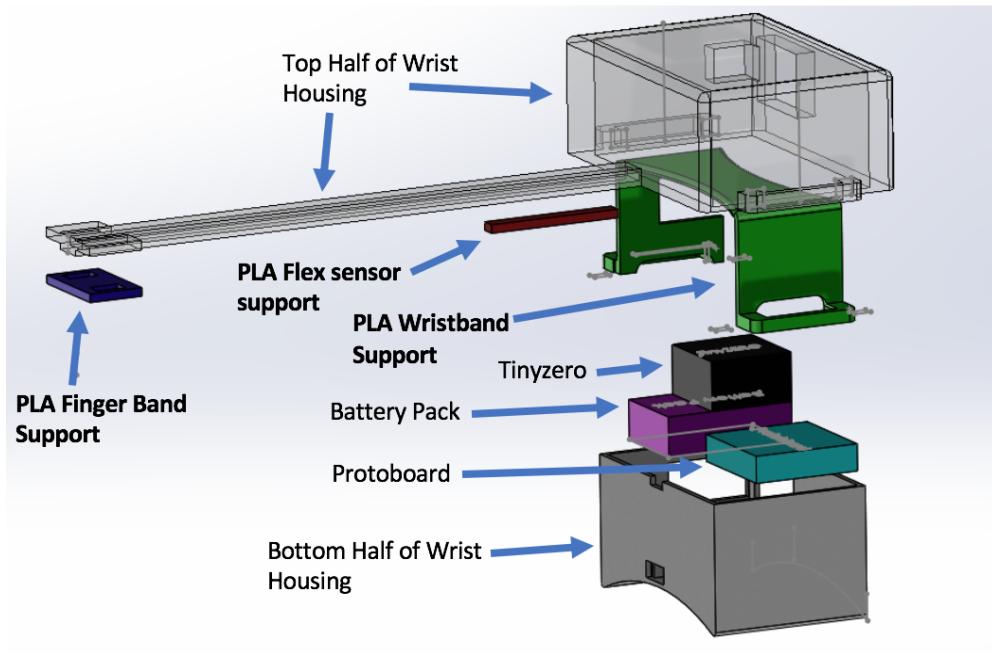


Figure 5: Exploded View of Mechanical System

2.3 Materials

Our design consists of a flex sensor, an adjustable wristband, mounting and connecting components, circuit board, and electronic enclosures. Since the device is designed to be wearable, the components that have contact with skin must be biocompatible following ISO 10993.⁴ A detailed bill of materials is shown in Appendix A.

The SpectraSymbol Flex sensor is printed with a polymer ink that is embedded with conductive particles (Figure 6). The exact materials of the flex sensor are not public information, but the following material properties are known: the sensor has a fatigue limit of greater than 1 million bend cycles and has a functional temperature range of -35 °C to +80 °C . The flex sensor has a flat resistance of 10k Ohms ± 30%, a bend resistance that reaches over two times the flat resistance at a 180 degree pinch angle, and a power rating of 0.5 Watts continuous and 1 Watt peak.²⁸ Given that the flex sensor can withstand a wide range of temperatures and has a high fatigue limit, it is suitable for continuous use during daily activity. In comparison to other flex sensors on the market, this flex sensor is short enough so that it covers the length of the MCP joint without being too long as to be an inconvenience.

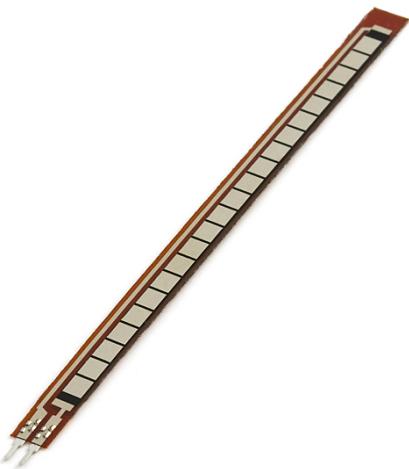


Figure 6. Image of flex sensor

This device's wrist and finger straps are made from elastic bands commonly found in clothing waistbands with small portions of hook and loop fasteners sewn to it. The flexibility of the elastic and the variability of the hook and loop fasteners allow the device to be worn by a wide range of finger and wrist sizes. The hook and loop fasteners were chosen as opposed to a watch band buckle due to user feedback, as the users found the buckle harder to fasten with one hand.

The skin needs to be protected from the flex sensor and electrical wiring that sits on the finger and the sensor needs to be able to bend along with the MCP motion. Silicone rubber insulates the system while its flexibility allows for free MCP bending. Smooth-On DragonSkin 10A has a Shore hardness of 10A, meaning its soft and comfortable to wear on the skin, and its thin application in our device along with the small Young's modulus allow for easy bending.²⁹ The silicone in this device was made with a custom 3D printed mold (Appendix B).

A 3D printed enclosure is used to protect the circuit board and components. A custom housing can better fit the custom circuit and minimize occupied space on the wrist. There are two major 3D printing materials used, ABS (Acrylonitrile Butadiene Styrene) and PLA (Polylactic Acid), with similar price ranges, around \$20 per kg and both biocompatible.³⁰ PLA is used because the printing process of PLA is simpler than ABS, and provides a more precise final product with less possibility of warping than ABS.³¹ PLA also has favorable insulating properties, which assists in shielding the electrical components.

2.4 Circuitry

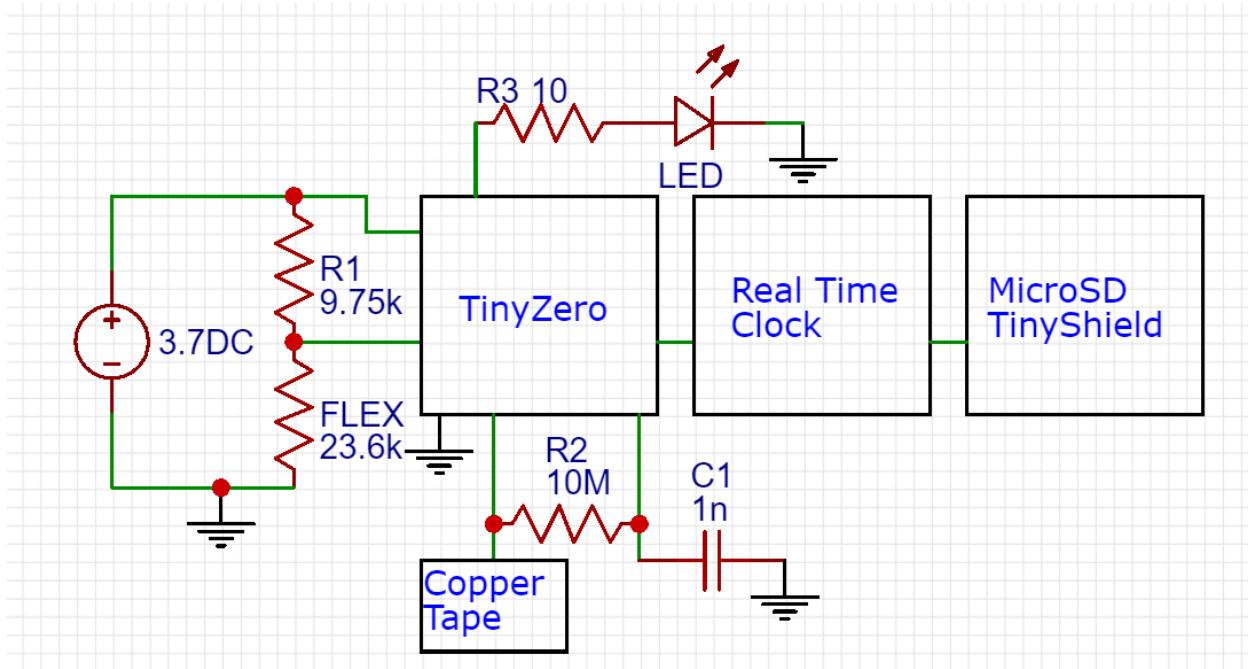


Figure 7. Circuit Diagram

The circuit is powered by a TinyCircuits 3.7V DC 500 mAh LIPOB. This battery was chosen due to its compatibility with the breadboards, its overall size, its large current capacity, and it's rechargeability via a microUSB port on the TPB. This battery is 1.22" by 0.79" by 0.37", whereas the diameter of a US quarter is 0.955".¹² The current from the battery flows into the voltage divider (R₁,FLEX) which allows the voltage in between the components to be measured. The resistor values were selected using Ohm's law

$$V = I * R \quad \text{Eq. 1}$$

And the formula for calculating equivalent resistance for resistors in series.

$$R = R_1 + R_2 \quad \text{Eq. 2}$$

This voltage value is then read into the TPB which analyzes the data. Once the RAM is maximized, the TPB sends the data to the MTS along with the timestamps from the RTC. The copper tape, R₂, and C₁ make up a capacitive sensor, which senses the proximity of conductive materials. When such a material, such as skin, is close enough for long enough, it triggers the calibration algorithm, which is denoted by a blinking LED (R₂ and LED). The LED blinks twice to denote calibration initiation and will stay lit until calibration is done. The LED also serves as a battery monitor, and will glow continuously when the device needs to be charged. This is to ensure that the user knows when to charge the battery and it does not suddenly die off while in use, as the LIPOB drastically depletes beyond 20% capacity.

For our final prototype, we built our circuit on a green 1" square protoboard as it was effective for quick iterations. However, the wires are bulky and the protoboard takes up more space, so

we attempted to create a custom printed circuit board (PCB) to reduce space. Unfortunately, this PCB board did not work fully and interface properly with the current TinyZero system, but the capacitive sensor on the PCB board worked well. Additionally, the capacitive sensor built on the protoboard did not work properly, likely because of interference from unclean soldering points on the board. Thus, we conducted testing on the capacitive sensor using the PCB board attached to the TinyZero system (Figure 8). In the final prototype with the protoboard, the capacitive sensor was not successfully implemented. We suspect that some of the pins used in the TinyZero system for other boards (i.e RTC shield) were also used on the PCB, causing the signals to clash with each other and not function properly. It's also possible that the connector piece used to connect the PCB board to the rest of the system was not soldered properly, as bridging could have occurred between the connections. Another PCB was going to be made, but we ran out of time to redesign, reorder, and implement into the system. This implementation of the PCB is further discussed in recommendations.

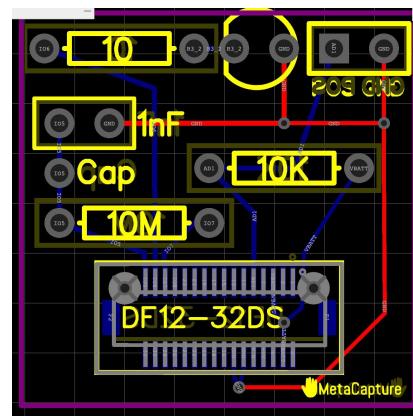


Figure 8. PCB layout. The capacitive sensor system worked, but the flex sensor system did not.

2.5 User Operation

The two primary users of this device are patients who underwent brachial plexus reconstruction surgery and clinicians or researchers using the device. The device is given to the patient during a check-up with the physician, likely a neurosurgeon, approximately one year after the patient has undergone surgery. At this point, the patient has been doing physical therapy regularly and should be able to move their hand to some extent in their daily life.

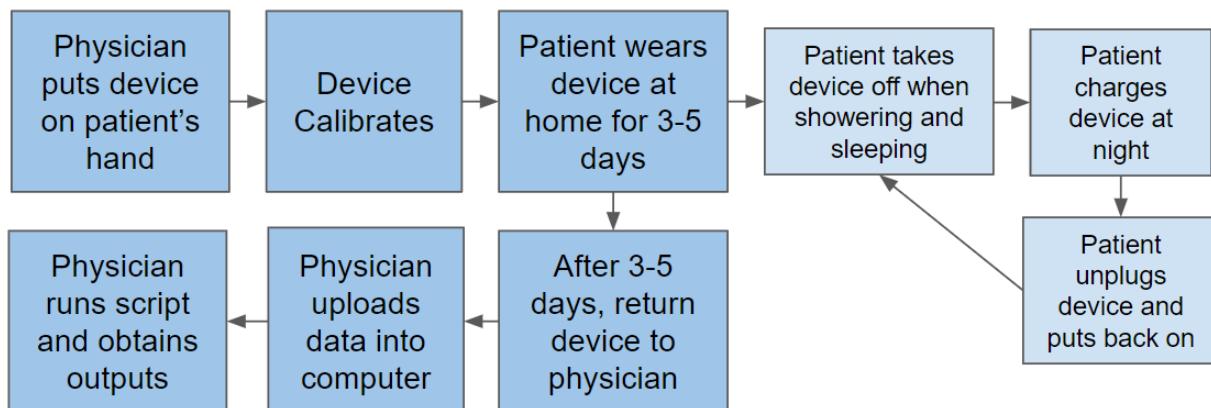


Figure 9. The process of device use from initial setup to data post-processing. This process begins with the physician giving the patient the device and ends with the physician acquiring the data of patient finger activity.

At the check-up, the physician takes the flex sensor portion of the device and places it over the middle finger of the patient. The colored portion of the sensor should be placed over the MCP joint and the end of the sensor should be secured over the middle and ring fingers. The physician should tighten the ring by pulling the hook and loop through the strap and securing tightly. The physician should rest the sensor straight against the back of the hand and tighten the wrist band around the patient's wrist. The Bottom of Wrist Housing should rest on the top of the wrist. The patient secures and tightens the device to their hand every time the patient puts the device on. This process requires one hand, so the patient is able to do this independently without the assistance of a caretaker.

The physician should explain that the device should be worn all day except during activities with potential water exposure and sleep, and should explain that changes in color in the usage light indicate the battery power and calibration stages of the device. Finally, the physician should explain the importance of safety instructions to the patients, such as not putting the device in contact with water.

The patient wears the device during the day for three to five days. This duration gathers sufficient amount of data over a time period that reflects daily living activities. The patient should take the device off during sleep and when showering or other water contact activities, but is expected to wear it at all other times. When the patient takes off the device to sleep, the patient must charge the device using its power cord and an outlet.

The device is only worn on the injured hand to monitor the activity of this hand at the outset, however the device can be worn on both hands to compare the activity of the injured hand against the healthy hand should the researchers need this data. Retrieving data for only the injured hand provides useful data that gives researchers a better understanding for whether patients are effectively using their injured hand.

When the device is returned to the physician, the physician should clean and disinfect the device using medical grade disinfectant wipes. The physician takes the microSD card and plug it into a microSD adapter and then into a computer. The physician uploads the text files to a program that analyzes the data and outputs processed data in text files.

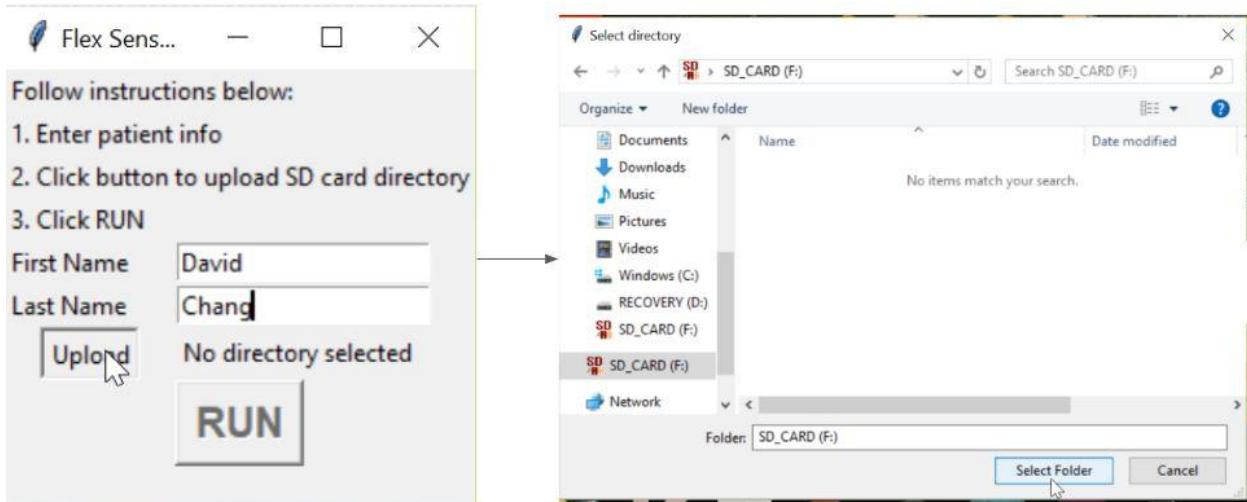


Figure 10. Post Processing Executable steps 1 and 2. (Left) The researcher inputs the patient's name and clicks Upload. (Right) The researcher selects the text files from the microSD card.

The researcher inputs the patient name and then selects upload to upload the SD card directory, which contains the raw data files. Once the directory is uploaded, the Run button turns green and the researcher clicks it to run the data analysis.

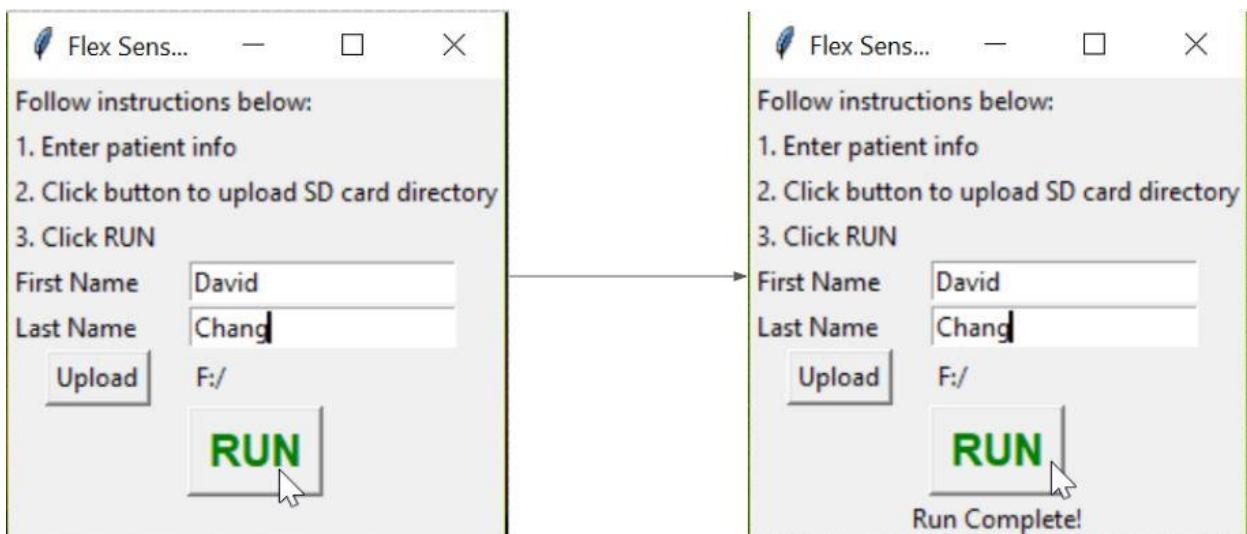


Figure 11. Steps 3 and 4. Once the files are selected, the "RUN" button turns green and the data analysis can now be completed.

The program automatically sorts and processes the files contained in the SD card directory. When the program has finishing running, there is a new file which contains the total event time, average event time, average max angle, and average angular velocity. The physician can access this file as well as the complete set of processed data for their research studies.

2.6 Software

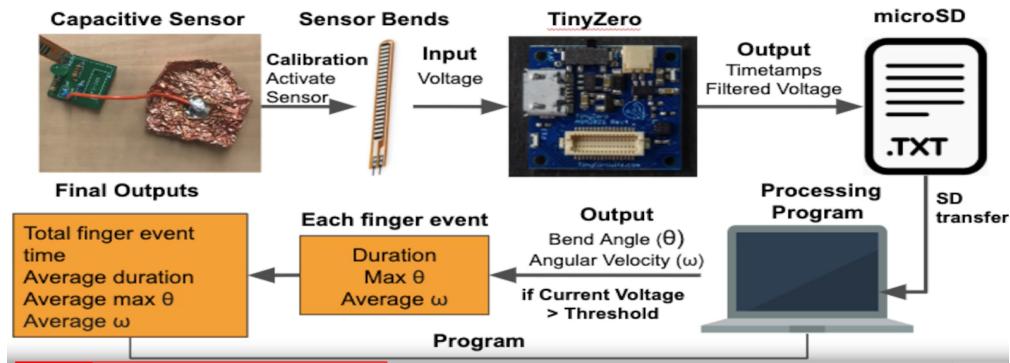


Figure 12. Overview of software algorithm and data acquisition process for each patient cycle of use.

2.6.1 Calibrate device

The capacitive sensor uses a threshold to detect whether the device is on or off the hand and when to conduct calibration. When the patient puts on the device, they should orient their hand in their natural resting position and keep the hand still. The capacitive sensor checks whether the patient is indeed putting the device on by taking 5000 sensor readings and tallying every time the reading passes the threshold. If the tally is at least half of the readings (2500), the device processes with calibration. The device waits 60 seconds for the user to fully put the device on. The LED blinks twice to signal calibration initiation. The calibration algorithm starts records the resting voltage to the text file "RESTING.TXT" inside the "RAW_DATA" folder, and will continue running while the light stays on. After 10 seconds the light turns off, and the output voltage is recorded every 25 millisecond to filter out finger twitches and unwanted noise. Every time the patient takes off and puts back on the device, the calibration program will run again and the another resting voltage will be calculated and added below the previous resting voltage in "RESTING.TXT". (All files created on an SD card by Arduino are in all caps).

```

1.99
2.03
2.02
1.98
2.02

```

Figure 13. "RESTING.txt" with the resting voltage values corresponding to each time the patient recalibrates the device.

This takes into account different locations and drifts in the sensor when the patient takes off and puts on the device, as each resting voltage will be used to determine events from their respective raw data files.

2.6.2 Logging Time and Recording Data

After the calibration ends, the device continuously records output voltage and filters it through a moving average filter to eliminate voltage changes that are shorter than a minimum muscle movement of 25 milliseconds. Approximately every 2.5 seconds, the TinyZero exports the output voltage, the timestamps from the RTC board, and the time difference from the initial data point in milliseconds to the microSD card in the text file "48R_1.txt" (Figure 14). 48 corresponds to the date (April 8) and R_0 is the raw data number. If the patient takes the device off during the day, there will be more than one raw data file, "48R_3.txt" for example. Each one of these

raw data files will also correspond to one of the resting voltages in “RESTING.TXT” and will all be used during post-processing.

ts	t	v
0:15:25	1	1.92
0:15:25	29	1.92
0:15:25	56	1.92
0:15:25	83	1.92
0:15:25	110	1.92
0:15:25	137	1.92
0:15:25	164	1.92
0:15:25	191	1.92
0:15:25	218	1.92
0:15:25	245	1.92
0:15:25	272	1.92
0:15:25	299	1.92
0:15:25	326	1.92
0:15:25	353	1.92
0:15:25	380	1.92
0:15:25	407	1.92
0:15:25	434	1.92
0:15:25	461	1.92
0:15:25	488	1.92
0:15:25	515	1.92
0:15:25	542	1.92
0:15:25	569	1.93
0:15:25	596	1.93
0:15:25	624	1.94
0:15:25	651	1.95
0:15:26	678	1.95
0:15:26	705	1.96
0:15:26	732	1.96

Figure 14. 49R_1.TXT file that holds the output voltage values (v), timestamps (ts), and time change (t).

2.6.3 Post Processing

The microSD card is removed from the device, inserted into the adapter, and inserted into the computer. The post-processing executable is opened and requires a directory upload. The user uploads the SD card directory, which may be named differently depending on operating system used (Windows vs. MacOS). This directory contains a “RAW_DATA” folder, “RESTING.TXT”, and “INIT.TXT”. The program runs the data analysis, and outputs four main files: “post_processing.txt,” “events.txt,” “events_processed.txt” and “final_outputs.txt.” The first three files listed have the corresponding raw data file name attached to the front of the name, for example for the raw data file “R9R_1.TXT”, the output files would be named “49R_1_post_processing.txt”, “49R_0_events.txt”, “49R_0_events_processed.txt”, and “final_outputs.txt.” Every raw data file has its own corresponding three output files, while there is only one “final_outputs.txt”. All these files are outputted in a folder titled with the patient name that’s typed into the program. The contents of each of these output files are explained in the sections below.

2.6.3.1 49R_0_post_processing.txt

The FlexiCapture system is designed to convert the output voltage into flex sensor resistance, and then into bend angles. The resistance is calculated from R1, the output voltage (Vout), and

the supply voltage (V_{cc}) and knowing the current is the same through both resistors because they are in series.

$$FLEX = \frac{R1 * V_{out}}{V_{cc} - V_{out}}$$

Eq. 3

Because the flex sensor's change in resistance is linear as it bends, the bend angles can be calculated using a linear interpolation from the preloaded 0° and 90° resistance values on the "INIT.TXT" file on the microSD card (Figure 15). "INIT.TXT" will be preloaded by the manufacturer (MetaCapture, in this case) because each sensor has different starting resistance values, so the FlexiCapture needs to be calibrated to its own sensor before being distributed to the clinicians.

23.62
49.34

Figure 15 - "INIT.TXT" file 0° and 90° resistance values, respectively

Because the output voltage is recorded every 25 milliseconds, the flex sensor resistance and the bend angles are also calculated every 25 milliseconds. This detail allows the angular velocity to be calculated by examining the change in angle over time in degrees/second.

$$\omega = \frac{\theta_2 - \theta_1}{t_2 - t_1}$$

Eq. 4

This calculation gives the clinician feedback on how fast the patients are able to move their hands and provides a more complete picture of their range of motion as opposed to just reporting bend angles.

ts	t	v	θ	ω
20:28:8	20639	2.44	22.75	0.0
20:28:8	20666	2.45	24.67	71.11
20:28:8	20693	2.45	24.67	0.0
20:28:8	20720	2.45	24.67	0.0
20:28:8	20747	2.45	24.67	0.0
20:28:8	20774	2.44	22.75	-71.11
20:28:8	20801	2.44	22.75	0.0
20:28:8	20828	2.43	20.89	-68.89
20:28:8	20855	2.43	20.89	0.0
20:28:8	20882	2.43	20.89	0.0
20:28:8	20909	2.43	20.89	0.0
20:28:9	20936	2.43	20.89	0.0
20:28:9	20963	2.44	22.75	68.89
20:28:9	20990	2.44	22.75	0.0
20:28:9	21017	2.45	24.67	71.11
20:28:9	21044	2.46	26.62	72.22
20:28:9	21071	2.46	26.62	0.0
20:28:9	21098	2.46	26.62	0.0
20:28:9	21125	2.45	24.67	-72.22
20:28:9	21152	2.44	22.75	-71.11
20:28:9	21179	2.43	20.89	-68.89
20:28:9	21206	2.43	20.89	0.0
20:28:9	21233	2.42	19.06	-67.78
20:28:9	21260	2.42	19.06	0.0
20:28:9	21287	2.42	19.06	0.0
20:28:9	21314	2.43	20.89	67.78
20:28:9	21341	2.44	22.75	68.89
20:28:9	21368	2.45	24.67	71.11
20:28:9	21395	2.47	28.63	146.67
20:28:9	21422	2.48	30.68	75.93

Figure 16. “49R_0_post_processing.txt” with calculated bend angles and angular velocities.

2.6.3.2 49R_0_events.txt

The current gold standard for objective finger bending measurements is $\pm 10^\circ$ by use of goniometers. The FlexiCapture is designed to cut that error in half, determining finger events by a bend angle greater than 5° . This threshold improves the gold standard while still filtering tiny movements like finger twitches. Using this threshold, the post-processing script extracts every line from “49R_0_post_processing.txt” with a bend angle higher than 5° and sends it to “49R_0_events.txt”, with each event separated by an empty line.

ts	t	v	θ	ω
20:28:13	24934	2.52	39.42	0.0
20:28:13	24961	2.52	39.42	0.0
20:28:13	24988	2.52	39.42	0.0
20:28:13	25015	2.51	37.15	-84.07
20:28:13	25042	2.5	34.94	-81.85
20:28:13	25069	2.48	30.68	-157.78
20:28:13	25096	2.45	24.67	-222.59
20:28:13	25123	2.42	19.06	-207.78
20:28:13	25150	2.38	12.15	-255.93
20:28:13	25177	2.34	5.82	-234.44
20:28:13	25555	2.35	7.36	272.59
20:28:13	25582	2.41	17.28	367.41
20:28:13	25609	2.46	26.62	345.93
20:28:13	25636	2.51	37.15	390.0
20:28:13	25663	2.55	46.59	349.63
20:28:13	25690	2.56	49.11	93.33
20:28:13	25717	2.57	51.7	95.93
20:28:13	25744	2.57	51.7	0.0
20:28:13	25771	2.56	49.11	-95.93
20:28:13	25798	2.55	46.59	-93.33
20:28:13	25825	2.54	44.14	-90.74
20:28:13	25852	2.51	37.15	-258.89
20:28:13	25879	2.47	28.63	-315.56
20:28:13	25906	2.43	20.89	-286.67
20:28:14	25933	2.39	13.82	-261.85
20:28:14	25960	2.35	7.36	-239.26
20:28:14	25987	2.34	5.82	-57.04
20:28:15	26934	2.34	5.82	163.33
20:28:15	26961	2.37	10.52	174.07
20:28:15	26988	2.38	12.15	60.37
20:28:15	27015	2.39	13.82	61.85
20:28:15	27042	2.39	13.82	0.0

Figure 17. “49R_0_events.txt” with events separated by empty lines.

2.6.3.3 49R_0_events_processed.txt

From “49R_0_events.txt”, the post processing script determines the starting and ending timestamps, total time, max bend angle, and average angular velocity for each event and outputs them to “49R_0_events_processed.txt” in chronological order.

Start Time	End Time	Time(s)	Max θ	Avg ω
20:28:1	20:28:13	11.75	46.59	-0.01
20:28:13	20:28:14	0.43	51.7	12.67
20:28:15	20:28:18	3.05	34.94	3.68
20:28:19	20:28:20	1.43	28.63	3.02
20:28:22	20:28:39	17.26	34.94	-0.15
20:28:49	20:28:50	0.94	19.06	1.54
20:28:50	20:28:50	0.27	10.52	5.05
20:28:51	20:28:52	0.78	24.67	3.75
20:28:52	20:28:52	0.22	13.82	12.22
20:28:53	20:28:53	0.32	13.82	8.46
20:28:53	20:28:55	1.24	26.62	5.29
20:28:55	20:28:55	0.54	7.36	2.64
20:28:56	20:28:56	0.51	8.92	2.77
20:28:56	20:29:47	50.36	82.09	0.03
20:29:47	20:29:48	0.24	39.42	35.18
20:29:48	20:29:48	0.11	12.15	22.00
20:29:50	20:29:50	0.19	10.52	13.74
20:29:50	20:29:50	0.59	39.42	7.40
20:29:51	20:29:51	0.08	5.82	13.89
20:29:56	20:29:58	1.86	26.62	0.79
20:29:59	20:30:6	6.74	22.75	0.85
20:30:7	20:30:7	0.68	17.28	4.33
20:30:10	20:30:10	0.05	5.82	18.52
20:30:10	20:30:11	0.46	17.28	9.07
20:30:11	20:30:11	0.27	19.06	10.00
20:30:11	20:30:12	0.32	12.15	4.27
20:30:13	20:30:13	0.27	10.52	10.23
20:30:13	20:30:15	1.7	49.11	1.71
20:30:16	20:30:17	0.76	26.62	-3.73
20:30:17	20:30:18	1.19	46.59	1.23
20:30:19	20:30:20	0.54	12.15	2.64
20:30:21	20:30:23	1.54	28.63	-0.07

Figure 18. “49R_0_events_processed.txt” with the calculations for each event

2.6.3.4 final_outputs.txt

The post processing executable takes all the “XXR_X_events_processed.txt” files from all the days and calculates the total event time, average event time, average max bend angle, and average angular velocity and outputs them to “final_outputs.txt”.

```
Total Event Time (Hours) = 0.082
Average Duration (sec) = 2.97
Average_max_angle (degrees) = 19.2
Average-angular_velocity (degrees/sec) = 5.96
```

Figure 19. “final_outputs.txt” with all the final outputs and their corresponding units.

3.0 Engineering Analysis

To determine whether the design is optimal, a series of quantitative analyses were conducted. First, a theoretical analysis using the governing equations defining current draw in a circuit was used to validate the battery selection that could supply the proper current over the device’s use. Next, SolidWorks bending and drop test simulations were run to evaluate the material selection and structural integrity of the device. Finally, functional mock-up testing with human subjects was conducted to evaluate the usability of the device.

3.1 Total Current Draw for Battery Selection

Battery capacity is rated on milliamp hours (mAh). If a battery is rated for 500 mAh, that means it can supply 500 mA of current for 1 hour, 100 mAh of current for 5 hours, etc. To determine the

needed battery capacity, the total current draw was calculated and determined to be 5.57 mA as seen the Table 4 below. In order to sustain this current for 18 hours, the battery needs 100 mAh (5.57 mA * 18 hrs) of current capacity. Employing a safety factor of 3 and rounding up to closest compatible battery capacity lead us to the 500 mAh battery from TinyCircuits. Using Eq.1, Eq. 2, the current draw of the resistors and the LEDs can be found using the battery voltage and the equivalent resistance.

Table 4. Total Current Draw

Systems	Current Draw (mA)	Quantity	Total (mA)
Voltage Divider	3.7V (10kΩ+23.6kΩ) = 0.1	1	0.11
LED + 10Ω Resistor	3.7/10 = 0.37	3/360*	3.06
TinyZero Processor Board ³⁸	1.2	1	1.2
Real Time Clock TinyShield	0.0006	1	0.0006
MicroSD TinyShield ³⁷	1.2	1	1.2
Total Current Draw			5.57

This table includes the current draw of the electric components of the device. The total current draw of the device is 5.57 mA.

*The LED is only on for ten seconds during calibration. If the device is calibrated three times per hour, it only draws 3.06 mA of current per hour.

3.2 Material Selection and Bend Simulation

Patients that undergo brachial plexus repair surgery are typically left with very minimal force generating capacity in their MCP joint, which originates from the transplanted gracilis muscle. Despite the existence of various joint range of motion measuring technologies, this specific case of injury is limited to devices that have very little motion resistance due to the patient's lack of force generation. These factors drove the decision to conduct a static load test on the flex sensor housing.

The purpose of this test was to apply very minute loads in accordance with patient's capabilities to bend the device to test if it would flex to a point in which the flex sensor housed inside would be able to bend and acquire data. This test was also run to determine whether the device would be too stiff and resist the movement of the fingers. This test measured stress (Eq. 5), strain (Eq. 6), and displacement (Eq. 7):

$$\sigma = F/A$$

Eq.5

$$\varepsilon = \frac{\Delta L}{L}$$

Eq. 6

$$\Delta x = \frac{F}{k}$$

Eq. 7

(F = force, A = area, ε = strain, ΔL = change in length, L = length, k = stiffness, Δx = displacement)

SolidWorks contains a simulation feature where the materials, forces, and geometries can be altered to create representative testing scenarios. For this test the material properties for Dragonskin 10A, and PLA were inputted as custom materials in SolidWorks (Table 5). The materials were assumed to be linearly elastic isotropic for the simulations.

Table 5. Material Properties

	DragonSkin	PLA
Yield Strength (MPa)	3.25	7.0
Elastic Modulus (GPA)	0.079	0.0035
Poisson's Ratio	0.50	0.36
Material Density (kg/m^3)	1250	1236

The force was exerted in a downward direction and centered on the loops in which the hook and loop fastener is threaded through. Two tests with forces of 1N and 2N were run with the fixed geometry remaining the same for each. The geometry was fixed at both the wrist housing/flex sensor housing interface and the point right above the MCP joint to simulate the resultant fulcrum.

Table 6. Bending Tests Results

Force (N)	Max Stress (MPa)	Max Displacement (mm)
1	2.9	5.2
2	1.5	10

The results from this test gave us values of displacement and stress of the system. These displacements show that even under very small forces, the flex sensor housing can bend without hindering finger flexion. Therefore the device should function well with the current materials selected. These stresses are all below the yield strength for the material and therefore it can be concluded that the device will not plastically deform due to bending. It should be noted that the stresses and strains were centered above the MCP fixation point because that is where the bending due to the finger's downward force occurred.

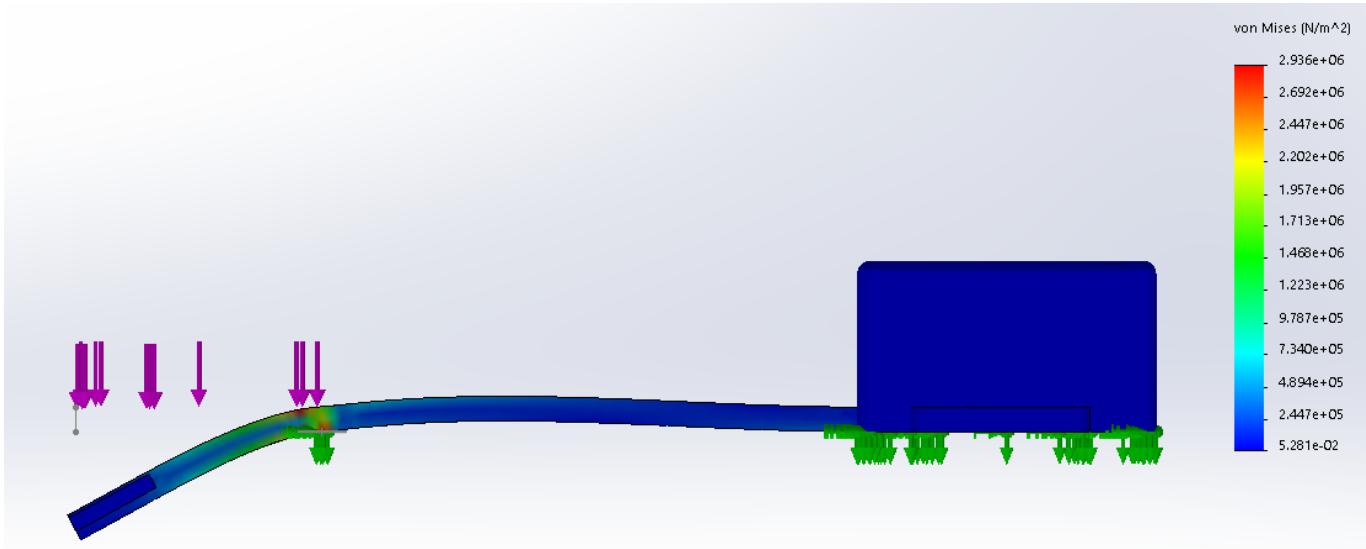


Figure 20. At 2N, max stress is below the yield strength, so there is no plastic deformation.

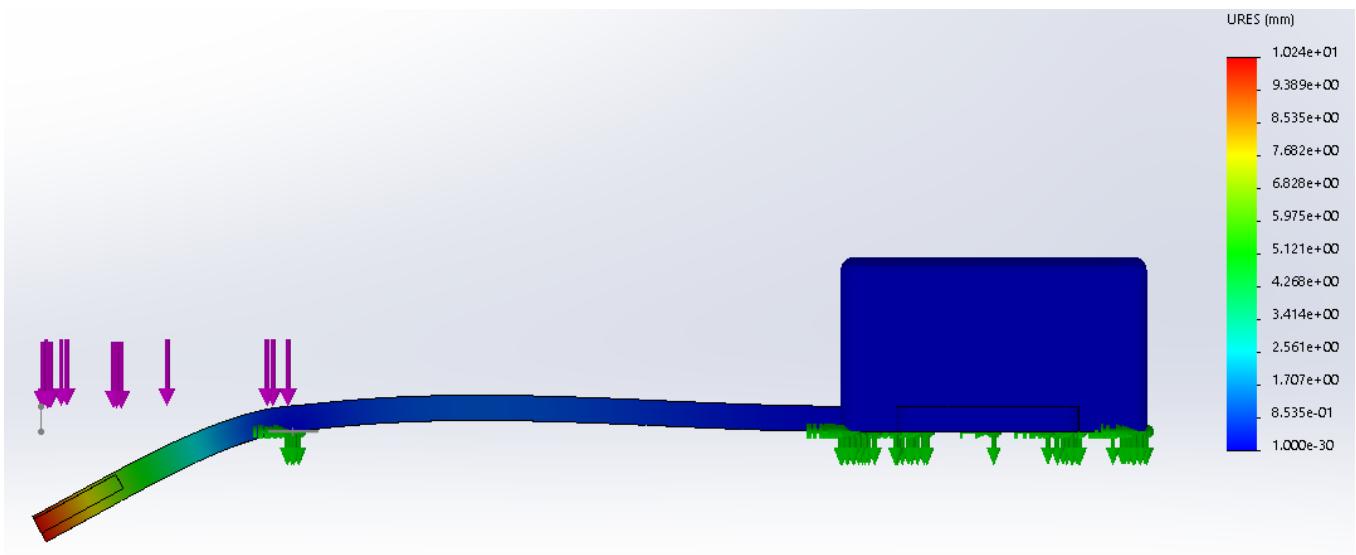


Figure 21. At 2N, the resultant displacement

The remaining plots for 1 N are located in Appendix C.

3.3 Drop Simulation

The second engineering analysis conducted on the device was a drop test on two different corners of the device to maximize the possible stresses. The max stresses are compared to the Young's modulus to see how the materials deform and whether they protect the circuit components. The governing equations for this test suite are the same as defined in the static load test for stress and strain, along with the equation

$$F = ma + cv + kx \quad (\text{Eq. 8})$$

(m=mass, a = acceleration, c = damping constant, v = velocity, k = stiffness, x = displacement, F = external forces). For the settings in this test, the point of contact, the height at which to drop the device, and the material properties were defined.

Table 7. Drop Test Results

Drop Test	Max Stress(MPa)	Max Strain
1) Flex Sensor Housing Corners (Dragonskin 10A)	0.35	0.014
2) Bottom of Wrist Housing Corner (PLA)	4.62E-10	1.6E-6

The max stress for Dragonskin corners fell well below its yield strength of 4.63 MPa (Figure 22). In Drop Test 2, The PLA showed a minuscule max stress and strain most likely due to Dragonskin dissipating the stress (Figure 23). In both tests, the max stresses do not surpass the yield strength, meaning no plastic deformation occurred. The FlexiCapture can be dropped over and over again and the materials will protect the inside components.

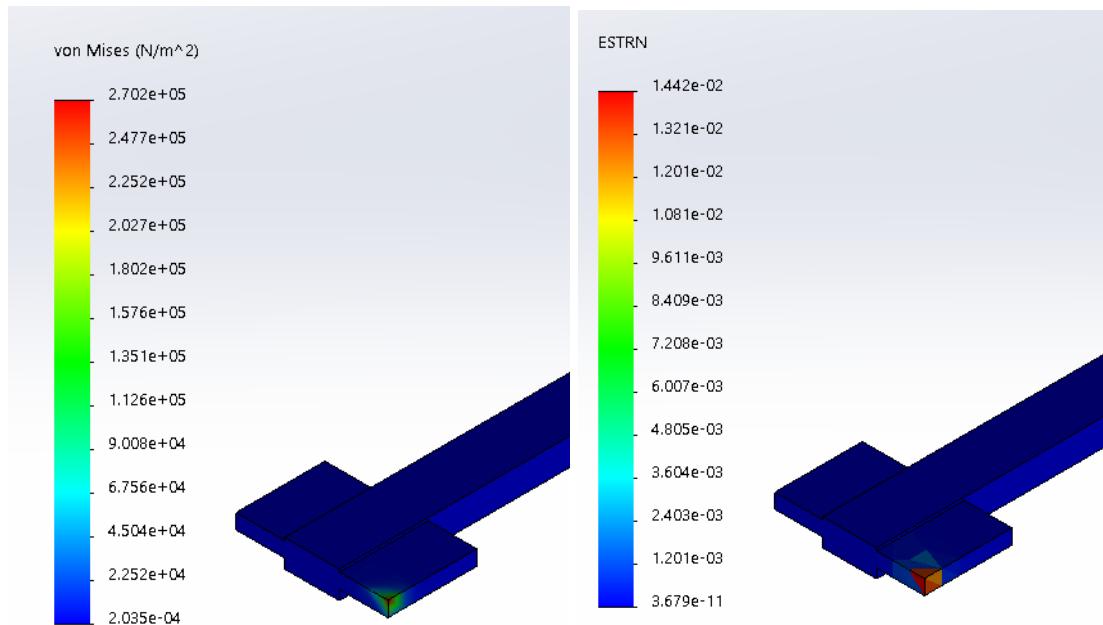


Figure 22. Drop Test 1 Finger Portion: Left) Stress results; Right) Strain results - No plastic deformation

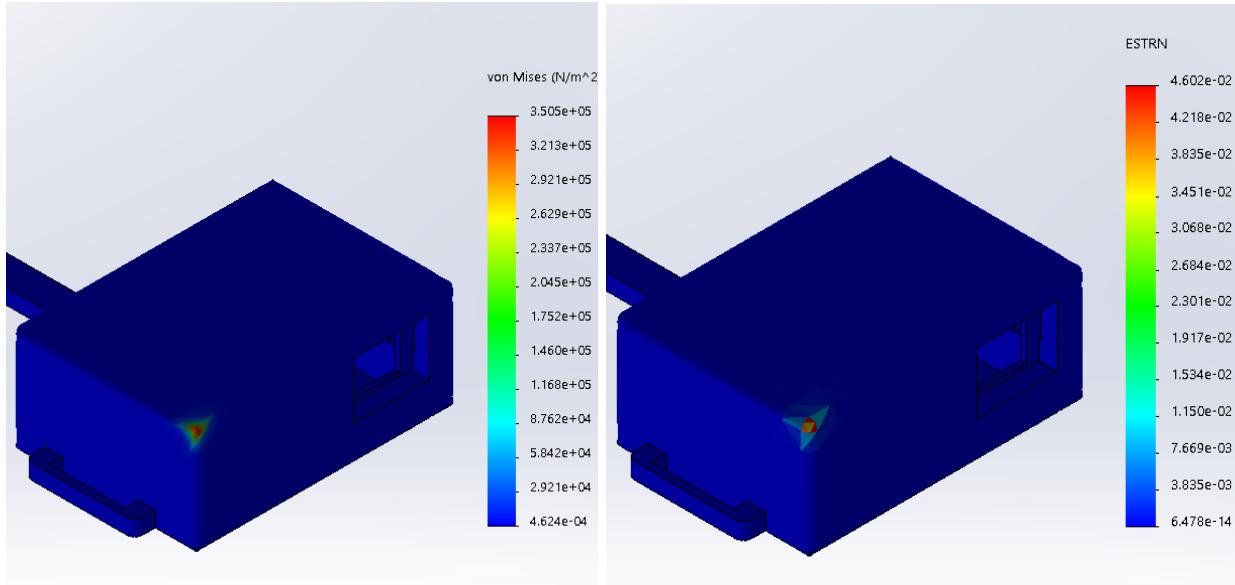


Figure 23. Drop Test 2 Whole Housing - Left) Stress results top portion of wrist housing; Right) Strain results top portion of wrist housing - No plastic deformation.

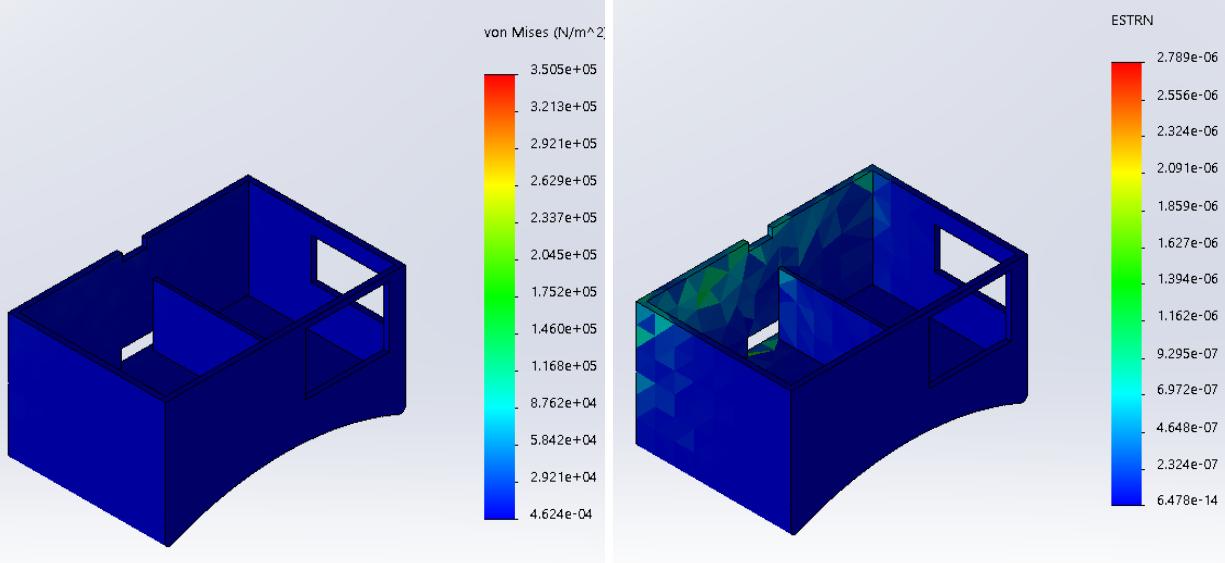


Figure 24. Drop Test 2: Left) Stress distribution on bottom portion of wrist housing; Right) Strain distribution bottom of wrist housing - No plastic deformation.

3.4 Data storage

We calculated the maximum storage needed for recording data for 18 hours for 5 days.

Decimals take up to eight bytes, which yields a total of 24 bytes per line for three columns of data. If data is recorded every 25 ms, 18 hours of data yields 0.06 GB of data storage needed.

$$24 \text{ bytes} * 18 \frac{\text{hours}}{\text{day}} * 60 \frac{\text{min}}{\text{hour}} * 60 \frac{\text{sec}}{\text{min}} * 1000 \frac{\text{ms}}{\text{sec}} * \frac{1}{25\text{ms}} = 0.06 \text{ GB}$$

Eq. 8

MicroSD cards come in multiple GB amounts, so any of these should suffice.

4.0 Failure Modes and Risk Analysis

After analyzing the top down hazards and bottom up task analysis, a DFMEA was generated (Appendix D). The hazards were broken down according to tasks and subtasks. Corresponding ratings of severity, occurrence, and detectability were assessed on a scale of 1-5, with 1 being the lowest severity, occurrence, and detectability. Risk priority number (RPN) was calculated by multiplying these ratings. The top three failure modes with the highest RPN rating are included in Figure 25.

One of the major failure modes, under the sub task of “pick up or hold objects”, is that the device limits the ability to handle objects. The hazard can be caused by a bulky and obtrusive device that restrains finger bending and leads to inaccurate data, discomfort, and failure of device functionality. Based on usability testing with our beta prototype, the occurrence rating is 4 due to the large size of circuit boards. The severity is 3 due to the potential finger motion restriction. The final RPN is 24. In order to reduce the occurrence rating, the corrective measure is to replace the protoboards with customized PCB boards to minimize the size of the circuitry and thus reduce the size of the housing. This could lower the occurrence rating to 2 and the new RPN becomes 12.

Another primary hazard is the failure to calibrate the device, caused by improper placement and size/fitting. This could result in inaccurate data. Since the device is not waterproof, the patients will need to put the device on and off multiple times during the day. Calibration is required every time patient put on the device for proper data analysis, which causes the high occurrence rating of 4. Failure to calibrate could be difficult to detect without checking the data, resulting in the detectability rating of 3. In order to lower both occurrence and detectability, the corrective measure is to display output in real time and ensure that the LED light on the device indicates correct calibration, for example the light could shine when the calibration values are within a specified range. This could lower both occurrence to 1 and detection to 2, and lower the RPN to 4.

The third failure mode is electric burning while the patient is performing daily tasks. This could be caused by circuit board overloads or short circuits, resulting in skin damage, pain, and incorrect data. After performing the electric current test on the alpha prototype, the maximum current through the LED light was higher than 1/3mA, which could cause electrocution. Due to potential physical damages to patients, the severity rating is 4. The current RPN value is 16. In order to minimize the RPN value, a different LED was implemented that requires less power to reduce the current. Also, the corrective measure is to lower the occurrence by adding a fuse to the block circuit in the event of circuit overload. This would reduce the occurrence to 1, giving a final RPN of 8.

Task	Subtask	Hazard	Causes	Harm	Corrective Measures/ Risk Controls			New Severity (1-5)	New Occurrence (1-5)	New Detection (1-5)	New Risk Priority Number (RPN)		
					Severity (1-5)	Occurrence (1-5)	Detectability (1-5)						
Patient returns home and goes about their daily life	Pick up or hold objects (fork, drink etc.)	Device design limits ability to handle objects	Device is bulky or obtrusive; The materials/connect ions restrain finger bending	Affects ability to perform tasks(won't use hand); device fails to provide accurate data; discomfort; May hit device on objects	3	4	2	24	Replace protoboards with customized PCB boards to minimize the size of the circuitry to reduce the dimension of wrist housing. Make the device in different sizes so as to fit the hands of different patients	3	2	2	12
Doctor puts device on patient	Calibrate if necessary	Fail to calibrate the device	Improper placement of device; improper size/fitting	Device fails to calibrate and obtain resting values results in inaccurate data	2	4	3	24	Display output in doctor's office in real time to ensure proper calibration. Have LEDs on the device that activate to show correct calibration as it is used.	2	1	2	4
Patient returns home and goes about their daily life	Perform daily tasks	Electric burning	Circuit board overloads/short circuits to skin	Skin damage; Pain; Incorrect data; Emotional distress	4	2	2	16	Add a fuse to block circuit in the event of a circuit overload	4	1	2	8

21 >= red 11-20= yellow 0-10 = green

Figure 25. Top three failure modes based on RPN ratings.

5.0 Verification/Validation

In order to verify and validate our device, we ran functional, safety, and usability tests to determine whether the device successfully tracks hand usage. These tests were developed to test the device in accordance with the design requirements.

5.1 Functionality Tests

5.1.1 Bend Angle Accuracy Test

The purpose of the bend angle accuracy test was to determine if the extrapolated bend angles changed whether the sensor was inside or outside the silicone. The sensor's function needed to be consistent when put inside our device. We taped the flex sensor to a fixed servo motor that has defined angles between 0° and 180° with an error of 5°, which was accounted for through servo calibration.



Figure 26. : Test bed setup for bend angle accuracy test. This picture shows the sensor inside the silicone, while the same setup was done for the sensor outside the silicone.

The servo bent the sensor at 5 degree increments and at each increment, the flex sensor system outputted a moving average of the voltage at each of those points. 17 trials were conducted both with the sensor alone and the sensor in silicone. At each increment, the average measured angle across all trials and the standard deviation was recorded (Figure 27). The data for the sensor inside and outside silicone can be visualized in the scatter plot below, with the standard deviations represented by vertical bars.

As evident by the scatter plot, there is significant overlap in both data sets. The data sets were compared with an unpaired two-tailed t-test (two-sample unequal variance), which resulted in a p-value of 0.3. This is greater than 0.05, which means the test could not determine any significant changes in the angles inside and outside the Dragonskin. It is important to note that there were noticeable difference in angles less than 30°. This is suspected to be from the quality of the sensor, and not our device or test bed set-up. This sensor is believed to be used for more of an ON-OFF based on large voltage changes rather than detecting fine bend movements, and therefore it struggled with consistency in the smaller angles.

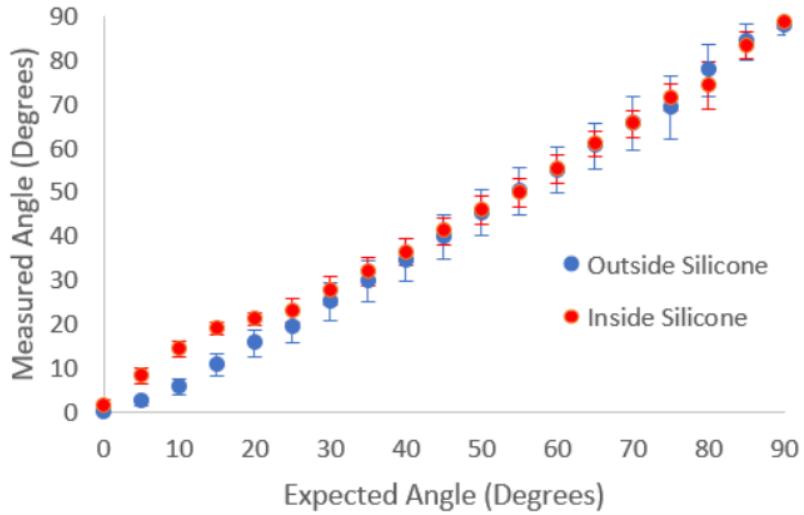


Figure 27 - Bend angle accuracy test results outside and inside Dragonskin 10. Unpaired two tailed t-tests resulted in a p - value of 0.30, showing no significant change between sensor inside or outside silicone.

5.1.2 Event Test and Time Accuracy Test

The event test and time accuracy test were performed to determine how well the device records the number of events and duration of motion to validate whether the device accurately records MCP motion. For both tests, the error must be smaller than 20% of total activity to pass. The same test bed was used as the bend angle accuracy test, with servo motor and Arduino (Figure 26). The motor gradually bent along to 6°, 8°, and 10° for 5 trials. The servo held the angle for 0.5 seconds and then returned to 0°. The data was recorded on the microSD card. The predetermined 5° threshold was applied to determine the events and the duration of the events

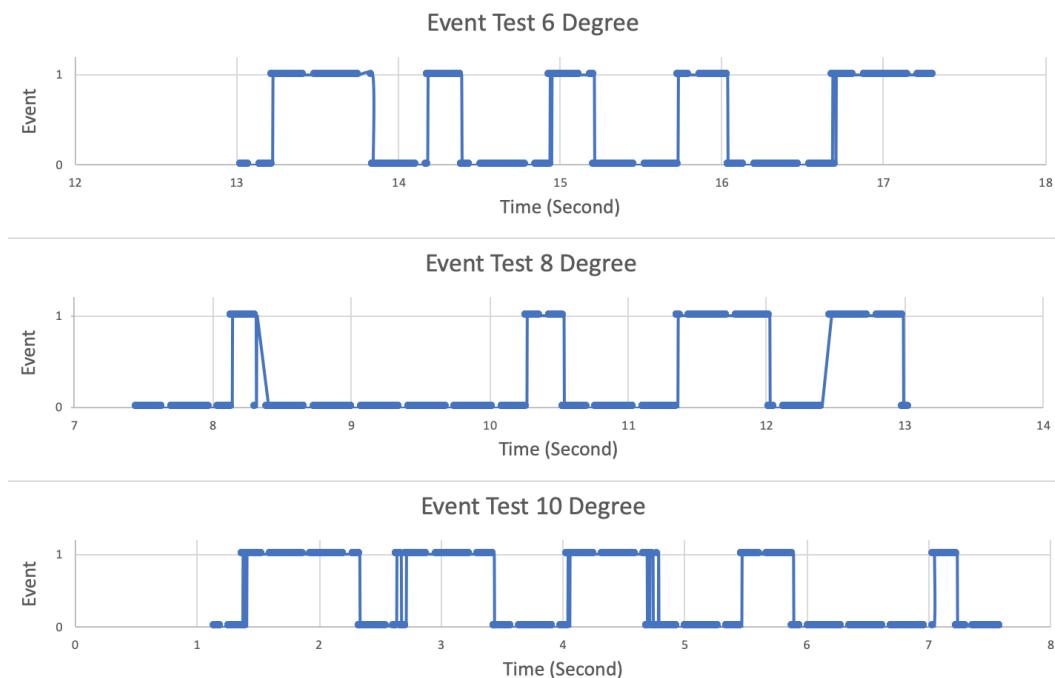


Figure 28. Event Tests with 6°, 8°, and 10° bending. The device recorded 14/15 events, but did not record them for the exact 0.5 seconds. The events were often cut short.

The device successfully recorded all 5 events for 6° and 10°, but missed one event in the 8° testing (Figure 28). The event recording error was 6.6%, less than the specified 20%. However, the time duration recorded was very inconsistent with values varying from 0.2 to 1.0 second, and the error was much greater than 20%. Therefore, our device did not pass the time duration accuracy test.

5.1.3 Shock Test

The shock test was performed to validate that the device will still function when dropped on the floor. According to Standard ISO 1413 for a shock-resistant watch, the device was dropped from 1 meter onto a hardwood floor with the shock directed parallel and perpendicular to the plane of the watch casing. We ran the bend angle accuracy test and the event and time accuracy test before and after dropping the device and a unpaired two tailed t-test to determine if there were significant changes in the corresponding outputs after being dropped. In order to pass this test, no significant changes should be detected, or a p - value should be greater than 0.05.

The device passed the bend angle accuracy portion of the shock test. 6 trials following the same protocol described above for bend angle accuracy test were conducted before dropping, and 7 trials were conducted after dropping (Figure 29). A two-sample unequal variance t-test (two-tailed distribution) was conducted between the two data sets and the p value = 0.62. This is much greater than 0.05 and indicates that there is no significant difference between the two data sets, which affirms that the device measured bend angle the same before and after dropping.

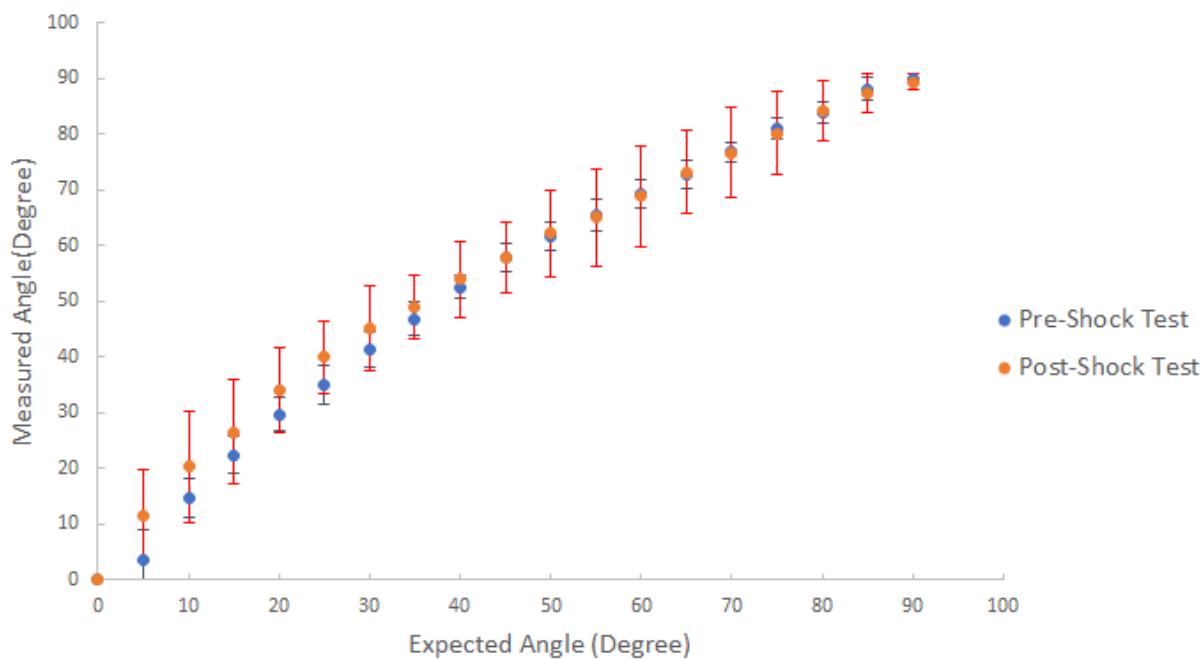


Figure 29. Accuracy testing before (Pre-Shock Test) and after (Post-Shock Test) dropping the device. The unpaired two tailed t-test resulted in a p - value of 0.62. This is much greater than 0.05, so no significant changes were detected before and after the drop.

For event and accuracy testing, the device failed this test. Prior to dropping the device, the device detected 14 out of 15 events (see data above under Section 5.1.3). After dropping the device, the device detected 10/15 events, therefore the device failed to detect at least 80% of the events (Appendix E). As was consistent with pre-drop data, the times of events were inconsistent and were significantly greater than 20% different from the expected time. At this point, we cannot conclude that dropping the device caused the device's ability to detect events to have failed, only that there was some correlation. The device's ability to detect events is ultimately a function of the sensor's sensitivity to change resistance (and subsequently output voltage) with bending. Based on testing, the sensor seems to inherently have poor sensitivity, although other factors could also influence the results. For post-drop event testing, the servo was operating at a faster speed, approximately twice as fast as during the pre-drop testing. The sensor might not have been sensitive enough to detect events at this speed. Also, the Dragonskin surrounding the flex sensor was thicker (4-5mm) for this particular prototype, which may have prevented the sensor from bending adequately at small angles if the sensor base wasn't fixed, especially when the servo was moving faster. In this case, the sensor would simply shift at the base while remaining unbent.

5.1.4 Location Test

The purpose of this test was to determine how the sensor outputs changed if it was bent at different points. We wanted the device to have a painted section to show the patients where the device should be replaced with respect to knuckles. The painted box will show the range that at least part of it should be aligned with the middle of the knuckle. The voltage output needed to stay constant in a certain range on the sensor to dictate the size of the painted section on the device. We measured the device's voltage outputs when we bent it every centimeter from 4.5 - 8.5 cm and compared the outputs (Table 10).

Table 9 - Location Test Results

Length (cm)	45° (V)	90° (V)
4.5	3.49	3.79
5.5	3.50	3.86
6.5	3.53	3.89
7.5	3.53	3.85
8.5	3.49	3.76

The voltage change increases the farther you bend the sensor away from the center of 6.5 cm. A one cm change from 6.5 cm in either direction showed little voltage change, so a safety factor of two results in a one cm box painted on the device. The patient should align the box with the middle of their knuckles to provide bending point consistency. If they can't align their knuckles with the box, they should use a different size of the device.

5.1.5 Battery Test

The battery test was performed to validate the design requirement of power lasts 18 hours without charge. During the test, the device was initially fully charged and then worn for 18 hours. The battery of the device was successfully able to provide power for at least 18 hours of use without charge. We determined this by checking the timestamps logged on the SD card, and saw that the device logged data correctly for 20 hours 27 minutes. The LED light was on during a large portion of the test since the start, even though it's only supposed to turn on when the battery is low power. This could either indicate that the battery can still last a significant amount of time when on low power, contrary to what we expected given the properties of lithium ion batteries, or our method for reading in battery voltage level is incorrect.

5.1.6 Size and Weight Test

The size and weight test was performed to ensure that the device would fit an average hand and not be too heavy as to hinder daily use. As per the design requirements, this test would be successful if the weight was less than 30g on the finger, 80g on the wrist, less than 17.9 cm long on the hand and less than 6.8 cm wide on the wrist. The device was cut at the wrist and finger and weighed separately. The device was also measured using calipers along with the length, width and circumference of the wrist and finger.

The device passed the size test. For the current prototype, the measurements are listed in the table below.

Table 10 - Size and Weight Measurements

Specifications	Measurements
Weight< 30g on finger	6g
Weight<80g on wrist	79g
hand length of 15.8cm < Size > hand length of 17.9cm	Flex sensor housing 13.85cm
wrist width 5.4cm< Size > wrist width 6.8cm	Wrist housing: length 6.48 cm, width 4.26 cm

The device comes in small, medium and large sizes for flex sensor housing to with lengths of 12.5 cm, 14 cm and 15.5 cm, respectively (Appendix F).

5.1.7 Capacitive Sensor Test

The purpose of this test was to examine the capacitive sensors response to possible materials the device could come into contact with. The threshold needs to be set to where the calibration initiates when the device is put on the skin, but not other materials such as countertops, tables, etc. The floor was counted as the control group as it was assumed to be the most common

resting place for the device. Each material was tested twice and the average capacitance range was recorded.

Table 11 - Capacitive Sensor Measurements

Material/Object	Absolute Capacitance
Floor	1900 - 2400
Wrist	5850 - 7500
On top of wrist and shirt	4800 - 5900
Desk with miscellaneous items	1200-1600
Laptop Keyboard	1300 - 2350
Laptop Charger	37000 - 70000
Cell phone	1300 - 2350
On hand with glove	1200 - 1600

The results from this test dictate what the threshold for capacitance should be. Based on these results, the threshold should be around 5200, but further testing is needed to determine an accurate threshold. It is worth noting that the laptop charger caused a huge rise in capacitance, and this is used to dictate the user manual instructions, telling patients not to set it near the chargers.

5.2 Safety Tests

5.2.1 Temperature Test

The temperature test was performed to validate the design requirement that the device does not cause burn or generate a lot of heat emission. The test was conducted to assess the temperature emitted by the device to ensure that the maximum temperature of the housing in contact with the skin is less than 92.3 °F. The device was turned on and worn by the test subject for 18 hours. An infrared thermometer was used to measure the temperature at the bottom housing where the device was in contact with the skin every five hours.

The value of temperature every five hours was stable during the test without significant increase or decrease. The average value of temperature was 70.3 ± 1.1 °F (21.3 ± 0.6 °C), which is lower than the specification of 92.3°F. Thus, the temperature requirement is fulfilled.

5.2.2 Current Test

The current of the system was measured using a multimeter. The multimeter leads were placed in contact with the resistor to obtain the voltage drop and the resistance value to calculate the current. Five measurements of the voltage were averaged, and then divided by resistance using

Ohm's law (Eq. 1) to obtain the current value. The current was calculated to be 0.12mA, much less than the $\frac{1}{3}$ mA from the IEC standard 60601, therefore this test was successful.

5.3 Usability Test

All usability tests were completed with a lower amount of test subjects due to time constraints. The subject pool should be expanded for future testing

5.3.1 Patient Training Test

Six subjects were given a set of written instructions and time per step, total time and the type of error that occurred were recorded. Some errors observed included difficulty finding the power switch, difficulty knowing what side goes against the hand on the wrist portion, and doing steps out of order. The average total time was 2 min 73 sec, which is within our design requirement specification. However, we did encounter one critical errors, which is not within the error specification of 0%. The subject wrapped the finger strap around one finger instead of two. We will use the feedback received and errors noted to improve the instructions. One specific change we will be making to the instructions is in the wording of the first step. The wording will be changed to "wrap velcro around middle and ring finger such that the colored horizontal line aligns with your big knuckles". We also received feedback that there was difficulty plugging the USB into the charging port due to the circuitry moving. To resolve this issue we are recommend that circuit elements be fixed (see 2.5).

5.3.2 User Interface Test

Four subjects were given a set of written instructions and time per step, total time and the type of error that occurred were recorded. Subjects were tested 3 days to a week later to observe improvement after one trial. The average time to conduct data processing was 3 minutes 22 seconds. We encountered 0% errors after the subjects waited to redo the test. All the subjects reported that instructions could be made more explicit, and labels could be made more obvious on the application. The step that took the longest was the computer opening up the data processing app, but the reason for this long loading time is yet to be determined and is not dependent upon the user. Uploading the SD card data into the application was also a bottleneck as instructions were unclear on what folder to upload.

5.3.3 Two hour wear test

During the two hour wear test, four usability tests were performed, including water safety rules, comfort, and obtrusiveness. Subjects wore the device for two hours and performed daily activities. After the test, subjects' feedback and ratings were recorded. All subjects took off the device when in contact with water and thus our device passed the water safety test. The average comfort rating was 5.8/10, with 10 being the most comfortable. The obtrusiveness is 5.6/10, because the device felt bulky and large to some subjects. Therefore, we passed the water safety test, but did not pass for general comfort or obtrusiveness. Obtrusiveness was most likely due to the subjects having full range of motion, so when they bend their hand backwards the device bows and is uncomfortable. Also, subjects reported that the wrist housing was particularly uncomfortable and scratched the skin. This is likely because the wrist housing bottom was rough which was caused by the inconsistency and imperfections of the 3D printer. These tests will need to be continued with patients with a BPI. These test results will be used to validate DFMEA hazard analysis ratings.

5.3.4 Irritation Test

Six subjects each wore the device for two hours during their daily living activities. The device application site was checked for dryness and/or erythema at 15 minutes, 30 minutes, 1 hour and 2 hours. If obvious irritation was present at any given check, then the test was stopped. The success criteria was that the device would cause less than or equal irritation to an Apple Watch (2nd Generation), which is a common wearable device that we used as a control.

Five out of the six subjects showed obvious signs of irritation such as redness and scratching on the top of the wrist after 30 minutes, while one subject wore the device for the full two hours and experienced no irritation. Therefore, the device failed this test.

Table 12. Summary of Verification/Validation Tests and Results - A summary of the results of the verification/validation tests and their corresponding design specifications

Requirements- Functionality	Design Specifications	Test	Pass
Measure range of motion of MCP joint during daily living activities	Measure joint angle from 0 to 90 degrees +/- 5 degrees	Bend Angle	✓
Measure duration of MCP joint in flexion/extension motion during daily living activities	Measure motion longer than 25ms without a change in direction	Accuracy and Location Test	✓
Measurements are accurate for at least 18 hours per day	Error ≤ 20% of daily activity recording repeatedly in conjunction with specification above	Event and Time Accuracy Test	✓ X
Shock-resistant	After falling from 1 meter on hardwood the device is still accurate according to the specification above (2)	Shock Test	X
Duration of use	Device power should be able to last 18 hours per day in a single use without charge	Battery Test	✓
Small (must not interfere with activities)	Hand length: 15.8cm < size > 17.9cm Wrist width: 5.4cm < size > 6.8cm Hand width: 6.9cm < size > 8.2cm Finger circ. 24.1mm	Size Test	✓
Lightweight	<30g for the finger; <80g for the wrist	Weight Test	✓
Requirements- Safety	Design Specifications	Test	Pass
Does not burn or have a lot	< 93.2F	Temperature	✓

of heat emission		Test	
Does not electrocute	Current < 1/3mA	Current Test	✓
Safely interface with hand and fingers	Biocompatible / no harm / irritation	Irritation Test	X
Requirements- Usability	Design Specifications	Test	Pass
Short patient training and initial setup of device time	Training: 5min Setup: 10min with error in tasks < 0%	Patient Training Test	In Progress
Short clinician/Researcher training time	Processing: 30min Training: 15min with error in tasks < 0%	Clinician Training Test	In Progress

6.0 Recommendations

6.1 Circuitry/PCB

The current device uses a series of TinyCircuit boards and reads in voltage and capacitive signals from the flex sensor circuit design. We used 21 gauge solder and 22 gauge wire to connect the flex sensor circuit to the Arduino board through the input/output pins. The flex sensor system was made on a solderable protoboard. We had problems with the wires and solder connections coming loose through handling the circuit and constantly inserting and removing circuit elements from the device. To avoid cumbersome and loose wires, we recommend manufacturing the circuit on a custom Printed Circuit Board (PCB). This will eliminate the unnecessary holes and wires in the protoboard and make the system more robust. Softwares like Eagle or EasyEDA make it easy to design one of these and JLCPCB offers cheap custom PCB orders for \$2 for five boards.³² With a PCB in place this would give the opportunity to make the entire wrist housing smaller and less bulky, however this is contingent on the PCB functioning properly. If the PCB is made properly, the capacitive sensor system and the flex sensor system will interface with the TinyZero system.

6.2 Silicone

In the latest prototype, the Smooth-On Dragonskin 10A silicone was used to ensure that silicone was the correct material for this project. By using this silicone we were able to confirm that the material allowed for adequate flexibility, had minimal bowing and was comfortable on the hand. Through the use of this type of silicone, we confirmed that it reduced the amount of bowing with low resistance when bending. However, it collects a lot of dirt and rips easily. We are therefore recommending the use of a different type of silicone - the Konark Soft Shore A 00-10 silicone, similar to a silicone watch band or soft phone case. This material should be generally cleaner and more durable.³³ Due to the lack of resources to pressurize silicone molds, we were unable to use this silicone in the current prototype. However, with more time and resources we recommend using the pressurized silicone molds which will result in less air bubbles and be more durable and uniform. We are also recommending that the part where the finger strap adheres be changed to a stiffer silicone, such as Shore D 00-8.³³ Right now, the Dragonskin is overlaid on a hard plastic piece to provide rigidness, but the silicone does not adhere to the

plastic well and sometimes rips off. Combining two different silicones can improve the structural integrity.

6.3 Injection Mold

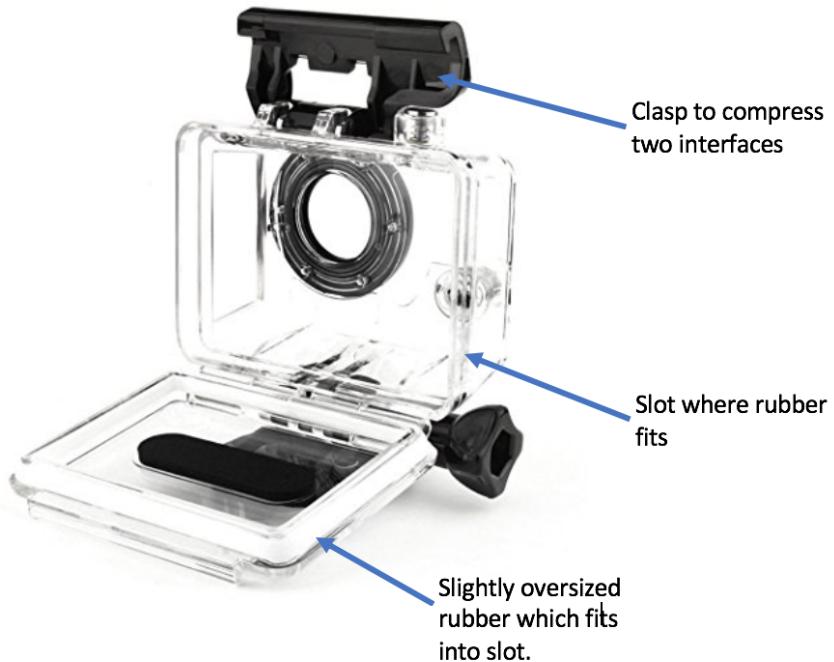
The layers of plastic from 3D printing the device causes grooves and could potentially be uncomfortable and lead to bacterial growth. We recommend injection molding all plastic parts due to the smoothness, reduced bacterial growth and improved comfort. Injection molding is affordable with large quantities compared to 3D printing. Companies such as ProtoLabs offer custom injection molding services.³⁴ In addition, because of tolerance limits with the 3D printer, it is easier to cut out holes in the silicone for the straps and put the holes for access. Ideally, efficient manufacturing process could provide the holes built in to eliminate hand cutting.

6.4 Water Resistance

Another recommendation that we have is to make the device water resistant. This would eliminate water related failure modes during a patient's daily routine. To successfully make the device water resistant the device should be able to be submerged up to one meter of water for 30 minutes according to IP67²⁶.

The first change that needs to be made to allow for water resistance is to the material of the top portion of the housing. We would need the housing that encloses the circuit to be a stiff silicone, which would be fused through the pouring process to a flexible silicone containing the flex sensor over the finger. The stiff silicone would be a Shore D 00-80 silicone, which is similar to hard plastic. This silicone can be cured with the Shore A 00-10 to form one piece with stiff and flexible parts.

The next step is to ensure that the rest of the circuitry is isolated as well. To do that, we would make the bottom and top of the housing the same dimensions and have them meet at an interface. At this interface, there will be a slot on both halves. One will have a rubber insert, one will not. This is very similar to a GoPro camera housing (Figure 30). When the two halves of the housing are tightened together, the rubber compresses into the empty slot to create a watertight seal. The fastening mechanism could be screws, nuts and bolts, or clasps which are commonly used. Additionally, the holes in the device would need to be filled. A latch mechanism would be used for the charging port. Similar to waterproof phone cases, there will be a removable silicone medium firm ShoreA latch that snaps into the charging port covering it (Figure 31).



35

Figure 30. GoPro waterproof casing - Similar technology



36

Figure 31. Example of charging port waterproofing mechanism

6.4.1 Bluetooth

To make our device Bluetooth enabled, we would use the Bluetooth low energy tinyshield which is compatible with our TinyZero processor board.³⁷ This additional tinyshield board uses Bluetooth Low Energy (Bluetooth Smart and Bluetooth 4.1) and draws a low amount of current. Due to this low current draw, Bluetooth would be good for our project which involves long term continuous data logging. Bluetooth would be useful if we wanted to display the data in real time so researchers could monitor their patients. Data could be sent wirelessly from Flexicapture to the user's device. This information would be sent to a private server which the researchers could log in to and view through a website. This would also be helpful when making the device water resistant as it would remove the need for a microSD port making it easier to create water resistance.

6.5 Circuit Immobility

To ensure the circuit boards are safely placed inside the housing, they need to be fixed to minimize the consequences of mechanical shocks. Properly securing the circuit elements will make inserting the charging cable into the charging port easier. Currently, circuit boards can still move around inside the housing, which might damage the electronic components. We recommend applying epoxy glue to the boards so that they secure inside the housing. Moreover, mounting the boards with screws to the housing can also be used to secure the boards. The reason this has not been accomplished for the beta prototype is because we have to be able to constantly change and adapt to new situations and to do that, the circuit needs to be removable at least for our current prototype.

6.6 Proposed Next Steps

6.6.1 Water Resistance Test

A test will be needed to assess whether or not the design can actually function when exposed to water, after implementing the recommendations described above. This test must be in accordance with the IP67 Standard. To ensure the device meets this standard, the device should be placed in an artificial dusty environment for 8 hours and submerged in one meter of water. After running these tests, an accuracy tests should be conducted to ensure the device is functioning properly.

6.6.2 Clinical trials with patients who had brachial plexus reconstruction surgery

The next step is to conduct clinical research studies with patients who had brachial plexus surgery to determine whether our device is effective, safe, and comfortable for daily use. The device would have to be fully validated and verified before being tested on patients. Detailed protocols as well as IRB approval will be completed formally to ensure the study is ethical and safe. During the study, patients will be wearing the device for three days during their daily activities. Accuracy results will be analyzed to determine the efficacy and success of the design, and usability ratings will also be recorded to improve the comfort and satisfaction of wearing the device. These patient clinical trials would be valuable for further development.

7.0 Budget

The total amount of budget for this project is \$1000-1500. The team finished under the budget with a total of \$903.56. The completed itemized lists of budget and bill of materials are included in Appendix A.

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Appendices

Appendix A - Budget and BOM

Budget

Category	Item No.	Material	Unit Price	Quantity	Price	Shipping	Total Price	Source
3D Printing Material	1	Eco-Flex 00-30 Trial Unit 2lbs	\$32.21	1	\$32.21	N/A	\$32.21	Smooth-On
	2	Flexible Filament	\$130	1	\$130	N/A	\$130	MakerBot
	4	Tinyduino Processor Board w/ Lithium Batter	\$19.95	2	\$39.90	N/A	\$39.90	TinyCircuits
	5	MicroSD Tinyshield	\$14.95	2	\$29.90	N/A	\$29.90	TinyCircuits
	6	Lithium Ion Polymer Battery - 3.7V 500mAh	\$6.95	7	\$48.65	N/A	\$48.65	TinyCircuits
	7	RGB LED 5 pack	\$2.95	2	\$5.90	N/A	\$5.90	Sparkfun
	8	ProtoBoard - Square 1" Single Sided	\$1.50	2	\$3.00	N/A	\$3.00	Sparkfun
	9	1K Ohm Resistor 1/4 Watt	\$0.95	1	\$0.95	N/A	\$0.95	Sparkfun
	10	10K Ohm Resistor 1/4 Watt	\$0.95	1	\$0.95	N/A	\$0.95	Sparkfun
	11	1M Resistor	\$0.95	1	\$0.95	N/A	\$0.95	Sparkfun
	12	AD620ANZ-ND	\$10.64	4	\$42.56	N/A	\$42.56	Digikey
	13	ProtoBoard Tinyshield	\$3.95	7	\$27.65	N/A	\$27.65	TinyCircuits
	14	Tiny Battery Charger	\$6.95	2	\$13.90	N/A	\$13.90	Tiny Circuits
	15	MicroUSB Cable - 3 feet	\$3.95	2	\$7.90	N/A	\$7.90	TinyCircuits
	16	Tinyduino Mounting Hardware Kit	\$3.95	2	\$7.90	N/A	\$7.90	Tinycircuits
	17	Heat shrinking tube	\$19.39	1	\$19.39	N/A	\$19.39	Mcmaster Carr
	18	LM741 Opamp	\$0.87	4	\$3.48	N/A	\$3.48	digikey
Hardware	19	MicroSD Card with Adapter - 16GB (Class 10)	\$9.95	2	\$19.90	N/A	\$19.90	TinyCircuits
	20	Silicone Rubber Watchband 18mm	\$10.95	2	\$21.90	N/A	\$21.90	Benchmark Basics
	21	Hook and Loop Cable Ties 1/2"	\$7.40	1	\$7.40	N/A	\$7.40	Mcmaster Carr
	22	SpectraSymbol Flex Sensor	\$7.95	10	\$79.50	N/A	\$79.50	Sparkfun
	23	MicroSD Card 8GB	\$3.99	1	\$3.99	N/A	\$3.99	Amazon
	24	Clock board	\$19.95	1	\$19.95	\$4	\$23.95	Sparkfun
	25	Micro USB Cable 3Feet	\$8.99	1	\$8.99	N/A	\$8.99	Amazon
	26	Flex sensor 4.5"	\$15.95	4	\$63.80	N/A	\$63.80	Tiny Circuits
	27	ProtoBoard - Square 1" Single Sided	\$1.50	5	\$7.50	\$6.64	\$14.14	Sparkfun
	28	Electrical Tape	\$3.99	1	\$3.99	N/A	\$3.99	Amazon
	29	Velcro Band	\$5.95	1	\$5.95	N/A	\$5.95	Amazon
	30	Elastic Band	\$7.59	1	\$7.59	N/A	\$7.59	Amazon
	31	Copper Foil Tape	\$11.90	1	\$11.90	N/A	\$11.90	Amazon
	32	Spray Paint	\$6.29	1	\$6.29	N/A	\$6.29	Hardware Store
	33	Dragon Skin	\$48.47	1	\$48.47	N/A	\$48.47	Smooth-On
	34	Wrist band with velcro	\$12.95	4	\$51.80	\$7	\$59	Amazon
Testing	35	Anametronic wooden hand	\$11.99	1	\$11.99	N/A	\$11.99	Amazon
	36	Force Sensitive Resistor 0.5"	\$6.95	4	\$27.80	N/A	\$27.80	Sparkfun
	37	Servo Motor- Generic (Sub-Micro Size)	\$8.95	2	\$17.90	N/A	\$17.90	Sparkfun
	38	Arduino kit for preliminary flex sensor testing	\$44.12	1	\$44.12	N/A	\$44.12	Sparkfun

Summary:

3D Printing Material \$162.21

Hardware \$639.54

Testing \$101.81

Total: \$903.56

Total amount of money available for the project: \$1000-1500

Team is ON budget

Bill of Materials

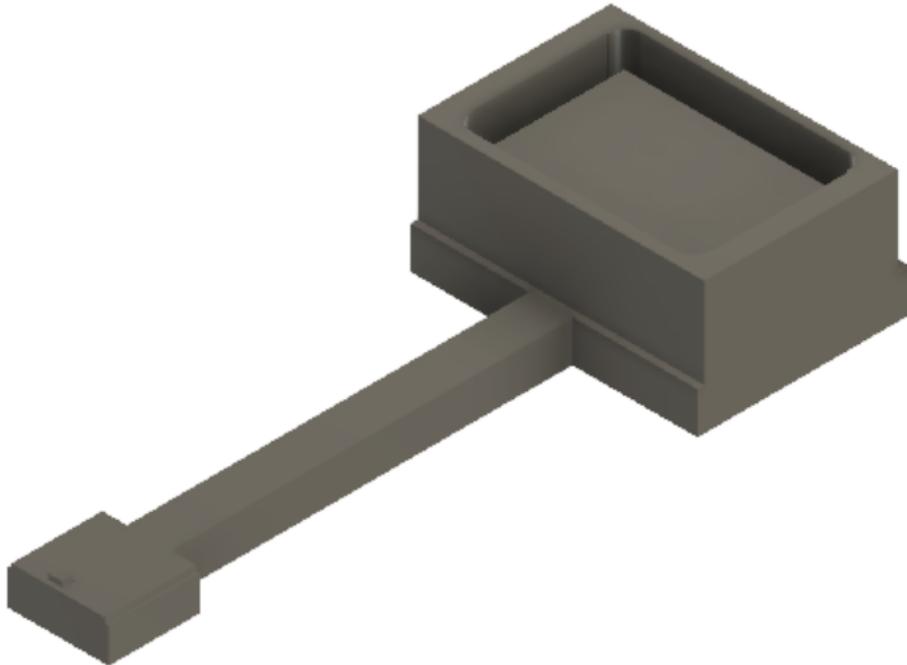
Category	Item No.	Item	Unit Cost	Quantity	Total Cost	Description (Material; Dimensions)	Source
	1	Tinyduino Processor Board w/ Lithium Battery Support	\$19.95	1	\$19.95	20 x 20 x 3.23 mm3	TinyCircuits
	2	Real-Time Clock TinyShield	\$19.95	1	\$19.95	20 x 20 x 3.23 mm3	Sparkfun
	3	MicroSD Tinyshield	\$14.95	1	\$14.95	20 x 20 x 3.23 mm3	TinyCircuits
	4	Lithium Ion Polymer Battery - 3.7V 500mAh	\$6.95	1	\$6.95	Lithium Ion Polymer 30.99 x 20.07 x 9.40mm3	TinyCircuits
	5	Light emitting diode	\$0.17	1	\$0.17	5mm - circumference	Sparkfun
	6	10 MOhm Resistor	\$0.06	1	\$0.06	5mm - circumference	Sparkfun
Hardware Circuit	7	10 Ohm Resistor	\$0.06	1	\$0.06	5mm - circumference	Sparkfun
	8	1 nF Capacitor	\$0.06	1	\$0.06		Sparkfun
	9	ProtoBoard - Square 1" Single Sided	\$1.50	2	\$3.00	25.4 x 25.4 x 6.35 mm3	Sparkfun
	10	10K Ohm Resistor 1/4 Watt	\$0.06	1	\$0.06	5mm circumference	Sparkfun
	11	Wire- 300V AC, 22 Gauge	\$10.74	1	\$10.74	Tin-Plated Copper 170.26 ft x 1.5mm	Mcmaster Carr
	12	Copper Tape	\$0.05	1	\$0.05	2in x 4in	Tiny Circuits
	13	MicroUSB Cable - 3 feet	\$3.95	1	\$3.95	3ft x .5 in	TinyCircuits
	14	Tinyduino Mounting Hardware Kit	\$3.95	1	\$3.95	N/A	Tinycircuits
	15	microSD Card with Adapter - 8GB (Class 10)	\$9.95	1	\$9.95	20 x 15 x 2 mm	Tinycircuits
	16	Elastic band	\$0.50	1	\$0.50	20cm	Amazon
Hardware Other	17	Ring	\$1.00	1	\$1.00	Velcro Strap Adjustable	Home Depot
Hardware Sensor	18	SpectraSymbol Flex Sensor	\$15.95	1	\$15.95	55.8 mm length	Sparkfun
	19	Top of Wrist Housing Dragon Skin 10A	\$3.39	1	\$3.39	Dragon Skin 48.26 x 86.44 x 14.94mm3 13.25g	Makerbot
3D Printing	20	Finger Insert	\$0.08	1	\$0.08	PLA 36.07 x 50.55 x 12.40mm3 11.14 g	Makerbot
	21	Bottom of Wrist Housing	\$0.59	1	\$0.59	PLA	Makerbot
	22	Flex sensor Insert	\$0.10	1	\$0.10	PLA	Makerbot
	22	Top of Wrist Housing Insert	\$0.38	1	\$0.38	PLA 115 x 5 x 30 mm3	MakerBot

Summary:

Hardware - Circuit	\$93.85
Hardware -Other	\$1.50
Hardware - Sensor	\$15.95
3D Printing	\$4.54

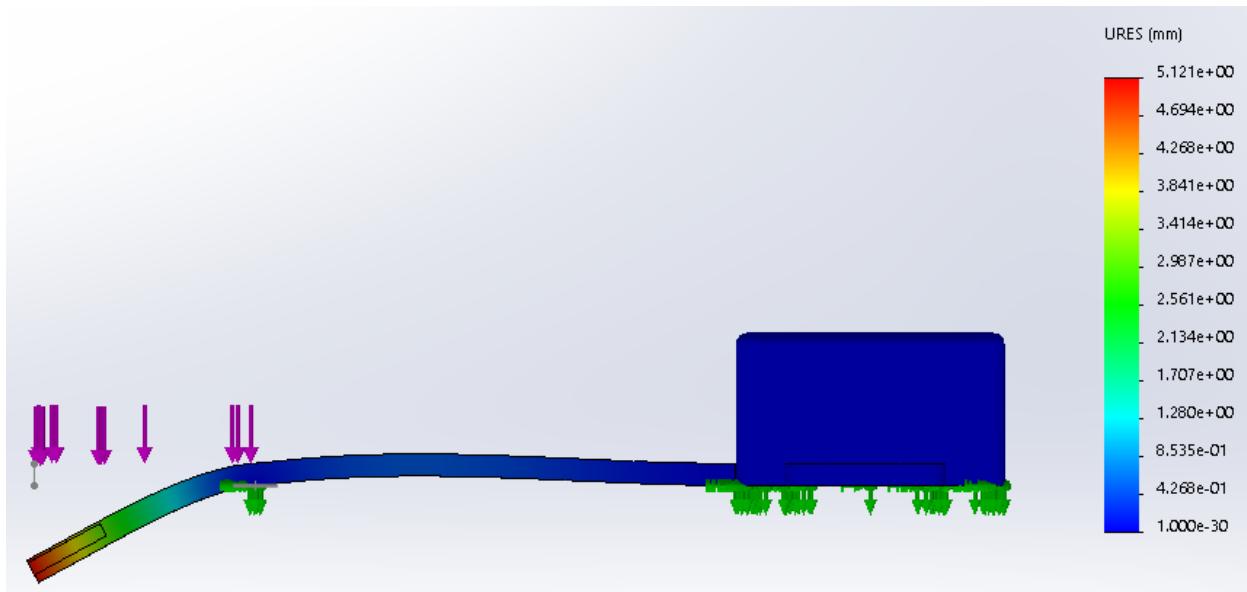
Total: \$115.84

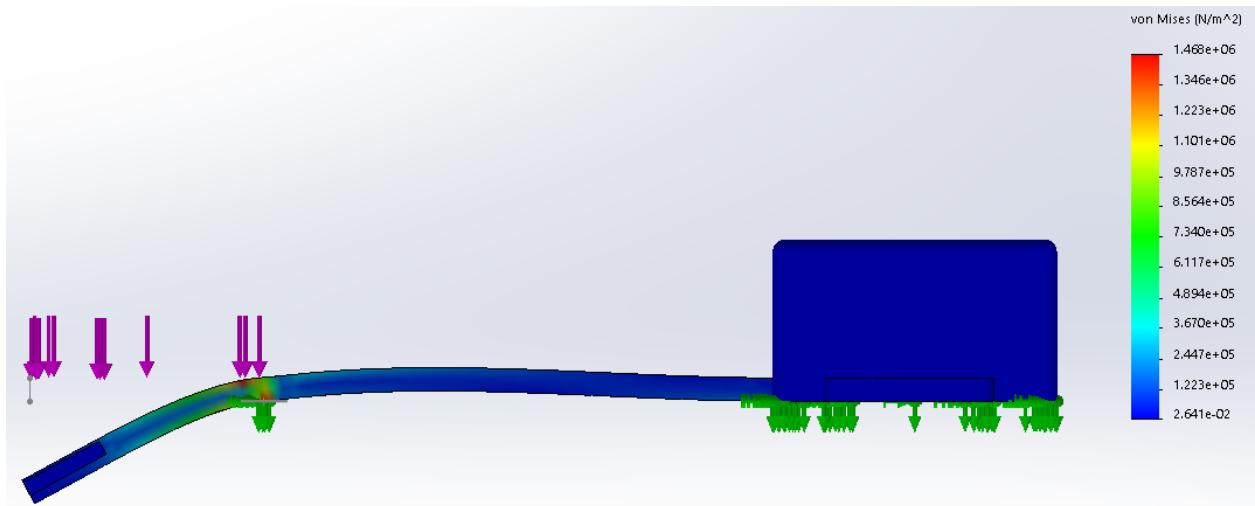
Appendix B - 3D Printed Silicone Mold



This mold was 3D printed and was designed to be an exact outermold of the Top of Wrist Housing (Appendix G). The dimensions for the part can be found there. This mold is 4 parts, so when the Dragonskin cures, the mold can be taken apart for the device to be removed as easily as possible. In order to ensure the silicone did not leak out of the mold, the cracks were hot glued together. The flex sensor and the PLA Inserts were all put in the mold before pouring. This allowed the silicone to “overmold” the plastic parts to make them all one piece.

Appendix C - 1N Bend Simulation Results





Appendix D - DFMEA

Task	Subtask	Hazard	Causes	Harm	Severity (1-5) Occurrence (1-5) Risk Priority Number (RPN)				Corrective Measures/ Risk Controls	New Severity (1-5) New Occurrence (1-5) New Risk Priority Number (RPN)				
					Severity (1-5)	Occurrence (1-5)	Risk Priority Number (RPN)	New Severity (1-5)		New Occurrence (1-5)	New Risk Priority Number (RPN)			
Go to doctor	No Device Analysis	-	-	-	-	-	-	-	-	-	-	-	-	
	Remove device from packaging	-	-	-	-	-	-	-	-	-	-	-	-	
	Secure to patient	Secure in wrong location	Unclear how or where to secure based on design of device	Cannot provide optimized data results	2	2	3	12	Create orientation specific design so that it only fits on the hand one way; add	2	1	3	6	21 >= Red
	Turn on	Device doesn't last 18 hours/device not prepared for next patient	Device isn't fully charged; failure to charge device between patients	Delayed start; waste time; Emotional distress	2	2	2	8	Add an LED display that shows percentage of complete charge on the device in real time	2	1	1	2	11-20 = Yellow
Doctor puts device on patient		Battery failure	Prolonged use and deterioration of battery	Waste time in clinician office; Delay in use due to replacement battery; Emotional distress	2	3	2	12	Add an indicator into the software that warns when the battery is close to failure that appears upon connection to a computer	2	1	2	4	0-10 = green
		Battery leakage	Exposure to corrosive elements; battery puncture	Burning and irritation of skin; Emotional distress	4	2	2	16	Thicken battery housing; secure housing in isolated area	4	1	2	8	
	Calibrate if necessary	Fail to calibrate the device	Improper placement of device; improper size/fitting	Device fails to provide accurate data	2	4	3	24	Create a testing suite that is administered in the doctor's office and outputs to a display in real time. Have LEDs on the device that activate to show correct calibration as it is used.	2	1	2	4	
Doctor instructs patient on how to use	Describe interaction/use of device	Patients does not understand how to charge device	Unclear device labels/instructions	Battery dies and device doesn't function, no data	2	3	2	12	Color code charger and charging port. Annotate "charge" in text above the port	2	1	2	4	
	Describe Safety of Device	Patients ignore water safety rules	Insufficient warning/information provide to the users/user negligence	Increased safety risks; physical damages to patients	4	2	2	16	Put a label in the design of the outer shell that demonstrates no water	4	1	2	8	
		Patient exposes internal components or alters them	Device can be opened by all users including patients	Device loses functionality, potential patient exposure to electric current	4	2	2	16	Use a screw to secure the device so the doctor/researcher and manufacturer are the only individuals with access to internal components	4	1	2	8	
	Pick up or hold objects (fork, drink etc.)	Device design limits ability to handle objects	Device is bulky or obtrusive; The materials/connections restrain finger bending	Affects ability to perform tasks(won't use hand); device fails to provide accurate data; skin irritation, discomfort; May hit device on objects	3	4	2	24	Make device lighter and as unobtrusive as possible by minimizing size; make adjustable; make shockproof and more durable	3	2	2	12	
		Device does not stay fixed; sensor becomes misaligned	Hit device on something; improper mounting/fastening	Affects ability to perform tasks; device fails to provide accurate data; skin irritation, discomfort	2	3	2	12	Ensure easy and secure fastening mechanism; add surface friction	2	1	3	6	
		Device falls off hand and breaks	Hit device on something; improper mounting/fastening	Could hit a body part and cause pain; distress	4	2	1	8	Ensure easy and secure fastening mechanism; add surface friction	4	1	1	4	
		Device is bulky or obtrusive	Design and component constraint	Affects ability to perform tasks; device fails to provide accurate data; skin irritation, discomfort	3	3	1	9	Make device lighter and as unobtrusive as possible	3	1	2	6	
Move pill bottle, water or other items close to them		Device does not stay fixed; sensor becomes misaligned	Hit device on something; improper mounting/fastening	Affects ability to perform tasks; device fails to provide accurate data; skin irritation, discomfort	2	3	2	12	Make device adjustable for many sizes	2	1	2	4	
		Device falls off hand and breaks	Hit device on something; improper mounting/fastening	Could hit a body part and cause pain; distress	3	2	1	6	Make device shockproof and more durable; add surface friction to prevent device slipping from hand	3	1	1	3	
		Device is bulky or obtrusive;	Design and component constraint	Affects ability to perform tasks; device fails to provide accurate data; skin irritation, discomfort	3	3	2	18	Make device lighter and as unobtrusive as possible	3	2	2	12	
Patient returns home and goes about their daily life		Device does not stay fixed; sensor becomes misaligned	Hit device on something; improper mounting/fastening	Affects ability to perform tasks; device fails to provide accurate data; skin irritation, discomfort	2	3	2	12	Make device adjustable for many sizes	2	1	3	6	
	Grocery shopping	Device falls off hand and breaks	Hit device on something; improper mounting/fastening	Could hit a body part and cause pain; distress	4	2	1	8	Make device shockproof and more durable; add surface friction to prevent device slipping from hand	4	1	2	8	

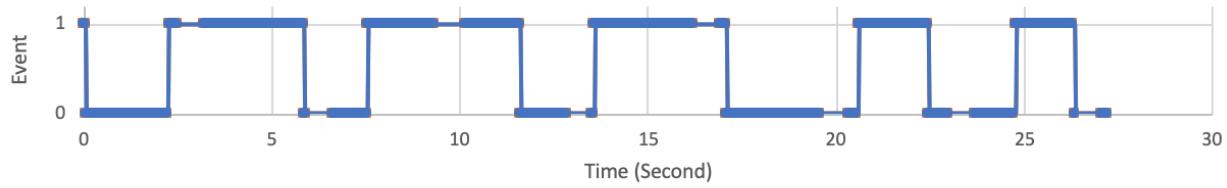
Task	Subtask	Hazard	Causes	Harm	Corrective Measures/ Risk Controls			New Severity (1-5)			New Occurrence (1-5)		
					Severity (1-5)	Occurrence (1-5)	Risk Priority Number (RPN)	New Severity (1-5)	New Occurrence (1-5)	New Risk Priority Number (RPN)	New Severity (1-5)	New Occurrence (1-5)	New Risk Priority Number (RPN)
Patient returns home and goes about their daily life	Take off device when going to bed	Electric burning	Circuit board overloads/shortcircuits in skin	Skin damage; Pain; Incorrect data; Emotional distress	4	2	2	16	Add a fuse to block circuit in the event of a circuit overload	5	1	2	10
		Pain from sharp edges	Components have sharp edges, such as the circuit and flex	Bleeding and pain due to sharp edges, skin irritation	4	2	2	16	Redesign the shape of the device; smooth the corners of the housing	4	1	2	8
	Store device safely at night	Cannot remove device	Securement difficult to use; not enough force exerted or inadequate grip on the device	Discomfort; Emotional distress	2	3	1	6	Redesign the wrist band fastener so that it is easier to put on and take off as well as adjust sizing	2	1	1	2
	Turn device off when sleeping	Device breaks	Device not stored safely	Device fail to record data; Waste time; Emotional distress	2	3	2	12	Injection mold for strength, create clearer instructions on how to store	2	2	1	4
		Device doesn't turn off	Power Switch is hard to slide; power switch breaks	Emotional distress	2	3	1	6	Change switch to button	2	2	1	4
	Turn device back on in the morning	Misunderstand what the LED light on the device represents	It may be unclear what the LED is showing	Device fails to record data; Emotional distress	2	2	2	4	Label the LED light more clearly on the device, instruction manual, and packaging	2	1	1	2
		Device doesn't turn on	Device ran out of battery; Switch is hard to use	Device fails to record data; Waste time; Emotional distress	2	3	1	6	Add warning LED for low battery	2	1	1	2
After each day patient charges device at night	Turn off device	Device runs out of battery	Failure to turn off device	Device fail to record data; Waste time; Emotional distress	2	3	1	6	Add an LED to display low battery and need to charge; Include a battery with larger capacity to provide extra battery time	2	1	1	2
	Plug in device to charge	Device doesn't charge	Cord is broken, microUSB port breaks	Doctor/Researcher replaces cord/circuit port; Can't record data; Emotional distress	2	2	2	8	Manufacture a cord that's stronger due to more durable rubber coating; provide two cords	2	1	2	4
Patient returns to Doctor	-	-	-	-	-	-	-	-	-	-	-	-	-
Doctor/Researcher processes and analyzes data	Turn off device	Device runs out of battery	Failure to turn off device	Device fail to record data; Waste time; Emotional distress	2	3	1	6	Add an LED to display low battery and need to charge; Include a battery with larger capacity to provide extra battery time	2	1	1	2
	Plug in charge device	Device doesn't charge	Cord is broken, microUSB port breaks	Doctor/Researcher has to replace battery frequently; Can't Record data; Emotional distress	2	3	2	12	Manufacture a cord that's stronger due to more durable rubber coating; provide two cords	2	1	2	4
	Connect computer to device	Connection method is broken/misplaced	Connecting cable broken/misplaced	Waste time in clinician office; Emotional distress	2	2	1	4	Provide extra connecting cable in case the cable is lost	2	1	1	2
	Download raw data file from device to computer	Fail to transfer data to computer	Broken/lost connection cable	Losing important data information; Waste time; Emotional distress	2	2	1	4	Provide extra connecting cable in case the cable is lost/broken	2	1	1	2
	Load data analysis software	Computer/software crashed	Error in software program	Waste time; Cannot analyze data; Emotional distress	2	2	1	4	Test software with different data extremes to minimize bugs in the code	2	1	1	2
	Run data analysis software	Computer/software crashed; incorrect data analysis	Too much data to analyze for the software; data corruption; confusing	Losing important data information; Waste time; Emotional distress; preventing future best	2	2	1	4	Analyze/Transfer files in sections	2	1	1	2

Task	Subtask	Hazard	Causes	Harm	Risk Assessment Matrix				Corrective Measures/ Risk Controls	New Severity (1-5)	New Occurrence (1-5)	New Detectability (1-5)	New Risk Priority Number (RPN)	
					Severity (1-5)	Occurrence (1-5)	Detectability (1-5)	Risk Priority Number (RPN)						
Doctor/Researcher prepares device for next patient	Clean all parts of device	Fail to clean the device for next user	Unclear disinfecting reminder	Infection; microbial growth, skin irritation	2	2	3	12	Injection mold to minimize the grooves and holes on the device to prevent trapping the bacteria and dirt; Reminder	2	1	3	6	
		Clean device with inappropriate method	Unclear instructions on how to clean device; device has components that are difficult to clean	Microbial growth if not properly cleaned; Infection; Skin irritation	2	2	3	12	Injection mold to minimize the grooves and holes on the device to prevent trapping the bacteria and dirt	4	1	3	12	21 >= Red
	Delete all data from device	Fail to delete all data from device	Failure to wipe microSD card	Device can not store new data for next patient; New patient has patient data from old patient. Emotional Distress	2	2	1	4	Implement as part of the script a reminder to delete data from microSD card so that when done processing a window pops up that asks if the researchers have deleted the data	2	1	1	2	11-20 = Yellow
	Plug in charge device	Device doesn't charge	Cord is broken, microUSB port breaks	Doctor/Researcher has to replace battery frequently; Can't Record data; Emotional distress	2	2	2	8	Manufacture a cord that's stronger due to more durable rubber coating; provide two cords	2	1	2	4	0-10 = green
	Put device back into packaging	-	-	-	-	-	-	-	-	-	-	-	-	

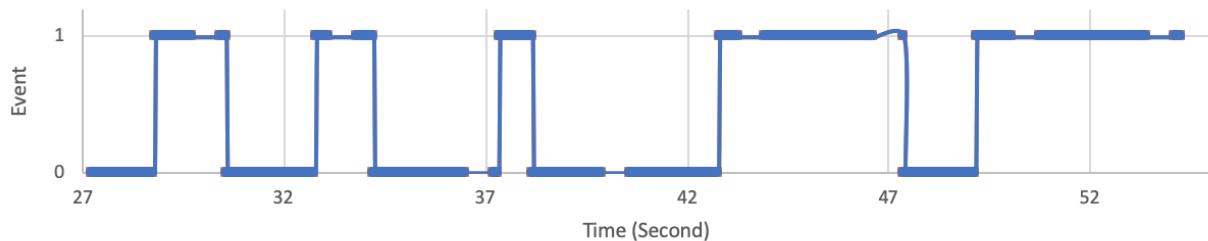
Appendix E - Shock Test Extra Plots

Post Shock Test- Event Test

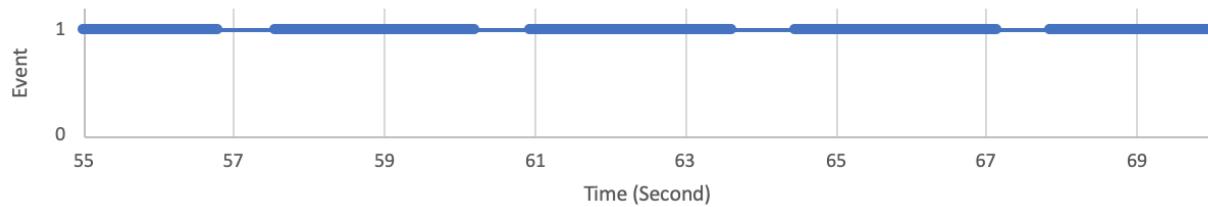
Post Shock Test- Event Test 10 Degree



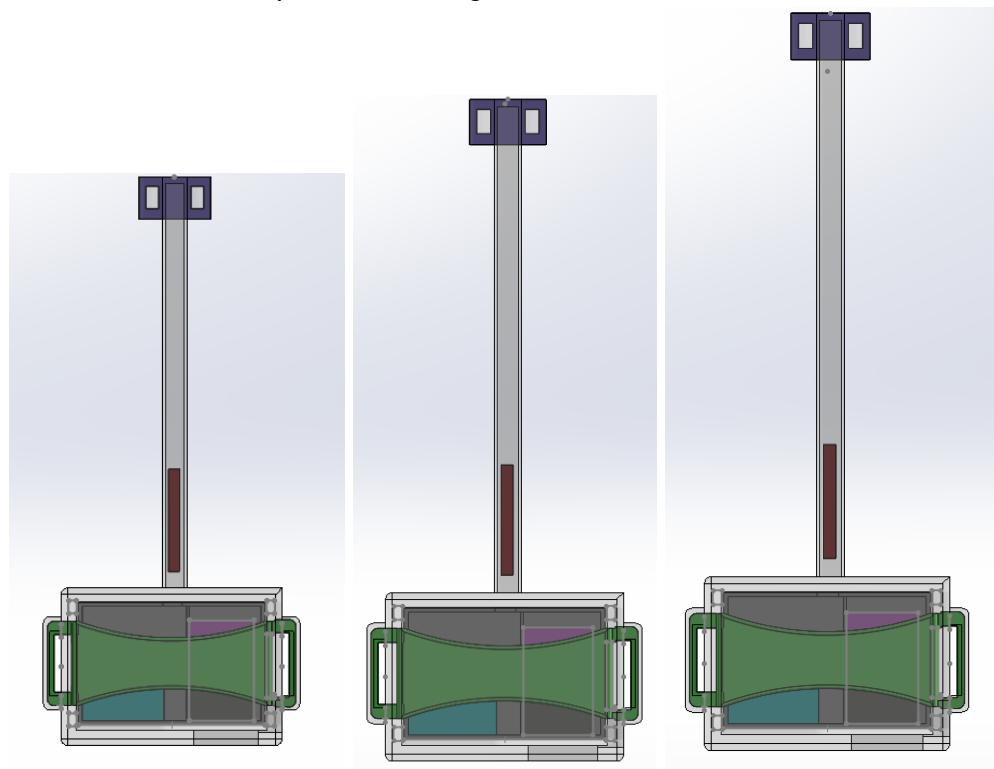
Post Shock Test- Event Test 8 Degree



Post Shock Test- Event Test 6 Degree

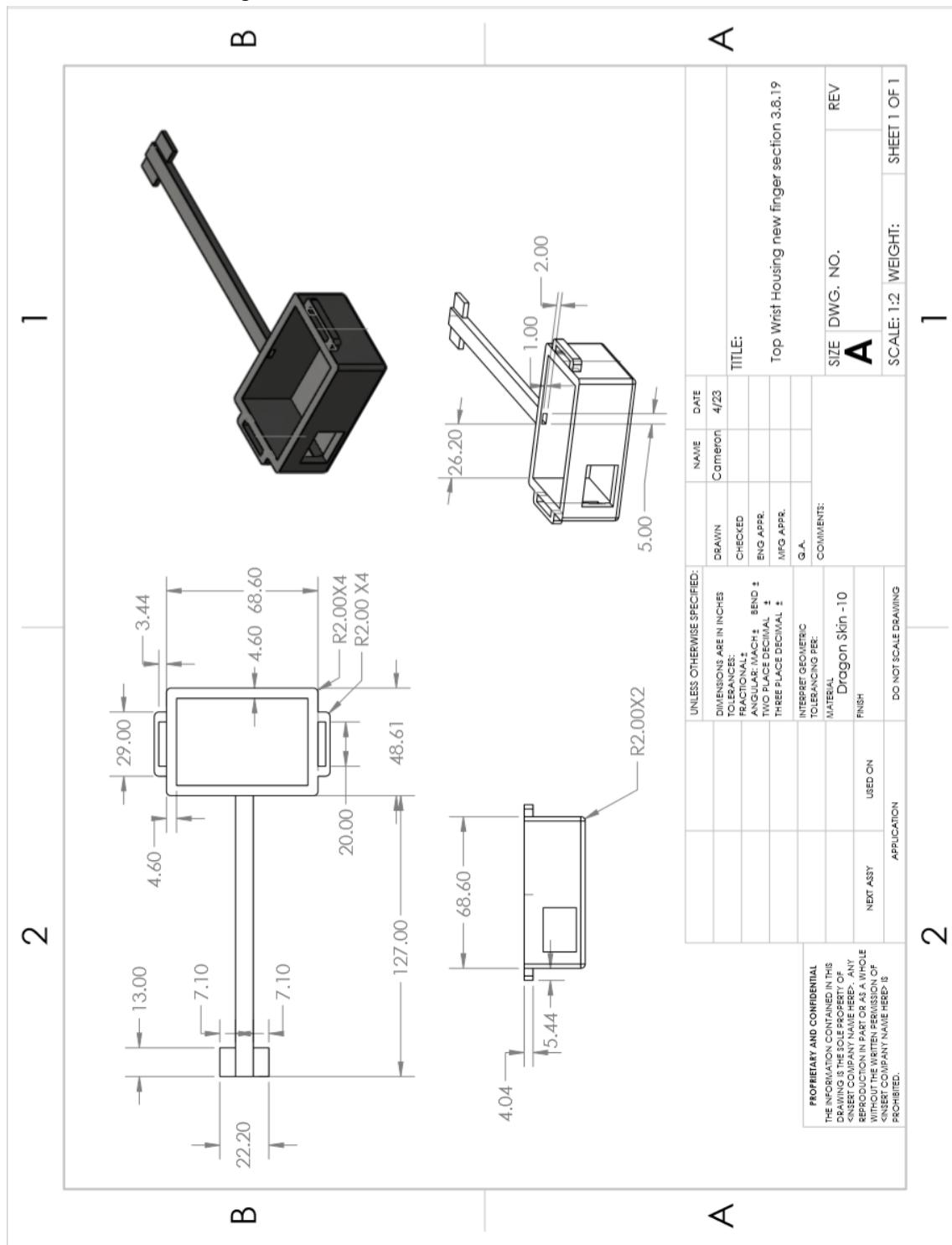


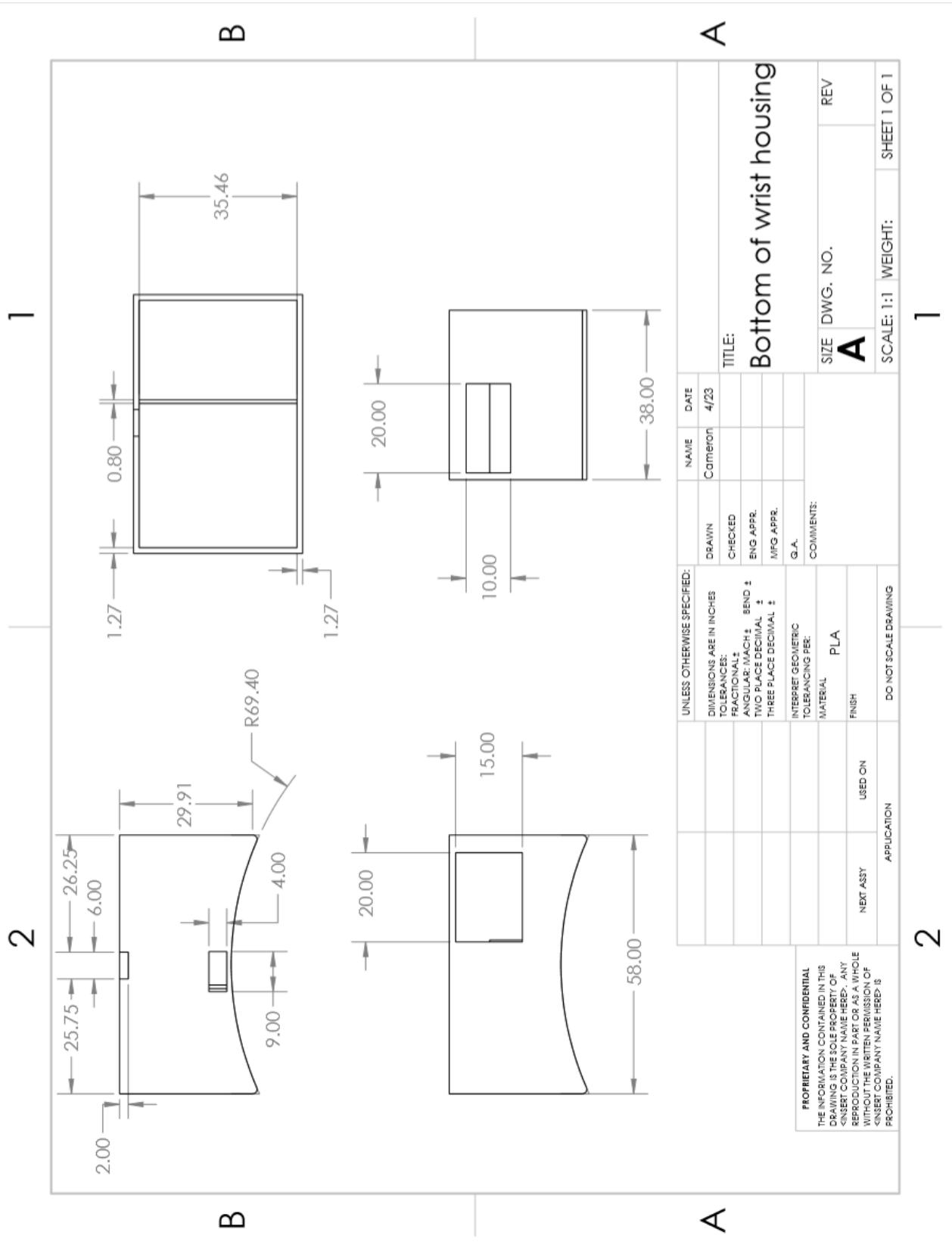
Appendix F - Three sizes of Top Wrist Housing



Small, medium and large flex sensor housing sizes of 12.5 cm, 14 cm and 15.5 cm, respectively.

Appendix G - Part Drawings

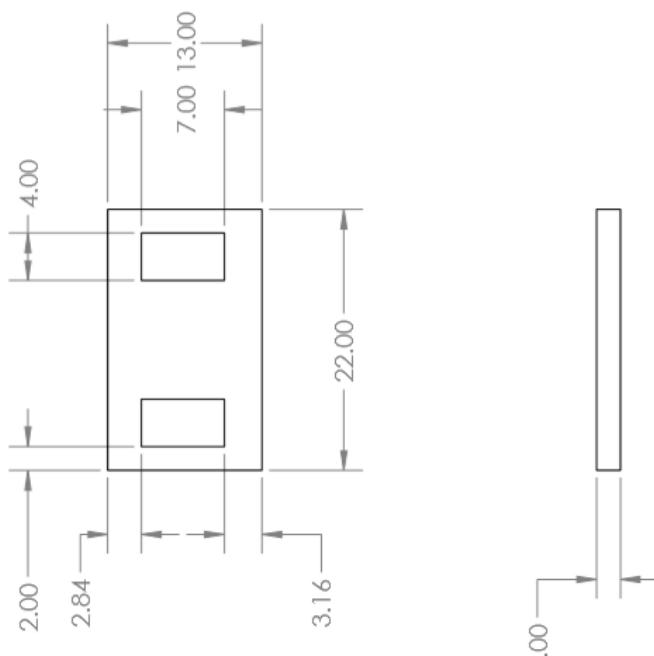




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2

B



B

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A

Finger strap PLA insert

DATE:
4/23

TITLE:
A

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL: #
ANGULAR: MACH #: BEND #
TWO PLACE DECIMAL: #
THREE PLACE DECIMAL: #
INTERPRET GEOMETRIC
TOLERANCING PER:
MATERIAL: PLA
FINISH: FINSH

SIZE	DWG. NO.	REV
A		

SCALE: 2:1 WEIGHT: SHEET 1 OF 1

COMMENTS:
NEXT ASSY USED ON APPLICATION DO NOT SCALE DRAWING

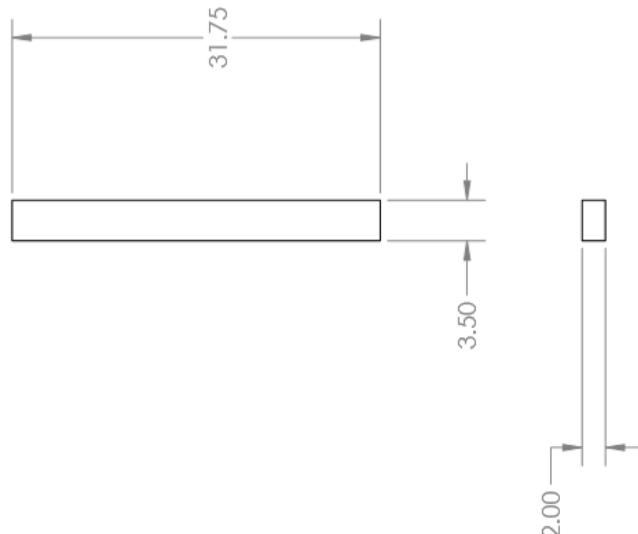
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS
DRAWING IS THE SOLE PROPERTY OF
[REDACTED] COMPANY NAME HEREIN. ANY
REPRODUCTION IN PART OR AS A WHOLE
WITHOUT THE WRITTEN PERMISSION OF
[REDACTED] COMPANY NAME HEREIN IS
PROHIBITED.

1

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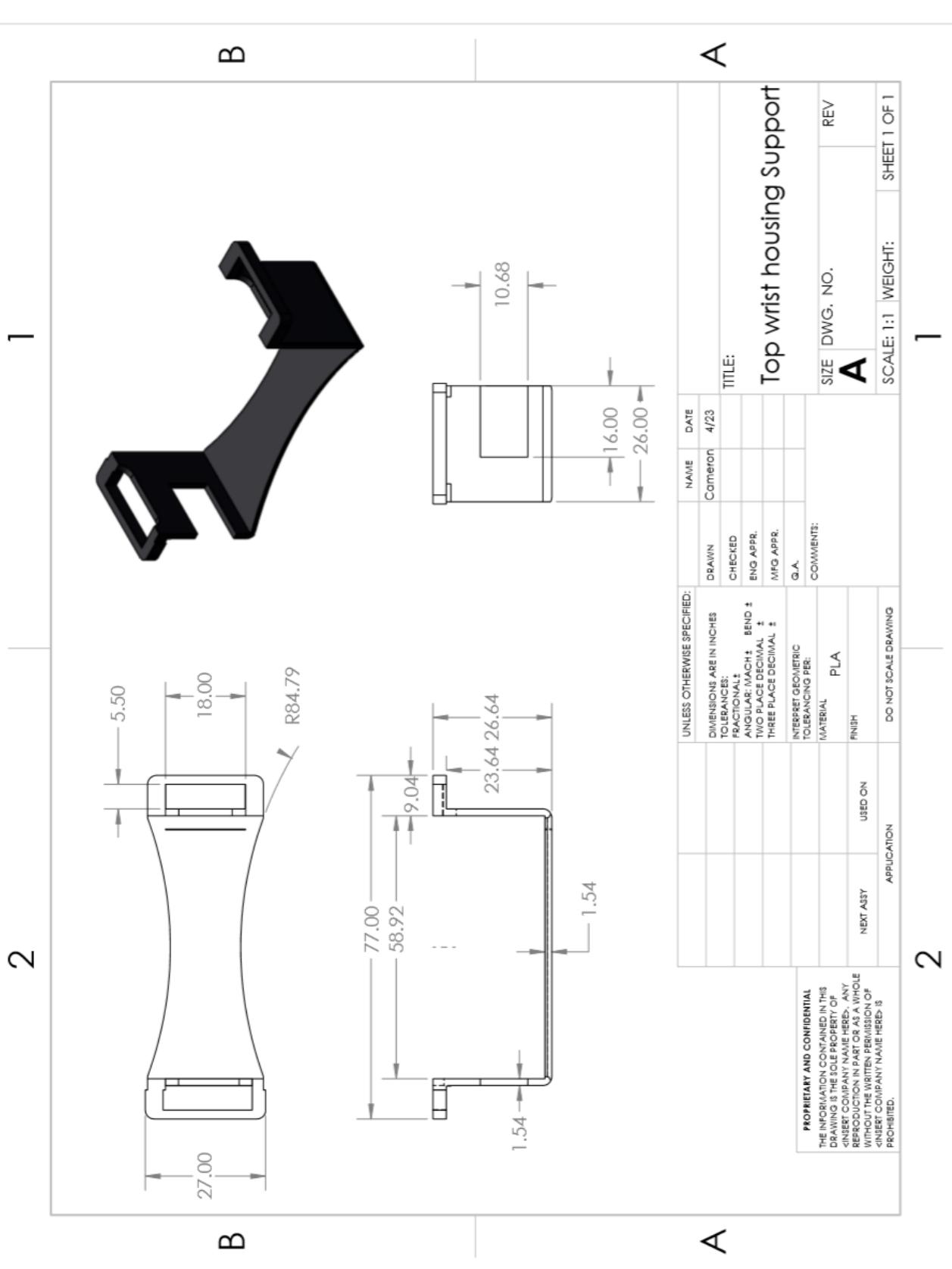


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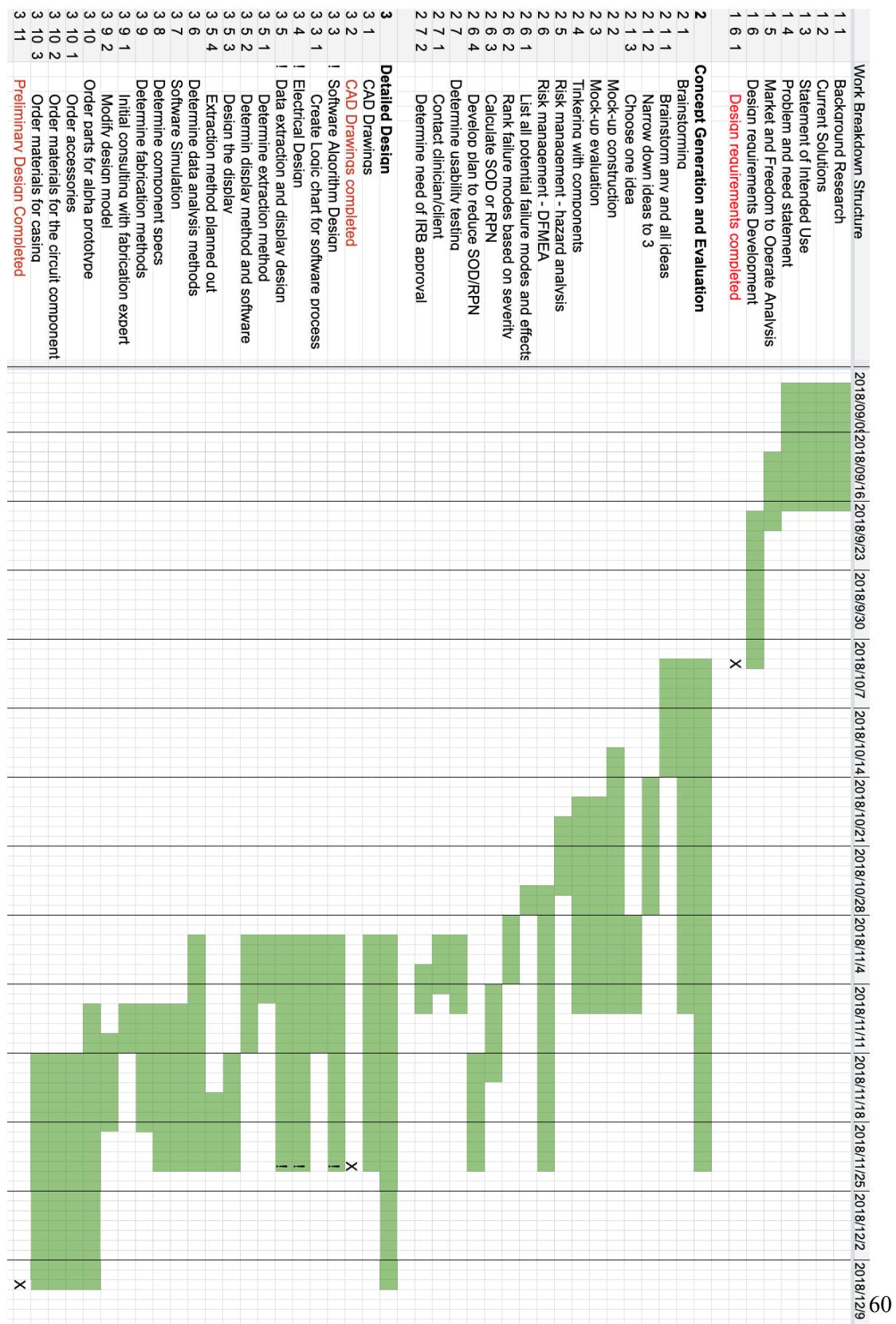
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UNLESS OTHERWISE SPECIFIED:		NAME: Cameron		DATE: 4/23	
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TO TOLERANCES:					
FRACTIONAL:					
ANGULAR: MACH 4° BEND 4°					
TWO PLACE DECIMAL .4°					
THREE PLACE DECIMAL .4°					
INTERPRET GEOMETRIC					
TOLERANCING PER:					
MATERIAL:	PLA				
USED ON:	FINISH				
APPLICATION:	DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL					
THE INFORMATION CONTAINED IN THIS					
<INSERT COMPANY NAME HERE>, ANY					
REPRODUCTION IN PART OR AS A WHOLE					
WITHOUT THE WRITTEN PERMISSION OF					
<INSERT COMPANY NAME HERE> IS					
PROHIBITED.					
COMMENTS:					
SIZE DWG. NO.					REV
A					
SCALE: 2:1					SHEET 1 OF 1

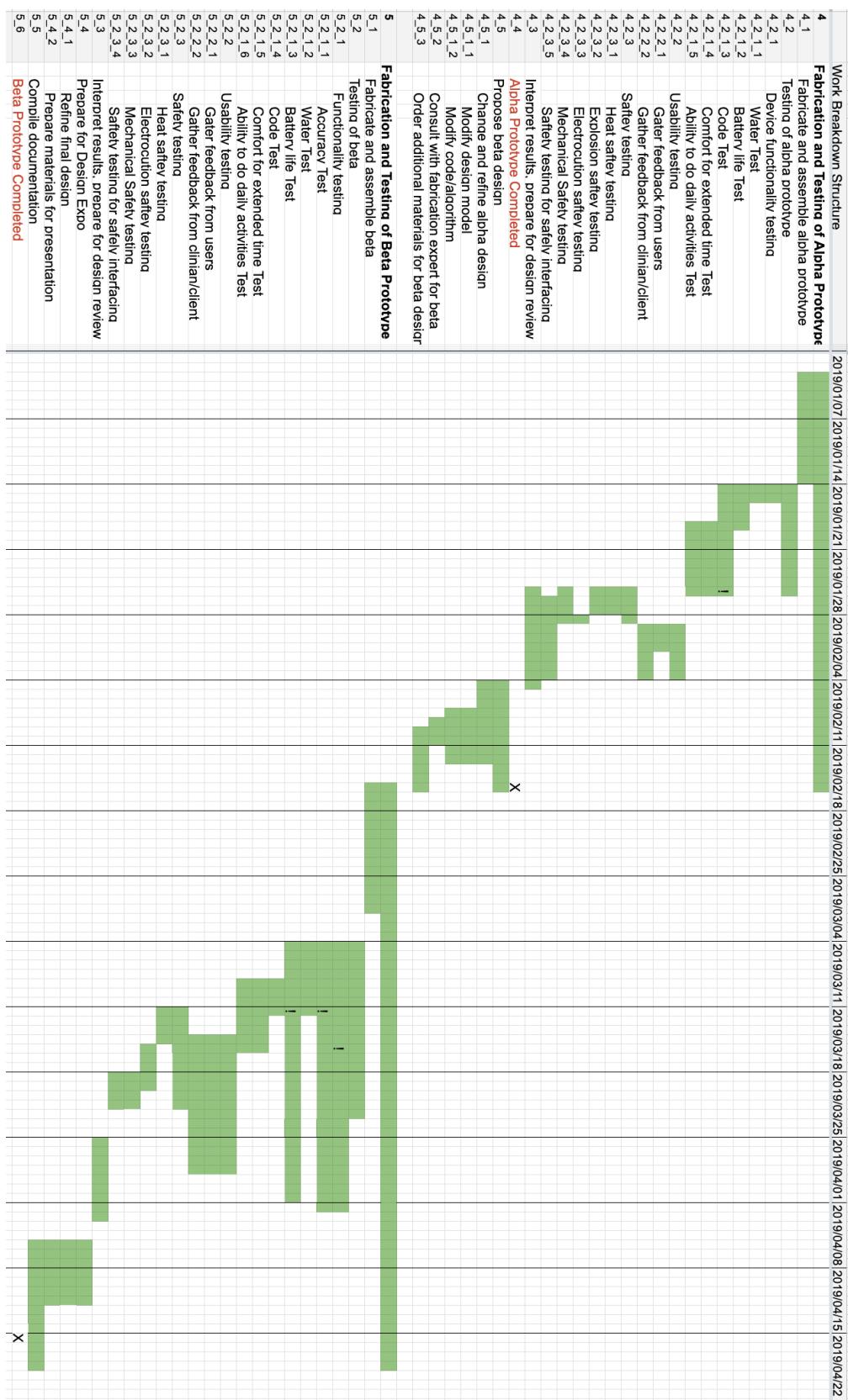
1
2



Appendix F - Gantt Chart
Gantt Chart Fall Semester



Gantt Chart Winter Semester



Appendix I - Accreditation and Project Resources

Accreditation Outcomes

Designing the FlexiCapture allowed us to develop a device that has future implications on the quality of care for thousands of patients. The results from this device will guide clinicians in the development for new treatments for patients around the world who suffer from brachial plexus injuries.

This project showed us the importance of personal and institutional ethical standards. MetaCapture could have falsified data or doctored validation tests to demonstrate non existing functionality. When we pass on the device to clients and they eventually implement it in their research studies, it would record false or inaccurate data. It would have no impact on those wearing the device, but what if that non existing functionality caused the researchers to believe the patients were moving their hands when they really weren't? The current surgical reconstruction methods would be deemed satisfactory and the future patients wouldn't receive an improved repair method because the device showed the current patients hands are useful. It's important to design, validate, and report with objectivity in order to not harm any patients.

Project Resources

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Consultants/Tech Experts

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