Senior Design 2018/2019

Notorious EMG

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DR 1.2 Docs

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Executive Summary

For those who have experienced physical therapy, they know it is painful and at times, an inconvenience. Physical therapy helps to take care of patients in all phases of healing, from initial diagnosis to a final preventative stage of recovery. By doing what a therapist prescribes, and properly triggering the target muscles, we can often avoid any delays to the rehabilitation process.

Surface electromyography (SEMG) provides therapists vast amounts of information on measurable patient data. Only 35% of patients in physical therapy will completely follow through on their routine, both in and out of the clinic. This already low number drops significantly upon discovering that only 30% of all patients who receive outpatient services attend the entirety of their sessions. Taking both statistics into consideration, it becomes plain to see why a significant number of patients, roughly 70% overall, physical therapy with the intended results for recovery.

The goal is to determine a way to encourage those recovering from long-term musculoskeletal injuries to follow through on their physical therapy and to see it through to the end. We would go about this by creating the Muscle Guide: a device that alerts patients to when they are not firing the proper muscles, as set by their therapist. Muscle use would be monitored by electromyography, or EMG sensors, and that information would be relayed back to a microcontroller. Based on set parameters, the Muscle Guide will pinpoint when muscles are being fired incorrectly and alert the user.

Our highest risk path is, by far, successfully integrating the EMG sensor with the microcontroller and having the data processed in real-time. This is because the signal must be picked up by the electrodes, conditioned, and then sent to the MCU where the signal will be sent wirelessly to the terminal. As a result, by the end of the quarter, we intend to not only become familiar with EMG, but also to integrate it with the microcontroller entirely. This will be demonstrated by showing the ability to process at least one set of incoming data from the EMG sensors.

Risk Reduction Prototype

We intend to split our RRP into two separate parts. RRP 1 will process and record muscle activity data wirelessly through EMG electrodes using a MyoWare Muscle Sensor. To demonstrate successful integration and communication between the MyoWare Muscle Sensor and the PSOC4, we will display an LED when the sensor detects a signal exceeding 5mVpp. The signal conditioning will be done by a MyoWare Muscle Sensor. The data acquisition will be read wirelessly through a PSOC4 microcontroller's Bluetooth capabilities up to 30'. We propose for this quarter that the data will output to and read from a terminal. This RRP will not only integrate the PSOC4 and MyoWare Muscle Sensor to report accurate data, it will also eliminate the need for wires by processing and reporting data wirelessly. Correct data can be validated by comparing the output signal from the MyoWare Muscle Sensor with the output signal from an oscilloscope when connected to the EMG electrodes.

RRP 2 will similarly record muscle activity through EMG electrodes, but we will be implementing our own signal conditioning unit, eliminating the need for the MyoWare Muscle Sensor. Again, the EMG electrodes will be integrated with a PSOC4 microcontroller and an LED will indicate when the user has exceeded 5 mVPP to demonstrate the PSOC and sensor successfully communicate with each other. The signal conditioning unit will include an amplifier, a bandpass filter, and an offset adjustment circuit. The data acquisition will not be wireless, rather the EMG electrodes will be connected to the microcontroller via wires. The signal conditioning unit will again be validated by comparing the output signal from the MyoWare Muscle Sensor with the output signal from an oscilloscope. Additionally, the signal from the signal conditioning unit will be clean and amplified, resembling the signal given by the MyoWare Muscle Sensor. The amplitude of the signal will be within 5% of the peak voltage of the MyoWare signal.

Both RRPs will allow for the EMG electrodes to interface with the PSOC4 microcontroller, process the signals sent from the electrodes, and report results. While RRP1 eliminates wires and reads the data via Bluetooth using an already assembled conditioning unit, RRP2 requires us to build our own filtering unit, while using wire connections.

Risk Reduction Prototype 1

Critical Paths Diagram

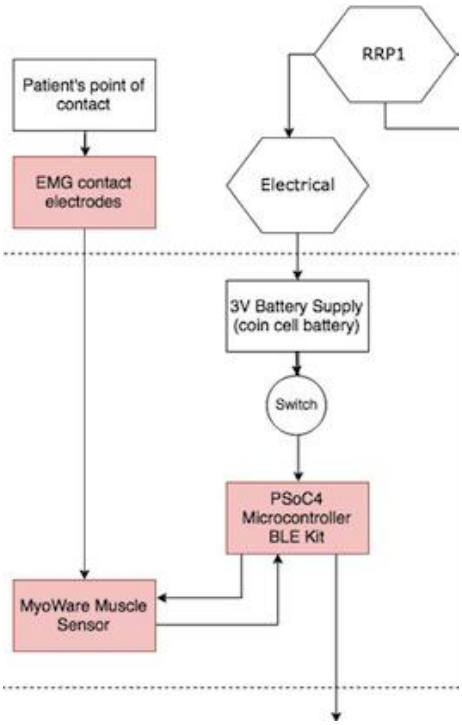


Figure 1. RRP1 Critical Path Diagram

The critical path of RRP1 includes the MyoWare Muscle Sensor to the PSoC4 BLE Microcontroller Kit. The challenges associated with this is the ability to correctly code the appropriate GPIO pin needed to communicate the MyoWare Sensor's output muscle signal to the input of the MCU. Additionally, the code to be written to save the data to eventually use for the audio alert function will also propose a challenge.

Risk Reduction Prototype 2

Critical Paths Diagram

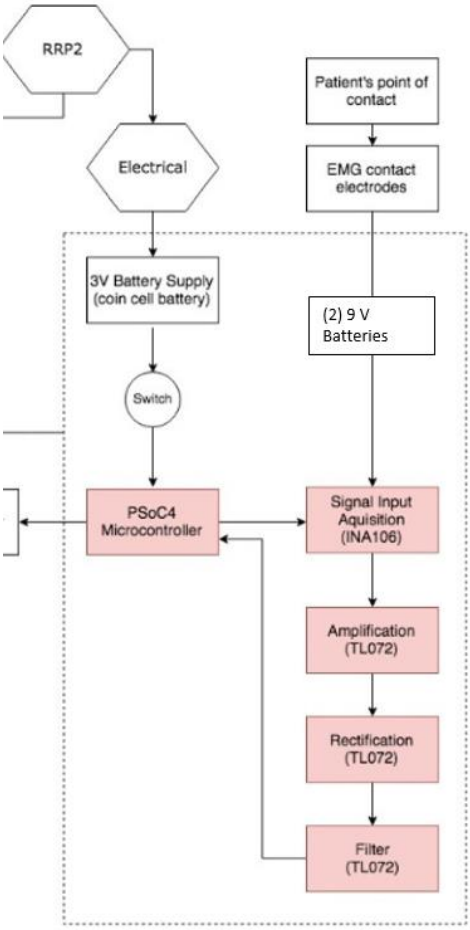


Figure 2. RRP2 Critical Path Diagram

The critical path of RRP2 includes the overall signal conditioning unit and interfacing with the MCU. The conditioning unit includes three crucial elements, the data acquisition, amplifier, and filter for the signals output form the EMG electrodes. Because the initial muscle signals are both noisy and of a microvolt amplitude, the filter and the amplifier are crucial to attain a workable output signal. The filter design must be designed with the appropriate frequency cut off and must output a signal like the MyoWare Muscle Sensor's amplitude.

Specifications and Validations

Risk Reduction Prototype Specs

RRP 1:

- EMG001: EMG Integration: **The EMG electrodes will be read through a MyoWare Muscle Sensor and integrated with a PSoC4 microcontroller to read and store data.** *Through direct contact, the electrodes will successfully detect a voltage signal and then transmit the data to the PSoC4 to be written to memory.*
- EMG002: Wireless Data Acquisition: **The PSoC4 shall receive detected muscle activity from the MyoWare wirelessly from 20 feet. The PSoC4 should detect muscle activity from the MyoWare wirelessly from 30 feet.** *Wireless capability will make the device more user friendly, and it will also decrease the chance of damaging the device by entanglement of loose wires.*
- EMG003: Data Processing & Reporting: **The microcontroller will be able to correctly process one set of incoming data and output the results correctly and continuously.** *The purpose of this device is to alert people to when they are not firing the proper muscles, so correctly processing the incoming data is a necessity. By detecting data points outside of the parameters, we will be able to implement this alert system.*
- EMG004: Wireless Data Rate: **The system shall have a Bluetooth radio system (EMG005) that transfers data at Bluetooth standard 4.1 rates. The system should have a Bluetooth radio system that transfers data at Bluetooth standard 4.2 B.L.E. rates.** *Current availability of Bluetooth devices with low power consumption make the PSoC4 Bluetooth capable devices a suitable option. With the ability to integrate with the PSoC4 creator, the IDE we are familiar with, the likelihood of meeting final specifications is increased by utilizing this standard. Verification will be accomplished by way of the datasheet.*

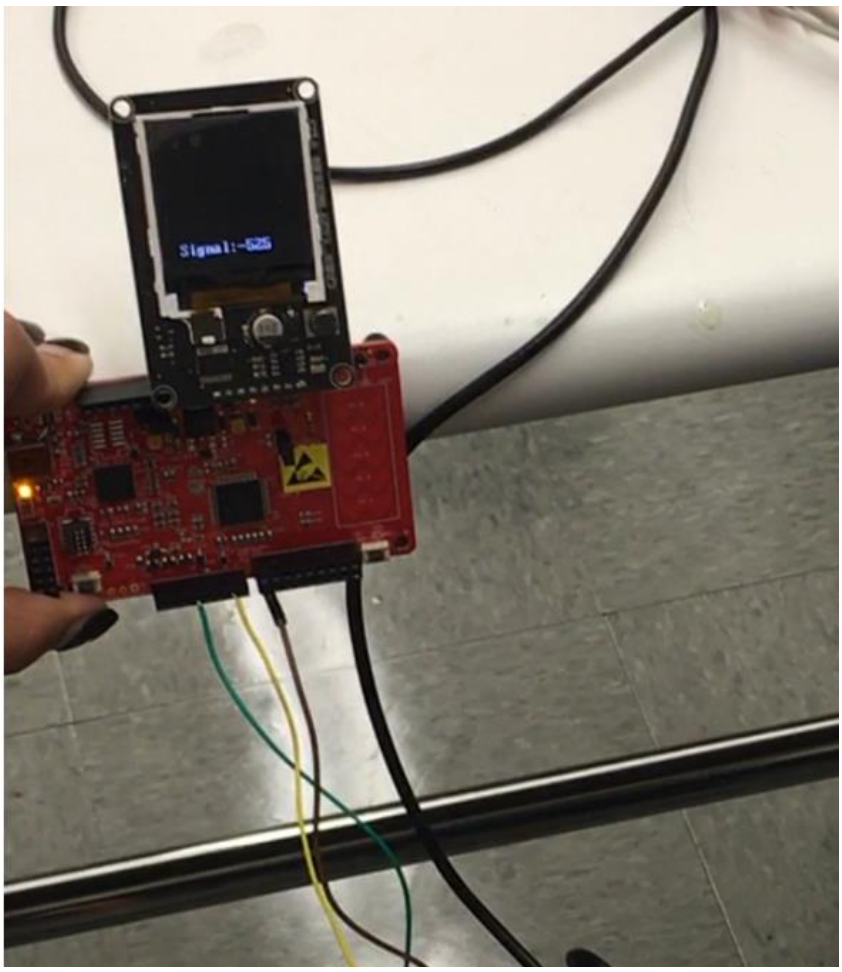
Spec ID	Requirement	Threshold (Shall)	Objective (Should)	Validation Method	Notes
EMG001	EMG Integration	MyoWare integrated with PSoC4 Achieved	N/A	Analog signal converted to digital and displayed numerically on PSoC GLCD screen	Value difference: ~980 Relax: ~-540 Contract: ~440
EMG002	Wireless Data Acquisition	20 feet Not Achieved	30 feet Not Achieved	Increase distance while monitoring output signal until the signal is no longer received	
EMG003	Data Processing & Reporting	Reports accurate set of outputs Achieved	N/A	Compare the mean voltage with SCU	MyoWare & SCU avg. voltage 53% difference because SCU half the amplitude
EMG004	Wireless Data Rate	Compliant with Bluetooth 4.1 Achieved	Compliant with Bluetooth 4.2 Achieved	Datasheet, Experimental Data Capture	Throughput = Payload size/ Time for single transaction

Table 1 – RRP1 Specifications

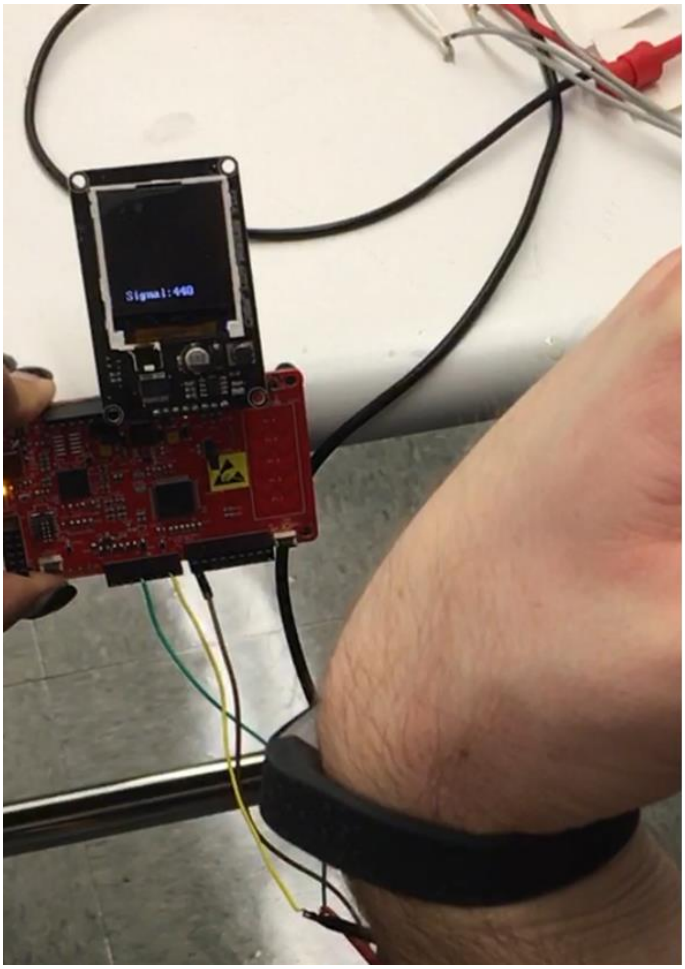
Test Plan Specification EMG001

1. Setup
    a. Attach MyoWare Muscle Sensor directly to desirable measure area
    b. Power PSoC4 BLE Kit with 9V coin cell battery
    c. Power MyoWare Muscle Sensor with Power PSoC4 BLE Kit
    d. Connect MyoWare Muscle Sensor output to input GPIO PSoC4 input pin
    e. Write and execute PSoC4 code to convert analog muscle signal to digital signal
    f. Print numerical digital signal value to PSoC4 GLCD screen
2. Test
    a. Observe numerical value at rest
    b. Contract muscle(s)
    c. Observe numerical value at contraction
3. Successful Test
    a. Numerical value is stable at rest
    b. Value increased when muscle(s) contracted
    c. Value returns to initial stabilized value when returning to rest
4. Failed Test
    a. Numerical value is not stable at rest
    b. Value does not increase when muscle(s) contracted
    c. Value is not stabilized at rest or when holding a contraction

Numerical value (stable) at rest: -525



Numerical value (stable) at contraction: 440



Test Plan Specification EMG002

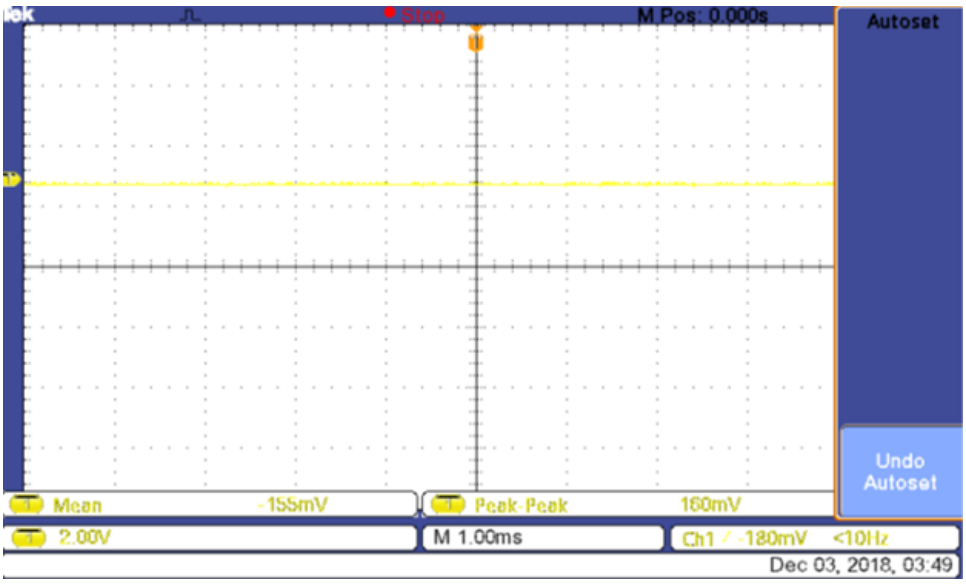
1. Setup
    a. Attach MyoWare Muscle Sensor directly to desirable measure area
    b. Power PSoC4 BLE Kit with 9V coin cell battery
    c. Power MyoWare Muscle Sensor with Power PSoC4 BLE Kit
    d. Connect MyoWare Muscle Sensor output to input GPIO PSoC4 input pin
    e. Write and execute PSoC4 code to transmit data to terminal via Bluetooth
2. Test
    a. Connect to Bluetooth device
    b. Relax and contract muscle(s)
    c. Open terminal to display incoming muscle activity data
3. Successful Test
    a. Bluetooth device available to connect to
    b. Display real-time data of muscle activity
4. Failed Test
    a. No available Bluetooth device to connect to
    b. Does not display muscle activity data

Test Plan Specification EMG003

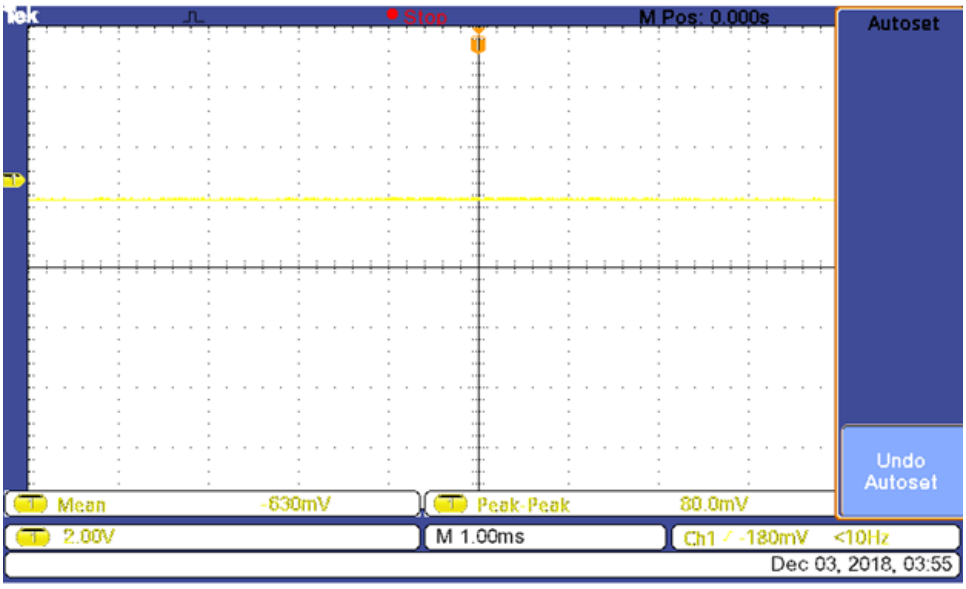
1. Setup
    a. Attach EMG contact electrodes at desirable measure area and attached electrodes to EMG cables on one arm
    b. Power SCU circuit with (2) 9V batteries for a voltage difference of 18V
    c. Connect EMG cables to SCU input
    d. Attach MyoWare Muscle Sensor directly to desirable measure area on the other arm
    e. Power MyoWare Muscle Sensor using PSoC4
    f. Connect first oscilloscope probe to SCU output
2. Test
    a. Display both SCU and MyoWare Muscle Sensor outputs on oscilloscope simultaneously at the same scale
    b. Measure mean voltage value of SCU at rest
    c. Measure mean voltage value of SCU at contraction
        i. Calculate voltage difference
    d. Measure mean voltage value of MyoWare Muscle Sensor at rest
    e. Measure mean voltage value of MyoWare Muscle Sensor at rest
        i. Calculate voltage difference
    f. Calculate percent difference between SCU and MyoWare Muscle Sensor mean voltage difference
3. Successful Test
    a. Percent difference between SCU and MyoWare Muscle Sensor mean voltage difference is equal to or less than 5%
4. Failed Test
    a. Percent difference between SCU and MyoWare Muscle Sensor mean voltage difference is greater than 5%

Signal Conditioning Unit

Resting: 155mV



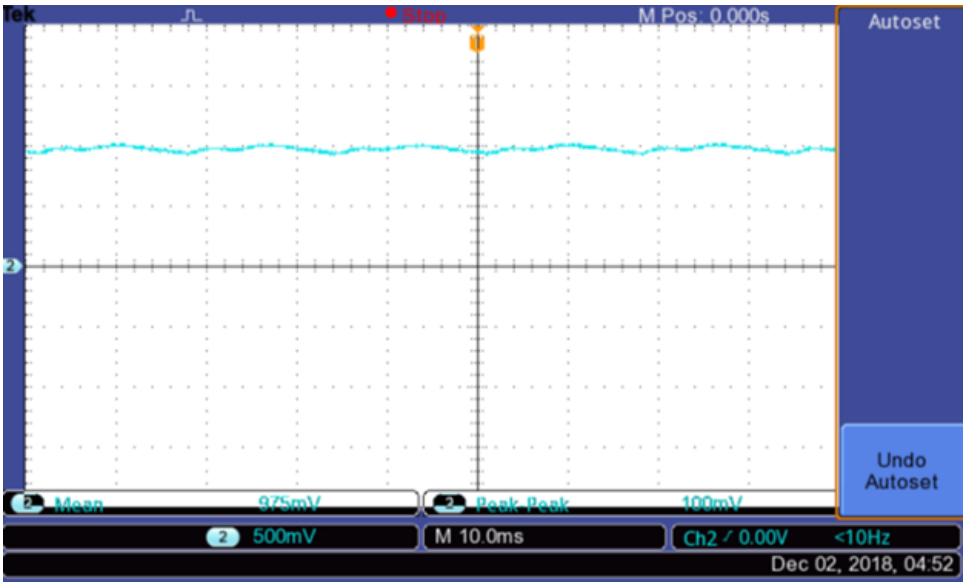
Contract: 630mV



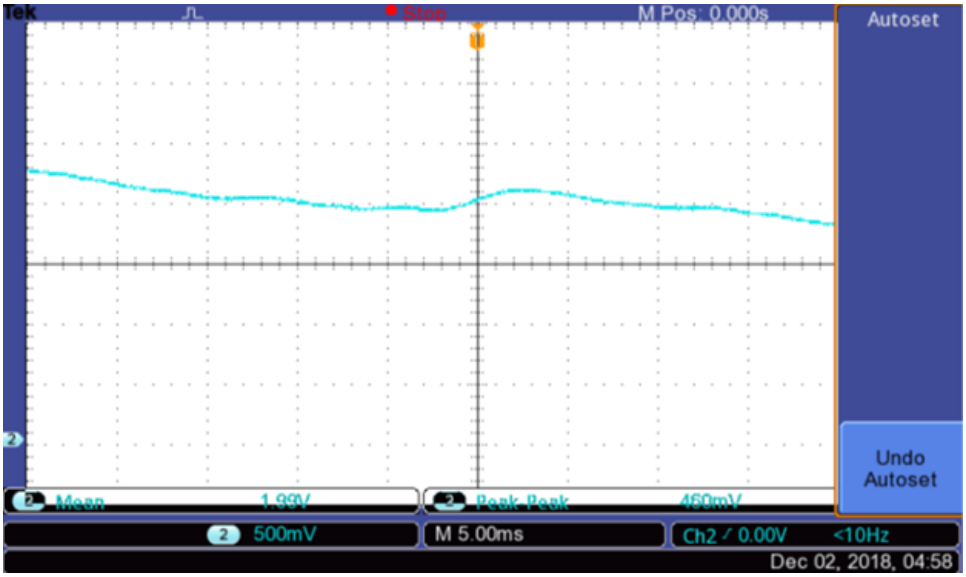
Voltage difference: +0.475

MyoWare Muscle Sensor

Resting: 975mV



Contracting: 1.99V



Voltage difference: +1.015V

Because the gain of the SCU is half the gain of the MyoWare Muscle sensor, the percent difference is double the desirable value by a factor of 2. Corresponding to the amplitude discrepancy, the data output still yields accurate results.

Percent difference: 1.015-0.475/ 1.015 x 100% = 53% difference

Test Plan Specification EMG004

1. Setup
    a. Attach MyoWare Muscle Sensor directly to desirable measure area
    b. Power PSoC4 BLE Kit with 9V coin cell battery
    c. Power MyoWare Muscle Sensor with Power PSoC4 BLE Kit
    f. Connect MyoWare Muscle Sensor output to input GPIO PSoC4 input pin
    g. Write and execute PSoC4 code to transmit data to terminal via Bluetooth
2. Test
    a. Connect to Bluetooth device
    b. Relax and contract muscle(s)
    c. Open terminal to display payload and transaction time
3. Successful Test
    a. Payload is between 2 – 257 bytes and transaction time is ~ 2500 µs
4. Failed Test
    a. Payload is between 2 – 33 bytes and transaction time is ~ 708 µs

RRP 2:

- CU001: EMG Integration: **The EMG electrodes will be read through a signal conditioning unit and integrated with a PSoC4 microcontroller to read and store data.** *Through direct contact, the electrodes will successfully detect a voltage signal and then transmit the data to the PSoC4 to be written to memory.*
- CU002: Signal Conditioning Unit: **The signal conditioning unit will output a noise-reduced, amplified, and accurate muscle signal that is within 5% of the peak voltage of the signal received from an open source board.** *Using the output from the MyoWare Muscle Sensor as the standard, the signal conditioning unit we build will output a cleaner signal with significant noise reduction when compared to the characteristics of an unconditioned EMG signal.*
- CU003: Data Processing & Reporting: **The microcontroller will be able to correctly process one set of incoming data and output the results correctly and continuously.** *The purpose of this device is to alert people to when they are not firing the proper muscles, so correctly processing the incoming data is a necessity. By detecting data points outside of established parameters, we will be able to implement this alert system.*

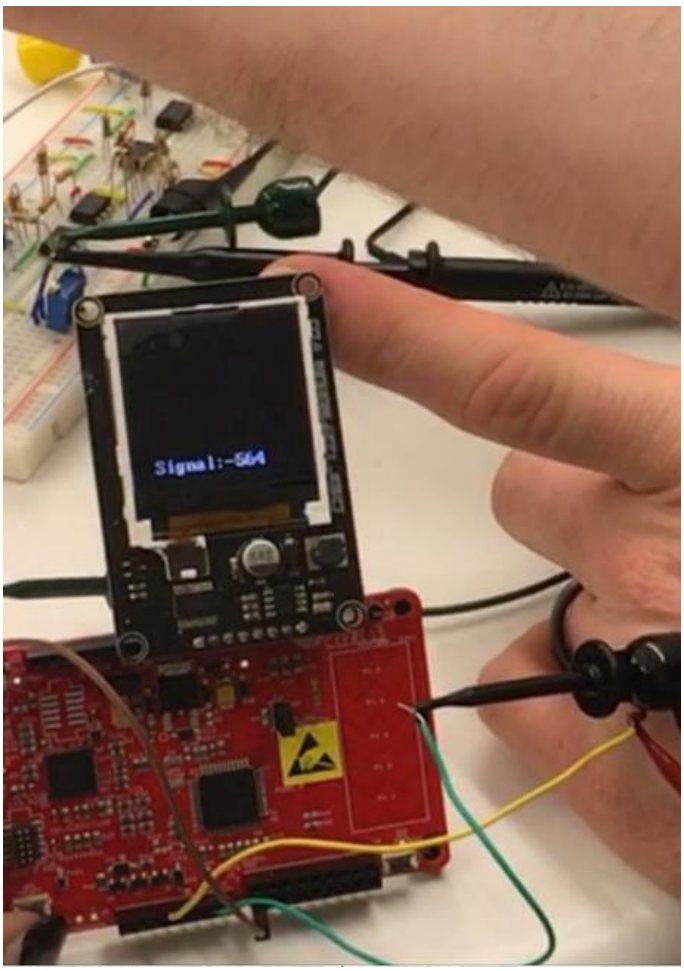
Spec ID	Requirement	Threshold (Shall)	Objective (Should)	Validation Method	Notes
CU001	EMG Integration	Signal conditioning unit integrated with PSoC4 Achieved	N/A	Output measured by oscilloscope, peak values printed to terminal	Voltage difference:~300 Relax: ~-500 Contract: ~-800
CU002	Signal Conditioning Unit	Within 5% of MyoWare Sensor's peak voltage Partially Achieved	N/A	Compare the signal with MyoWare Muscle Sensor	Lower amplitude
CU003	Data Processing & Reporting	Reports accurate set of outputs Achieved	N/A	Compare the mean voltage with MyoWare Muscle Sensor	MyoWare & SCU avg. voltage 53% difference because SCU half the amplitude

Table 2 – RRP2 Specifications

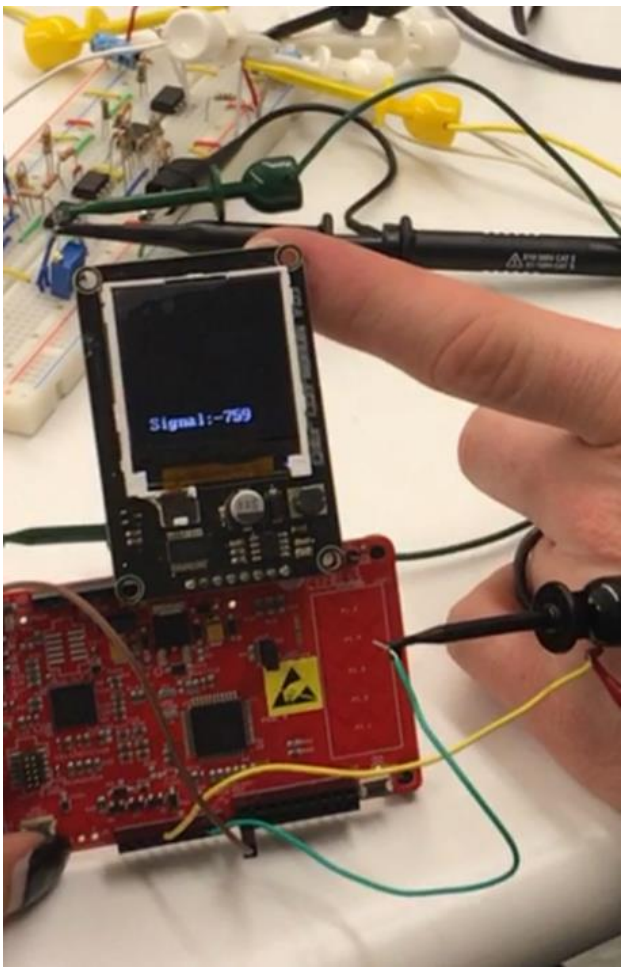
Test Plan Specification CU001

1. Setup
    a. Attach EMG contact electrodes at desirable measure area and attached electrodes to EMG cables
    b. Power SCU circuit with (2) 9V batteries for a voltage difference of 18V
    c. Connect EMG cables to SCU input
    d. Connect SCU output to input GPIO PSoC4 input pin
    e. Write and execute PSoC4 code to convert analog muscle signal to digital signal
    f. Print numerical digital signal value to PSoC4 GLCD screen
2. Test
    a. Observe numerical value at rest
    b. Contract muscle(s)
    c. Observe numerical value at contraction
3. Successful Test
    a. Numerical value is stable at rest
    b. Value increased when muscle(s) contracted
    c. Value returns to initial stabilized value when returning to rest
4. Failed Test
    a. Numerical value is not stable at rest
    b. Value does not increase when muscle(s) contracted
    c. Value is not stabilized at rest or when holding a contraction

Numerical value (stable) at rest: -564



Numerical value (stable) at contraction: -759



*These numerical values of analog signals can be converted to an accurate voltage value by a factor of (5/1023)

Test Plan Specification CU002

1. Setup
    a. Attach EMG contact electrodes at desirable measure area and attached electrodes to EMG cables on one arm
    b. Power SCU circuit with (2) 9V batteries for a voltage difference of 18V
    c. Connect EMG cables to SCU input
    d. Attach MyoWare Muscle Sensor directly to desirable measure area on the other arm
    e. Power MyoWare Muscle Sensor using PSoC4
    f. Connect first oscilloscope probe to SCU output
    g. Connect first oscilloscope probe to MyoWare Muscle Sensor output
2. Test
    a. Display SCU and MyoWare Muscle Sensor outputs simultaneously at the same scale
    b. Observe both waveforms at rest
    c. Contract both arms at the same magnitude, specifically the noise
    d. Observe both waveforms at contraction, specifically the noise and amplitude
    e. Compare and contrast both waveforms
    f. Measure peak-peak voltage of both waveforms
3. Successful Test
    a. Overall, the SCU signal must resemble the signal of the MyoWare Muscle Sensor
    b. The signal of the SCU indicates little noise to show the filtering system was successful
    c. Pulses are displayed when muscle(s) are contracted to show the signal acquisition stage was successful
    d. The amplitude of the SCU signal is amplified within 5% of the MyoWare Muscle Sensor's peak voltage to show the amplification stage was successful
    e. The signal of pulses of the SCU when muscle(s) are contracted to show the inverted amplification stage was successful
4. Failed Test
    a. Pulses are not displayed when muscle(s) are contracted
    b. Signal indistinguishable from the noise
    c. The amplitude of the SCU signal is not amplified within 5% of the MyoWare Muscle Sensor's peak voltage
    d. The signal pulses are inverted

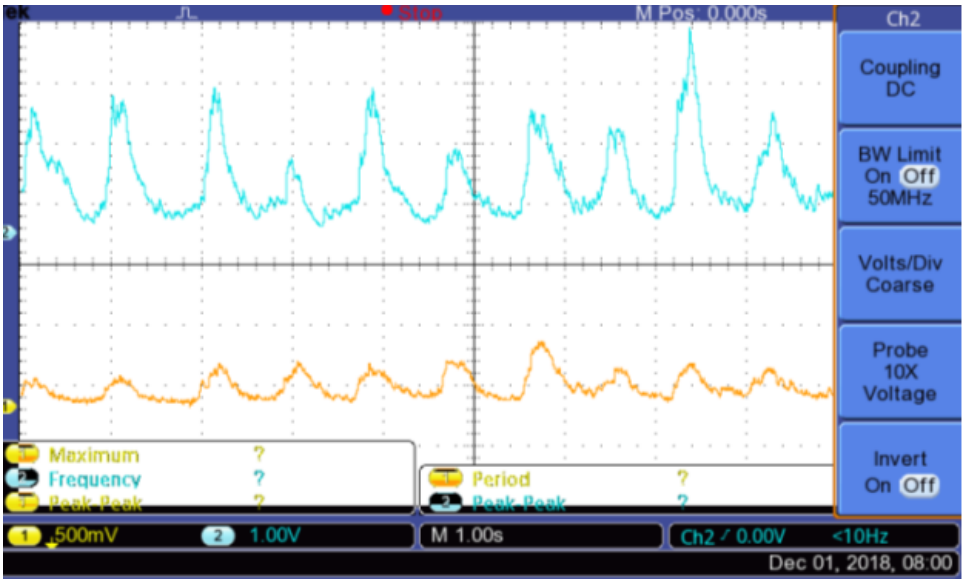


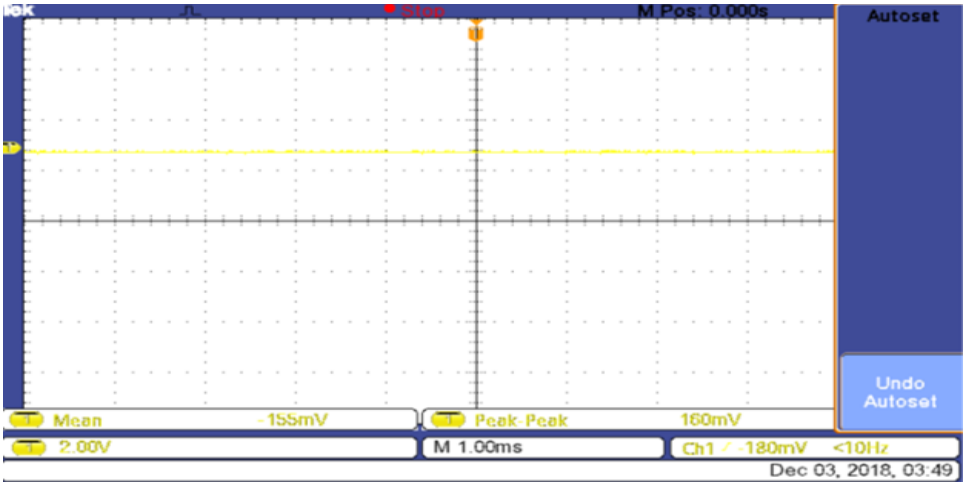
Figure # - MyoWare Muscle Sesor (Blue) and SCU (Orange) signal output from oscilloscope

Test Plan Specification CU003

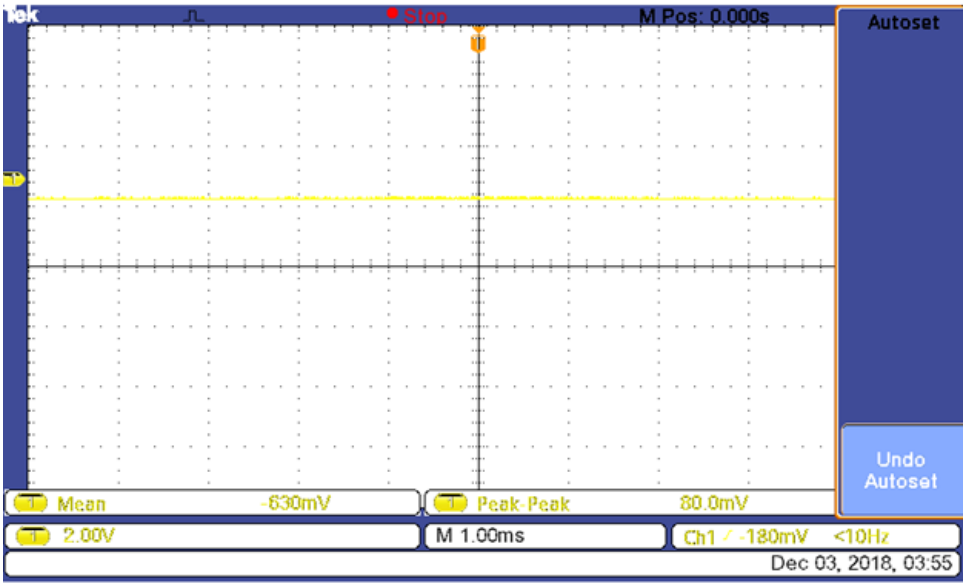
1. Setup
    a. Attach EMG contact electrodes at desirable measure area and attached electrodes to EMG cables on one arm
    b. Power SCU circuit with (2) 9V batteries for a voltage difference of 18V
    c. Connect EMG cables to SCU input
    d. Attach MyoWare Muscle Sensor directly to desirable measure area on the other arm
    e. Power MyoWare Muscle Sensor using PSoC4
    f. Connect first oscilloscope probe to SCU output
2. Test
    a. Display both SCU and MyoWare Muscle Sensor outputs on oscilloscope simultaneously at the same scale
    b. Measure mean voltage value of SCU at rest
    c. Measure mean voltage value of SCU at contraction
        i. Calculate voltage difference
    d. Measure mean voltage value of MyoWare Muscle Sensor at rest
    e. Measure mean voltage value of MyoWare Muscle Sensor at contraction
        i. Calculate voltage difference
    f. Calculate percent difference between SCU and MyoWare Muscle Sensor mean voltage difference
3. Successful Test
    a. Percent difference between SCU and MyoWare Muscle Sensor mean voltage difference is equal to or less than 5%
4. Failed Test
    a. Percent difference between SCU and MyoWare Muscle Sensor mean voltage difference is greater than 5%

Signal Conditioning Unit

Resting: 155mV



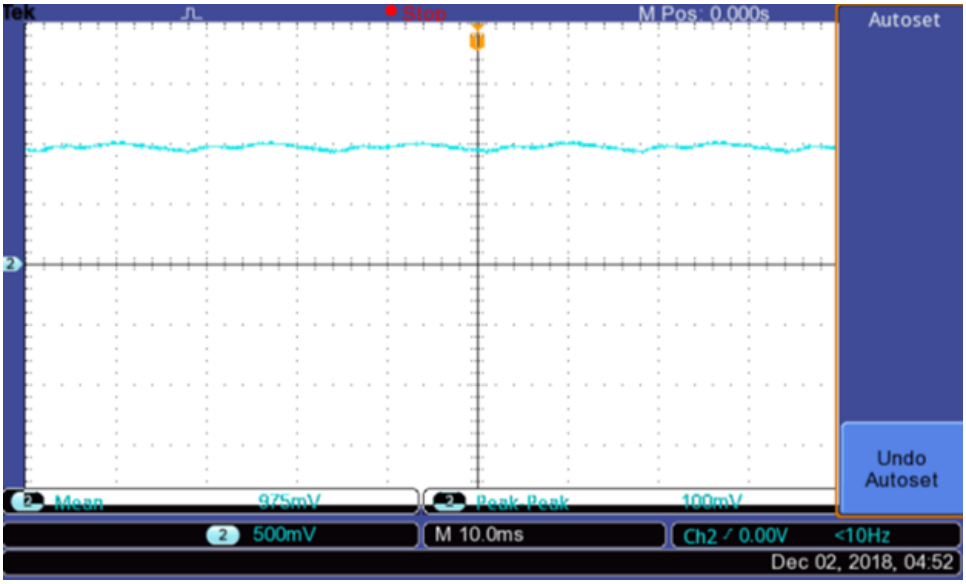
Contract: 630mV



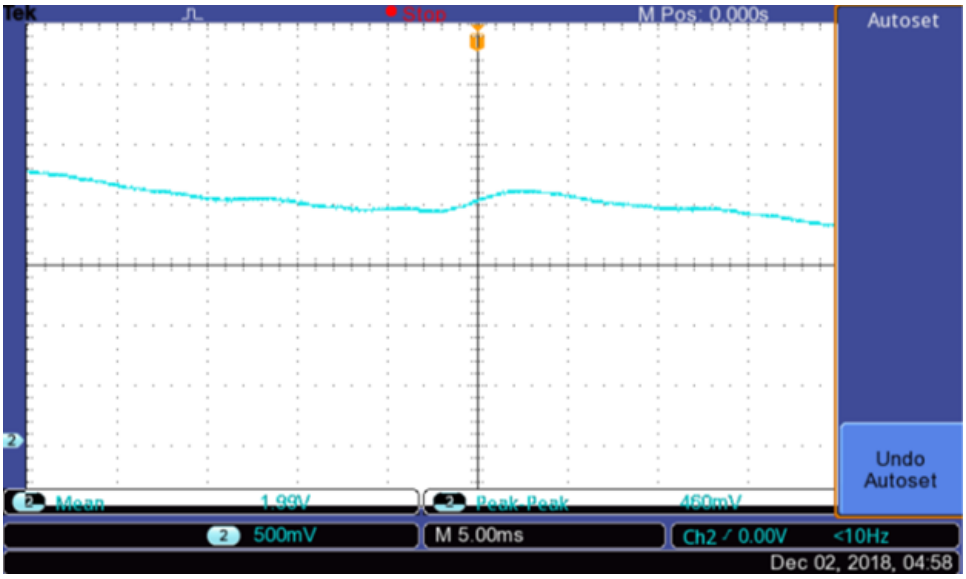
Voltage difference: +0.475

MyoWare Muscle Sensor

Resting: 975mV



Contracting: 1.99V



Voltage difference: +1.015V

Because the gain of the SCU is half the gain of the MyoWare Muscle sensor, the percent difference is double the desirable value by a factor of 2. Corresponding to the amplitude discrepancy, the data output still yields accurate results.

Percent difference: 1.015-0.475/ 1.015 x 100% = 53% difference

Engineering Analyses

Estimated Heat Transfer Analysis

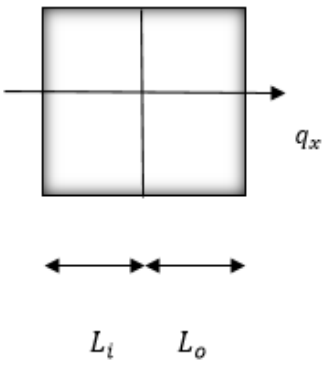
Planned

The system will contain a few electrical components that are densely packed into a panel. To promote higher operating efficiencies and longer electrical component life, it is recommended that the heat be transferred and dissipated away from the housing system. By using the lumped capacitance method, the thermal resistance network can be applied to the system. Hence, the heat transfer and material choice can be interpolated from the results.

Actual

We will assume a steady state, one dimensional, constant property system with no heat source since it is known that our electrical components operate at low energy levels. The following three-dimensional second-order differential heat equation can be modified and applied to the Muscle Guide.

1. $\rho c_p \frac{\partial T}{\partial t} = \frac{\partial}{\partial x}\left(k\frac{\partial T}{\partial x}\right) + \frac{\partial}{\partial y}\left(k\frac{\partial T}{\partial y}\right) + \frac{\partial}{\partial z}\left(k\frac{\partial T}{\partial z}\right) + \dot{q}$ Where, k=constant
2. $0 = \frac{\partial}{\partial x}(k\frac{\partial T}{\partial x})$ We can solve this given two boundary conditions. T(x=0)=T_1 ; T(x=L)=T_2
3. $\int \frac{d^2T}{dx} dx = \int 0\, dx \longrightarrow \int \frac{dT}{dx} dx = \int c_1 dx$
4. $T(x) = c_1 x + c_2 \longrightarrow T(x=0) = c_2 \longrightarrow T_1 = c_2$
5. $T(x=L) = c_1 L + T_1 \longrightarrow T(x) = \frac{T_2 - T_1}{L} x + T_1$
6. And $T_1 > T_2 \longrightarrow q_x^{"} = -k\frac{\partial T}{\partial x} = -k\frac{d}{dx}\left(\frac{T_2 - T_1}{L} x + T_1\right) = k\frac{T_1 - T_2}{L} = \frac{T_1 - T_2}{\frac{L}{k}}$
7. Even further.... $q_x = q_x^{"} A = \frac{T_1 - T_2}{\frac{L}{k}} A = \frac{T_1 - T_2}{\frac{L}{kA}}$
8. $R_{eff} = \frac{1}{h_i A} + \frac{L_i}{k_i A} + \frac{L_o}{k_o A} + \frac{1}{h_o A}$ Units: $\frac{K}{W}$
9. $q_x = \frac{T_{\infty,i} - T_{\infty,o}}{R_{eff}}$
10. $q_x^{"} = \frac{q_x}{A_x}$



The result can be found by implementing the correct material values for thermal conductivity (k) and heat transfer coefficients (h). The other values are given through the choice of cross-sectional dimensions and known surface temperatures. T**he heat transfer analysis will be ongoing into Q2 and modified with each mechanical consideration**. Once the material and final shape of the design is decided, the final heat transfer (flux) analysis will be calculated.

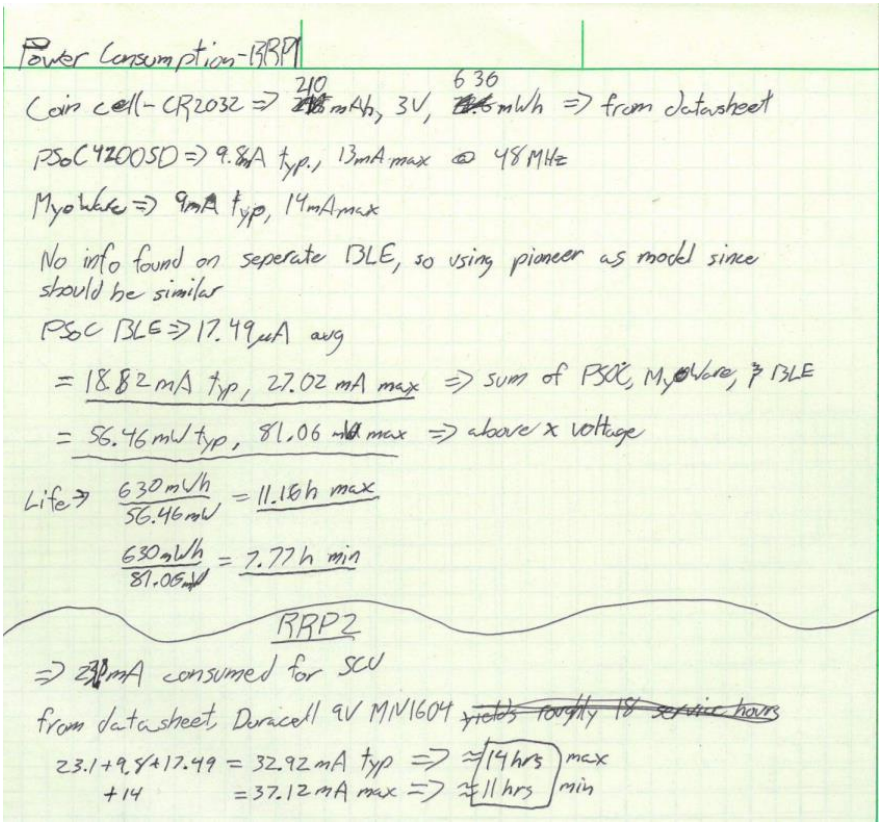
Power Consumption

Planned

The maximum power consumed by the MCU, MyoWare, and the signal conditioning unit must be determined. This will allow for selecting the smallest power source needed for the device to function and to make the device more user friendly and portable. A coin cell (CR2032) is intended to power the PSoC4 and MyoWare Muscle Sensor. For RRP 2, the coin cell will be used to power the PSoC4, and two 9V batteries will be used to power the signal conditioning unit (SCU).

Actual

RRP 1:



The capacity of the CR2032 coin cell battery is 210 mAh (milliAmp hours). The average current consumption of the PSoC 4 BLE is 17.49 µA, and the average current consumption of the MyoWare Muscle Sensor is 14 mA maximum. Therefore, under these conditions the expected service life for the CR2032 coin cell battery is 7.77 hours on average and 11.16 hours at maximum.

RRP 2:

Component	Volts (V)	Current (A)	Power Consumed (W)
1NA106	18	2.00E-03	0.036
R1- 1M Ω	2.18E-03	2.18E-09	4.73498E-12
R6 – 150 Ω	1.59E-02	1.05E-07	1.64065E-09
R7 - 10 kΩ	2.11E-06	3.04E-10	6.40385E-16
R8 - 10 kΩ	2.11E-06	3.04E-10	6.40385E-16
D1 - Signal Diode	1.51E-05	2.07E-09	3.13191E-14
D2 - Signal Diode	1.07E-05	7.57E-10	8.10204E-15
R9 - 10 k Ω	6.55E-06	9.43E-10	6.17744E-15
R16 - 585 Ω	8.93E-05	6.12E-03	5.46516E-07
100 kΩ Pot	2.80E-06	3.14E-09	8.792E-15
R5 - 150 kΩ	2.35E-06	1.57E-11	3.6895E-17
R14 - 1 kΩ	7.79E-06	1.12E-04	8.68585E-10
R13 - 80.5 kΩ	7.80E-06	9.65E-11	7.527E-16
C3 - 1 µF	7.78E-06	9.66E-11	7.51548E-16
C4 - 0.01 µF	1.57E-02	1.05E-07	1.64065E-09
R12 - 80.6 kΩ	1.26E-05	1.56E-10	1.96812E-15
R11 - 10 kΩ	6.98E-06	6.98E-10	4.87064E-15
R10 - 10 kΩ	6.53E-06	6.53E-10	4.26278E-15
C2 - 1 µF	0	0	0
R3 - 10 kΩ	1.05E-03	8.88E-05	9.31875E-08
R2 - 1 MΩ	1.23E-03	1.24E-08	1.525E-11
R4 -150 kΩ	1.57E-02	1.05E-07	1.64065E-09
Total		8.32E-03	0.0360

Measuring the voltage and current for each component except the TL 072 amplifiers, the 1 µF tantalum capacitors, and the 1NA106 differential amplifier gives a total current consumption of 23.1 mA. The datasheet was referenced for the current consumed by the amplifiers and tantalum capacitors. The total power consumed by the signal conditioning unit was calculated directly from the voltage and current measurements and added to the values found in the datasheets for a total power consumption of 298.5 mW. From the datasheet, one TL072 will consume 87.5 mW peak, so 3 chips will consume 262.5 mW. The 1.0 µF Tantalum capacitor consumes 0.5 µA at ~ 18 V for a power consumption of 8 µW. Therefore, 2 Tantalum capacitors consume 16 µW of total power. So, 262.5 mW + 36 mW + 16 µW gives a total power consumption of 298.52 mW. With the PSoC and Bluetooth module, the total current draw was, on average, 32.92 mA, and 37.12 mA at a maximum. Reviewing the datasheet for the Duracell 9V MN 1604, one of the graphs places these values at expected service lives of around 14 hours and 11 hours, respectively.

Safety and FDA Compliance Analysis

Planned

The EMG electrodes are a passive element that allows electrical current to run through the user to communicate with the MCU. The device must avoid the risk of shocking the patient or potentially causing serious harm. Therefore, U.S. Food and Drug Administration (FDA) Compliance research much be done to ensure that the amount of contact the user has with electrical current is safe and allowed. This analysis will ensure that the potential for serious harm will not happen when using the Muscle Guide.

Actual

Using information from the FDA compliance research and known data from circuit analysis, it can be determined whether the Muscle Guide is sufficiently safe or not. After more research, it is known that around **3 mA is the threshold of sensation, severe shock occurs at 50 mA, and death above 100 mA.** Besides avoiding the risks involved, there is also an **FDA compliance process (510(k)) that takes up to 100 days, after which, if no decision is reached, the submission is rejected. These 510(k) processes are necessary for marketing clearance.**

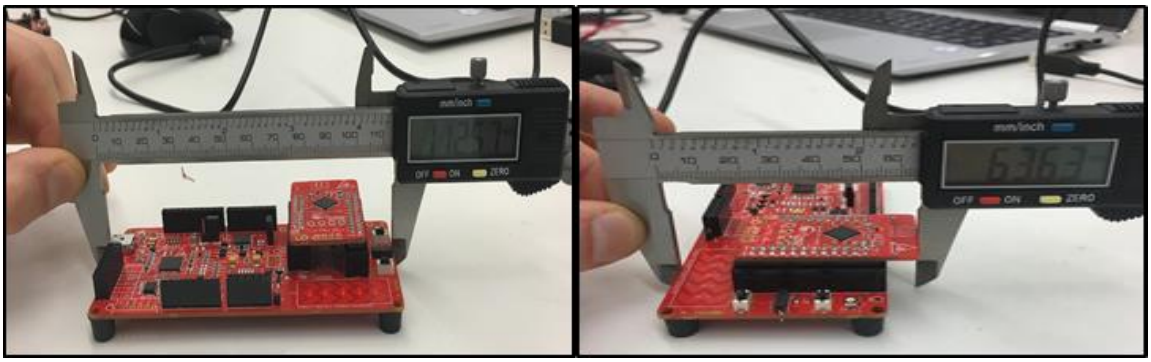
Weight & Size Analysis

Planned

Because this device is to be portable, small, and lightweight for the user to use while exercising, a weight and size analysis must be done to ensure that this device is not inconvenient for the user or makes their exercise regime towards recovery more difficult. The vision for this device is to be the size and weight of a typical cell phone.

Actual RRP1

	Quantity	Weight (g)	Dimensions (mm)
MyoWare Sensor	1	7.8	53 x 22 x 5
PSOC4 BLE	1	87.7	113 x 64 x 23
Coin Cell Battery (3V)	1	3.0	20 (dia.) x 3 (t)
Total	**3**	**98.5**	**Area = 117,983 mm^3**



Actual RRP2

	Quantity	Weight (g)	Dimensions (cm)
PSOC4 Pioneer Kit	1	26.65	89 x 52 x 16
Electrodes	1	2.65	40 x 34 x 5.5
9V Batteries	2	90.9	48 x 26 x 17
EMG cables	3	17.5	350 (L)
SCU Circuit	1	80.8	127 x 55 x 26
Total	**8**	**214.47**	**Area = 284,354 mm^3**

Data Rate Analysis

Planned

The analog signal detected by the EMG electrodes must be converted to a digital signal that the MCU can use. A higher data rate will allow the PSoC to function in a low-power state for longer periods of time, so Bluetooth 4.2 data rates are desirable for this application. This alert system must be accurate in real time so that the user knows when and what action took place when something was done incorrectly and what to improve at which point in time during their workout.

Actual

Throughput, the rate of data transfer that we are interested in, is the number of bits transmitted per transaction time. In Bluetooth standard 4.1, the capacity of the Protocol Data Unit has a capacity of 2 to 33 bytes. Bluetooth standard 4.2 has a Protocol Data Unit capacity of 2 to 257 bytes. At 27 bytes, the transaction time for Bluetooth standard 4.1 is 708 μs, and, at 251 bytes, the transaction time for Bluetooth standard 4.2 is 2500 μs. Though the transaction time is lower in Bluetooth 4.1, the number of times that the radio must be active is higher. The longer transaction time in Bluetooth 4.2 allows the system to remain in a low-power state for longer periods since the radio does not need to repeatedly wake the device. The PSoC4 BLE has a specified data rate, or throughput, of 1-Mbps. When considering multiple layers of protocol, the controller design, and certain connection parameters, the actual throughput is much slower. Although RF modulation can reach the maximum capacity of 1-Mbps, the theoretical throughput maximum for the device is around 950 kbps for Bluetooth 4.2.

Data Storage Analysis

Planned

The device will store activity data from the user to be reviewed later with a physical therapist. The data sampled from both the MyoWare Muscle Sensor and the signal conditioning unit will need to store this data directly to the MCU. The amount of Random-Access Memory, RAM on the MCU will need to be looked at an analyzed. If necessary, to accommodate the amount of data sampled and needed to be store, an alternative MCU with larger RAM will be considered.

Actual

The PSoC 4200DS's datasheet indicates that the device has up to 64 kB of flash and up to 8 kB of SRAM. The SRAM is important, as when a signal marked as improper muscle firing is stored, this is where it will be held. The specifications of the kit indicate a 32-bit MCU subsystem with a 48-MHz Cortex-M0 CPU and up to 8 kB of Static random-access memory, SRAM. This means that the microprocessor can process data and memory addresses that are represented by 16 binary bits and transmit them in parallel. By converting the EMG analog signal to a digital signal, we are not only enabling the device to read in the data, using digital memory we are also able to store and access it through binary data. Given the available 8 kB of SRAM, approximately 12 kB were used in writing the program to the chip. This means either the program needs to shrink somehow, or we need a microcontroller with more SRAM.

Risk Reduced and Remaining

Bluetooth RRP

The purpose of the Bluetooth RRP was to transmit accurate muscle activity data wirelessly using a PSoC4 BLE MCU. After the completion of the code for the PSoC4 BLE and testing, we successfully converted the EMG analog signal to a digital signal for PSoC4 BLE. In conclusion, the remaining risk for this RRP is the Bluetooth data transmission.

Signal Conditioning Unit RRP

Completion of the Signal Conditioning Unit (SCU) and testing established that we have reduced 90% of the risk involved. The objective of the SCU was to rectify, amplify, and filter a raw EMG muscle signal to output a useful waveform. Using the MyoWare Muscle sensor as the "gold standard" for the final output signal. Reading from an oscilloscope, we found the circuit to successfully reduce initial noise of the signal, convert the analog signal to digital, and amplify the signal correctly. The SCU successfully interfaced with the PSoC4 to report numerical voltage values at rest and at contraction and compared to the MyoWare Muscle Sensor was reporting an accurate set of data. The 10% remaining risk is due to the amplification stage. When compared to the output signal of the MyoWare Muscle sensor, the amplitude of the MyoWare Muscle sensor was still larger than the SCU by a factor of 2. We were successful in building this RRP and testing that it can rectify, filter, and amply the raw EMG signal. In conclusion, the remaining risk for this RRP is the output gain of the SCU.

Remaining Risks

The remaining risks for our specifications include sending the converted digital muscle activity data via Bluetooth and increase the gain from the SCU output signal to an amplitude as large as the output signal from the MyoWare Muscle Sensor. Per our test plan, we were to use the BLE dongle included in the PSoC4 BLE kit to debug and test the Bluetooth pairing and transmit data through Cypress' program CySmart 1.3. After configuring the ADC and creating a custom profile for the BLE, a program was written to read and write this data to CySmart included the ADC and Cypress' BLE module. At this point, the device was being used at the GATT servicer, and the BLE dongle would be used to debug the GAP. GAP, or Generic Access Profile, is how the devices connect, in our case the CySmart 1.3 terminal. GATT, or General Attribute Profile is how the devices trade information, in our case we configured the PSoC4 BLE to tun a GATT server. The server is what essentially stores the information to be traded at a later time between two devices. The code was written to simply send digital signals in numerical form to CySmart

1.3. While the ACD and BLE were configured and the code written was built and successfully executed, the problem with RRP1 was that the PSoC4 BLE failed to pair with the dongle. Coming into Winter quarter, pairing the PSoC4 BLE with the dongle to debug our program will be a high priority. Determining the host of our muscle data will also be determined to properly send data to a desired location for user access.

The difference in gain between the output of the MyoWare Muscle Sensor and the Signal Conditioning Unit may be attributed to the potentiometer we used in the SCU as well as the EMG cables used to connected the output of the circuit. The amount of gain output from the SCU is adjustable using the potentiometer. Based on our Multisim simulation, a 100k ohm was used to get a gain similar to to the MyoWare Muscle sensor. Unfortunately, that was not the case and come Winter quarter, we will continue trouble shooting the SCU to provide a larger gain. Another possible contributing factor to the lower gain is the EMG cables we used to connect to the output of the SCU. The cables themselves have an internal impedance, therefore the longer the cables, the more power loss throughout. Because the EM cables used for the SCU was longer compared to the EMG cables of the MyoWare Muscle Sensor, we also suspect this to be a contributing factor to the lower gain. Once again, come Winter quarter, we will continue working with the circuit and the cables to come up with a solution.

Updated Projects

As of now, our overall project does not include any changes. Coming into the next quarter, per Mr. Mansfield's inputs, we will reconsider the target audience for this device. If we continue to design this product for physical therapy patients, the device will be adjusted so that it will be solely used in the PT clinic, but the overall design/project diagram does not change. If we modify the device to work with athletes instead, the alarm system will be removed from the overall project. This decision will be made the first week of Winter Quarter.

Project Diagram

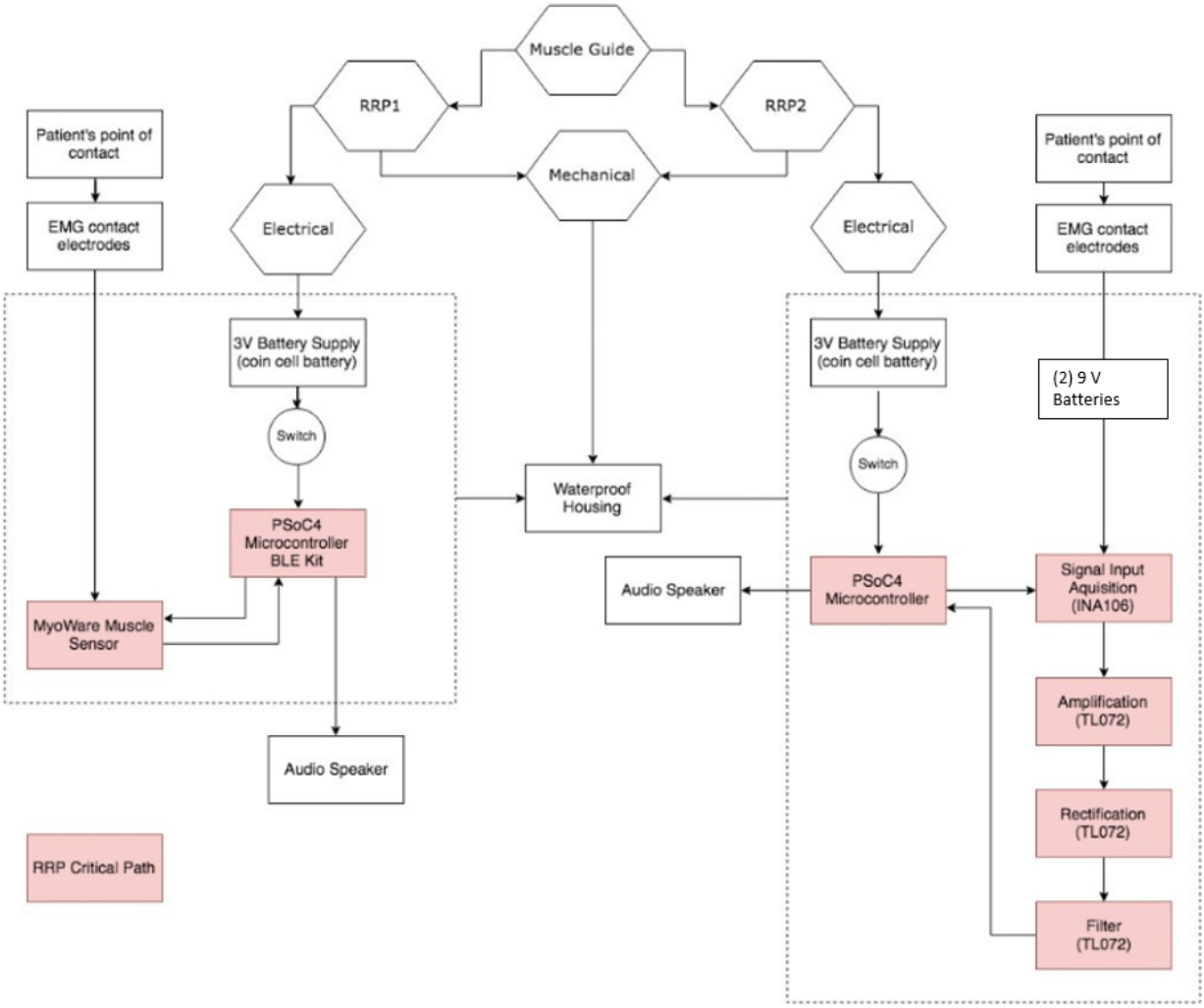


Figure #. Project Diagram

Explanation and Consideration of Changes

On November 30th, team members Vi Tran and Marshall Kabat met with Lance Mansfield. Mr. Mansfield is a member of the advisory board and reached out to our group that showed interest in being an advisor for the project. During the meeting, we discussed how this product can be commercialized and explored different target audiences. As of now, the Muscle Guide is a medical device used by both physical therapy patients and physical therapists. If we desire to adhere to this audience, Mr. Mansfield advised that we keep this device solely in the PT clinic for the PT to use, rather than the user outside of the clinic. By doing so, it eliminates the need to design a device that must satisfy separate needs – the needs of the patient and the needs of the PT. Designing a device for use solely in the clinic, the PT would be the main user thus simplifying the device so improvements can be made. Additionally, the idea of creating a PT device further complicates the design because it would need to function for all types of body parts. Therefore, we discussed the option of shifting the scope of the device to monitor the muscle activity/power of athletes instead. With this new target audience, the alert system initially designed to let the PT patient know they are not adhering to their exercise regime would be abandoned. Instead, the new design for this device would be design for a specific type of athlete. If designed for runner, for example, the device would be used only in the lower body. If design for climbers, for example, the device would be used only for the upper body. With this input from Mr. Mansfield, the team will discuss and consider changing the target audience to athletes and abandoning the alert system.

Upcoming Design Choices

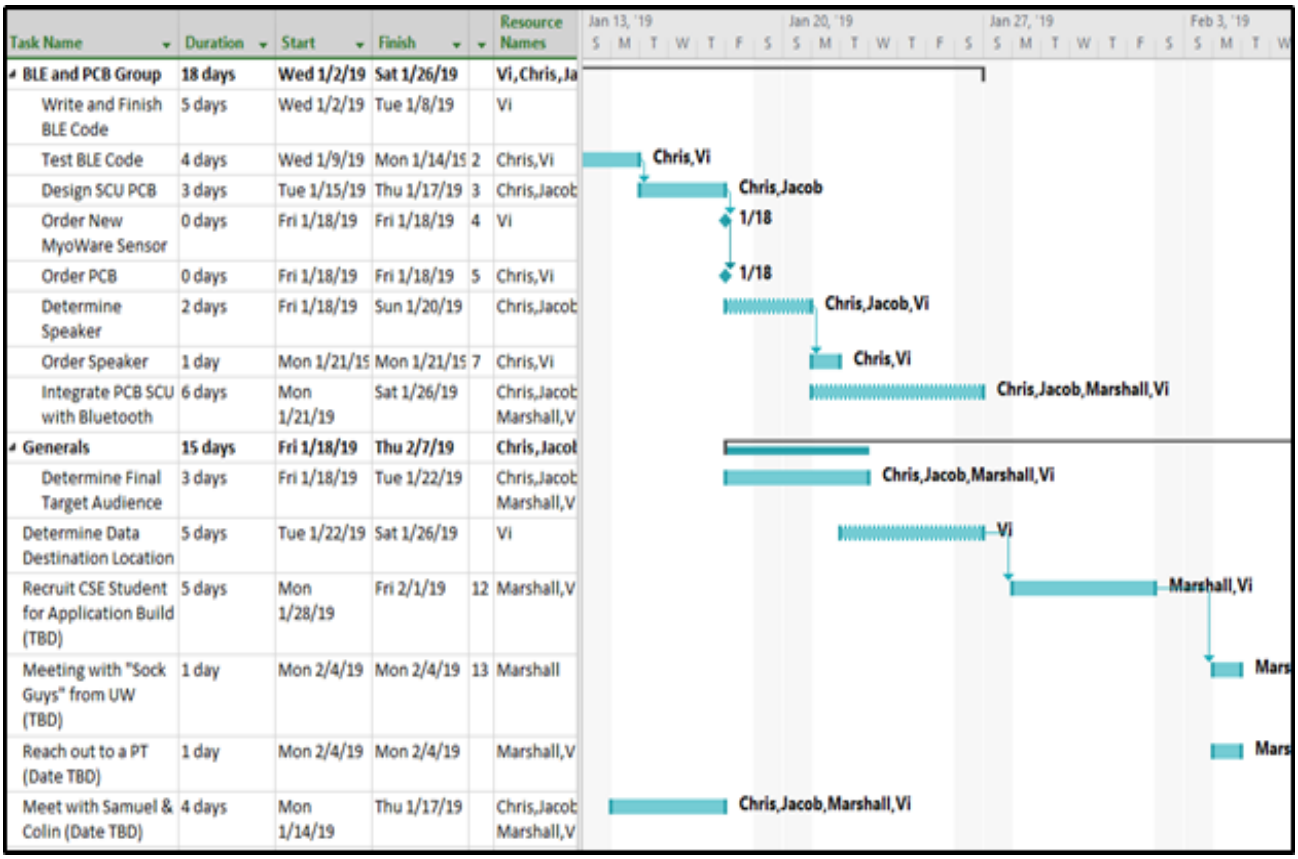
Two upcoming design choices will be to be made. The first upcoming design choice is whether to continue to pursue a device for PT use or a device for athlete use. If we continue with our design for PT, the device will still need to be adjusted so that it will be used solely in the clinic. By doing so, we eliminate the need to design for two separate audiences and the device will be used mainly by the PT instead of both the user and the PT. If we choose to modify our device to be used by athletes instead, we will remove the alert system and concentrate solely on making the device more wearable, user-friendly, and convenient for an athlete to use.

Another upcoming design choice, if we decide to modify the device for athletes only, will to determine which part of the body the device will be used for. The decision is either the lower body or the upper body and which athletes would benefit from which body part.

In the beginning of Winter Quarter, we will decide which target audience we would like to design the Muscle Guide for. Within this decision, we will have to decide if we will need to abandon the alert system, the type of potential athlete it will be designed for, and the shape and size of the final product.

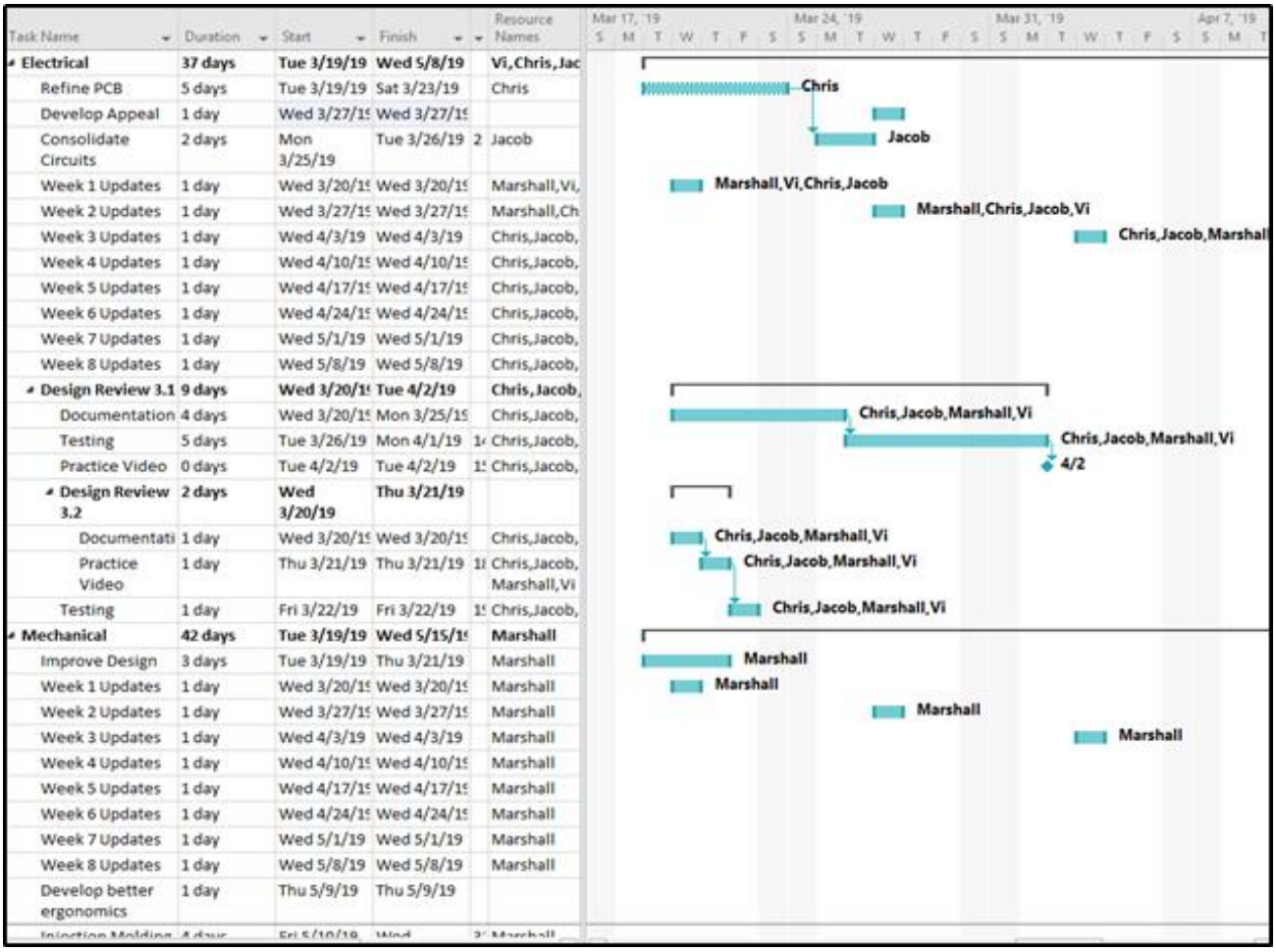
Full Year Schedule

Winter Gantt Chart



Task Name	Duration	Start	Finish		Resource Names
BLE and PCB Group	**18 days**	**Wed 1/2/19**	**Sat 1/26/19**		**Vi,Chris,Ja**
Write and Finish BLE Code	5 days	Wed 1/2/19	Tue 1/8/19		Vi
Test BLE Code	4 days	Wed 1/9/19	Mon 1/14/19	2	Chris,Vi
Design SCU PCB	3 days	Tue 1/15/19	Thu 1/17/19	3	Chris,Jacob
Order New MyoWare Sensor	0 days	Fri 1/18/19	Fri 1/18/19	4	Vi
Order PCB	0 days	Fri 1/18/19	Fri 1/18/19	5	Chris,Vi
Determine Speaker	2 days	Fri 1/18/19	Sun 1/20/19		Chris,Jacob
Order Speaker	1 day	Mon 1/21/19	Mon 1/21/19	7	Chris,Vi
Integrate PCB SCU with Bluetooth	6 days	Mon 1/21/19	Sat 1/26/19		Chris,Jacob Marshall,V
Generals	**15 days**	**Fri 1/18/19**	**Thu 2/7/19**		**Chris,Jacob**
Determine Final Target Audience	3 days	Fri 1/18/19	Tue 1/22/19		Chris,Jacob Marshall,V
Determine Data Destination Location	5 days	Tue 1/22/19	Sat 1/26/19		Vi
Recruit CSE Student for Application Build (TBD)	5 days	Mon 1/28/19	Fri 2/1/19	12	Marshall,V
Meeting with "Sock Guys" from UW (TBD)	1 day	Mon 2/4/19	Mon 2/4/19	13	Marshall
Reach out to a PT (Date TBD)	1 day	Mon 2/4/19	Mon 2/4/19		Marshall,V
Meet with Samuel & Colin (Date TBD)	4 days	Mon 1/14/19	Thu 1/17/19		Chris,Jacob Marshall,V

Spring Gantt Chart



Task Name	Duration	Start	Finish	Resource Names
Electrical	**37 days**	**Tue 3/19/19**	**Wed 5/8/19**	**Vi,Chris,Jac**
Refine PCB	5 days	Tue 3/19/19	Sat 3/23/19	Chris
Develop Appeal	1 day	Wed 3/27/19	Wed 3/27/19	
Consolidate Circuits	2 days	Mon 3/25/19	Tue 3/26/19	2 Jacob
Week 1 Updates	1 day	Wed 3/20/19	Wed 3/20/19	Marshall,Vi,
Week 2 Updates	1 day	Wed 3/27/19	Wed 3/27/19	Marshall,Ch
Week 3 Updates	1 day	Wed 4/3/19	Wed 4/3/19	Chris,Jacob,
Week 4 Updates	1 day	Wed 4/10/19	Wed 4/10/19	Chris,Jacob,
Week 5 Updates	1 day	Wed 4/17/19	Wed 4/17/19	Chris,Jacob,
Week 6 Updates	1 day	Wed 4/24/19	Wed 4/24/19	Chris,Jacob,
Week 7 Updates	1 day	Wed 5/1/19	Wed 5/1/19	Chris,Jacob,
Week 8 Updates	1 day	Wed 5/8/19	Wed 5/8/19	Chris,Jacob,
Design Review 3.1	**9 days**	**Wed 3/20/19**	**Tue 4/2/19**	**Chris,Jacob,**
Documentation	4 days	Wed 3/20/19	Mon 3/25/19	Chris,Jacob,
Testing	5 days	Tue 3/26/19	Mon 4/1/19	1 Chris,Jacob,
Practice Video	0 days	Tue 4/2/19	Tue 4/2/19	1 Chris,Jacob,
Design Review 3.2	**2 days**	**Wed 3/20/19**	**Thu 3/21/19**	
Documentati	1 day	Wed 3/20/19	Wed 3/20/19	Chris,Jacob,
Practice Video	1 day	Thu 3/21/19	Thu 3/21/19	1 Chris,Jacob, Marshall,Vi
Testing	1 day	Fri 3/22/19	Fri 3/22/19	1 Chris,Jacob,
Mechanical	**42 days**	**Tue 3/19/19**	**Wed 5/15/19**	**Marshall**
Improve Design	3 days	Tue 3/19/19	Thu 3/21/19	Marshall
Week 1 Updates	1 day	Wed 3/20/19	Wed 3/20/19	Marshall
Week 2 Updates	1 day	Wed 3/27/19	Wed 3/27/19	Marshall
Week 3 Updates	1 day	Wed 4/3/19	Wed 4/3/19	Marshall
Week 4 Updates	1 day	Wed 4/10/19	Wed 4/10/19	Marshall
Week 5 Updates	1 day	Wed 4/17/19	Wed 4/17/19	Marshall
Week 6 Updates	1 day	Wed 4/24/19	Wed 4/24/19	Marshall
Week 7 Updates	1 day	Wed 5/1/19	Wed 5/1/19	Marshall
Week 8 Updates	1 day	Wed 5/8/19	Wed 5/8/19	Marshall
Develop better ergonomics	1 day	Thu 5/9/19	Thu 5/9/19	
Injection Molding	4 days	Fri 5/10/19	Wed	3 Marshall

Explanation and Considerations of Schedule

After documentation, fall quarter was a major build period with two prototypes to build for our team. These builds will continue into winter quarter, and modifications to the design and/or additional builds may be required based off the decisions of some upcoming design choices. The EE team will continue working on the Bluetooth integration, which we hope to achieve wireless data storage and transmission, via Bluetooth, of the muscle signals detected by the SCU. We made the mistake fall quarter ordering parts for the SCU too late in the quarter, which pushed back the date to build the circuit. With the circuit so behind schedule, the time originally allocated for the BLE implementation was put into building the SCU instead. For winter quarter, the immediate priority is to complete the BLE implementation and successfully send muscle activity data wirelessly. A significant difference between this schedule and our previous fall schedule is we are allocating less time, reasonably, for tasks so that they do not delay the end process since many tasks depend on the completion of previous tasks.

For Spring quarter, we have only included the dates for documentation and presentations. This schedule will be revised to include detailed dates closer to Spring quarter.

Potential Risks

A potential risk is the collection of wrong electrical and mechanical parts needed to proceed the first few weeks of winter quarter. Electrically, we need the right microcontroller and wireless module to be as small as possible so we can focus more on the user side of the product. This part is crucial, especially since each wrong decision cuts into a scarce resource – time. To minimize these risks, we are dedicating more time to research and spending time over winter break reflecting on the product and how it can be improved.

Another potential risk is the risk of not providing what the user generally wants. The user will want something easy to handle, lightweight, and can interact with the device in real time. Mechanically, we need to determine how the user will interact with the device. We need to design this subsystem with an objective to minimize mass. It needs to be durable enough to withstand physical exercises. During the design process, all these factors have been considered. Moving forward with the build process, we need to ensure that all the criterion have been met.

Lastly, instead of focusing on the electrical needs and wants of the system, it might be beneficial to ponder other alternatives or solutions. Allocating some of the electrical rigor of the project to a software approach might prove to solve some of the issues we are having fall quarter. We will need to research greater solutions and analyze existing solutions in order to gain knowledge and increase the desirability of our project. Further testing will need to be explored.

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