

MUSCULAR ATROPHY DETECTION (M.A.D.) SLEEVE

ECE 445 Design Documentation
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3/9/17

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1 Introduction

1.1 Objective

Muscular atrophy affects many people throughout the world. It is a disease that is brought about due to neurogenic reasons in the tissues connecting to the affected muscle. Neurogenic muscular atrophy is caused by injury or disease to the nerves that connect to the affected muscle tissue. Some of the more common diseases that cause this form of atrophy are ALS (Lou Gehrig Disease), Guillain-Barre Syndrome, and polio. [1] Regardless of cause, those that suffer from muscular atrophy experience a deterioration of muscle tissue causing a reduction of muscle strength and motor skills. [2]

While our device has a direct application to muscular atrophy, there are other uses. The most similar one to our target application is muscular dystrophy. Muscular dystrophy is similar to muscular atrophy but differs in that it occurs from the lack of use of the affected muscle region or extended time in low gravity environments. [9] This would extend the range of target users from just those suffering from neurogenic diseases to those that are bedridden due to illness or weight and, in an extreme application, to astronauts, who experience muscle dystrophy after even just a few days of zero-gravity environments, regardless of workout regiment. [12] There are still more possible applications for our device. Research has shown that bioelectrical impedance can be used as a prognostic indicator for cancer. [10] The cited example is specific to breast cancer (A region not targeted by our device) but it stands to reason that similar results could be expected in different regions of the body and the future development of a C.D.S (Cancer Detection Shirt) using bioelectrical impedance is a possibility.

While the wide range of applications for wearable bioelectrical impedance sensors is exciting, we will focus on a device to measure and monitor atrophy in the upper arm of a patient. Our goal is to develop a device that allows us to monitor the health of muscle tissue in an affordable and time efficient manner. For our project, we will focus on the upper arm and develop a sleeve with embedded sensors that use bioelectrical impedance to measure muscle density. This will allow the patient to monitor their muscle health over time in a quick and efficient manner. For the device to be considered a success, the data it collects needs to be comparable with the data obtained through conventional methods. We will either set up an appointment with a professor doing research using conventional methods, or set up an appointment to get a fat-free mass test performed by another method (currently the BOD-POD seems to be a top option), so that we may use both devices and compare data.

1.2 Background

Currently, the most common methods of detecting and monitoring this disease are blood tests, CT scans, and MRI's. [2][3] Blood tests can take long periods of time and are invasive. CT scans can result in large doses of ionizing radiation while MRIs are very expensive. Additionally, monitoring of muscle health would require repeated performances of these tests, which only amplifies these issues. A device that is cost efficient, accurate, and provides the ability to be used often with minimal risk is long overdue. This device will need to allow a physician to properly monitor the patient while being less than \$250 in total costs. We expect the actual cost of the device and a fresh set of electrodes to be well below \$100 but given that the electrodes are only good to be reused a handful of times (ideally, no more than 3), for extended uses the user will have to maintain a supply of electrodes. As seen in **Table 10**, the electrodes are very cheap for sets of six and become even cheaper if you buy in greater volume. [13] Regardless of this, our project still remains much more cost effective for a series of tests when compared to the same amount of tests through existing means. If we were to pursue this project beyond the ECE 445 classroom though, we would want to pursue a way of having sensors last for more extended periods of time. For reference, the cost of a single MRI scan in the United States is generally over \$2500 before insurance kicks in, putting our device (which can be used many times) at 10% of the cost of a single conventional test. [11] This reduction in cost will be a great relief for patients suffering from muscular atrophy. We also have the advantage of the device being usable anywhere which saves the user time by no longer requiring them to drive to a testing facility and waiting for hours to get a test. Our test should be able to be run from start to finish in less than 20 minutes. Additionally, our device will consistently give accurate values with repeated tests. Even if the user were to swap out electrodes or move electrodes to different locations, we will still obtain accurate measurements.

1.3 High Level Requirements

- Sensors must be able to safely and accurately measure muscle density within 15% of the measured value through currently existing means while minimizing current to below 100[μ A].
- Sensor data must be transmitted with less than 5% attenuation to the computer and be analyzed to display muscle density clearly within 500[ms].
- Sensor setup and supplies should cost no more than 10% of the cost for 5 tests performed with existing technologies.

2 Design

Our design consists of three modules that work together. These modules are the Power and Communication Unit (PCU), the Sensor Unit (SU), and the Computer Software Unit (CSU). The PCU will allow us to power our sensors and local data storage as well as allowing us to transmit our measured data to the CSU. In the CSU we will process this data and display it in a way convenient for the user. The SU will be used for gathering our data. The design can be seen below in **Figure 1**.

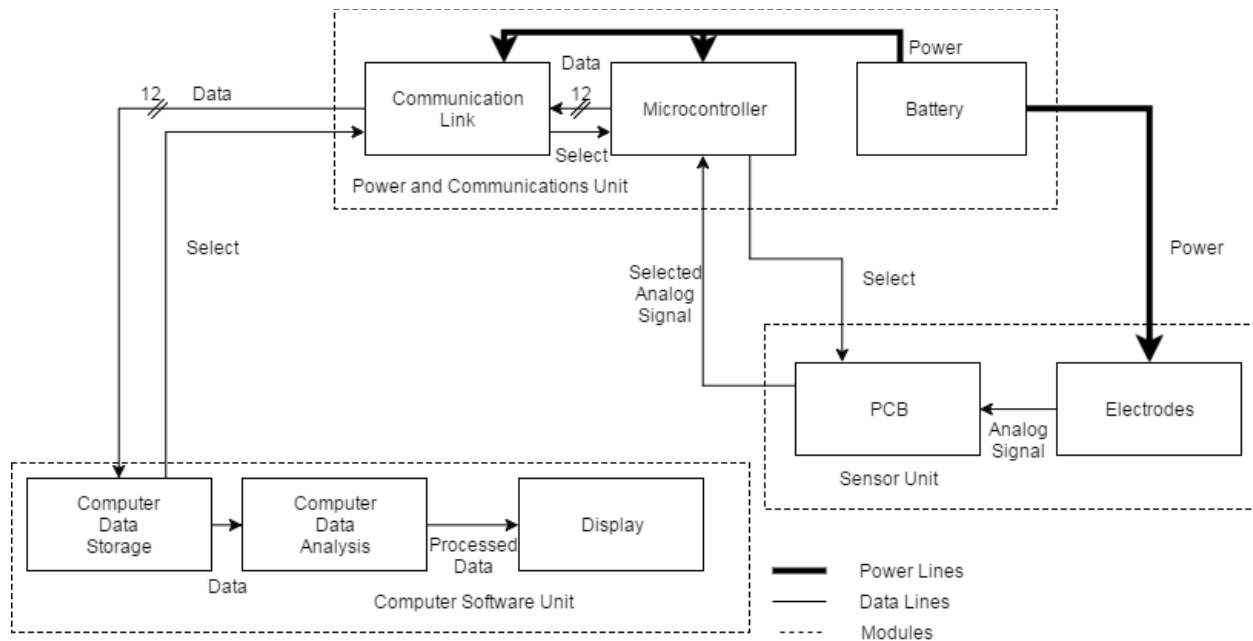


Figure 1: Block diagram for circuit

The design consists of a sleeve worn on the upper arm. Within the sleeve are the stimulating electrodes used for emitting current and collecting electrodes used for measuring voltage. The electrodes will be located along one of the muscle heads in the tricep (the long head) and one of the muscle heads in the bicep (the short head). This can be seen below in **Figure 4** and **Figure 5**, respectively. These electrodes will be individually connected with wires to the PCB in our PCU. The PCU unit will contain the power supply as well as our printed circuit board. The printed circuit board will be used to direct the flow of data from the electrodes to the local data storage unit. On the PCB we will have an analog multiplexor with which we will use to control the flow of data from the electrodes. It will be an analog multiplexor to maintain our signal integrity. Also on the PCB we will be using an instrumentation amplifier, circuit diagram in **Figure 3**. We will read the voltage output from one sensor at a time. We tested this by measuring the sensor

output from a 1V DC source, with the results seen in **Figure 2** and **Calculation 1**. The electrodes in this test were placed roughly 5 centimeters apart in the middle of the short head of the bicep. We can use our select signal to control the select pins of our multiplexor to determine which sensor to obtain data from.

With regards to safety, we want to ensure that the current we have is properly controlled. To do this, we must ensure that all of the current flows through the resistor we use. We will do this by having the current supplied from the battery flow through an isolated resistor on the pcb. This resistor will be on an isolated plane similar to how the ground is on an isolated plane. This ensures that all of the current is kept to the appropriate levels or that no current will flow at all.

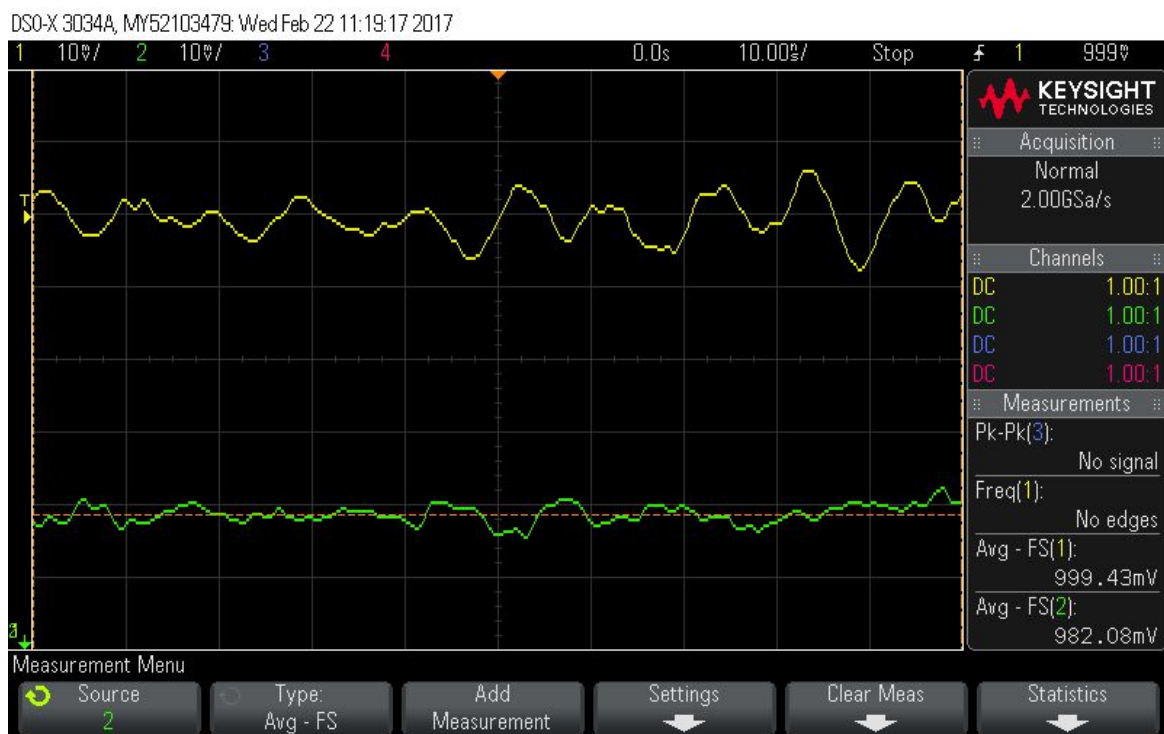


Figure 2: Raw data acquired from DC testing

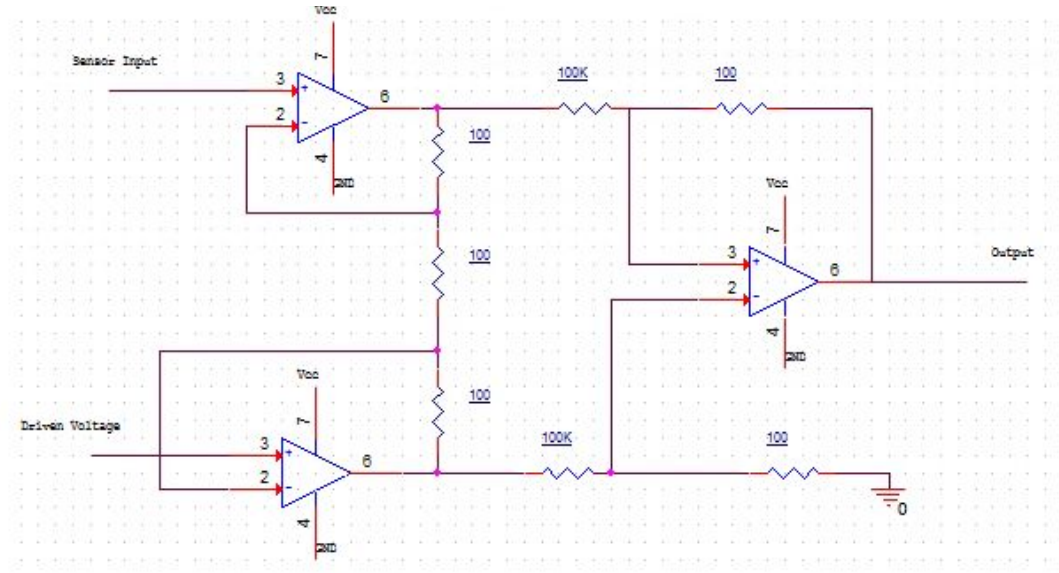


Figure 3: Circuit Mock-up for Instrumentation Amplifier

$$V_{Resistor} = I_{Resistor} * R_{Resistor}$$

$$(993.43 - 982.08)[mV] = I_{Resistor} * 15[k\Omega]$$

$$I_{Resistor} = I_{Arm} = 1.1567e-6[A] = 1.1567[\mu A]$$

$$V_{Arm} = I_{Arm} * Z_{Arm(between\ electrodes)}$$

$$982.08 [mV] = 1.1567[\mu A] * Z[\Omega]$$

$$Z = 849060.519[\Omega] \approx .85[M\Omega]$$

Calculation 1: Arm Impedance

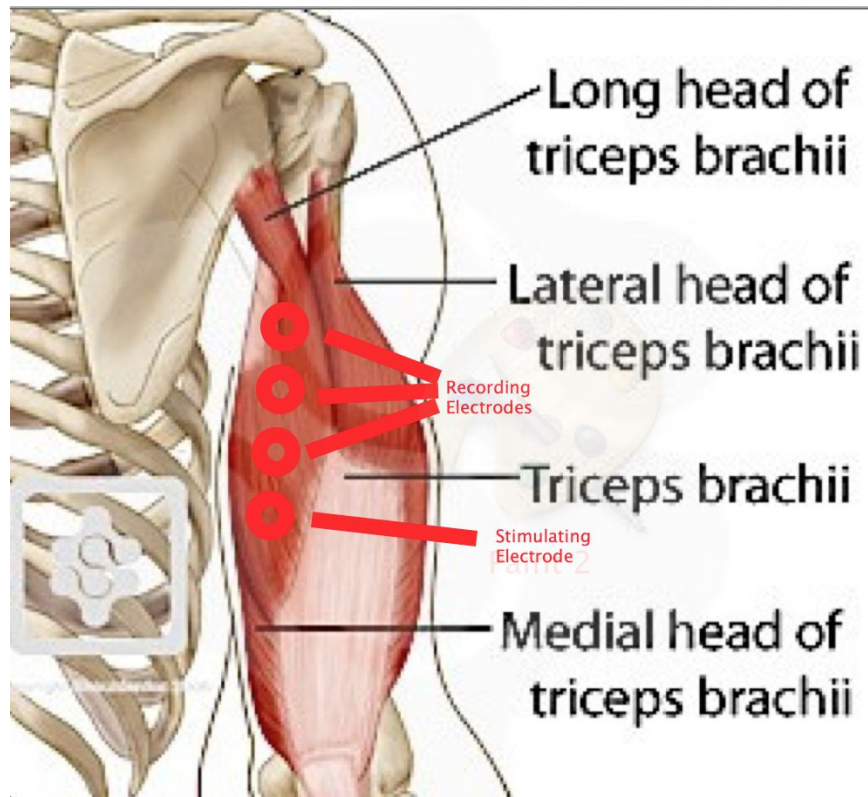


Figure 4: Electrode placement on the tricep

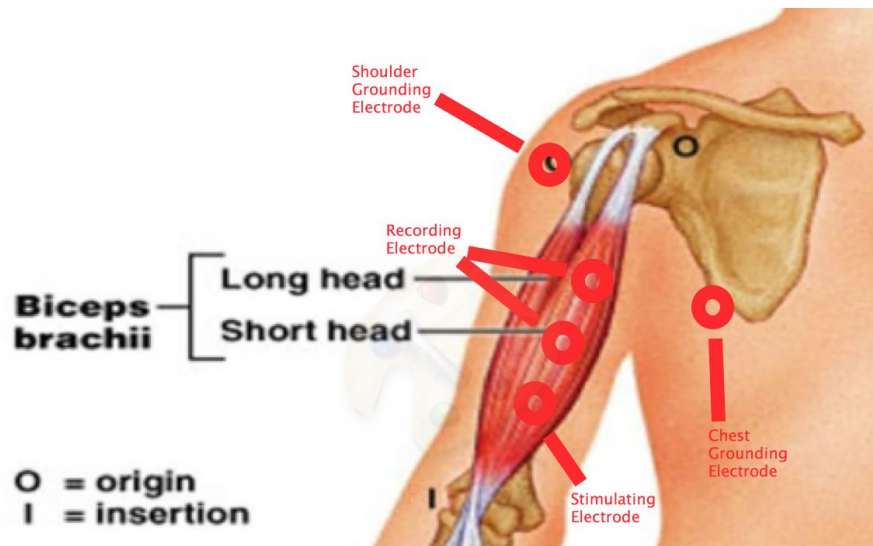


Figure 5: Electrode placement on the bicep with ground electrode placements on deltoid and chest

2.1 PCU (Power and Communications Unit) [12 points total]

The Power and Communications Unit is comprised of three separate units. These units are the Communications Link, the Local Data Storage, and the Battery. This module is responsible for receiving data from the sensors and transferring that data to the computer as well as supplying power to the sensors.

2.1.1 Communication Link [2 points]

The communication link will be used to send data stored in the local data storage to the computer data storage. It will do this based off of a trigger signal from the computer data storage. It will connect and send data via USB. To test that it works properly we will send **Test File 1** through the link. This test file will be 100 [bytes] in size and will consist of binary values from 1 (00000001) to 100 (01100100) incremented by 1. This will allow us to determine the rate by which we can send values from our PCU to our CSU and also ensure accuracy as we can verify that the sent test file remains the same.

Requirements	Verifications
<i>1. Must be able to connect to the Computer Data Storage unit via USB</i>	<i>1. Will connect microcontroller and attempt to send Test File 1 via microcontroller to the computer to be read. This can be read via a protected protocol on the MSP430.</i>

Table 1: Communication Link Requirements and Verification

2.1.2 Microcontroller [10 Points]

The microcontroller is a temporary storage unit for collecting sensor data and converting it from analog to digital. It will be powered by the battery and will send data to the communication link upon receiving a trigger signal from the computer. For the controller, we will be using the Texas Instruments MSP430.

Requirements	Verifications
<ol style="list-style-type: none">1. <i>Microcontroller must be able to acquire the signal output from the electrodes with <1% of signal loss.</i>2. <i>Must be able to open the switch to begin sensing when sent trigger command by the computer.</i>	<ol style="list-style-type: none">1. <i>Will directly display microcontroller output following successful linkage to system to determine signal strength of controller using the display feature present on the MSP430.</i>2. <i>Will send trigger signal to microcontroller from the computer and read the output of the electrodes. If the output is high, then we know the electrodes have been triggered successfully.</i>

Table 2: Microcontroller Requirements and Verification

2.1.3 Battery [0 points]

The battery will be used to supply power to the communication link, local data storage unit, and sensors. We will be using a standard 1.5 [V] AA battery to supply the voltage to our sensors.

Requirements	Verifications
<ol style="list-style-type: none">1. <i>Must supply a consistent voltage of 1.5 [V] within $\pm 5\%$</i>	<ol style="list-style-type: none">1. <i>Probe the positive and negative terminals of the battery with a voltmeter and ensure it reads within ± 75 [mV] of 1.5 [V]</i>

Table 3: Battery Requirements and Verification

2.2 CSU (Computer Software Unit) [18 points total]

The Computer Software Unit will be comprised of 3 separate items: Computer Data Storage, Computer Data Analysis, and Display. These will all run in a linear fashion. This module will be used to analyze and display the sensor data and will also function as the starting point for the trigger to activate sensing.

2.2.1 Computer Data Storage [7 points]

The computer data storage will act as the dump for the data. The data will be from the local storage and sent into a text file via the communication link. This file will be stored into the computer awaiting parsing from the data analysis unit.

Requirements	Verifications
<ol style="list-style-type: none">1. <i>Must store a packet of data with less than 2% error from microcontroller within 10[ms].</i>2. <i>Must parse data correctly from computer into file with less than 1% error within 50[ms].</i>	<ol style="list-style-type: none">1. <i>Will store Test File 1 in the computer storage unit to determine if the values are accurate and will use markers at the ends of each to determine completion and timing.</i>2. <i>Will send data file into the parsing algorithm to ensure that the data is in the properly named text file. We will use start and stop markers to determine timing.</i>

Table 4: Computer Data Storage Requirements and Verification

2.2.2 Computer Data Analysis [11 points]

The data analysis unit will parse the data from the storage unit and perform calculations on said data in order to properly analyze the muscle density. We use two formulas to calculate this. The first equation, **Equation 1**, is a correlation equation that determines muscle mass in units of centimeters cubed. [14] This equation is very straight-forward and has an r-squared value of .953 which indicates a strong correlation between our dependent and independent variables. The second equation, **Equation 2**, is a correlation equation that determines muscle volume where L is the distance between sensors [cm] and Z is the measured impedance [. [15] It is a more complicated equation than the first and accounts for the height in [cm] (Ht), gender [1 for male, 0 for female], and age [years] of the user. It also uses the measured impedance as variable R [Ω]. It has an r-squared value of .86 which also indicates a strong correlation. With these two equations, we can determine muscle density with a third equation, **Equation 3**. Because these equations only depend on known values (height, weight etc.), we can ensure our algorithms work properly by running a test value through and ensuring that the outputted value is consistent with hand calculated values. **Test File 2** will be created to do this. Test file 2 will contain a test impedance value of 1,000,000 [Ω]. We can determine the muscle density for this test value by hand. We will assume the user is 6 [ft] tall (182.88 [cm]), is a male (gender value=1), has an age of 21 [years], and that the electrodes making this measurement are 5 [cm] apart. To get accurate values we must determine a way to remove the effects of skin and bone in our measurement.

$$\text{skeletal muscle volume [cm}^3\text{]} = -72.71 + 70.681 * \frac{L^2}{Z} \text{ (1)}$$

$$\text{skeletal muscle mass (kg)} = [(\frac{Ht^2}{R} \times 0.401) + (\text{gender} * 3.825) + (\text{age} * -0.071)] + 5.102 \text{ (2)}$$

$$\text{muscle density [cm}^3\text{/kg]} = \frac{\text{skeletal muscle mass [cm}^3\text{]}}{\text{skeletal muscle volume [kg]}} \text{ (3)}$$

Requirements	Verifications
<ol style="list-style-type: none"> 1. Must acquire data from computer storage unit within 5[ms] 2. Successfully computes data from sensors using specified algorithm from Equations 1, 2, and 3. 	<ol style="list-style-type: none"> 1. Will have it read Test File 1 and use start and stop markers to measure timing. 2. Will have it compute muscle density using Test File 2.

Table 5: Computer Data Analysis Requirements and Verification

2.2.3 Display [0 points]

When the data is finished being analyzed, the computer will then display it on the screen in a format that will be easy to follow and readily organized.

Requirements	Verifications
<i>1. Must correctly display data as calculated with 0% error.</i>	<i>1. Will Test File 2 that will give us a known output. We will compare the known output to the display output, and will match up.</i>

Table 6: Display Requirements and Verification

2.3 SU (Sensor Unit) [20 points total]

The Sensors Unit is comprised of two units. These units are the Sensors and the Switch. This module is responsible for the collection of raw data from the muscles.

2.3.1 Sensors [10 points]

The sensors are the main source of data collection for the M.A.D. Sleeve. They will measure the muscle density of the wearer via bioelectrical impedance. They will receive power from the battery, send their data to the local data storage unit, and operate based off of a trigger signal from the switch. They will be sets of Ag/AgCl surface EMG electrodes measured at 3 points on the arm. The electrodes have a conducting hydrogel applied to them so that they maintain a quality attachment to the wearer. The setup will consist of an electrode that produces current located near the elbow and a ground electrode at the shoulder. In between there will be electrodes to measure the voltage at various points along the length of the arm.

Requirements	Verifications
<ol style="list-style-type: none"> 1. <i>Must accurately measure voltages within $\pm 5\%$ of actual voltage drop</i> 	<ol style="list-style-type: none"> 1. <i>a) Apply a DC voltage (1.5 V) to a breadboard b) Place a resistor in series with the voltage source c) Put one sensor in series with the resistor and the other connected to ground d) Measure the voltage between sensors on the arm and on the breadboard</i>

Table 7: Sensors Requirements and Verification

2.3.2 PCB [10 points]

The PCB is used to control the sensors. We will use it to prevent the sensors from operating continuously, which would be a drain on our battery, and will give our device time to transfer data between units. It will receive a trigger signal from the microcontroller and permit the sensors to begin transferring.

Requirements	Verifications
<ol style="list-style-type: none"> 1. <i>Must be able to select different electrode to read from.</i> 2. <i>Must correctly amplify signal using bioinstrumentation amplifier shown in Figure 3.</i> 	<ol style="list-style-type: none"> 1. <i>Will send select bits directly to PCB and ensure that the correct voltages are being output by the output of the MUX.</i> 2. <i>Will read signal directly off of PCB and calculate signal amplification by monitoring the known driven voltages and the read voltages by the electrodes. The differential should provide an output with the desired gain of 100.</i>

Table 8: Switch Requirements and Verification

2.4 Points Summary

A summary of the point allocations is seen in **Table 9** below:

Section	Points Allotted (50 Points Total)
PCU	12
-Communication Link	2
-Local Data Storage	10
-Battery	0
CSU	18
-Computer Data Storage	7
-Computer Data Analysis	11
-Display	0
Sensor Unit	20
-Sensors	10
-PCB	10

Table 9: Points Summary

2.5 Tolerance Analysis

One of the more important tolerance concerns for our design is maintaining a consistent placement of sensors. As we have seen through our research into the matter, and as can be seen clearly on page 5 of citation 8 (which regards the raw signal output of sensors placed in different regions of the bicep), improper placement of sensors can result in the loss of quality measurements. It is possible, however, to ensure that we have the sensors where we want them each time we perform the test. If we model the upper arm as a cylinder, we can model the tight,

form-fitting sleeve as a cylinder as well. This allows us to model the placement of each sensor in the sleeve through polar coordinates where the center of the inner elbow (with the arm fully extended to make it simple) is set at 0° of rotation and the distance vector, $r \rightarrow$, originates from the outer edge of the skin at this point. From here, we can determine the coordinates of known anatomical components of the arm. For example, the Basilic vein and the Median Cubital veins will always be in the same position of the arm each time the same user wears the device and will, roughly, be in the same position for any arm. Upon wearing the sleeve for the first time, we can make marks (likely with a sharpie of some sort) indicating where these known features are located on the wearer and determine the degrees of rotation from the origin that these features are located (with a clockwise rotation being defined as positive, a counterclockwise rotation being defined as negative, and each going a magnitude of 180°). Once we have these positions marked on the sleeve, we can ensure in future tests that the sleeve is never more than 3° of rotation in either the clockwise or counterclockwise directions from the initial testing position to make sure we are recording from about the same position (with respect to rotation) each time. Additionally, we can make marks on the sleeve that measure precise distances from the origin of the distance vector (such as a mark 1 [cm] out and 5 [cm] out from the elbow). If we can make sure the center of the sensors are within 5 millimeters of their original placement, we can ensure consistent results. We now have a means for maintaining consistent sensor placement for each test. As long as we ensure that the initial sensor placement provides quality data, we will be sure to obtain quality data in each test that follows.

3 Cost and Schedule

3.1 Cost Analysis

3.1.1 Labor

From our research into the average salary of a University of Illinois ECE graduate, we will set our pay grade at \$35/hour. This amounts to an annual salary of roughly \$70,000. We expect our project to take roughly 100 hours of focused work, each. With this in mind, we expect the cost of labor for the two of us combined to be:

$$35 \text{ [$/hr]} \times 2.5 \times 100 \text{ [hr/person]} \times 2 \text{ [person]} = \$17,500$$

With the cost of labor accounted for, we must also account for the cost of labor snacks (mainly Monster and Doritos, but also the occasional pizza) that will accompany our work bringing our total labor cost to:

$$\$17,500 \text{ (cost of labor)} + \$250 \text{ (cost of labor snacks)} = \$17,750 \text{ (total labor cost)}$$

3.1.2 Parts

The parts required for this project are seen in **Table 10** below.

Description	Manufacturer	Part #	Quantity	Cost [\$]
Muscle Sensor Surface EMG Electrode (set of 6)	Adafruit	H124SG Covidien	5	24.75 for sensors 18 for shipping 42.75 total
Sports Sleeve	Eastbay	68691020	2	4.99 each 9.98 total
Wires	N/A	N/A	Many	Provided in senior design lab
Snap Leads	Electrode Store	BS-24SAF	1	27 total
Microcontroller	Texas Instruments	MSP430	1	12.99 for microcontroller 3.99 for shipping 16.98 total
AA Batteries (set of 4)	Energizer	<u>EVEE91BP4</u>	1	5.94 total
TOTAL				99.65 total

Table 10: Total cost of project parts

3.1.3 Grand Total

The grand total of our project is the total cost of labor plus the total cost of parts. This comes out to:

$$\text{\$17,750 (cost of labor)} + \text{\$99.65 (cost of parts)} = \text{\$17,849.65 (total cost)}$$

3.2 Schedule

The schedule can be seen below in **Table 11**.

Week of	Jason	Patrick
2/13/17	Choose sleeve, sensor testing	Sensor testing, Pick controller
2/20/17	Design Documentation, Sensor testing with snaps	Design Documentation, Initial Circuit/PCB design
2/27/17	PCB design, Initial Power/Power Safety Design	PCB Design, Initial Control design
3/6/17	PCB design, Power/Power Safety	PCB Design, Control design
3/13/17	Finish PCB	CSU
3/20/17	PCB tweaks, Spring Break	CSU, Spring Break
3/27/17	Aid with CSU	CSU
4/3/17	Connecting Units (sensors to PCB to CSU)	CSU
4/10/17	Final demonstration preparation	Final demonstration preparation
4/17/17	Mock demo preparations	Mock demo preparations
4/24/17	Final demo tweaks, Final paper	Prepare mock presentation, Final Paper
5/1/17	Final Paper,	Final Paper

Table 11: Schedule

4 Discussion of Ethics and Safety

The safety of our project has one major obstacle. The fact that we will be applying a current through the body may pose a risk to the patient should the current pass through the heart or if the current is too large. We must ensure that we have control over this current at all times throughout our sleeve. To help avoid this hazard, we will be applying the current to the right arm, grounding the shoulder as well as the the right pectoral muscle to avoid current going to the heart. Additionally, we will be placing our battery in series with a large resistor to limit current in the arm to the microamp range. The extremely high impedance of the arm itself (nearly a megaOhm!), in series with our resistor, will ensure this and that our supplied current is well below safety regulations. The maximum allowed patient DC leakage current for medical devices is 300[μ A]. [7] From the testing we performed we obtained currents of less than 2[μ A]. This means the current in our test is a factor of 150-200 times smaller than the maximum allowed current. Thus, the current we produce has little to no risk of reaching the heart and is well within accepted safety standards. Additionally, we have chosen to use Ag/AgCl electrodes because they don't react with human skin like other common electrode materials do, preventing the risk of poisoning the user.

Ethically, we face no barriers outside of what we deal with in our obligation to safety. We must ensure that our device cannot be used to harm or maim a person, purposefully or accidentally. This corresponds to IEEE Code of Ethics (CoE) #9. [4] As this project pertains to biomedical engineering, we must also follow the Biomedical Engineering Society (BMES) Code of Ethics. We would want our device, in order for it to have practical use, to be able to have FDA certification under a 510k. This would run along with the BMES CoE for Research #1, "Comply fully with legal, ethical, institutional, governmental, and other applicable research guidelines..." [5]

We hope that during this semester we will be able to properly test this machine as much as possible. However, we are aware of the fact that this may not be completely feasible. As such, we fully and completely accept what this device will do, whether we intend for said use or not, complying with #1 in the IEEE CoE. [4]

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