Electro-Muscle-to-Muscle Transfer
Final Design Report
March 9, 2021

Sponsor:
Charlie Gutierrez

Contributors:

Jake Javier	jkjavier@calpoly.edu
Hailey Casino	hcasino@calpoly.edu
Sam Borda	sjborda@calpoly.edu
Charlotte Anderson	cander85@calpoly.edu

Table of Contents

I. Executive Summary

This document includes a brief summary of the effects and costs of paralysis, the potential therapies to treat it, and the makings of a device that harnesses the power of those therapies. To devise this product, customer and engineering specifications were generated. A plan and budget were proposed after brainstorming possible configurations and evaluating and refining these ideas. Proper code and circuit models were also created. A manufacturing plan was constructed and followed, and a prototype device was completed. The necessary tests to verify and validate the device were then determined and carried out. These processes are detailed below, as well as any decisions that resulted from them.

II. Introduction

Paralysis is a condition that has the possibility to be a lifelong and unchanging condition. However, recent research has shown that there is the potential to regain function, and possibly foster adaptation of the nerves and brain to regain function of previously paralyzed muscles[1,3]. There have been a variety of therapies, surgeries, and scientific techniques that have proven the viability of this concept, and we aim to develop a product that will harness similar concepts, with enhanced effects.

Our goal is to develop a device that allows partially paralyzed patients to regain use and function of paralyzed muscles, while simultaneously promoting nerve growth and brain function. Below we will describe our proposed device, along with deliverables, and the management of the project. Background on the condition of paralysis and other successful treatments, along with who it may affect, are described below in order to provide a solid foundation for the understanding of the project.

Background

It has been estimated that there are approximately 5.4 million people living with paralysis in the world[2]. All of these individuals must learn to adapt to daily life with their limited or nonexistent physical abilities. The following tables, taken from The Christopher & Dana Reeve Foundation, outlines the cost of living with various levels of spinal cord injury (SCI), which make up 27.3% of all paralyzed patients[2].

Table 1. Average Yearly Costs of Paralysis [2]

Severity of Injury	First Year	Each Subsequent Year
High Tetraplegia (C1-C4) ASIS ABC	$1,064,716	$184,891
Low Tetraplegia (C5-C8)	$769,351	$113,423
Paraplegia	$518,904	$68,739
Incomplete motor function (any level)	$347,484	$42,206

Table 2. Estimated Lifetime Costs [2]

Severity of Injury	25 Years Old	50 Years Old
High Tetraplegia (C1-C4) ASIS ABC	$4,724,181	$2,596,329
Low Tetraplegia (C5-C8) ASIS ABC	$3,451,781	$2,123,154
Paraplegia ASIS ABC	$2,310,104	$1,516,052
Incomplete motor function (any level) ASIS D	$1,578,274	$1,113,990

These costs fall on hospitals, insurance companies, and even individual patients and their families. However, studies have shown that it is possible for paraplegics to regain motor function through the use of brain-machine interfaces[1]. A new field of therapy opening up is electrical stimulation. Stimulation of peripheral nerves in musculoskeletal tissue has led to the return of function and recovery of injury secondary conditions[5]. This has shown that it is possible for paralyzed individuals to regain function, and allows for the innovation of new devices to aid in this endeavor[4]. Said devices would expect to lower average and overall costs while improving quality of life.

Table 3. Currently Available Similar Devices

Product Name	Basic Functions
TENS 3000	Muscle Stimulation - Recovery
RT300	Arm Ergometer & Muscle Stimulation - Therapy
Powerdot 2.0	Muscle Stimulation - Exercise & Recovery
MyoWare Muscle Sensor	EMG
Muscles Buddy	Muscle Stimulation - Exercise

As Table 3 references, there are plenty of currently available devices that either sense muscle activity or stimulate muscle contractions. Most muscle stimulators are marketed as exercise replacements or tools for injury recovery. Our device will differ from the current market as it combines multiple device functions and addresses the field of neuro recovery, not a basic exercise.

There is a type of nerve transfer surgery that has been proven to allow paralyzed muscles to function while also promoting nerve growth and brain function to improve the state of the paralyzed muscle[3]. This entails taking a nerve from a functioning muscle in the arm, and extending it to connect with a paralyzed muscle in the hand, allowing for the contraction impulse created in the arm to translate to the hand and allow for a contraction (and use) of a previously paralyzed muscle.

This project should produce a device that will electronically recreate what is functionally accomplished through the described surgery. This was proposed as a project already for the winter-spring 2020 Senior Project. This project had successfully fulfilled a proof of concept using a crude rendition of

lab equipment. This project was unfortunately cut short due to COVID-19 and is being renewed as an entirely new project. While the last project focused more on proving the ability to actually stimulate the muscle using an EMG input, this project focuses on the development of a singular device to interface the nerves and subsequent muscle function specifically between the wrist extensor/flexor muscles and the finger extensor/flexor muscles.

This device would most likely need Class II FDA clearance with a Traditional 510(k) as it's a non-invasive device with the use of pre-existing technology.

Intellectual Property Assessment

Table 4. Intellectual Property Assessment (highlighted numbers are issued)

Patent Number	Claim Description	Claim Discussion
10137299: Engaging the cervical spinal cord circuitry to re-enable volitional control of hand function in tetraplegic subjects.	Claim 1: *"A method of improving motor control and/or strength in a hand of a subject with a neuromotor disorder affecting motor control of the hand, said method comprising: neuromodulating a cervical spinal cord of said subject by administering transcutaneous stimulation to the cervical spinal cord or a region thereof; ..."*	We would avoid this claim by not administering any transcutaneous stimulation over the area of the spinal cord. We would purely stimulate peripheral nerves to restore tetraplegic hand function.
10639235: Systems, apparatuses, devices, and processes for synergistic neuro-physiological rehabilitation and/or functional development.	Claim 1: *"A system for facilitating rehabilitation of a body part of a subject, the system comprising: a first set of sensing devices configured for sensing signals corresponding to the subject's mind state; a second set of sensing devices configured for sensing signals corresponding to the subject's body state; a subject interaction unit comprising a set of display devices configured for providing a visual interface to the subject, the visual interface..."*	This claim involves a stimulation sensation interface that later describes a visual audio system that provides the patient feedback. We would have to first establish the interface we have designed is purely between muscles; it does not include the brain. Next, we would have to redesign our video audio feedback signal to encompass only muscle signals, again excluding the brain.
10772200: Fabric coated with functional silicone rubber to form an electrically conductive layer.	Claim 1: *"A fabric coated with functional silicone rubber, the fabric comprising: a woven fabric made by weaving and comprising uniform pores therein; and a coating layer formed by coating a*	This claim refers to the electrically conductive layer that coats the fabric. We would avoid this claim by designing our fabric sleeve to incorporate electronic stimulation in specific sites on the fabric. The

	surface of the woven fabric with liquid silicone rubber in which electrically conductive particles larger than the pores of the woven fabric are dispersed and mixed, …"	electrically conductive portion will also not be woven within the fabric and will instead be sewn in.
20200155825: MEDICAL THERAPY ARRANGEMENT FOR APPLYING AN ELECTRICAL STIMULATION TO A HUMAN OR ANIMAL SUBJECT	Claim 4: *"The garment according to claim 1 wherein the electrode having a tubular portion that extends through the fabric of the garment."*	This claim could be avoided by keeping the entire electrode inside of the garment/sleeve and running that signal through a wire. The wire would go through the fabric rather than the electrode itself. Alternatively, we could make the device wireless and keep the electrode completely inside the garment and transmit the data through bluetooth.
20200246614: Systems and methods for ***electrical muscle stimulation***	Claim 10: *"The system of claim 1, wherein the processing structure is configured to cause the signal generator to generate new biphasic electrical stimulation signals based on the digital exertion data."*	This claim would be tough to avoid, as it is the premise of the entire project. However, it may be avoided by changing the description of how the signal is generated. We could be a bit more specific by saying that a microcomputer acts as the processing structure and possibly the signal generator as well instead of two separate pieces (if that exists).

III. Objectives

The Electro Muscle to Muscle Transfer (EMMT) system will entail designing, manufacturing, and providing a wearable device that stimulates paralyzed muscles in the hand by sampling and amplifying muscles from the forearm. With further development, the system may be capable of using different muscle inputs other than the forearm muscles along with different stimulated muscle outputs other than the hand.

The system functions as a rehabilitative device for spinal cord injuries, irreparable nerve loss and/or damage, and improper neuromuscular function. It is not for total treatment nor for curing of the disabilities listed above but to alleviate the side effects of the disability and help reduce muscular dysfunction.

Indications for Use

The Electro Muscle to Muscle Transfer (EMMT) system is a rehabilitation device intended for patient use that electrically stimulates unresponsive muscles in the hand based on bioelectric signals from functioning muscles in the forearm for use in patients with partial paralysis. Patients can improve grip strength and carry out common everyday tasks while electrically stimulated, as well as can avoid muscle atrophy by actively working out an unresponsive muscle. The EMMT system functions as a rehabilitative device for spinal cord injuries, irreparable nerve loss and/or damage, and improper neuromuscular function. The EMMT system is not for total treatment nor for curing of the disabilities listed above. The device works to alleviate the side effects of the disability and help reduce muscular dysfunction.

Customer Requirements

The primary customers for the EMMT system are patients, researchers, insurance companies, rehabilitation hospitals, and physical therapists. All customer requirements can be grouped into one of the following categories: functional use, convenience, reliability, comfort, aesthetic, price, and safety.

The most important requirements for the patients are increased grip strength and decreased time to complete tasks. For the researchers, the most important requirements are neuroplastic change and increased grip strength. For insurance companies, the most important aspects are price and safety. For rehabilitation hospitals and physical therapists, the most important are safety and neuroplastic change. A full list of all customer requirements and their corresponding importance for each customer can be found in Appendix A.

Engineering Specifications and HOQ

In order to objectively analyze and test the effectiveness of the EMMT system, engineering specifications were created to match each customer requirement. These specifications initially included grip strength, time to write, time to pour a cup of liquid, time to use a key on a lock, the ISNCSCI test, total weight, steps to turn on the device, time to put on the device, lag time, comfort, shock pain, appearance, cost, pinch points, electrode temperature, and skin redness after use. Some of these tests were later removed from the final test plans due to them being unnecessary or unable to do with our device, and include time to put on a device, battery life, lag time, material tensile strength, range of motion, blood pressure

The most high-risk of these specifications would be those that could potentially cause bodily harm including shock pain, pinch points, electrode temperature, and skin redness after use. These will be closely monitored and tested to ensure the safety of our device. All customer requirements can be tested using one of these specifications and can be measured to determine if these requirements are being fulfilled. A full list of all engineering specifications, their corresponding units, directions, and targets can be found in Appendix B. The customer requirements and engineering specifications were used to construct a House of Quality, shown in Figure 1.

Figure 1. House of Quality.

IV. Project Management

Overall, the design process involves creating many concepts and narrowing and refining those into one design. The device has to be designed, prototyped, refined and finalized. Currently, the prototype is close to being finished. Throughout this process, multiple progress reports and status update memos will keep our sponsor and administrators up to date.

The full Gantt chart can be found in Appendix C. Key deliverables for this project include the reports: Statement of Work, Conceptual Design Review, Critical Design Review, Test Plan, and Senior Project Design. Other than the reports and their corresponding presentations, the prototypes and final model construction will be key factors.

Network Diagram

The majority of this quarter focused on the manufacturing and testing of the finalized design. A lot of issues came up while trying to use the MikroElektronika chips. Currently, the prototype sensor and stimulator work separately but have not been successfully connected. The code has been finalized and runs without any error messages. The problem occurs while attempting to use the Myoware EMG sensors to detect wrist hyperflexion. The data sometimes comes out clear and other times there is unknown interference. The testing was completed by connecting a switch to the TENS unit. The network diagram can be found in Figure 2.

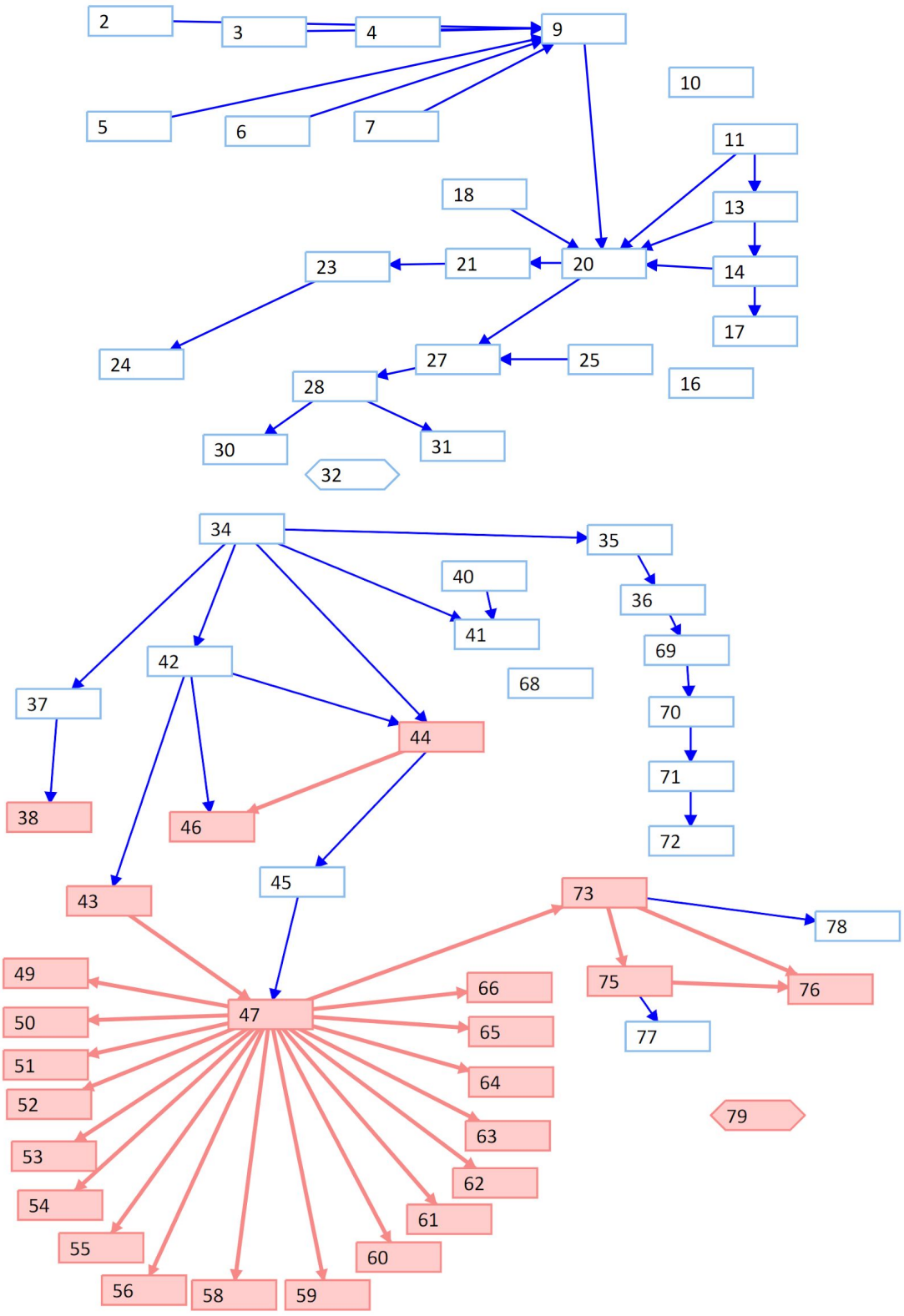


Figure 2a. Network Diagram with Critical Path.

Legend:

1 **Deliverable 1**
2 HOQ
3 IFU
4 Budget
5 Network Diagram
6 Patent Search
7 Conjoint Surveys
8 **Deliverable 2**
9 SOW
10 Project Plan Meeting Slides
11 Conjoint Analysis ANOVA
12 **Deliverable 3**
13 Morphology and Concept Sketches
14 Conceptual Model
15 **Deliverable 4**
16 Status Update Memo #1
17 FMEA
18 Pugh Chart
19 **Deliverable 5**
20 Concept Design Report
21 Concept Design Review Presentation
22 **Deliverable 6**
23 Status Update Memo #2
24 Status Update Memo #3
25 Hazard and Risk Assessment
26 **Deliverable 7**
27 Critical Design Report
28 Critical Design Review Presentation
29 **Deliverable 8**
30 Critical Design Review Peer Questions
31 Winter Quarter Project Plan
32 Design Notebooks
33 **Deliverable 9**
34 Updated Project Plan
35 Status Update Memo #1
36 Status Update Memo #2
37 Test Plan Report
38 Test Plan Presentation
39 **Prototype Manufacturing**
40 Obtain Software
41 Code
42 Signal Detection Assembled
43 Signal Detection Tested
44 Stimulator Assembled
45 Stimulator Tested
46 Functional Prototype Video
47 Finalize Prototype
48 **Testing**
49 ISNCSCI Test
50 Grip Strength
51 Time to unlock
52 Skin Redness
53 Time to Write
54 Time to Pour
55 Electrode Temp
56 Stimulus Amplitude
57 **Measurements**
58 Weight
59 Pinch Points
60 Steps to Turn On
61 Time to Put On
62 Comfort
63 Appearance
64 Lag Time
65 Shock Pain
66 Cost
67 **Deliverable 10**
68 Ethics Reflection
69 Status Update Memo #3
70 Status Update Memo #4
71 Status Update Memo #5
72 Status Update Memo #6
73 Final Prototype Demo
74 **Deliverable 11**
75 Senior Project Design Report
76 Design Review Presentation
77 Upload to Digital Commons
78 Poster Presentation
79 Finish Design Notebooks

Figure 2b. Network Diagram Legend.

Budget

The budget has changed since the start of this project. Initially, a MikroElektronika chip was chosen to process the EMG data rather than an Arduino, after consulting with Dr. Szlavik. Utilizing MikroElektronika components entailed purchasing an EMG processing chip with ECG/EMG cables and electrode pads, a PIC24 Clicker 2 target board for processing and development, and a USB UART 3 Click board to connect the boards to a computer for programming. After multiple issues with the MikroElektronika components, the decision was made to switch the project back to the initial idea of using Arduino components listed below, which have the same functions as the MikroElektronika components. Rocker switches were added to turn the device on and off. A breadboard added to provide connections between the Arduino, MyoWare, and TENS Unit. Visual and audio displays were retracted due to the unnecessary complexity they may add in coding and manufacturing the device. The budget comes out to a current total of $164.65 and can be found in Table 5 below.

Table 5. Budget

Item	Purpose	Quantity	Cost	Link
ECG/EMG Sensors	Detect muscle contraction	1 pack (30 count)	$14.00	https://www.mikroe.com/ecg-30pcs
Arduino Nano	Run our code and transfer digital signal to TENS Unit	1	$20.70	https://store.arduino.cc/usa/arduino-nano
ECG/EMG Cable	Transfer signal	1	$24.00	https://www.mikroe.com/ecg-cable
MyoWare Muscle Sensor	Filter and amplify EMG	1	$37.95	https://www.sparkfun.com/products/13723
MyoWare Cable Shield	Plug in 3.5 mm jack	1	$4.95	https://www.sparkfun.com/products/14109
MyoWare Power Shield	Combine CR2032 batteries in parallel	1	$4.50	https://www.sparkfun.com/products/13684
9 V Battery	Provide power to Arduino Nano & TENS Unit	2	$4.00	N/A
CR2032 Battery	Provide power to MyoWare	2	$1.50	N/A
Rocker switch	Safety switch	2	$1.50	https://www.sparkfun.com/products/11155
Breadboard	Hold electrical components together	1	$4.67	https://www.mikroe.com/breadboard-400-points
EMS TENS Unit	Stimulate muscle contraction	1	$34.99	https://tensunits.com/products/ems-7500-digital-ems-unit?variant=32146504581257
20 cm Wire pack	Connect components	1 pack (16 count)	$3.40	https://www.mikroe.com/ribbon-cable-16-wire-male-male-20-cm
Trimmer Potentiometer	Control TENS unit stimulus	1	$1.49	Coast Electronics

V. Design Analysis

Conjoint Analysis

The conjoint card analysis consisted of testing for preferences between combinations of battery arrangements, attachment methods, and casing materials, shown in Table 6 and 7. The full Google form data can be found in Appendix D. Performing the ANOVA and linear regression produced the data in Tables 8a-c.

As seen in Table 8c, none of the factors had a P-value < 0.05, so Y = 3.13 is the Customer Attraction equation. Either the sample size was too small or the factors chosen were not of significant importance to the sample group. The sample group was not necessarily composed of the target demographic for the product, so their answers may mostly be based on speculation rather than what a user would actually prefer. The factor levels were defined in the google form in the question description, as seen in Appendix D, but maybe the factors themselves were not well-defined such that the sample group could not envision how their choices would affect the device outcome. From this data, it is inconclusive if any factors are significant to the design of the device and further testing would need to be performed.

Table 6. Factors and Levels

	Factor		
	Battery Arrangement	Attachment Method	Casing Material
Level 1	Removable	Sleeved	Metal
Level 2	Built-in	Exposed	Plastic

Table 7. Conjoint Cards

Translated Taguchi Array			
Option 1	Removable	Sleeved	Metal
Option 2	Removable	Exposed	Plastic
Option 3	Built-in	Sleeved	Plastic
Option 4	Built-in	Exposed	Metal

Table 8a. Regression Statistic Values

Regression Statistics	
Multiple R	0.14922642
R Square	0.022268525
Adjusted R Square	-0.016326139
Standard Error	1.111246337
Observations	80

Table 8b. ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	3	2.1375	0.7125	0.576985	0.631895876
Residual	76	93.85	1.234868		
Total	79	95.9875			

Table 8c. Coefficients

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	3.13	0.66	4.75	0.00	1.82	4.43	1.82	4.43
Battery	0.03	0.25	0.10	0.92	-0.47	0.52	-0.47	0.52
Attachment	-0.27	0.25	-1.11	0.27	-0.77	0.22	-0.77	0.22
Casing	-0.18	0.25	-0.70	0.48	-0.67	0.32	-0.67	0.32

Morphology

The morphology table as shown in Table 9 was created to document the different functions necessary for the project as well as the concepts for addressing those functions. After consulting Dr. Szlavik, the table was updated to include Mikroelektronika components as concept 6 for the "Process Signal" function.

Table 9. Design Morphology

Morphology						
Product: EMMT		Organization Name: EMMT Team				
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Input Signal	EMG (e.g. Biopac)	Force Sensitive Resistor	Gyroscopic sensor			
Process Signal	Arduino/C++	Cell phone/app	Raspberry Pi	Arduino/ MATLAB	Powerlab/ MATLAB	Mikroelektronika components
Convert to physical response	Transcutaneous electrodes	Robotic prosthesis	Subcutaneous electrodes	Transcutaneous Electromagnetic Stimulation		
Attachment	Components strapped to arm	Components in pocket	Components enclosed in sleeve	Components attached to waist	Components carried by user	
Feedback	light	beep	Light and beep	No feedback		
Team member: Jake Javier	Team member: Sam Borda	Prepared by: Hailey Casino				
Team member: Charlotte Anderson	Team member: Hailey Casino	Checked by:		Approved by:		
The Mechanical Design Process Copyright 2008, McGraw Hill				Designed by Professor David G. Ullman Form # 15.0		

Concept Evaluation

One conceptual sketch was created by each team member, and each sketch was scored against one another using the Pugh Method. The categories that were evaluated in order to compare the designs were accuracy, ease of putting on, dynamic comfort, and appearance. Each team member individually completed four Pugh charts, with each concept sketch serving as a baseline for one chart. All Pugh charts are displayed in Appendix E.

After analyzing the results, the original front-runner design was Concept 4.1 shown in Figure 3, the design with the sleeve housing electrodes. This design best addressed the conversion of input signals to output signals by supporting the tenodesis motion in the hand and forearm via wrist control. It also had the best potential to be the basis for the design because the sleeve contains the circuitry and electrical components in a compact and aesthetic manner. Aspects from the other concept designs were to still be considered to add to the winning design, and these sketches can be found in Appendix F. As in Concept 2, the heaviest components (batteries, circuit board, signal generator, Arduino) will be attached to the upper arm rather than the forearm as in the Concept 4.1 and Concept 4.2 sketches. After reviewing the different sensors in each concept, the possibility of using multiple types of sensors to gather a variety of input signals to create a broader range of distinct motions was also being considered. However, in the end, it was decided that multiple input sensors would over complicate our design and, for the time being, will not be included. Lastly, in regards to software, a decision was made between the MikroElektronika coding platform or MATLAB. The MikroElektronika coding platform is more available and easier to integrate with the microcontroller so it was initially the finalized choice. After encountering multiple obstacles while trying to get the MikroElektronika components to work correctly, the decision was made to switch the project to Arduino.

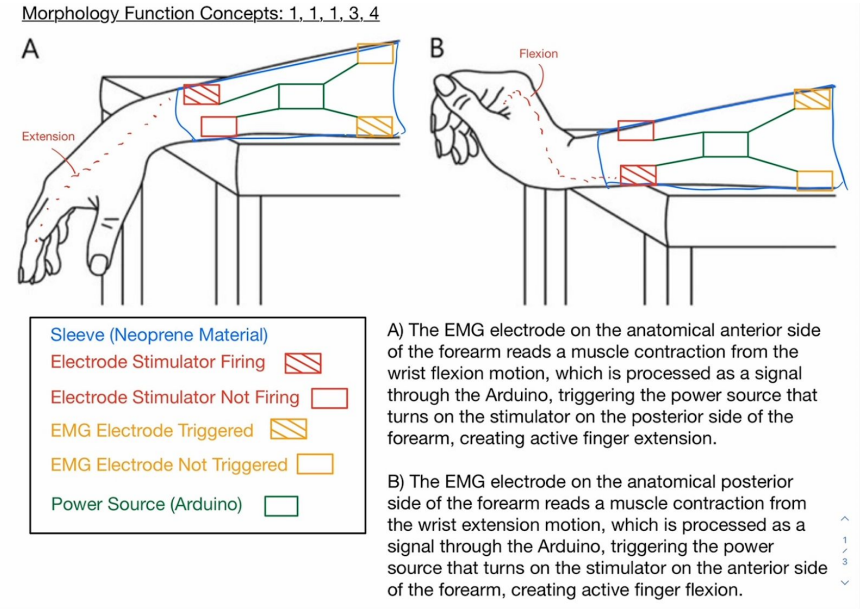


Figure 3. Concept 4.1

Since our Conceptual Design Report, Figure 3 has been updated to reflect our finalized design ideas and provide us a blueprint for manufacturing. The power source was changed from Arduino to a TENS unit stimulation component and the Mikroelektronika microcontroller was added in. It does not accurately depict where the electrical components (outside of the electrodes) will be placed. They will be attached to the upper arm to reduce bulk on the forearm and increase ease of movement. They are drawn onto the forearm for the purpose of the concept sketch to accurately represent how the flow of information and energy shall be carried out. After many attempts to get this concept working, the processing component had to be switched back to Arduino after multiple issues with MikroElektronika.

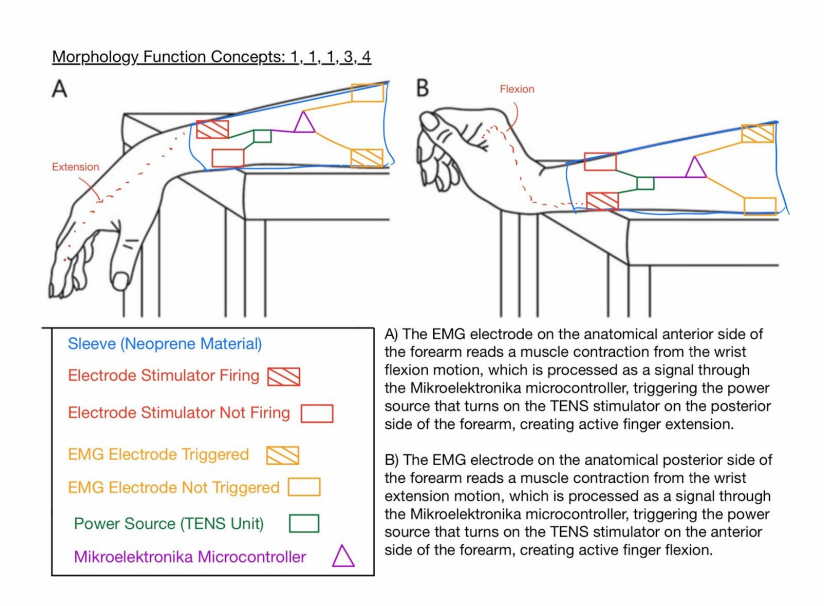


Figure 4. Concept 4.2

Conceptual Model

EMG Band Pass Active Filter Circuit

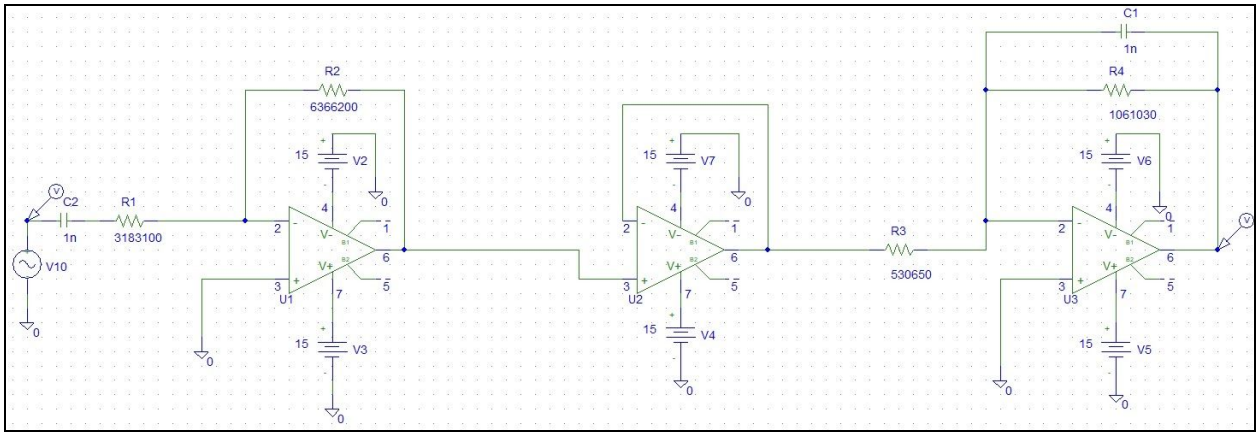


Figure 5. PSPICE Bandpass Filter Schematic.

A bandpass active filter will filter out high-frequency and low-frequency signals. In the case of an EMG, this filter will be applied to remove high-frequency noise and low-frequency variations in the sample. In the model code below, this filter is inherently built into the code. In research and in speaking with professors who do research in this field, it was found that it would be most efficient to filter out frequencies outside of the 50-150 Hz range. In order to conceptually see this, the simulation was run as an AC Sweep within PSPICE. An arbitrary 1 V AC power source was used to provide an input stimulus. However, as seen in the PSPICE Schematic from Figure 4, particular resistance values were used in order to filter the frequency range. In order to find these values, Equations 1 & 2 from Figure 5 were used. An arbitrary value of 1 nF was used for capacitance values.

$$f_{cHP} = \frac{1}{2\pi R_{1HP} C_{HP}} \qquad f_{cLP} = \frac{1}{2\pi R_{fLP} C_{LP}}$$

Figure 6. Filter Cutoff Frequency Governing Equations.

Figure 6 presents low pass filter resistance values and Figure 7 presents high pass filter resistance values. These values are also labeled in Figure 4. The equations on the right are amplifying governing equations. Arbitrary 2 V/V gain was used across both filters.

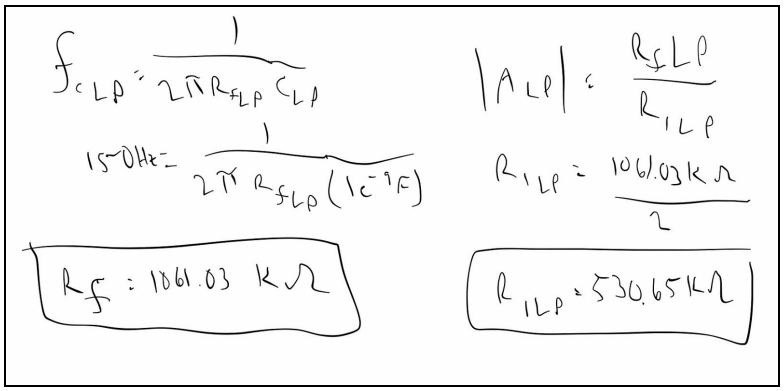


Figure 7. Low-Pass Filter Cutoff Frequency Calculations.

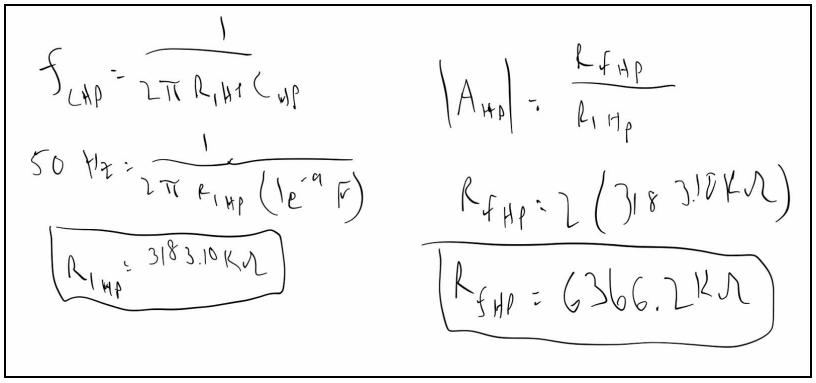


Figure 8. High-Pass Filter Cutoff Frequency Calculations.

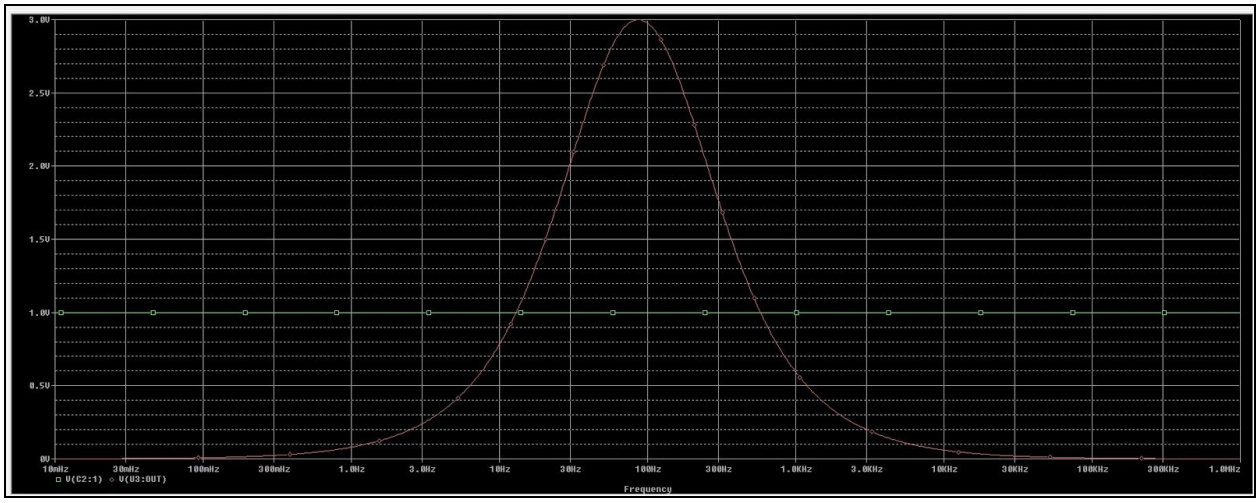


Figure 9. Bandpass Filter Bode Plot.

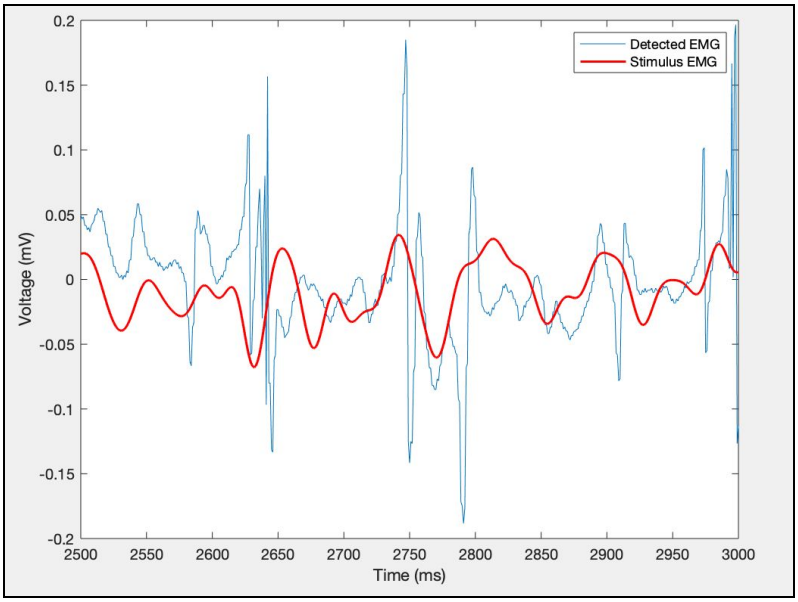


Figure 10. MATLAB Filtering of Sample EMG signal.

Conceptual Model Analysis

The initial schematic is a physical representation of the circuitry that is within the EMG. When a PSPICE simulation is run, a model of what is happening within the EMG is produced. In running this model, Figure 8 was produced as a representation of how the band-pass filter works based on the established parameters. This simulation took an arbitrary input voltage of 1 V (in green) and presented a curve of output voltages (in red) depending on the frequency along the x-axis. This plot visually analyzes how frequencies are filtered. Equations and the resulting graph are used to choose how much signals are amplified across the circuit. For example, the 2 V/V arbitrary amplification across each filter takes the 1

V input and receives a 3 V output. Using PSPICE models as a simulation will visually present how to filter and amplify the signals by changing resistors.

Another way of filtering the EMG signal is by doing it virtually through MATLAB code. This would have the same function as filtering using electrical components, as shown in Figure 3. Figure 8 shows the effect of MATLAB virtual bandpass filtering on an EMG signal. The filtering reduces unwanted noise interference in the signal (e.g. lights, bluetooth) and limits signal frequencies to only appear between 50 and 150 Hz, which is the typical dominant frequency range of muscle electrical activity. The stimulus can also be easily amplified in MATLAB if necessary. This code is shown in Appendix G.

Conceptual Model Discussion

The band-pass filters can be used to filter frequencies and amplify our signals by manipulating resistance values. This will be useful when deciding how to process the input EMG into the output signal generator. This should be achievable through the MATLAB code, which can be reviewed in Appendix A. After reviewing current options on the market, along with discussing the project with knowledgeable professors, it was initially decided to design the device around a Mikroelektronika chip rather than using an Arduino. These chips would have a more complete design which would mitigate any software/hardware problems that may come about by coding an Arduino. They would also come with an EMG click board and electrodes, which would help to reduce the budget and allow the focus to be more on the coding and stimulation aspects of our device. This was later changed back to an Arduino after encountering multiple setbacks while trying to get the MikroElektronika chips to work. A TENS unit could be used in conjunction with the processing chip to produce enough stimulation to contract the desired muscles. A nine-volt power supply is also needed to power the TENS unit to allow for enough stimulation to produce a contraction. Coding was carried out within MATLAB to gain a general understanding of how we want our device to filter and analyze the signal, but this information was later transferred over into the appropriate C++ code used by Arduino.

VI. Safety Analysis

FMEA

As shown in Table 10 below, an FMEA was created to list and rank the possible failure modes. The highest risk failures were determined to be any false positive caused by software or hardware issues or a signal that is too strong due to a hardware malfunction. As of completing this document, the ‘Taken Actions’ column is yet to be determined, as there is no physical model to test yet.

Table 10. FMEA

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person	Taken Actions
Input signal	Wrong signal read	False positive	7	3	6	126	Hardware malfunction	Review placement of electrodes	Hailey	TBD
		False positive	6	3	7	126	Software malfunction	Adjust code	Sam	TBD
		False negative	5	4	3	60	Hardware malfunction	Review placement of electrodes	Hailey	TBD
		False negative	5	4	4	80	Software malfunction	Adjust code	Sam	TBD
Output signal	Inaccurate signal delivered	Stimulation too strong	7	3	6	126	Hardware malfunction	Review placement of electrodes	Hailey	TBD
		Stimulation too strong	5	3	7	105	Software malfunction	Adjust code	Sam	TBD
		Stimulation too weak	7	4	4	112	Hardware malfunction	Review placement of electrodes	Hailey	TBD
		Stimulation too weak	5	4	6	120	Software malfunction	Adjust code	Sam	TBD
Heat Control	Battery overheated	Skin burns	1	2	10	20	Inappropriate battery interface	Change battery	Charlotte	TBD
	Circuit overheated	Skin burns	1	3	9	27	Too much voltage	Wire insulation; change circuitry; optimize code	Sam	TBD
	Electrode overheated	Skin burns	4	3	10	120	Electrode pad malfunction	Change out electrodes	Jake	TBD
	Electrode overheated	Skin burns	3	3	10	90	Overuse	Allow cool down time	Jake	TBD
Structure of device	Wire tugging	Device fails to function	5	2	3	30	Wire disconnects from circuitry	Re-solder device; plug wire back in	Charlotte	TBD
		Device fails to function	5	3	6	90	Electrode displacement	Reattatch electrodes	Charlotte	TBD
	Attachment system malfunction	Device parts detach	1	1	4	4	Components too loose	Reattatch device; tighten components	Jake	TBD
		Sleeve/Wrap tear	1	3	1	3	Overuse	Replace sleeve	Charlotte	TBD
	Attachment discomfort	Loss of circulation	3	3	10	90	Sleeve/Wrap too tight	Loosen sleeve	Charlotte	TBD
		Pressure sores	3	3	9	81	Sleeve/Wrap presses	Add more padding	Jake	TBD
		Loss of range of motion	2	1	7	14	Sleeve/Wrap too constricting	Change sleeve material; change sleeve size	Jake	TBD

Design Hazard Checklist and Risk Assessment

A Design Hazard Checklist was created to determine the risks that may affect testing and operating the device and is shown in Figure 11 below. This list was used to construct safe testing and operating procedures, detailed below in Figure 12. The potential hazards applicable to our device shown below include pinch points, battery voltage, and misuse of the device, with detailed countermeasures.

DESIGN HAZARD CHECKLIST

Team: EMMT Advisor: Dr. Heylman & Dr. Berg-Johansen Y / N

1. Will any part of the design create hazardous revolving, reciprocating, running, shearing, punching, pressing, squeezing, drawing, cutting, rolling, mixing, or similar action, including pinch points and sheer points? **Y**
2. Can any part of the design undergo high accelerations/decelerations? **N**
3. Will the system have any large moving masses or large forces? **N**
4. Will the system produce a projectile? **N**
5. Would it be possible for the system to fall under gravity creating injury? **N**
6. Will a user be exposed to overhanging weights as part of the design? **N**
7. Will the system have any sharp edges? **N**
8. Will any part of the electrical systems not be grounded? **N**
9. Will there be any large batteries or electrical voltage in the system above 40 V? **N**
10. Will there be any stored energy in the system such as batteries, flywheels, hanging weights, or pressurized fluids? **Y**
11. Will there be any explosive or flammable liquids, gases, or dust fuel as part of the system? **N**
12. Will the user of the design be required to exert any abnormal effort or physical posture during the use of the design? **N**
13. Will there be any materials known to be hazardous to humans involved in either the design or the manufacturing of the design? **N**
14. Can the system generate high levels of noise? **N**
15. Will the device/system be exposed to extreme environmental conditions such as fog, humidity, cold, high temperatures, etc? **N**
16. Is it possible for the system to be used in an unsafe manner? **Y**
17. Will there be any other potential hazards not listed above? If yes, please explain on reverse.

For any "Y" responses, add (1) a complete description, (2) a list of corrective actions to be taken, and (3) date to be completed on the reverse side.

Figure 11. Design Hazard Checklist.

Description of Hazard	**Planned Corrective Action**	**Planned Date**	**Actual**
1. Pinch points may arise from the location where the electronics are strapped/connected to the user.	This can be fixed by closely monitoring potential pinch point areas of our device and adjusting/padding problem areas.	02/05/2020	
10. A battery has to be used to supply the voltage necessary to electrically stimulate muscles.	There will be electrical components in place to regulate voltage output, like buffer amplifiers, acting as a safeguard to prevent overstimulation.	01/29/2020	
16a. Patients may attempt to use the device on areas not intended for use, such as legs. This device is specifically intended for use with the forearm.	Include safety labels and an instructions manual.	03/20/2020	
16b. The extended use of this device could potentially lead to skin sores from heat and pressure.	Check skin during testing and ensure there is a set time limit on usage. There can also be further padding and insulation to minimize heat and pressure.	02/03/2020	

Figure 12. Risk Assessment.

VII. Design & Manufacturing

Detailed Design, Iteration #1

The device will have the ability to read an EMG signal, process and filter it, use that signal to trigger an external power source, and electrically stimulate a muscle. This requires a series of electrical components to be assembled. See outline of EMG Click in Figure 13 below. The full written description can be found in Appendix H.

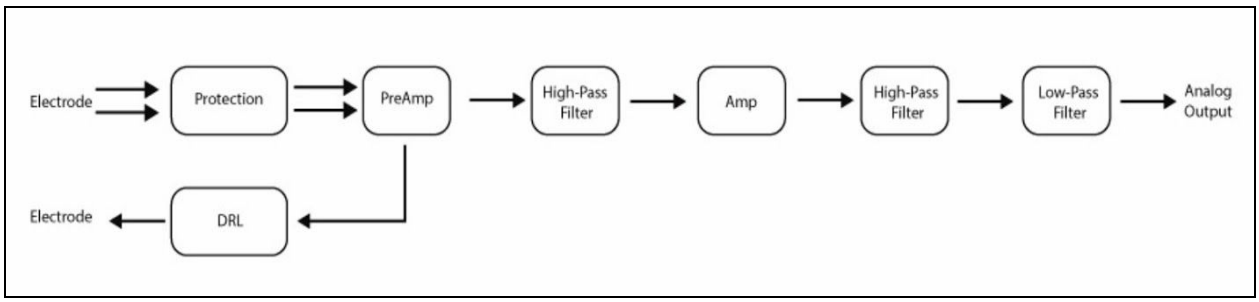


Figure 13. EMG Click Capabilities.

This EMG signal will be sent to the PIC24 Click, a 24 bit microcontroller that will act as the development board. This development board has the capability to attach a second click board. A USB UART 3 click board will also be attached, providing the ability to visually monitor and adjust the signal parameters using MikroPlot, a free software application. The development board has output analog pins that can be programmed to output our signal through wires soldered to these pins. See Figure 14 below, example point of attachment RB11.

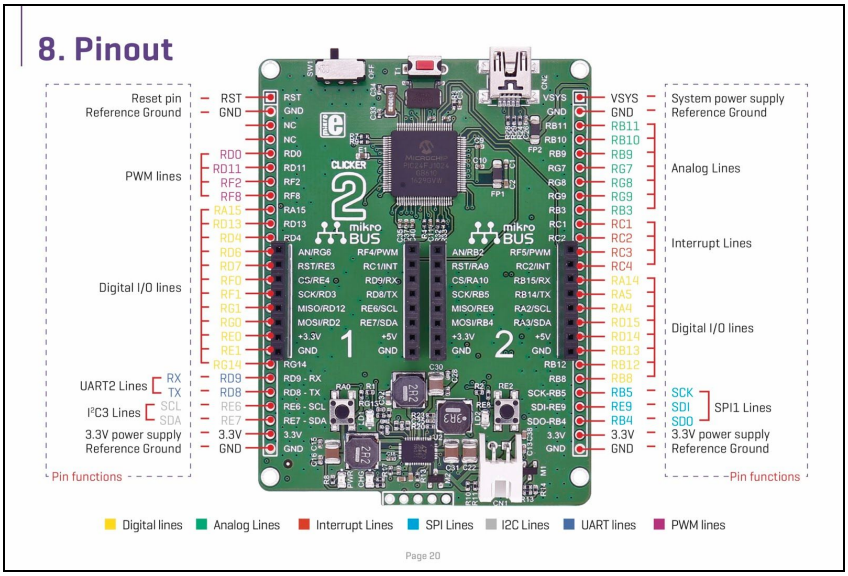


Figure 14. Pinout of Clicker 2 for PIC24 Development Board.

Five wires are needed to properly translate the signal from the development board to the TENS unit, replacing its original input signal component. Two of the wires are used to signal to the device when to turn on and off, while the other three wires are used to translate a variable resistance to change the amplitude of the TENS unit output. The variable potentiometer wire will then be connected to a transistor which will act as a switch, turning the TENS unit on and off. The TENS unit uses its own internally connected 9V battery to power the electrical stimulation that exits the TENS unit via its attached stimulation electrodes. See Figure 15 below for the layout of the TENS unit.

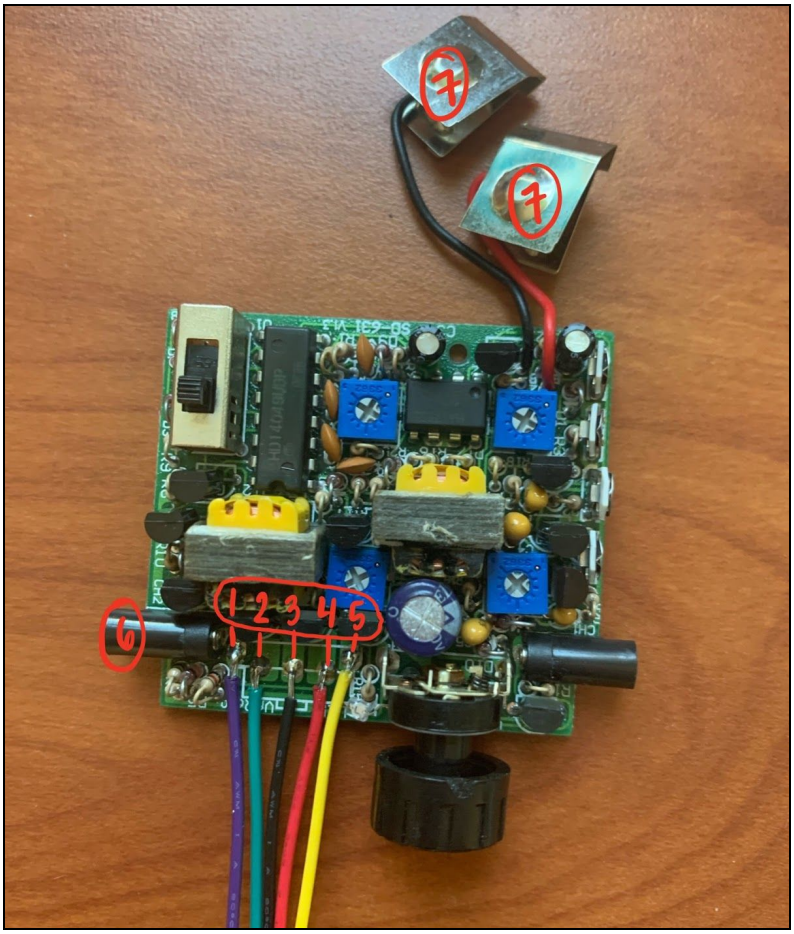


Figure 15. Layout of TENS unit.

In Figure 15, components labeled 1-5 (wires) connect the TENS unit to the development board. Wires 1 and 5 regulate turning the device on and off. Wires 2, 3, and 4 allow for the resistance to be changed from the signal received from the MikroElektronika chips. Wire 3 will then be connected to the transistor which receives the signal from the Arduino. Component 6 displays the output of the TENS unit and where the electrodes will be connected. Component 7 displays where the 9V battery will be connected.

Figure 16 below lays out the flow of information and energy from start to end in box diagram form. As a reference the physical layout can be seen in Figure 17, showing the relative placement of electrodes and wires with stand-in circuit boards.

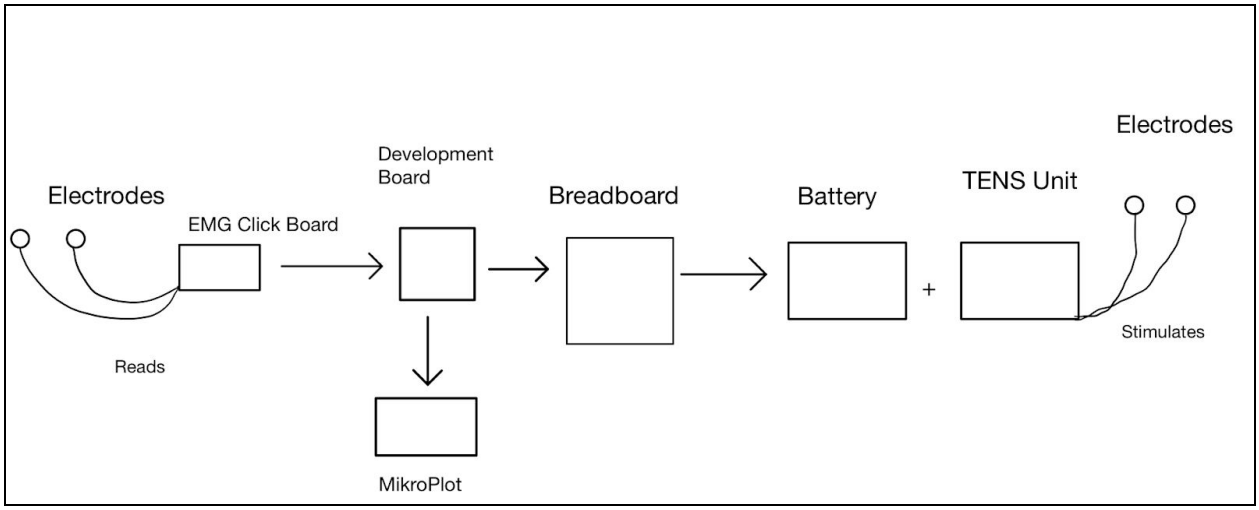


Figure 16. Flow of Information & Energy.

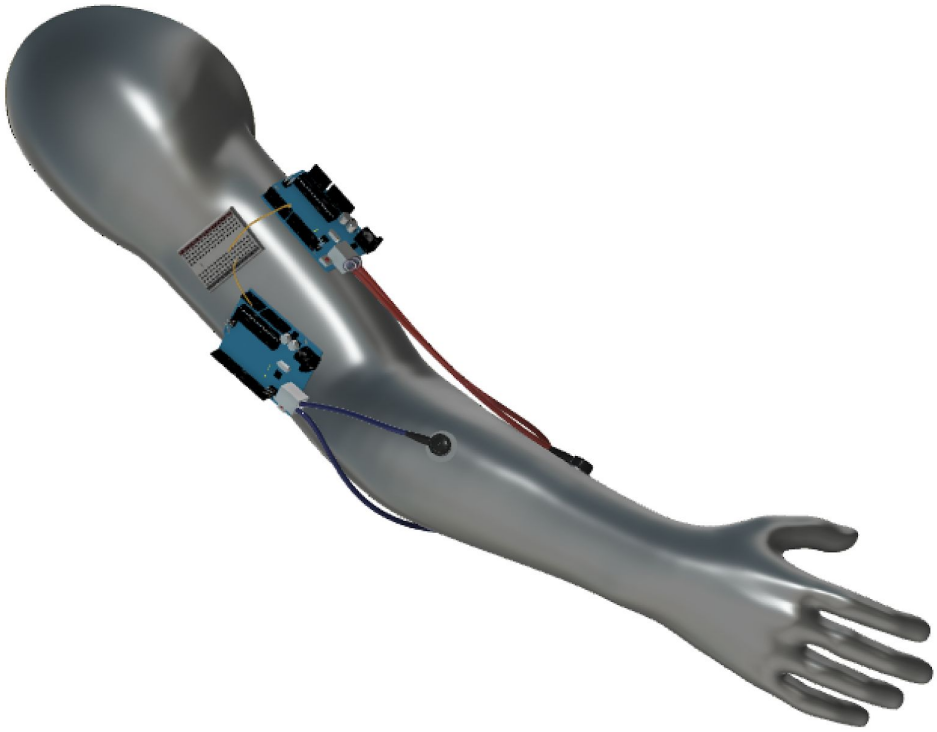


Figure 17. 3D Model.

Pseudocode

- Electrode input signal received
- Convert signal to frequency domain
- Bandpass filter accepts 50-150 Hz, otherwise repeat loop
- Convert signal to time domain
- Amplify signal
- Normalize signal to appropriate TENS unit input range

- Output signal to MikroPlot software for monitoring
- Turn on TENS unit
- Trimmer potentiometer outputs the signal to TENS unit
- Turn off TENS unit

Detailed Design, Iteration #2

Most of the design has stayed consistent with Iteration #1, however there are some component changes because the MikroElektronika electronics did not function. We switched out the MikroElektronika boards with the Arduino Nano, MyoWare muscle sensor, MyoWare power shield, and MyoWare cable shield. These fulfill the capabilities we need for our device to work. Additionally, these already come with some basic functions that we had planned to do separately: filtering, amplification, and signal monitoring capabilities when paired with adequate code. The arduino code can be found in Appendix I. The new boards are shown in Figure 18, below.

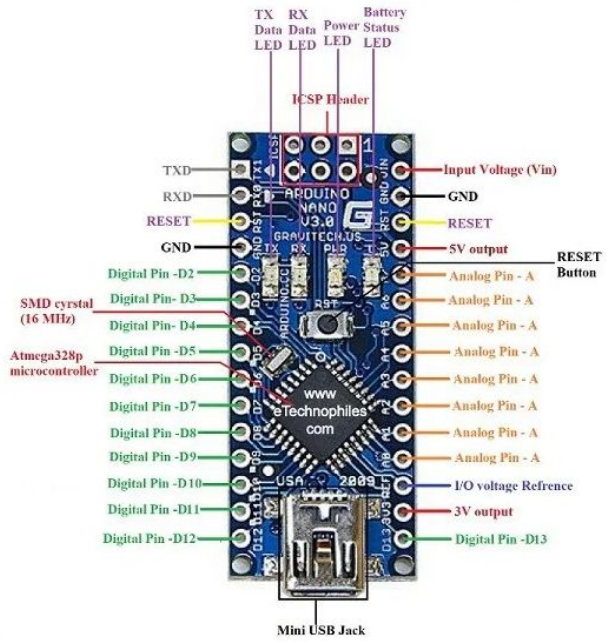


Figure 18a. Pinout of Arduino Nano.

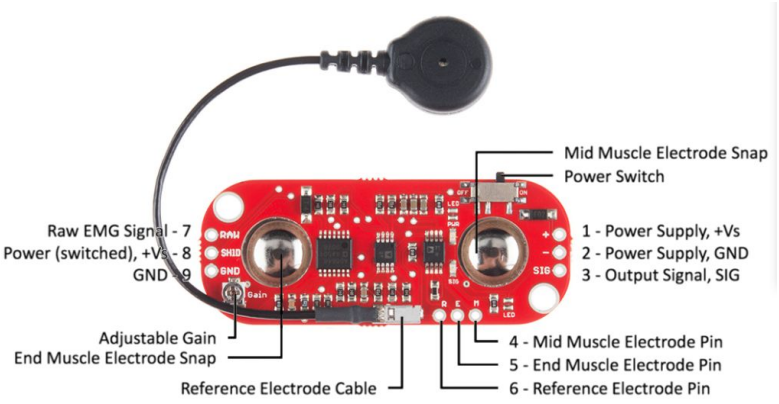


Figure 18b. MyoWare Muscle Sensor.

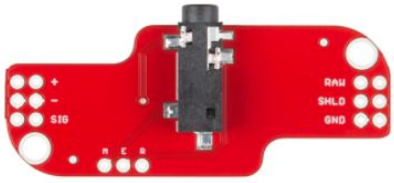


Figure 18c. MyoWare Cable Shield.

Figure 18d. MyoWare Power Shield.

The code for our devices has also been simplified since some of the capabilities are present within the boards themselves. The new pseudocode is as follows:

- Initialize bitrate at 9600 bps
- Receive analog EMG signal from MyoWare
- Check if that signal is above 500 mA
- If so, output a digital transfer signal to turn on TENS Unit (HIGH). If not, keep/turn off TENS Unit (LOW).
- If connected to the computer, then output an EMG plot to monitor the live signal.

The flow of information/energy and the 3D model have both stayed the same as in Iteration #1. The worn prototype can be found in Figure 19.

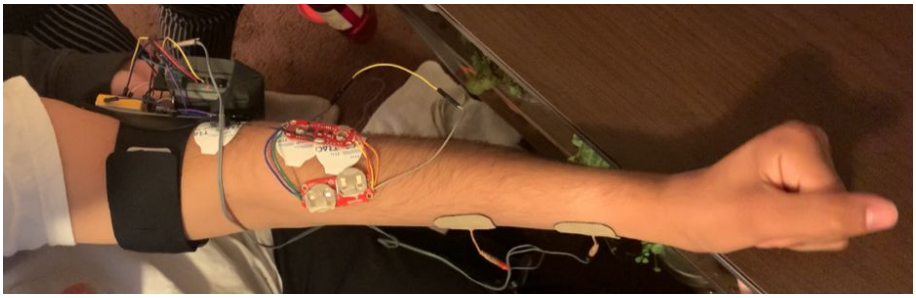


Figure 19a. Top-down prototype view.

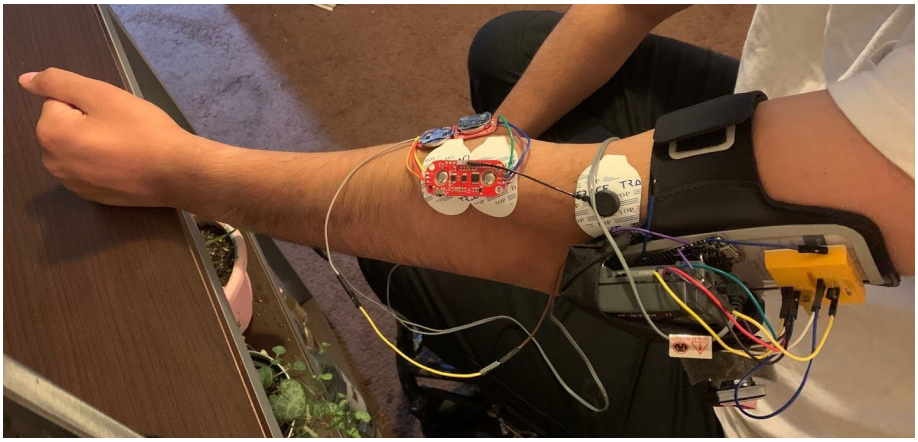


Figure 19b. Myoware view.

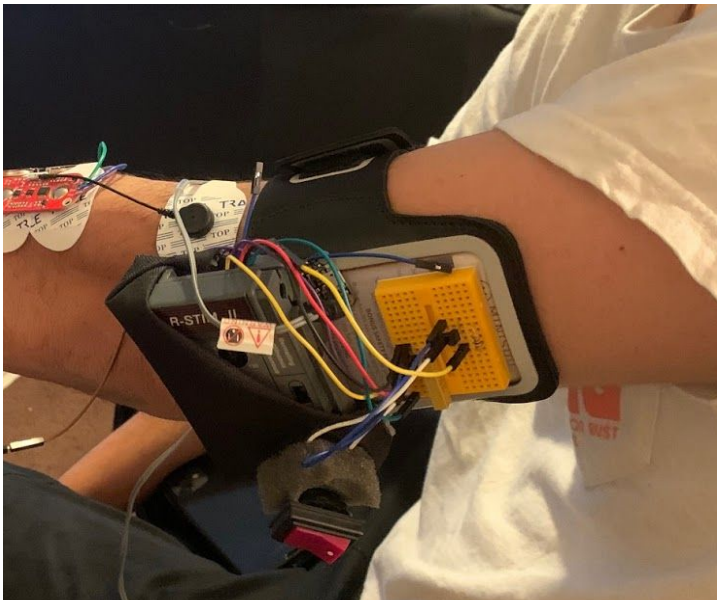


Figure 19c. TENS unit view.

Prototype Manufacturing Plans

The manufacturing process was carried out on two fronts; the building and compilation of the code and the building of the physical device. The bulk of the physical manufacturing involved assembling all electrical components into one device. For the initial testing phase, this was a crude prototype that did not meet the standards of aesthetic and comfort that is set in the House of Quality. As the design was verified through testing, however, the focus shifted toward meeting these standards. This involved manufacturing a strap or fastener made of velcro that will keep the components attached tightly yet comfortably to the user's upper arm. There was also a 3D printed protective case to house the Arduino components, keeping them protected and discreet.

The majority of manufacturing involved the debugging and optimization of code and software. Many error codes were encountered when trying to work with the MikroElektronika chips. After researching the function files available from MikroElektronika, there was still no way to tell if the signal was going through as the device would not connect to MikroPlot, which would allow for visual analysis of the signal. The Mikroelektronika support team and the Cal Poly IT department were reached out to for more information on how to connect the device to MikroPlot, but this problem was not able to be fixed within the timeframe of this project. After realizing this, the project was switched back to Arduino in order to read and output the signal correctly.

The other portion of manufacturing involved physically connecting and interfacing all of the components in our device. Since the Arduino components are all separate, they had to be connected with wires which were then all housed in a protective case. After completing this, physical manufacturing was mainly focused on interfacing the TENS unit with the Arduino components. This required soldering wires to connect the input pins on the TENS unit to a potentiometer, an ON/OFF switch, and a transistor. The operation manual can be found in Appendix J.

Prototype Manufacturing Steps

- Download the Arduino software interface
- Write the code
- Attach the Myoware boards and Arduino together
- Attach a 9V battery to the Arduino
- Connect the Arduino to the computer with the USB cable and download the code
- Monitor the input signal using a data serial plotter
- Desolder the TENS unit input knob
- Solder the on/off switch wires (2) and potentiometer wires (3) to the TENS unit.
- Attach the other ends of the 5 wires to the breadboard.
- Wire the trimmer potentiometer on the breadboard
- Connect the variable wire to a transistor
- Connect the TENS unit on/off wires to the on/off rocker switch
- Connect the transistor wire to the Arduino through a 1k ohm resistor
- Verify the on/off rocker switch functions
- Monitor the output electrodes using a multimeter and adjust the code

Bill of Materials

Table 11. Bill of Materials

BOM Level	Part Number	Part Name	Quantity
1	MIKROE-2456	ECG/EMG Sensors	1 Pack (30 count)
2	A000005	Arduino Nano	1
3	MIKROE-2457	EMG Cable	1
4	SEN-13723 ROHS	MyoWare Muscle Sensor	1
5	DEV-14109 ROHS	MyoWare Cable Shield	1
6	DEV-13684 ROHS	MyoWare Power Shield	1
7	N/A	9 V Battery	1
8	N/A	CR2032 Battery	2
9	COM-11155	Rocker Switch	2
10	MIKROE-1098	Breadboard	1
11	DE7502	EMS TENS Unit	1
12	MIKROE-2312	20 cm wire	1 Pack (16 count)
13	Spectrol 43P502	Trimmer Potentiometer	1

VIII. Test Plans

Device testing consisted of a series of tests in place to determine the functionality, convenience, reliability, comfort, aesthetic, and safety of the product. Some tests will require the patient to complete them, while others will not require the patient to be present. Tests for each specification are detailed below, including sample sizes, experimental groups, expected outcomes, experimental set-ups, data acquisition, and analysis protocols, equipment, supplies, and personnel.

Grip Strength

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm; Feb. 16, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Grip w/ device, grip w/o device
- Experimental set-up: Have the user use the dynamometer to squeeze one time with maximum force, and record the measurement. Wait 30 minutes to regain maximum strength, then repeat. This will occur for 5 reps per day so as to not induce muscle fatigue.
- Expected outcomes: increased strength of 25%
- Data Acquisition: Hand dynamometer
- Data Analysis: t-test, alpha = 0.05
- Equipment & supplies: dynamometer
- Personnel: Jake

Time to write

- Test date/time slot: Feb. 11, 2:00pm - 4:00pm; Feb. 18, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Write w/ device, write w/o device
- Experimental set-up: Have the user use a pen to write their name on the paper, and record the amount of time it takes. This will occur for 5 reps per testing day.
- Expected outcomes: Decrease in time of 80%
- Data Acquisition: Stopwatch
- Data Analysis: t-test, alpha = 0.05
- Equipment & supplies: Pen, paper, stopwatch
- Personnel: Jake

Time to pour a cup of liquid

- Test date/time slot: Feb. 11, 2:00pm - 4:00pm; Feb. 18, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Pour w/ device, pour w/o device
- Experimental set-up: Set up two glasses, one with liquid and one empty. Have user pick up the glass with liquid and pour it entirely into the glass without liquid. Record any instances of spilling.
- Expected outcomes: Decrease in time of 70%
- Data Acquisition: Stopwatch
- Data Analysis: t-test, alpha = 0.05
- Equipment & supplies: Two glasses, liquid, stopwatch
- Personnel: Jake

Time to use a key in a lock

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm; Feb. 16, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Time w/ device, time w/o device
- Experimental set-up: Record the time it takes the user to unlock the lock with a key. Wait 30 seconds and repeat until finished.
- Expected outcomes: Decrease of 75%
- Data Acquisition: Stopwatch
- Data Analysis: t-test, alpha = 0.05
- Equipment & supplies: key, lock, stopwatch
- Personnel: Jake

ISNCSCI Test

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm; Feb. 16, 2:00pm - 4:00pm
- Sample size: n = 2 per ISNCSCI test
- Experimental groups: Score w/ device, score w/o device
- Experimental set-up: One cotton swap, one pin
- Expected outcomes: Increase of 1 point

- Data Acquisition: Use the ISNCSCI scoring scale, 0-5
- Data Analysis: Increase in points = success
- Equipment & supplies: Pin, Cotton Swab
- Personnel: Jake

Electrode temperature

- Test date/time slot: Feb. 11, 2:00pm - 4:00pm; Feb. 18, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Electrode temperature pre- and post-use
- Experimental set-up: Use a digital thermometer to record the temperature of the electrode pads before and after Jake has used the device.
- Expected outcomes: 38 degrees Celsius
- Data Acquisition: Thermometer
- Data Analysis: 4/6 pass = success
- Equipment & supplies: Thermometer
- Personnel: Charlotte

Skin redness (post use)

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm; Feb. 16, 2:00pm - 4:00pm
- Sample size: n = 10 per group
- Experimental groups: Skin color post-device use, baseline skin color
- Experimental set-up: Maintaining a consistent lighting setup, have users use the device and record skin color. Compare with baseline color.
- Expected outcomes: 2 redness on a 0-5 scale, with 5 being extremely red
- Data Acquisition: Visual inspection
- Data Analysis: 4/6 pass = success
- Equipment & supplies: camera
- Personnel: Hailey

Some measurements will not require a statistical test, compared to a control group, and will only require testing a small number of times. However, the experimental set-ups, expected outcomes, data acquisition, data analysis, personnel, equipment, and supplies are listed below for each measurement.

Weight

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm
- Experimental set-up: Place the EMMT device on a scale and record the weight of the device 5 times.
- Expected outcome: Weight less than 0.8 kg
- Data Acquisition: Scale
- Data analysis: Calculate the mean and percent difference between our value and our target.
- Equipment & supplies: Scale
- Personnel: all group members

Number of pinch points

- Test date/time slot: Feb. 9, 2:00pm - 4:00pm
- Experimental set-up: Equip the device and have users record the number of pinch points.
- Expected outcome: One or fewer pinch points
- Data Acquisition: Physical sensation
- Data Analysis: Calculate the mean and the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: all group members

Number of steps to turn on the device

- Test date/time slot: Feb. 11, 2:00pm - 4:00pm
- Experimental set-up: After equipping the device, the user will turn on the device and record the number of steps to do so. Repeat 5 times.
- Expected outcome: < 3 steps
- Data Acquisition: Manual count
- Data Analysis: Record the highest count, calculate the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: Jake

Comfortable

- Test date/time slot: Feb. 16, 2:00pm - 4:00pm
- Experimental set-up: The user will review how comfortable the device is while on.
- Expected outcome: Comfort will be judged on a 1-5 scale with an expected comfort level of 3
- Data Acquisition: Point scale (1-5)
- Data Analysis: Calculate the mean and the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: all group members

Appearance

- Test date/time slot: Feb. 16, 2:00pm - 4:00pm
- Experimental set-up: The user will look at and review the design of the device once it is on.
- Expected outcome: Visually appealing at a level of 3 out of 5 points
- Data Acquisition: Visual point scale (1-5)
- Data Analysis: Calculate the mean and the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: all group members

Shock pain

- Test date/time slot: Feb. 18, 2:00pm - 4:00pm
- Experimental set-up: The user will put on the device and describe the pain felt by the stimulation on a 1-5 scale
- Expected outcome: pain at a level of 2 or less
- Data Acquisition: Physical sensation point scale (1-5)

- Data Analysis: Calculate the mean and the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: all group members

Cost

- Test date/time slot: Feb. 18, 2:00pm - 4:00pm
- Experimental set-up: The cost of all equipment and components will be reviewed
- Expected outcome: $200
- Data Acquisition: Component receipts
- Data Analysis: Calculate the percent difference between our value and our target.
- Equipment & supplies: N/A
- Personnel: all group members

IX. Test Results

Grip Strength

Table 12. Grip strength test result

Target	Threshold	Experimental Result
Increase > 25%	Increase < 5%	Increase of 4620%

Design specification met? YES

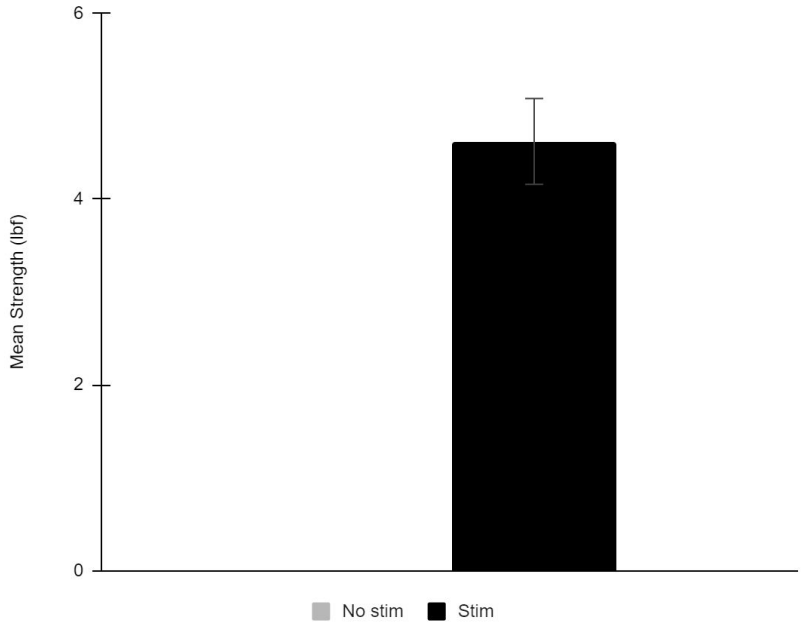


Figure 20. Grip Strength with vs. without Device. The user gripped the dynamometer for 2s at a time with 10s in between. n = 6 control and n = 6 test trials were conducted. $p < 0.05$

Time to Write

Table 13. Time to write test result

Target	Threshold	Experimental Result
Decrease > 80%	Decrease < 10%	Decrease of 11.42%

Design specification met? YES

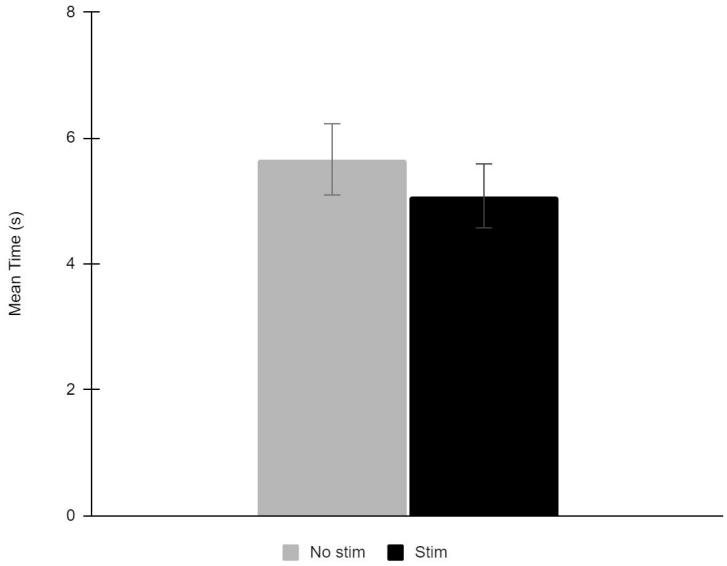


Figure 21. Time to Write Name, with vs. without Device. The user was timed while writing their name. n = 5 control and n = 5 test trials were conducted. $p < 0.05$

Time to Pour a Cup of Liquid

Table 14. Time to pour a cup of liquid test result

Target	Threshold	Experimental Result
Decrease > 70%	Decrease < 20%	Decrease of 39.27%

Design specification met? YES

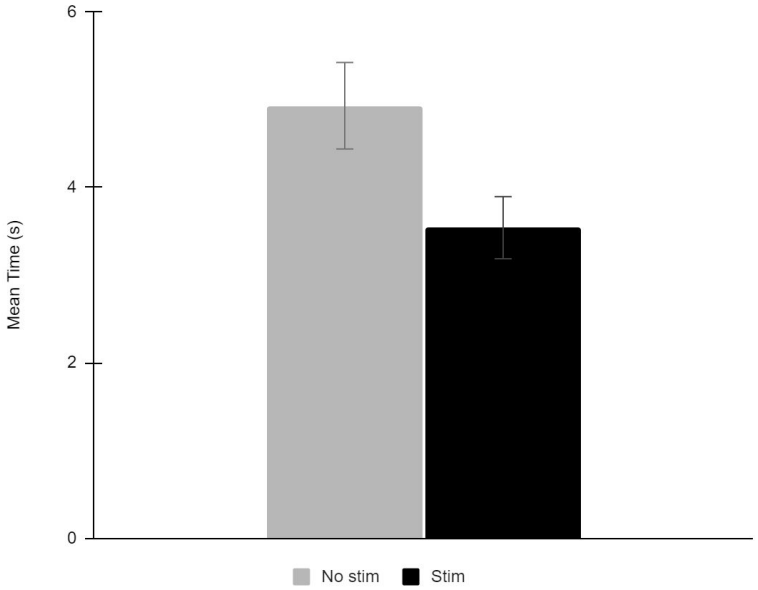


Figure 22. Time to Pour Water, with vs. without Device. The user was timed while pouring a cup of liquid from one cup to another. n = 5 control and n = 5 test trials were conducted. $p < 0.05$

Time to Use Key in Lock

Table 15. Time to use key in lock test result

Target	Threshold	Experimental Result
Decrease > 25%	Decrease < 20%	Decrease of 45.51%

Design specification met? YES

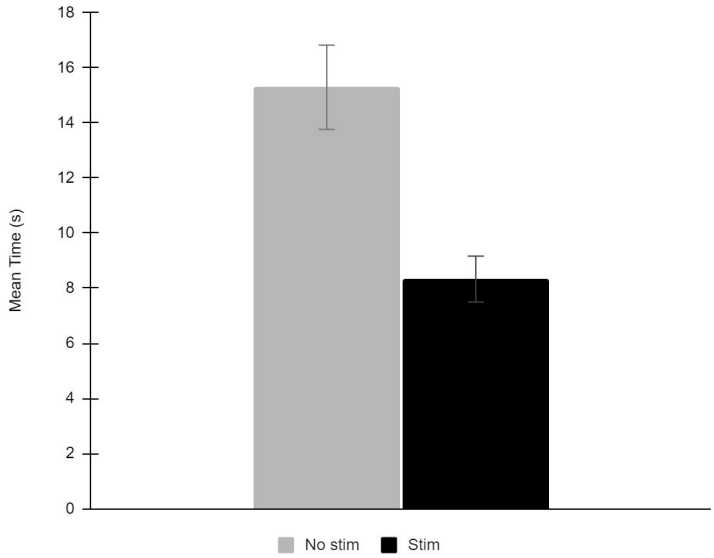


Figure 23. Time to Unlock a Lock, with vs. without Device. The user was timed while picking up a key, inserting it into a deadbolt lock, and unlocking the door. n = 5 control and n = 5 test trials were conducted. $p < 0.05$

ISNCSCI Test

Table 16. ISNCSCI test result

Target	Threshold	Experimental Result
Increase of 1 point (out of 5)	Increase of 0 points (out of 5)	Increase of 0

Design specification met? YES

Electrode Temperature

Table 17. Electrode temperature result

Target	Threshold	Experimental Result
< 38 °C	> 40 °C	Mean of 36.16 °C

Design specification met? YES

Table 18. Electrode temperature data

	Rep. #1	Rep. #2	Rep. #3	Rep. #4	Rep. #5	Rep. #6
Temperature (°C)	36.16	36.16	36.16	36.16	36.2	36.2

Skin Redness (Post-use)

Table 19. Skin redness result

Target	Threshold	Experimental Result
Increase of 0 points (out of 5)	Increase of 3 points (out of 5)	Increase of 1 point (out of 5)

Design specification met? YES

Table 20. Skin redness data

	Rep. #1	Rep. #2	Rep. #3	Rep. #4	Rep. #5	Rep. #6
Redness (0-5)	0	0	1	1	3	1

Weight

Table 21. Weight result

Target	Threshold	Experimental Result
0.5 kg	0.8 kg	0.29344 kg

Design specification met? YES

Number of Pinch Points

Table 22. Number of pinch points result

Target	Threshold	Experimental Result
< 2	> 3	0

Design specification met? YES

Steps to Turn On Device

Table 23. Steps to turn on device result

Target	Threshold	Experimental Result
< 3 steps	5 steps	5 steps

Design specification met? YES

Comfort

Table 24. Comfort result

Target	Threshold	Experimental Result
> 3 points (out of 5)	< 2 points (out of 5)	4.33 points (out of 5)

Design specification met? YES

Appearance

Table 25. Appearance result

Target	Threshold	Experimental Result
3 points (out of 5)	1 point (out of 5)	1 point (out of 5)

Design specification met? YES

Shock Pain

Table 26. Shock pain result

Target	Threshold	Experimental Result
< 2 points (out of 5)	> 2 points (out of 5)	2 points (out of 5)

Design specification met? YES

Cost

Table 27. Cost result

Target	Threshold	Experimental Result
< $150	$200	$164.65

Design specification met? YES

X. Functional Test Analysis

In order to test grip strength, we used a hand dynamometer and measured the recorded grip strength with and without stimulation. The actual recorded number without stimulation was 0 lbs, which was problematic for our analysis of a percent increase, so we just used .01 lbs for our baseline. We saw a huge increase in grip strength with the stimulation on, with the highest recorded number being 7.0 lbs.

To test time to write, the subject wrote their name five consecutive times with the simulation of and then with the stimulation on. We found the quality of the hand writing to be consistent and the average time it took to decrease with the stimulation on. The subject noted that there was a slight adjustment period when writing with the stimulation on and that the quality of handwriting would increase with further use.

When carrying out the pouring of liquid test, the subject had one glass half way full of water and another glass empty on a table in front of him. He successfully poured the water from one glass to the other without any spilling both with and without stimulation. We found that with stimulation there was a higher confidence in gripping the glass and less time spent pouring.

The key in the lock test was carried out with a single key being put into a locked deadbolt lock on a door and turned to unlock the door. The subject felt this showed the largest improvement when the stimulation was on as the test required the most dexterity. On top of the time being nearly cut in half, the subject felt much more confidence in picking up and inserting the key. There was one key drop recorded without stimulation, which would have substantially increased the amount of time to carry out the task. It is important to note this as the subject felt much more comfortable and functional with the stimulation on throughout this test.

The subject carried out their own ISNCSCI test before and after all the tests were completed. We did not expect to see any neuroplastic change, which is what the ISNCSCI test measures, so this test, while showing no improvement, went as expected. Perhaps after using the device more extensively there could be a neuroplastic change recorded but that will take more time to come to fruition.

XI. Conclusion

The purpose of this project is to provide a device that can be used on a day-to-day basis in order to provide a functional and therapeutic treatment to combat chronic paralysis. While the device that we produced was not fully functional, we were able to test parts of the device and demonstrate the potential for this idea moving forward. We were able to connect the TENS unit to the microcontroller so that the stimulus could be controlled via a switch. The EMG sensors were more sensitive to changes in the

environment than expected, so they were disconnected from the TENS unit during testing. In the future, the EMG sensors need to be further tested and the factors that affect the signal quantified so that they can be mitigated. This should improve the quality of life for all patients and caregivers affected while decreasing the overall cost of this often permanent condition.

XII. References

1. “Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury.” J Spinal Cord Med. 2013, https://pubmed.ncbi.nlm.nih.gov/24094120/.

2. “Nerve Transfer Surgery Restores Hand Function and Elbow Extension in 13 Young Adults with Complete Paralysis.” ScienceDaily, ScienceDaily, 4 July 2019, www.sciencedaily.com/releases/2019/07/190704191425.htm.

3. “Neuromuscular electrical stimulation attenuates thigh skeletal muscles atrophy but not trunk muscles after spinal cord injury.” J Electromyogr Kinesiol, Aug 2013, https://pubmed.ncbi.nlm.nih.gov/23683374/.

4. “Paralysis Statistics.” Reeve Foundation, www.christopherreeve.org/living-with-paralysis/stats-about-paralysis.

5. “Paraplegics Regain Some Feeling, Movement after Using Brain-Machine Interfaces.” ScienceDaily, ScienceDaily, 11 Aug. 2016, www.sciencedaily.com/releases/2016/08/160811101008.htm

XI. Appendices

Appendix A: Customer Requirements

Table 28. Customer Requirements List.

Customer Requirements		User	Researchers	Rehab hospitals/PT	Insurance companies
	increased grip strength	12	20	9	10
short-term functional use	decreased time for tasks	13	19	10	10
	lightweight	8	2	2	0
	not complicated	2	1	2	0
convenience	easy to put on	5	1	3	0
	good battery life	3	3	3	0
	accurate	8	14	9	2
reliability	durable	3	3	6	5
	ergonomic	10	1	3	0
	not painful	3	1	8	0
comfort	dynamic	5	3	6	0
	not obvious	4	0	0	0
aesthetic	not "scary looking"	4	0	0	0
price	afforable cost	1	5	8	34
safe for user	doesn't overheat	8	9	11	13
	doesn't rub	8	9	11	13
	doesn't overstimulate	3	9	9	13
		100	100	100	100

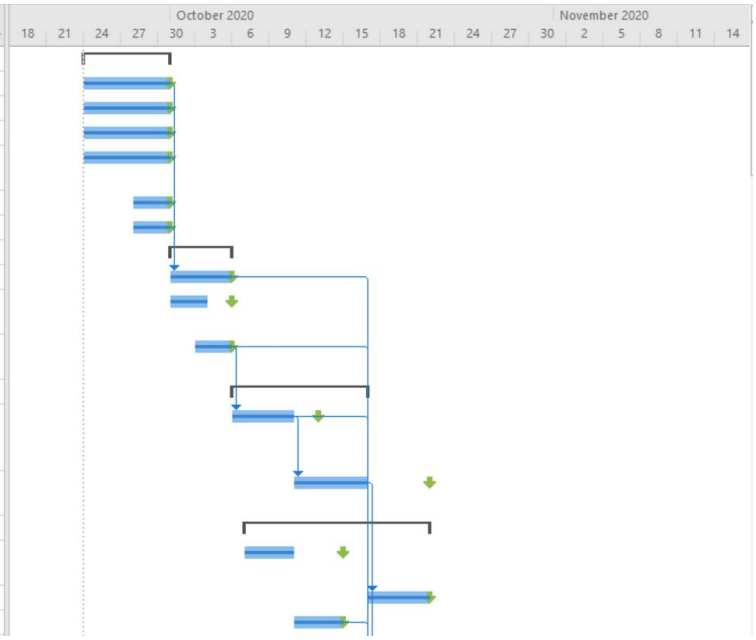
Appendix B: Engineering Specifications

Table 29. Engineering Specifications List

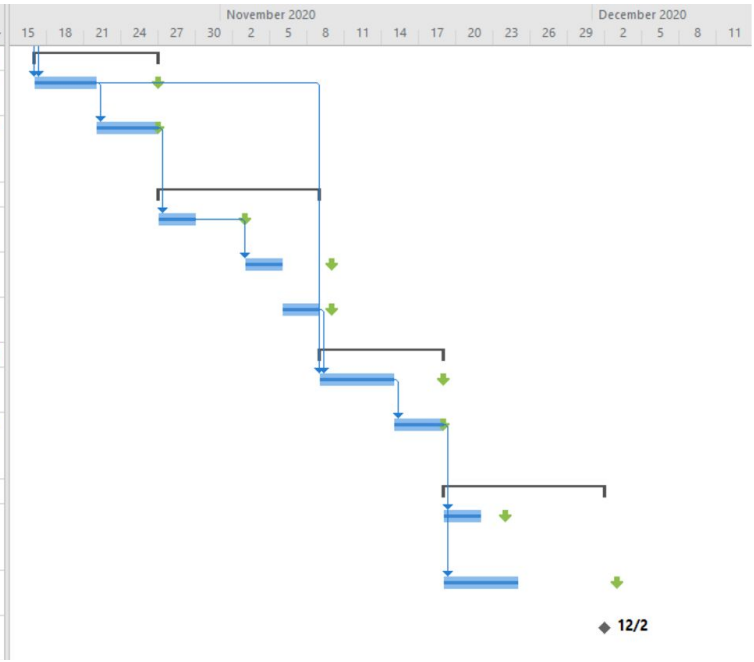
	Engineering Specifications					
	grip strength	time to write	time to pour cup of liquid	time to use key in lock	ISNCSCI test	Mass
Direction	^	v	v	v	^	v
Unit	%	%	%	%	Δ points	kg
Target	50	70	60	60	1	0.25
Threshold	10	90	90	90	0	0.75
	steps to turn on device	time to put on device	battery life	lag time	material tensile strength	comfortable
Direction	v	v	^	v	^	v
Unit	steps	s	mAh	s	MPa	points
Target	2	60	54000	0.1	270	2
Threshold	5	120	18000	0.5	25	5
	shock pain	range of motion	appearance	cost	pinch points	electrode temperature
Direction	v	^	^	v	v	v
Unit	points	%	points	$	count	degrees celsius
Target	1	10	4	100	0	36
Threshold	3	1	2	300	2	40
	blood pressure (finger v body)	skin redness (post device)	accurate stimulus amplitude	accurate stimulus frequency		
Direction	v	v	^	^		
Unit	Δ %	points	%error	%error		
Target	0	2	0.5	0.5		
Threshold	5	4	1	1		

Appendix C: Gantt Chart

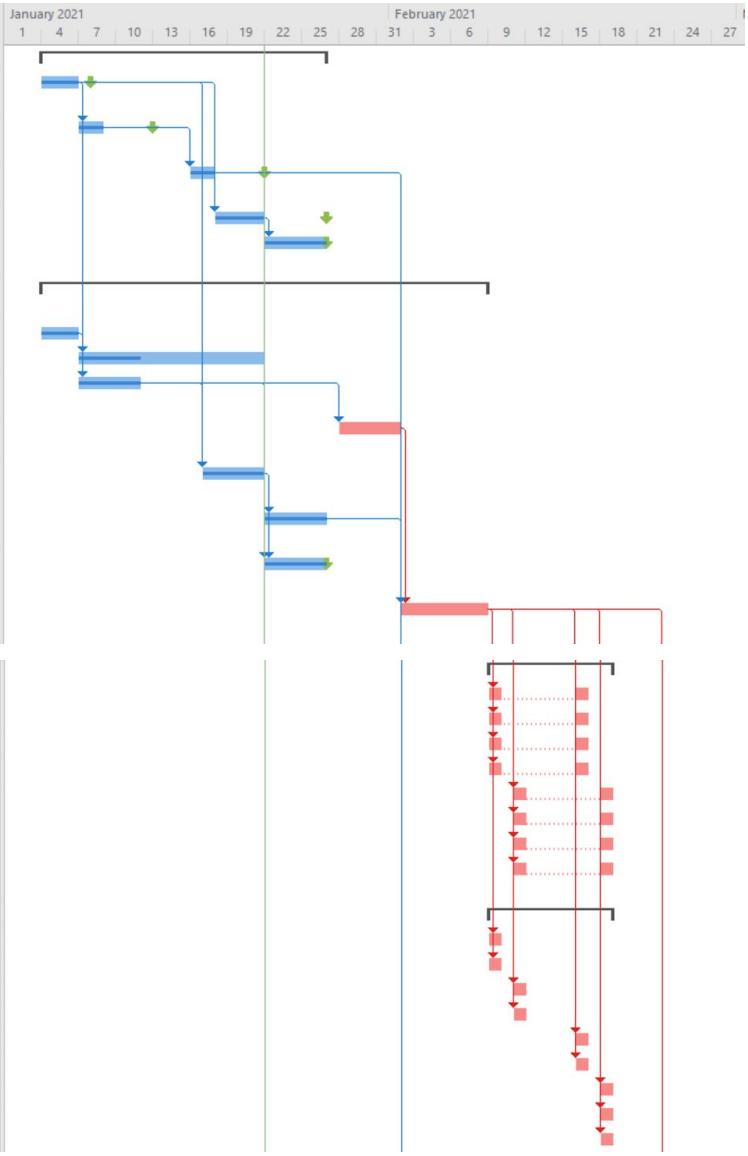
ID	Task Name	Duration	Start	Finish
1	**Deliverable 1**	**7 days**	**Thu 9/24/20**	**Wed 9/30/20**
2	HOQ	7 days	Thu 9/24/20	Wed 9/30/20
3	IFU	7 days	Thu 9/24/20	Wed 9/30/20
4	Budget	7 days	Thu 9/24/20	Wed 9/30/20
5	Network Diagram	7 days	Thu 9/24/20	Wed 9/30/20
6	Patent Search	3 days	Mon 9/28/20	Wed 9/30/20
7	Conjoint Surveys	3 days	Mon 9/28/20	Wed 9/30/20
8	**Deliverable 2**	**5 days**	**Thu 10/1/20**	**Mon 10/5/20**
9	SOW	5 days	Thu 10/1/20	Mon 10/5/20
10	Project Plan Meeting Slides	3 days	Thu 10/1/20	Sat 10/3/20
11	Conjoint Analysis ANOVA	3 days	Sat 10/3/20	Mon 10/5/20
12	**Deliverable 3**	**11 days**	**Tue 10/6/20**	**Fri 10/16/20**
13	Morphology and Concept Sketches	5 days	Tue 10/6/20	Sat 10/10/20
14	Conceptual Model	6 days	Sun 10/11/20	Fri 10/16/20
15	**Deliverable 4**	**15 days**	**Wed 10/7/20**	**Wed 10/21/20**
16	Status Update Memo #1	4 days	Wed 10/7/20	Sat 10/10/20
17	FMEA	5 days	Sat 10/17/20	Wed 10/21/20
18	Pugh Chart	4 days	Sun 10/11/20	Wed 10/14/20



ID	Task Name	Duration	Start	Finish
19	**Deliverable 5**	**10 days**	**Sat 10/17/20**	**Mon 10/26/20**
20	Concept Design Report	5 days	Sat 10/17/20	Wed 10/21/20
21	Concept Design Review Presentation	5 days	Thu 10/22/20	Mon 10/26/20
22	**Deliverable 6**	**13 days**	**Tue 10/27/20**	**Sun 11/8/20**
23	Status Update Memo #2	3 days	Tue 10/27/20	Thu 10/29/20
24	Status Update Memo #3	3 days	Tue 11/3/20	Thu 11/5/20
25	Hazard and Risk Assessment	3 days	Fri 11/6/20	Sun 11/8/20
26	**Deliverable 7**	**10 days**	**Mon 11/9/20**	**Wed 11/18/20**
27	Critical Design Report	6 days	Mon 11/9/20	Sat 11/14/20
28	Critical Design Review Presentation	4 days	Sun 11/15/20	Wed 11/18/20
29	**Deliverable 8**	**13 days**	**Thu 11/19/20**	**Wed 12/2/20**
30	Critical Design Review Peer Questions	3 days	Thu 11/19/20	Sat 11/21/20
31	Winter Quarter Project Plan	6 days	Thu 11/19/20	Tue 11/24/20
32	Design Notebooks	0 days	Wed 12/2/20	Wed 12/2/20



ID	Task Name	Duration	Start	Finish
33	**Deliverable 9**	**23 days**	**Mon 1/4/21**	**Tue 1/26/21**
34	Updated Project Plan	3 days	Mon 1/4/21	Wed 1/6/21
35	Status Update Memo #1	2 days	Thu 1/7/21	Fri 1/8/21
36	Status Update Memo #2	2 days	Sat 1/16/21	Sun 1/17/21
37	Test Plan Report	4 days	Mon 1/18/21	Thu 1/21/21
38	Test Plan Presentation	5 days	Fri 1/22/21	Tue 1/26/21
39	**Prototype Manufacturing**	**36 days**	**Mon 1/4/21**	**Mon 2/8/21**
40	Obtain Software	3 days	Mon 1/4/21	Wed 1/6/21
41	Code	15 days	Thu 1/7/21	Thu 1/21/21
42	Signal Detection Assembled	5 days	Thu 1/7/21	Mon 1/11/21
43	Signal Detection Tested	5 days	Thu 1/28/21	Mon 2/1/21
44	Stimulator Assembled	5 days	Sun 1/17/21	Thu 1/21/21
45	Stimulator Tested	5 days	Fri 1/22/21	Tue 1/26/21
46	Functional Prototype Video	5 days	Fri 1/22/21	Tue 1/26/21
47	Finalize Prototype	7 days	Tue 2/2/21	Mon 2/8/21
48	**Testing**	**10 days**	**Tue 2/9/21**	**Thu 2/18/21**
49	ISNCSCI Test	2 days	Tue 2/9/21	Tue 2/16/21
50	Grip Strength	2 days	Tue 2/9/21	Tue 2/16/21
51	Time to unlock	2 days	Tue 2/9/21	Tue 2/16/21
52	Skin Redness	2 days	Tue 2/9/21	Tue 2/16/21
53	Time to Write	2 days	Thu 2/11/21	Thu 2/18/21
54	Time to Pour	2 days	Thu 2/11/21	Thu 2/18/21
55	Electrode Temp	2 days	Thu 2/11/21	Thu 2/18/21
56	Stimulus Amplitude	2 days	Thu 2/11/21	Thu 2/18/21
57	**Measurements**	**10 days**	**Tue 2/9/21**	**Thu 2/18/21**
58	Weight	1 day	Tue 2/9/21	Tue 2/9/21
59	Pinch Points	1 day	Tue 2/9/21	Tue 2/9/21
60	Steps to Turn On	1 day	Thu 2/11/21	Thu 2/11/21
61	Time to Put On	1 day	Thu 2/11/21	Thu 2/11/21
62	Comfort	1 day	Tue 2/16/21	Tue 2/16/21
63	Appearance	1 day	Tue 2/16/21	Tue 2/16/21
64	Lag Time	1 day	Thu 2/18/21	Thu 2/18/21
65	Shock Pain	1 day	Thu 2/18/21	Thu 2/18/21
66	Cost	1 day	Thu 2/18/21	Thu 2/18/21



ID	Task Name	Duration	Start	Finish
67	**Deliverable 10**	**32 days**	**Mon 1/25/21**	**Thu 2/25/21**
68	Ethics Reflection	3 days	Mon 1/25/21	Wed 1/27/21
69	Status Update Memo #3	2 days	Tue 2/2/21	Wed 2/3/21
70	Status Update Memo #4	2 days	Wed 2/10/21	Thu 2/11/21
71	Status Update Memo #5	2 days	Mon 2/15/21	Tue 2/16/21
72	Status Update Memo #6	2 days	Mon 2/22/21	Tue 2/23/21
73	Final Prototype Demo	3 days	Tue 2/23/21	Thu 2/25/21
74	**Deliverable 11**	**12 days**	**Fri 2/26/21**	**Wed 3/10/21**
75	Senior Project Design Report	6 days	Fri 2/26/21	Wed 3/3/21
76	Design Review Presentation	6 days	Thu 3/4/21	Tue 3/9/21
77	Upload to Digital Commons	2 days	Thu 3/4/21	Fri 3/5/21
78	Poster Presentation	8 days	Mon 3/1/21	Mon 3/8/21
79	Finish Design Notebooks	0 days	Wed 3/10/21	Wed 3/10/21

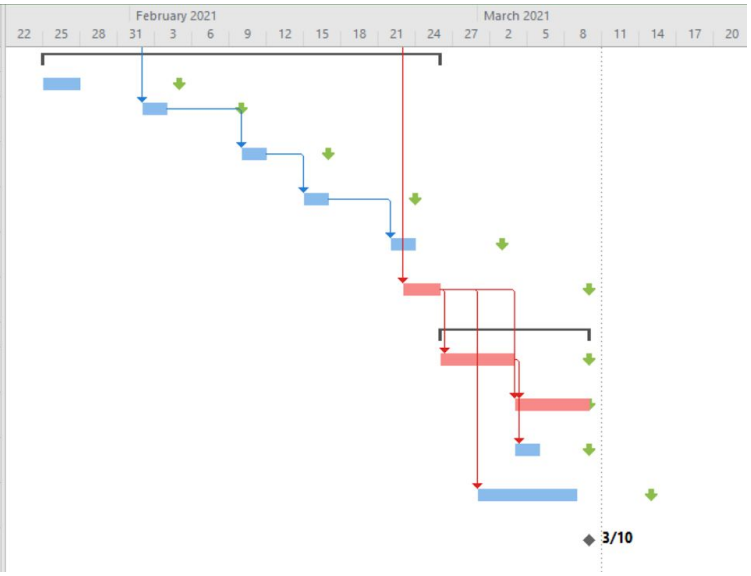


Figure 18. Gantt Chart.

Appendix D. Conjoint Analysis Google Form

Description

Battery: Removable - batteries can be swapped for charged batteries, but also more bulky. Battery built in - device needs to be plugged in to charge, but less bulky. || Attachment: Sleeved - device is encased within a sleeve. More aesthetically pleasing, but can generate more heat. Exposed - Electronics attached with minimal straps. Less aesthetically pleasing, but won't generate as much heat. || Casing: Plastic - cheaper, lighter, more customizable, but less durable. Metal - Durable, looks higher quality, heavier, more expensive.

Table 30. Google Form Data

What is your name?	What is your Group #?	What is your group name?	Please rank each device (1 is highest, 4 is lowest). [Removable battery, Sleeved, Metal Casing]	Please rank each device (1 is highest, 4 is lowest). [Removable battery, Exposed, Plastic Casing]	Please rank each device (1 is highest, 4 is lowest). [Battery built in, Sleeved, Plastic Casing]	Please rank each device (1 is highest, 4 is lowest). [Battery built in, Exposed, Metal Casing]
Marissa Martinez	6	Spaceflight Spinal Strength System	4	2	3	1
Cami Dozois	5	PEFAM	4	1	2	3
Joseph Gruchacz	6	Spaceflight Spinal Strengthening System (S4)	2	1	3	4
Michael	7	Tierni Resistance Training System	4	3	2	1
Abby Youngblood	7	Tierni Resistance Training System	1	2	3	4
Randy Hau	8	Thigh Support	2	3	1	4
Andrea Skattenborg	2	Hypoxic Incubation Chamber	2	1	3	4
Makenzie Jones	2	Hypoxic Incubation Chamber	4	3	1	2
Henry Elsner	2	Hypoxia Incubation Chamber	1	2	4	3
Courtnee	5	PEFAM	2	1	3	4
Evan Yap	4	Novel Sperm Separation Device	2	1	4	3
Jamison	3	Infared Knee Heating Pad	3	4	1	2
jaylynn markey	6	S4	3	2	3	1
Yael	8	Thigh Support	2	4	2	1
Spencer Ross	8	Thigh Support	4	2	1	3
Tyler Arias	5	PEFAM	3	1	4	2
Natalia Robles	3	Infrared knee heating pad	2	3	4	2
Gabriel	7	Tierni Resistance Training	4	2	3	1
Jaden Frazier	3	Infrared Knee Heating Pad	4	3	1	2
Troy Uysal	4	Sperm Separation Project	1	4	3	2

Appendix E: Concept Evaluation

Pugh Chart 1: Charlotte

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey	Concept 4: Jake
Accuracy	35		1	1	1
Easy to put on	15		1	1	0
Dynamic comfort	30		1	0	1
Appearance	20	Datum	0	0	1
		Total	1	2	3
		Weighted total	80	50	85

Pugh Chart 2: Charlotte

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Sam	Concept 2: Hailey	Concept 3: Jake	Concept 4: Charlotte
Accuracy	35		1	1	1
Easy to put on	15		1	0	1
Dynamic comfort	30		0	1	1
Appearance	20	Datum	0	1	-1
		Total	2	3	3
		Weighted total	50	85	60

Pugh Chart 3: Charlotte

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Hailey	Concept 2: Jake	Concept 3: Charlotte	Concept 4: Sam
Accuracy	35		1	1	1
Easy to put on	15		0	1	1
Dynamic comfort	30		1	1	1
Appearance	20	Datum	1	-1	0
		Total	3	3	1
		Weighted total	85	60	80

Pugh Chart 4: Charlotte

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Jake	Concept 2: Charlotte	Concept 3: Sam	Concept 4: Hailey
Accuracy	35		1	1	1
Easy to put on	15		1	1	1
Dynamic comfort	30		1	1	0
Appearance	20	Datum	-1	0	0
		Total	3	1	2
		Weighted total	60	80	50

Pugh Chart 5: Sam

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey	Concept 4: Jake
Accuracy	45		1	1	1
Easy to put on	10		0	0	1
Dynamic comfort	30		0	0	1
Appearance	15	Datum	-1	-1	0
		Total	0	0	3
		Weighted total	30	30	85

Pugh Chart 6: Sam

Issue: Choose an EMMT conceptual design		Baseline - Concept 2: Sam	Concept 1: Charlotte	Concept 3: Hailey	Concept 4: Jake
Accuracy	45		-1	-1	0
Easy to put on	10		1	0	1
Dynamic comfort	30		0	0	0
Appearance	15	Datum	1	0	1
		Total	1	-1	2
		Weighted total	-20	-45	25

Pugh Chart 7: Sam

Issue: Choose an EMMT conceptual design		Baseline - Concept 3: Hailey	Concept 1: Charlotte	Concept 2: Sam	Concept 4: Jake
Accuracy	45		-1	1	1
Easy to put on	10		1	0	1
Dynamic comfort	30		1	0	1
Appearance	15	Datum	1	0	1
		Total	2	1	4
		Weighted total	10	45	100

Pugh Chart 8: Sam

Issue: Choose an EMMT conceptual design		Baseline - Concept 4: Jake	Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey
Accuracy	45		-1	0	-1
Easy to put on	10		0	-1	-1
Dynamic comfort	30		0	0	0
Appearance	15	Datum	0	-1	-1
		Total	-1	-2	-3
		Weighted total	-45	-25	-70

Pugh Chart 9: Hailey

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey	Concept 4: Jake
Accuracy	35		1	-1	1
Easy to put on	25		0	1	0
Dynamic comfort	25		0	0	0
Appearance	15	Datum	0	0	1
		Total	1	0	2
		Weighted total	35	-10	50

Pugh Chart 10: Hailey

Issue: Choose an EMMT conceptual design		Baseline - Concept 2: Sam	Concept 1: Charlotte	Concept 3: Hailey	Concept 4: Jake
Accuracy	35		-1	0	0
Easy to put on	25		0	1	0
Dynamic comfort	25		0	0	0
Appearance	15	Datum	-1	0	1
		Total	-2	1	1
		Weighted total	-50	25	15

Pugh Chart 11: Hailey

Issue: Choose an EMMT conceptual design		Baseline - Concept 3: Hailey	Concept 1: Charlotte	Concept 2: Sam	Concept 4: Jake
Accuracy	35		0	1	1
Easy to put on	25		-1	0	0
Dynamic comfort	25		-1	1	0
Appearance	15	Datum	0	0	1
		Total	-2	2	2
		Weighted total	-50	60	50

Pugh Chart 12: Hailey

Issue: Choose an EMMT conceptual design		Baseline - Concept 4: Jake	Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey
Accuracy	35		-1	0	-1
Easy to put on	25		0	1	1
Dynamic comfort	25		0	1	0
Appearance	15	Datum	-1	-1	-1
		Total	-2	1	-1
		Weighted total	-50	35	-25

Pugh Chart 13: Jake

Issue: Choose an EMMT conceptual design		Baseline - Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey	Concept 4: Jake
Accuracy	30		1	0	1
Easy to put on	30		0	1	0
Dynamic comfort	20		0	0	1
Appearance	20	Datum	0	0	1
		Total	0	1	2
		Weighted total	30	30	70

Pugh Chart 14: Jake

Issue: Choose an EMMT conceptual design		Baseline - Concept 2: Sam	Concept 1: Charlotte	Concept 3: Hailey	Concept 4: Jake
Accuracy	30		-1	-1	0
Easy to put on	30		0	1	0
Dynamic comfort	20		0	0	1
Appearance	20	Datum	0	0	1
		Total	0	0	2
		Weighted total	-30	0	40

Pugh Chart 15: Jake

Issue: Choose an EMMT conceptual design		Baseline - Concept 3: Hailey	Concept 1: Charlotte	Concept 2: Sam	Concept 4: Jake
Accuracy	30		0	1	1
Easy to put on	30		-1	-1	-1
Dynamic comfort	20		0	0	1
Appearance	20	Datum	0	0	1
		Total	-1	0	2
		Weighted total	-30	0	40

Pugh Chart 16: Jake

Issue: Choose an EMMT conceptual design		Baseline - Concept 4: Jake	Concept 1: Charlotte	Concept 2: Sam	Concept 3: Hailey
Accuracy	30		-1	0	-1
Easy to put on	30		0	0	1
Dynamic comfort	20		-1	-1	-1
Appearance	20	Datum	-1	-1	-1
		Total	-3	-2	-2
		Weighted total	-70	-40	-40

Figure 19. Pugh Charts.

Appendix F: Concept Sketches

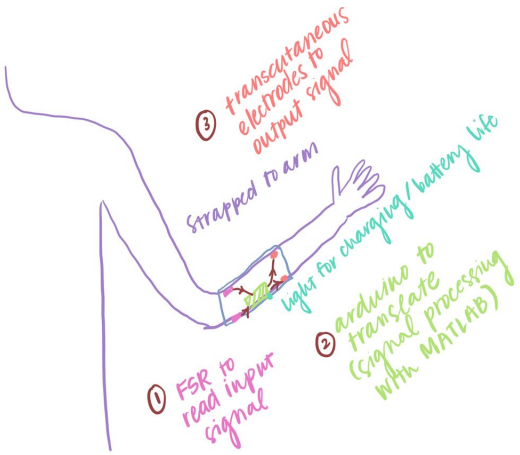


Figure 24. Concept 1, morphology concepts 2,4,1,1,1

This design requires the device to be strapped to the arm with all of the components exposed. It includes force sensitive resistors (FSR) to detect a range of muscle movement inside or outside the forearm depending on where we achieve the best signal per patient. This signal is then adjusted and translated to an output signal utilizing an arduino programmed in MATLAB. This requires software to make sure that the input signal is an actual contraction versus a twitch or accidental bumping of the arm. The signal is then outputted to the electrodes placed further distally down the arm on the target muscle most necessary per person. The design will also include a light to detail battery life and charging capability.

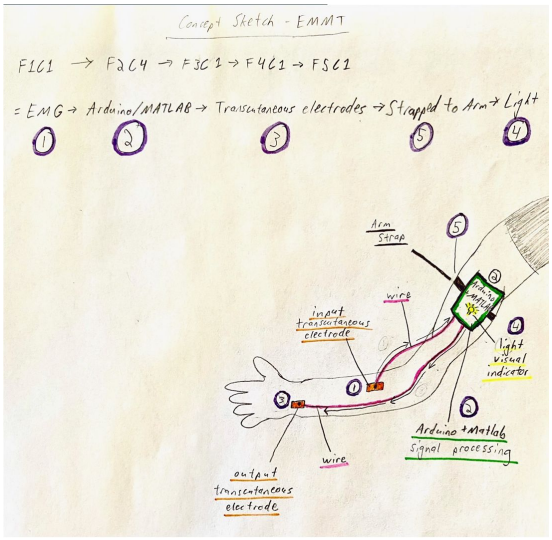


Figure 25. Concept 2, morphology concepts 1,4,1,1,1

The sketch shows the logical flow of information of the EMMT and how the device will function. First, the EMG signal from a properly functioning forearm muscle would be detected (1) and sent via wire to the Arduino, then filtered, amplified, and otherwise modified in Arduino and Matlab software. A new electrical signal will then be generated by a signal generator (2), then sent via wire to the transcutaneous electrode in the hand in order to stimulate the non-functioning muscle (3). Simultaneously, a light will turn on next to the microcomputer showing that it is currently detecting and sending electrical signals. The microcomputer is strapped to the arm using a simple velcro strap (5).

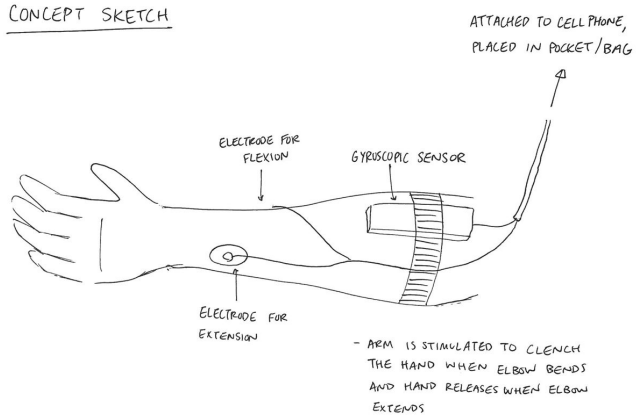


Figure 26. Concept 3, morphology concepts 3,2,1,2,4

The gyroscope design was developed to use the position of the forearm to determine whether the hand should be in the clenched or extended position. This design uses the user's cell phone as the power source and an app on the phone controls the interface between the input and output signals. An encased wire travels up the arm and down the user's torso into their pocket or bag where the phone would be kept, for easy portability. The gyroscope sensor would be easy to attach to the arm without the need for fine calibration.

Appendix G: Conceptual Model MATLAB code

```
clear;
close all;

% import EMG_in here from electrode/Arduino
% 'emg_healthy.txt' is sample EMG data
EMG_in = load('emg_healthy.txt');
EMG_in = EMG_in(:,2);

% change to freq domain
max_index = length(EMG_in);
for i = 1:max_index
    t(i) = (i-1);
    v(i) = EMG_in(i);
end

% bandpass filter accepts 50-150 Hz
EMG_fft = fft(v,max_index);
for i = 1:max_index
    if EMG_fft(i) < 50
        EMG_fft(i) = 0;
    elseif EMG_fft(i) > 150
        EMG_fft(i) = 0;
    else
    end
end

%change to time domain and amplify if necessary
amp = 1;
EMG_out = amp*ifft(EMG_fft);

% plot signals
plot(EMG_in,'LineWidth',0.5);
hold on;
plot(EMG_out,'r','LineWidth',1.5);
xlabel('Time (ms)');
ylabel('Voltage (mV)');
axis([2500 3000 -0.2 0.2]);
legend("Detected EMG", "Stimulus EMG");

% export EMG_out to signal generator
```

Appendix H: EMG Click Functions

HOW IT WORKS

1. The onboard 3.5mm audio jack is used to connect cables/electrodes to the click board. The electrode collects voltage from the skin (few millivolts). And the signal from the jack is amplified and filtered. Therefore, EMG click can be divided into seven blocks.
2. Protection - Provides ESD protection (protects click), Overvoltage protection (protects respondents) and Overcurrent protection (protects respondents). In addition to protection, input block has the role of filter that prevents radio waves to “enter” the preamplifier.
3. Preamplifier – Is implemented through three operational amplifiers configured as instrumentation amplifier (IA – amplifies the voltage difference between “+” and “-“ electrode) which at its output provides single-end signal.
4. High-Pass filter – Should eliminate the DC component of the signal (f_c=1.6Hz). It is passive RC filter (first order).
5. Amplifier – Need to provide additional amplification that can be adjusted using trimmer potentiometer VR1 so the analog output could accommodate to the input voltage range of ADC. The amplifier is implemented using operational amplifier configured as non-inverting amplifier.
6. High-Pass filter – Should eliminate the DC component of the signal (f_c=0.16Hz) this time after the amplifier. It is also passive RC filter (first order).
7. Low-Pass filter – Should limit frequency range to 60Hz. It is third order active filter with gain of 15 (second-order Sallen-Key filter topology + passive RC filter first order = third order filter).
8. DRL circuit (Driven Right Leg) – is an electronic circuit that is often added to biological signal amplifiers to reduce Common-mode interference. Biological signal amplifiers such as ECG (Electrocardiogram), EEG (Electroencephalogram) or EMG circuits measure very small electrical signals emitted by the body, often as small as several microvolts (millionths of a volt). Unfortunately, the patient's body can also act as an antenna which picks up electromagnetic interference, especially 50/60 Hz noise from electrical power lines. This interference can obscure the biological signals, making them very hard to measure. Right Leg Driver circuitry is used to eliminate interference noise by actively canceling the interference. That is selective amplifier stage that shifts phase of signal for 180° (inverting) and returns it to respondents in order to cancel.

Appendix I: Arduino Code

```
/*

Project: EMMT

Function: This code reads the amplitude of a human EMG signal, then turns on the TENS unit if the amplitude meets or exceeds a certain threshold value. If it does not meet the threshold, the TENS unit will remain off.

Input: EMG_amplitude

Authors: Hailey Casino, Sam Borda, Jake Javier, Charlotte Anderson

Date: 3/4/2021

*/

  int emg_pin = A0;
  int tens_pin = A2;
  int threshold_value = 500;

void setup() {
  pinMode(tens_pin, OUTPUT);
  // initialize serial communication at 9600 bits per second
  Serial.begin(9600);
}

void loop()  {

  int emg_value = analogRead(emg_pin);
  if (emg_value >= threshold_value) {
    digitalWrite(tens_pin, HIGH);
    }
  else{
    digitalWrite(tens_pin, LOW);
  }
  // prints the emg value to monitor or plotter
  Serial.println(emg_value);
}
```

Appendix J: Operation Manual

Put on device:

1. Apply the 3 detection electrodes to the skin above the extensor carpi radialis muscles and the 2 stimulus electrodes to the flexor digitorum muscles, as shown below in Figure 27. The extensor carpi radialis muscle can be found by hyperextending the wrist back and palpating the upper forearm on the lateral/posterior side. When the wrist is hyperextended, this muscle will protrude slightly. The detection electrodes should be placed over the apex of this protrusion with the ground electrode placed to the side, not over the muscle. For the stimulus electrodes, they can be placed approximately equidistant from the wrist and inner elbow. Some trial and error will likely be necessary for all electrode placements.

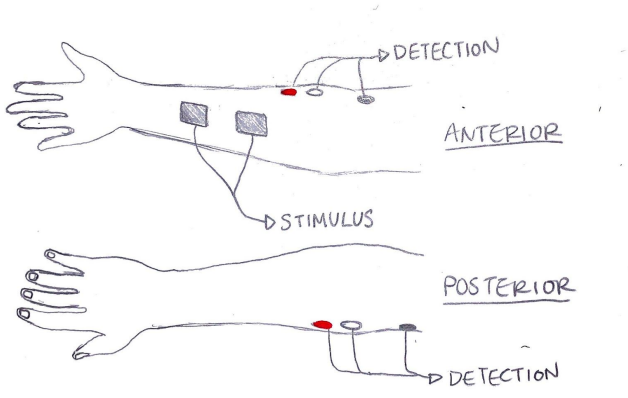


Figure 27. Electrode Placement.

2. Attach the rest of the device to the upper arm using the velcro strap, tucking the excess wires into the velcro.

Turn on the device:

1. Flip the switch on the Myoware boards to turn on the EMG sensors.
2. Flip rocker switch on TENS unit to the on position.

Device Usage:

1. Hyperextend the wrist, which will stimulate the fingers to flex in the tenodesis grasp.

Turn off the device:

1. Flip the switch on the Myoware boards to turn off the EMG sensors.
2. Flip rocker switch on TENS unit to the off position.

Remove device:

1. Remove electrodes from the arm.
2. Detach the velcro strap from the upper arm.