SURGICAL ELECTRONIC SOLUTIONS

April 14, 2016

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440W/305W Design Specifications for the MYOperator MK 1.0

Dear Dr. Rawicz,

The attached document is the design specifications for a biomedical device, the MYOperator MK 1.0. The objective is to create our ENSC 305W/440W Capstone project based on these design specifications, which are based on our functional specifications. Our goal is to design and implement the wireless MYOperator as a replacement for the current activating pedal that is used in all operating rooms. We will create a unique solution for the existing mobility restriction problem that surgeons face.

This design specification document will have the high level requirements for our device. The specifications are for the prototype, as well as the final product. The document has multiple sections which will cover the three components to our device, the: Calf Sleeve, Hip Station, and Base Station. In each section we will cover the descriptions and detailed implementations.

Surgical Electronic Solutions is comprised of five founding partners: Michael Wilkerson, Thomas Newton, Gabrijela Mijatovic, Darren Zwack and Jonathan Feng. You can contact us at mww3@sfu.ca or 604-992-9667 for any questions or concerns.

Sincerely,

Michael Wilkerson
CEO
Surgical Electronic Solutions
Enclosed: Design Specifications for MYOperator MK 1.0

ENSC 305W/440W CAPSTONE PROJECT

Group 11

Design Specifications

MYOperator MK 1.0

Project Team: **Darren Zwack**
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Issue Date: **April 14th, 2016**

Contact: **Michael Wilkerson, CEO**
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ABSTRACT

In modern operating rooms the primary technique for activating surgical tools is to step on a physical pedal. The current method is inconvenient for the surgeon because the foot pedal can be kicked out of the desired position and result in delays to the operating procedure. The associated cord with the pedal also creates a tripping hazard for everyone in the operating room. This document describes the design specifications for a prototype of our product, the MYOperator by Surgical Electronic Solutions. The MYOperator is a wearable biomedical device that will activate surgical tools via Bluetooth communication. The device is comprised of three main components. An EMG sensing Calf Sleeve that detects foot gestures, which act as the tool's power command. The Hip Station contains the device's power switch and has a knob for sensitivity control. Lastly, the Base Station processes the EMG signal received from the Calf Sleeve along with the sensitivity level from the Hip Station to determine the state of the tool. The MYOperator is a more favorable solution than the wired pedals because the tool activating capability is always with the surgeon and eliminates the tripping hazard. The design specifications outlined in this document should be followed so that the device meets the functionality the surgeon requires.

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GLOSSARY

Base Station - The component of the MYOperator located at the wired footswitch input port

Calf Sleeve - The component of the MYOperator around the user's calf

Device - The entire MYOperator

Electromyography - The electrical recording of muscle action potentials [1]

EMG Signal Processing Board - The SES designed filtering and amplification circuit that allows the Arduino to interpret the EMG data at a DC voltage between 0 and 5 volts.

Hip Clip - The component of the MYOperator clipped to the user's hip

IC – Integrated Circuit

In-Operation Functionality - The user/device interaction during a surgical operation

Non-Operation Functionality - The user/device interaction outside of a surgical operation

ON/OFF sensing - Reading the electromyography signal of the calf

ON/OFF resolution – The time between the tool turning on and the tool turning off

Sensitivity Switch – The switch that allows The User to adjust threshold

Switch-off-time - The time from when the surgeon un-flexes their calf to when the tool turns off (Figure 1)

Switch-on-time - The time from when the surgeon flexes their calf to when the tool turns on (Figure 1)

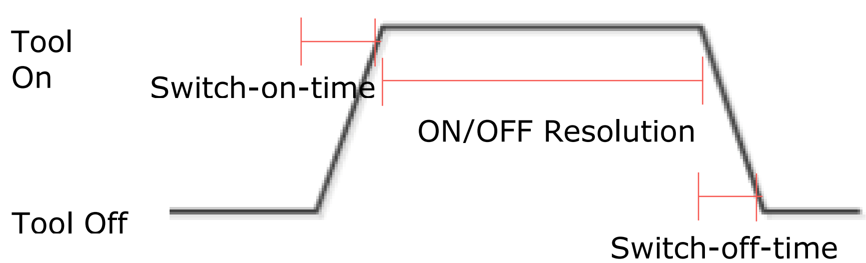


Figure 1 - Tool Timing Diagram

The User – The person using the device

Tool - the cauterizer or any surgical device the MYOperator is controlling

Tool Enable Switch – The switch that allows the tool to be activated

ACRONYMS

CSA - Canadian Standards Association

EMG - Electromyography

ENT - Ear Nose and Throat

HMI - Human Machine Interface

IEC - International Electrotechnical Commission

IoT – Internet of Things

ISO - International Organization for Standardization

PCBs - Printed Circuit Boards

SPST - Single Pole Single Throw

1. INTRODUCTION

Under operating room tables there are activating pedals that a surgeon uses to control whether a tool he is handling with his hands is on or off. A few problems with the current design are that the wired pedal creates a tripping hazard and often gets misplaced under the table, which creates a major safety issue that was brought to Surgical Electronic Solutions by a local doctor, who is the intended end user of our product and will be referred to as "The User" in this document.

Our team has designed a solution to solve the problem. The MYOperator is a wearable biomedical device that acts as a wireless activator for surgical tools, and therefore is a replacement for the current pedals. After meeting with a surgeon, who is the targeted end user of our product, we collected the minimal and ideal requirements for the MYOperator.

The system for our device can be broken down into three different components, the Calf Sleeve, the Hip Station and the Base Station. The three components will communicate with each other wirelessly over Bluetooth using the standard Firmata protocol and the Windows Remote Arduino library. The Calf Sleeve, using EMG, will contain our main sensing component responsible for collecting raw data from the surgeon's muscle movement. The Calf Sleeve will include electrodes which will sense small muscle signals generated when The User performs a muscle engaging gesture with their foot. The EMG data can then be processed and amplified by an analog signal processing circuit connected to an Arduino Uno. The Arduino Uno will communicate, using a Bluetooth shield, with a Raspberry Pi 2 B+, which acts as the Base Station.

Using digital signal processing, the Base Station interprets the EMG data and determines if the surgeon's tool should be on or off. The Hip Station, consisting of another Arduino Uno and a simple switching circuit, will enable The User to adjust the sensitivity and to turn the device on and off remotely. Surgical Electronic Solutions will integrate all of these components into one cohesive device and create a wireless solution for a currently wired pedal problem in operating rooms everywhere. Figure 2 shows our device on a user where the Calf Sleeve is shown in black, the Hip Station is shown in red and the Base Station is shown in blue.

Figure 2 – The MYOperator Prototype

1.1. Scope

The scope of this document is for the depth of a prototype version of the MYOperator. The designs in this document will meet the requirements described in *Functional Specifications for MYOperator MK 1.0* [1]*.* Since this document will be focusing on the proof-of-concept aspect of our device, only the functional requirements marked I will be discussed. The attached appendices describe the software process flow charts for how the MYOperator operates.

2. DESIGN OVERVIEW

The MYOperator device consists of three main components: Hip Station, Calf Sleeve, and Base Station. All three components are physically separate from each other and communicate with each other via Bluetooth. The MYOperator triggers a surgical tool to turn on by sensing the EMG activity of the tibialis anterior muscle, which is located on the front of the shin. The muscle is easily flexed by lifting the forefoot. This movement is easily done in both standing and sitting positions and does not require any upper-body movement, which is ideal for surgeons who needs their hands for detailed work. To actuate a surgical tool The User simply needs to lift their forefoot.

The Hip Station provides the user interface for the MYOperator. From the Hip Station the user and enable or disable the tool they are controlling, allowing them to move their legs freely without actuating the tool. The Hip Station also allows the user to adjust the sensitivity of the MYOperator device. Higher sensitivity settings require less muscle EMG activity to actuate the tool than lower settings. Sensitivity adjustments allow The User to find the sensitivity level that best works for them. The Hip Station will be discussed in more detail in Section 3.1. of this document.

The Calf Sleeve is responsible for sensing the EMG signal and transmitting the signal to the Base Station for processing. The Calf Sleeve for our prototype consists of a Grove EMG board, three disposable EMG electrodes, a custom made signal processing board, an Arduino and a Bluetooth Shield. The Calf Sleeve will be discussed in more detail in Section 3.2. of this document.

The Base Station does all of the processing for the MYOperator. Both the Calf Sleeve and Hip Station are constantly communicating with the Base Station and it is the Base Station's job to determine whether or not the actuate the tool. The Base Station makes the decision depending on the statuses of the EMG Data, ON/OFF Signal, and the Sensitivity Signal. The electrical and mechanical aspects of the Base Station will be discussed in more detail in Section 3.3. of this document and the software used in the MYOperator is discussed in detail in Section 4.

3. COMPONENT DESIGN

3.1. Hip Station

The Hip Station provides the HMI for The User. The Hip Station is responsible for setting the sensitivity level of the signal processing performed by the Base Station and for providing an easily accessible Tool Enable switch for The User to use during an operation. It is comprised of a circuit board, enclosure, external switches and knobs. The following figure is a Solidworks representation of the Hip Station.

Figure 3 - Solidworks of Hip Station

3.1.1. Electrical Design

The Hip Station is powered by a 9V battery which allows it to be mobile. The battery directly powers the Arduino which in turn powers the Bluetooth module, LED's, and the Tool Enable and Sensitivity switches with 5 volts.
The Sensitivity switch acts as a potentiometer switch with detent positions which will allow The User to adjust the threshold used by the Base Station software when determining whether or not to turn the tool on. Since the Sensitivity switch is essentially configured as a potentiometer with detent positions each position changes the voltage read at one of the Arduino analog input pins.
The state of the Tool Enable switch will be sent to the Base Station via Bluetooth, and change the state of the device. When Tool Enable is ON, The Tool can be activated using the Calf Sleeve, and when the Tool Enable is OFF The Tool cannot be activated. The Tool Enable switch is simply a SPST rocker switch connected in series with a resistor in series between the 5V power rail and GND as shown in Figure 4. The voltage across the resistor is read by a digital input pin on the Arduino and sent to the Base Station.

The Bluetooth Shield in the Hip Station is a Sparkfun Bluetooth Mate Silver. The Bluetooth Shield is discussed in more detail in Section 3.4.1. of this document. The Bluetooth Shield is provided with power from the 5V output of the Arduino and communicates with the Arduino using the Tx and Rx ports on the Arduino.

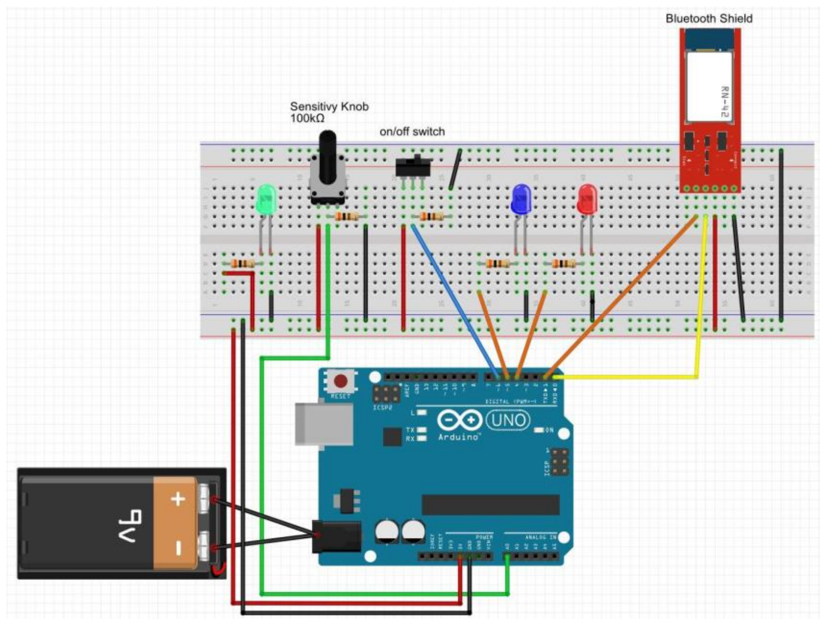


Figure 4 - Hip Station Fritzing

3.1.2. Mechanical Design

The Hip Station uses two enclosures that are connected together. The 15 x 8 x 5 cm enclosure contains an Arduino, and a prototyping board that interfaces between the Arduino, Bluetooth board, Sensitivity Knob, and the On/Off switches. A smaller 8 x 5 x 3 cm enclosure is attached to the larger enclosure and contains a 9V battery which powers the Hip Station. Two enclosures were used because it allowed us to use avoid a large jump in the size of the Hip Station enclosures, but having two enclosures has the added benefit of providing easy access to the batteries without interfering with the rest of the circuits. A belt clip is attached to the larger enclosure to allow the Hip Station to be worn by The User.

The sensitivity knob needs to have detents to provide the surgeon with tactile feedback when they adjust the dial so they can adjust sensitivity without looking and confidently know that it has changed levels. We selected a one pole twelve throw rotary switch and used stoppers to restrict the dial to only three of the twelve positions. On the enclosure is printed “L”, “M”, “H” at the three switch positions to indicate low, medium, and high sensitivity levels respectively. Another option we investigated were potentiometers with detent positions, however, we could not source any locally that had detent positions and therefore made our own.

The Tool Enable switch and the Power switch are one pole one throw rocker switches that The User will be able to easily use with gloves on. The power switch allows The User to turn off the device completely while it is not in use. The Tool Enable switch, when disabled, prevents The User from using the Calf Sleeve to activate The Tool.

3.2. Calf Sleeve

The primary function of the Calf Sleeve is to detect signals generated by the calf muscles when activated due to foot gestures. The Calf Sleeve will be worn on The User's calf, below the knee, above the ankle, and under the pants. It must be worn this way to acquire the desired EMG signal from the tibialis anterior muscle. It will be worn for the entire duration that The User is performing an operation. The Hip Station was designed to meet requirements R044 to R063 in the Functional Design Specifications document created by Surgical Electronic Solutions [Func Spec Ref]. The following figure is a Solidworks representation for the Calf Sleeve electronic components.

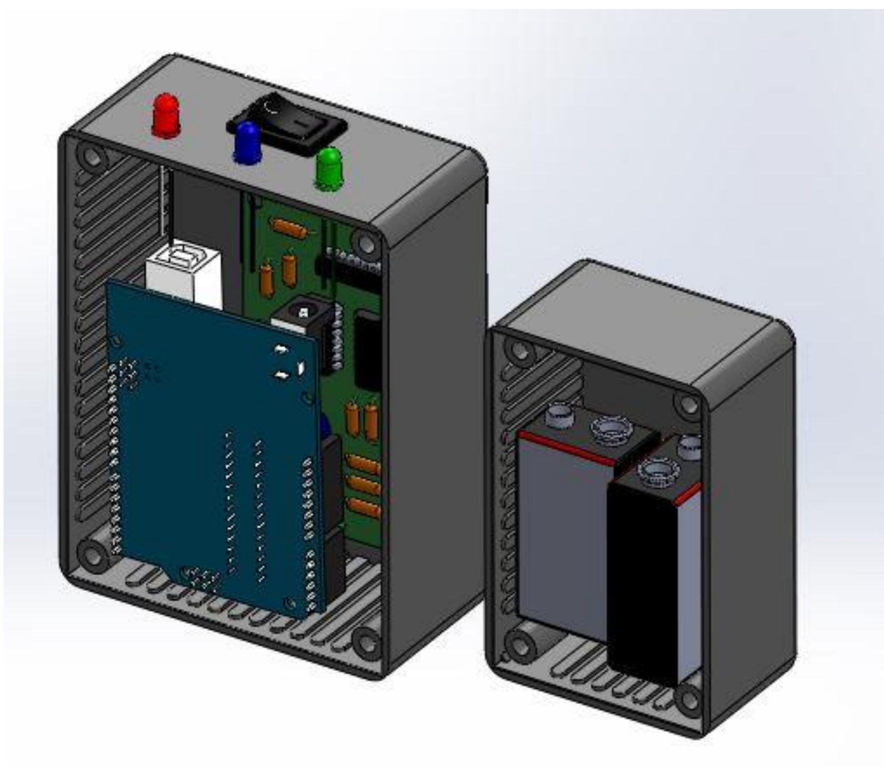


Figure 5 - Solidworks of Calf Sleeve Electronics

3.2.1. Electrical Design

The electrical design of the Calf Sleeve consists of an Arduino, Grove EMG Board with EMG electrodes, our custom EMG Signal Processing Board, Bluetooth module, power supply with a switch, and LEDs.

The Calf Sleeve has the EMG electrodes that read the EMG signal. The EMG sensors consist of three electrodes, positive, negative, and reference, which can detect muscle activation if properly positioned. We chose to monitor the Tibialis Anterior muscle during dorsiflexion of the foot. The positive electrode is positioned in the middle of the muscle, the negative electrode is placed at the end of the muscle body, and the reference electrode is placed on the Tibia bone above the ankle. The connecting points for the electrodes are shown in Figure 6.

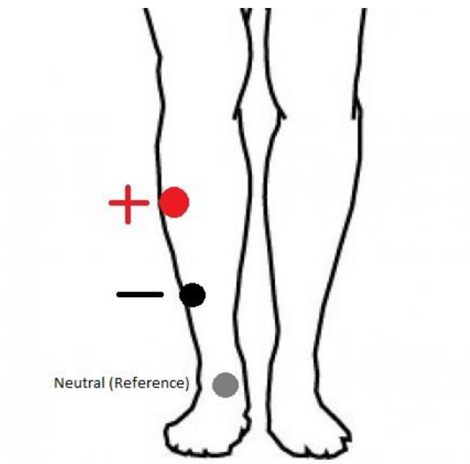


Figure 6 - Electrode Placement for EMG Sensors [6]

We also tested using the sensors at other locations on the lower leg with different foot motions. Plantarflexion of the foot with sensors on the Tibialis Anterior barely produced a signal. Another option was placing the sensors on the Gastrocnemius, however, the results of dorsiflexion or plantarflexion of the foot were less optimal than the chosen sensor placement and foot action.

The signal from the EMG electrodes is initially fed into an EMG Sensor Kit made by Grove Electronics. The Grove board reads potentials from three EMG probes and outputs a filtered and amplified waveform that goes into the EMG Signal Processing Board. The EMG Signal Processing Board is necessary because the output from the Grove EMG Board is an AC signal that varies in amplitude with muscle activity, but the Arduino analog inputs can only sample positive DC voltages.

In order to for the Arduino to read an analog voltage the signal must be a DC voltage between 0 and 5V. The Grove EMG sensors we are using in our design output an AC signal that varies between 50 and 100 mV depending on whether or not the muscle being sensed is flexed. The AC signal also has a DC bias of about 2V.

The EMG Signal Processing Board uses three stages to convert the Grove EMG sensor output to a DC voltage the Arduino can read. The three stages for processing the EMG signal are: a Sallen-Key high-pass filter, a non-inverting amplifier, and a peak-detector. The high-pass filter removes the 2V DC offset of the AC signal. The amplifier stage amplifies the AC signal so the positive peak of the signal is between 0.5V and 5V depending on whether the sensed muscle is flexed or not. The peak detector output follows the top of the amplified AC signal so the Arduino can read the peak voltage as a DC input. A schematic of the EMG Signal Processing Board is shown below in Figure 7.

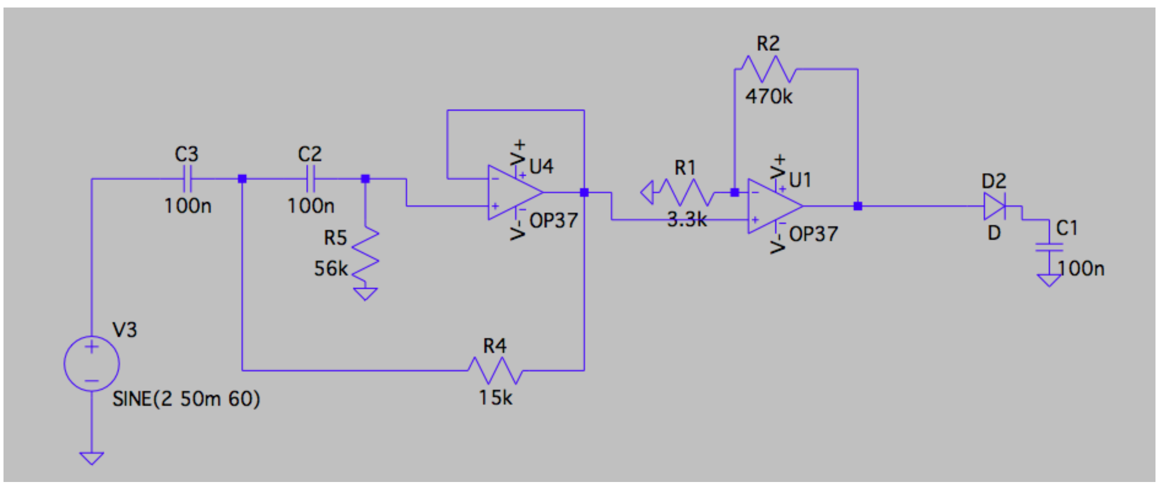
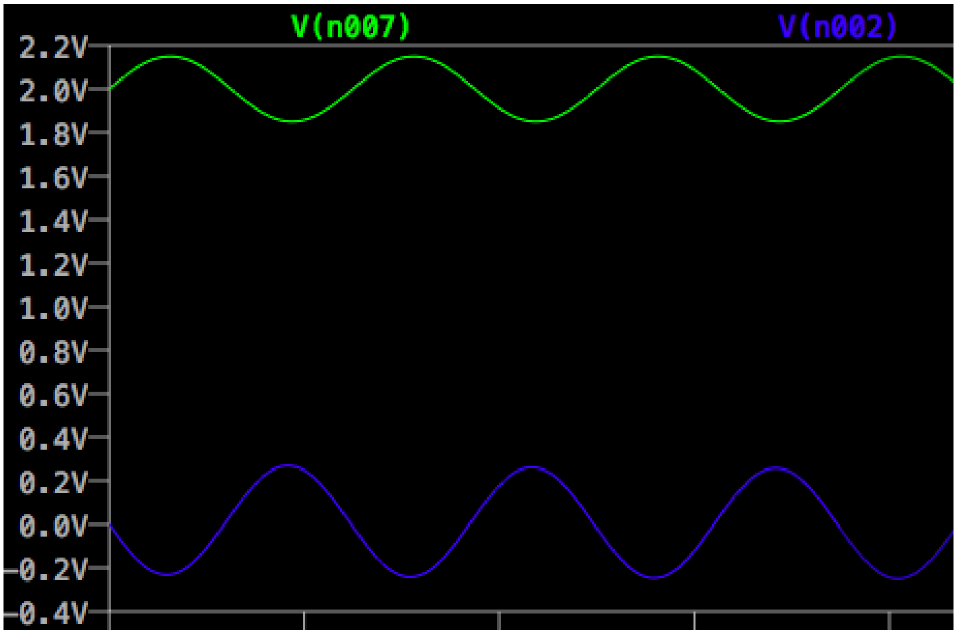


Figure 7 - EMG Signal Processing Board Schematic

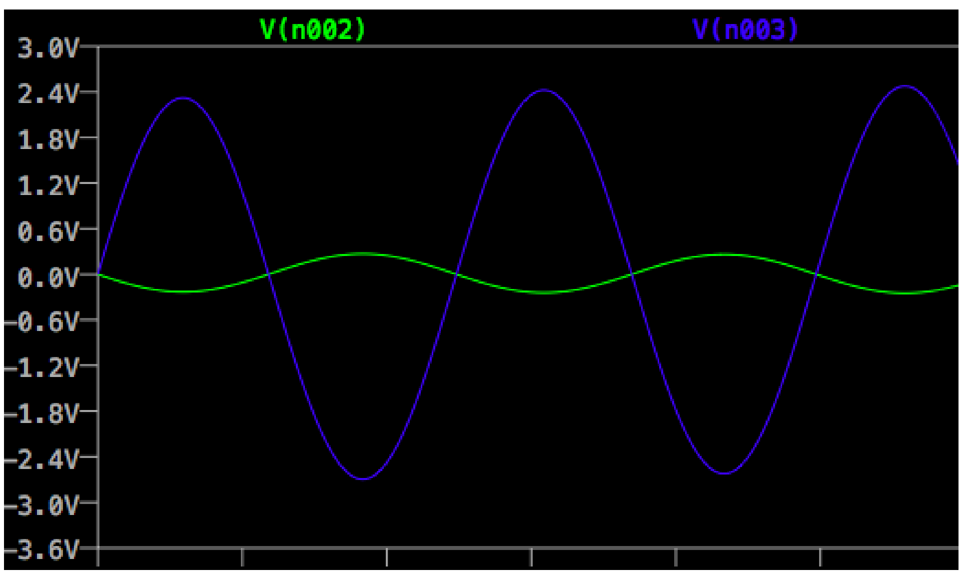
For the Sallen-Key filter and the non-inverting amplifier stages we used the RC4558 Dual General Purpose Op Amp IC. Both op amps within the IC are the same structure as a uA741 op amp, which our team is familiar with. The IC has low power consumption, short circuit protection, and a unity-gain bandwidth of 3 MHz, which is much more than we need for our application since the signal we are analyzing is only at 60 Hz.

Figures 8 through 10 show the inputs and outputs for the three stages of the EMG Signal Processing Board. The simulations were produced using LT Spice software. It can readily be seen that the output of the final stage produces a DC voltage with some ripple voltage that can be read by the Arduino.



High-Pass Filter Input High-Pass Filter Output

Figure 8 - Stage One Input-Output



Amplifier Input Amplifier Output

Figure 9 - Stage Two Input-Output

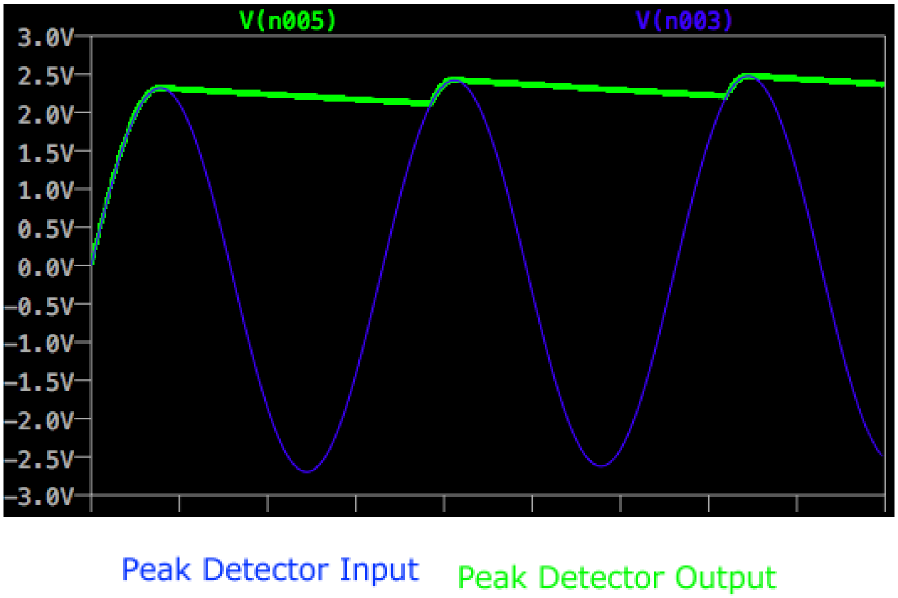


Figure 10 - Stage Three Input - Output

The Calf Sleeve is powered by two 9V batteries in series to create a +9V rail, GND rail, and a -9V rail. The Arduino is powered by connecting to the +9V rail and the Gnd rail while the EMG detection utilizes all three rails to power the op amps. The Arduino then powers the Bluetooth module and LED's each with 5V's. To connect and disconnect the power supply a double pole single throw rocker switch is used.

In an attempt to achieve a better signal to noise ratio and remove our dependency on the Grove EMG Board we built another EMG detection circuit based on the Sparkfun Muscle Sensor v3 circuit. The Sparkfun EMG detection circuit had six stages including:

- *Instrumentation Amplifier*
- *Inverting amplifier*
- *High-Pass Filter*
- *Full-Wave Rectifier*
- *Low-Pass Filter*
- *Inverting Amplifier*

The Sparkfun circuit detected signals too sensitively and during our testing would often falsely trigger an On signal. The output voltage produced by the Sparkfun circuit during testing was also typically either 0V or would fully saturate the output op amp which wouldn't allow us to adjust the sensitivity threshold. The schematic of the Sparkfun circuit is shown below in Figure 11.

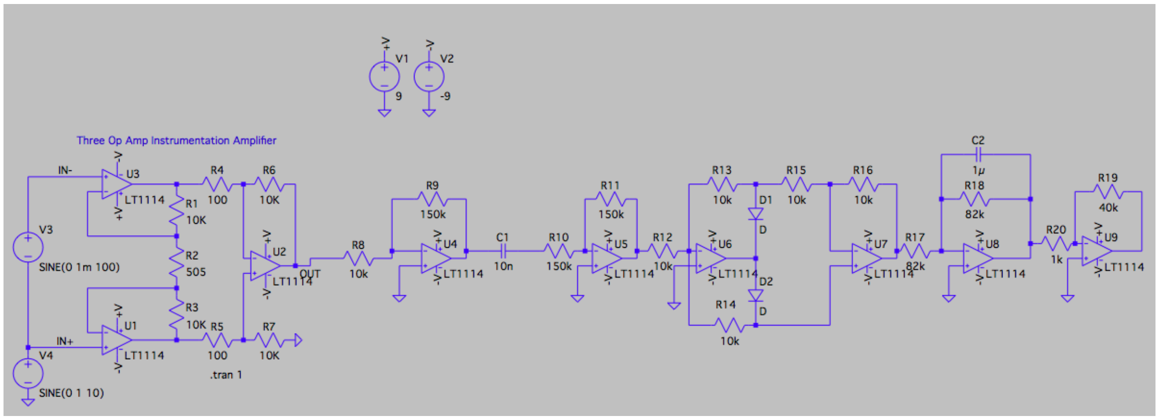


Figure 11 - Sparkfun EMG Sensing Circuit Schematic

In our testing the circuit using the Grove EMG Board as the front-end performed better than the Sparkfun circuit so we did not end up using the Sparkfun circuit.

3.2.2. Mechanical Design

The Calf Sleeve is similar to the Hip station since it also uses two enclosures, one for the circuitry and one for batteries. The circuitry enclosure of the Calf Sleeve is 11 x 8 x 4 cm and contains an Arduino, the Grove EMG sensor board, the EMG Signal Processing board, and a Bluetooth transmitter. The other enclosure is 8 x 5 x 3 cm and contains two 9V batteries connected in series which power the Calf Sleeve. The Calf Sleeve also features a calf sleeve which holds the EMG electrodes in the proper placement for muscle activity detection. Additionally, on the outside of the calf sleeve are velcro strips that the two enclosures will be mounted on. Since the two enclosures are not directly touching, and the power supply line runs between the two enclosures, these power lines will be covered with a flexible tubing.

3.3. Base Station

The Base Station is the main software component of the MYOperator device, and processes the human-machine interactions. The base station will use these human interactions, and its embedded software to determine whether or not the tool should or should not be activated. To accomplish activating the tool, the Base Station will utilize the Raspberry Pi 2's GPIO pins and a relay circuit. The following Figure is the Solidworks representation for the Base Station.

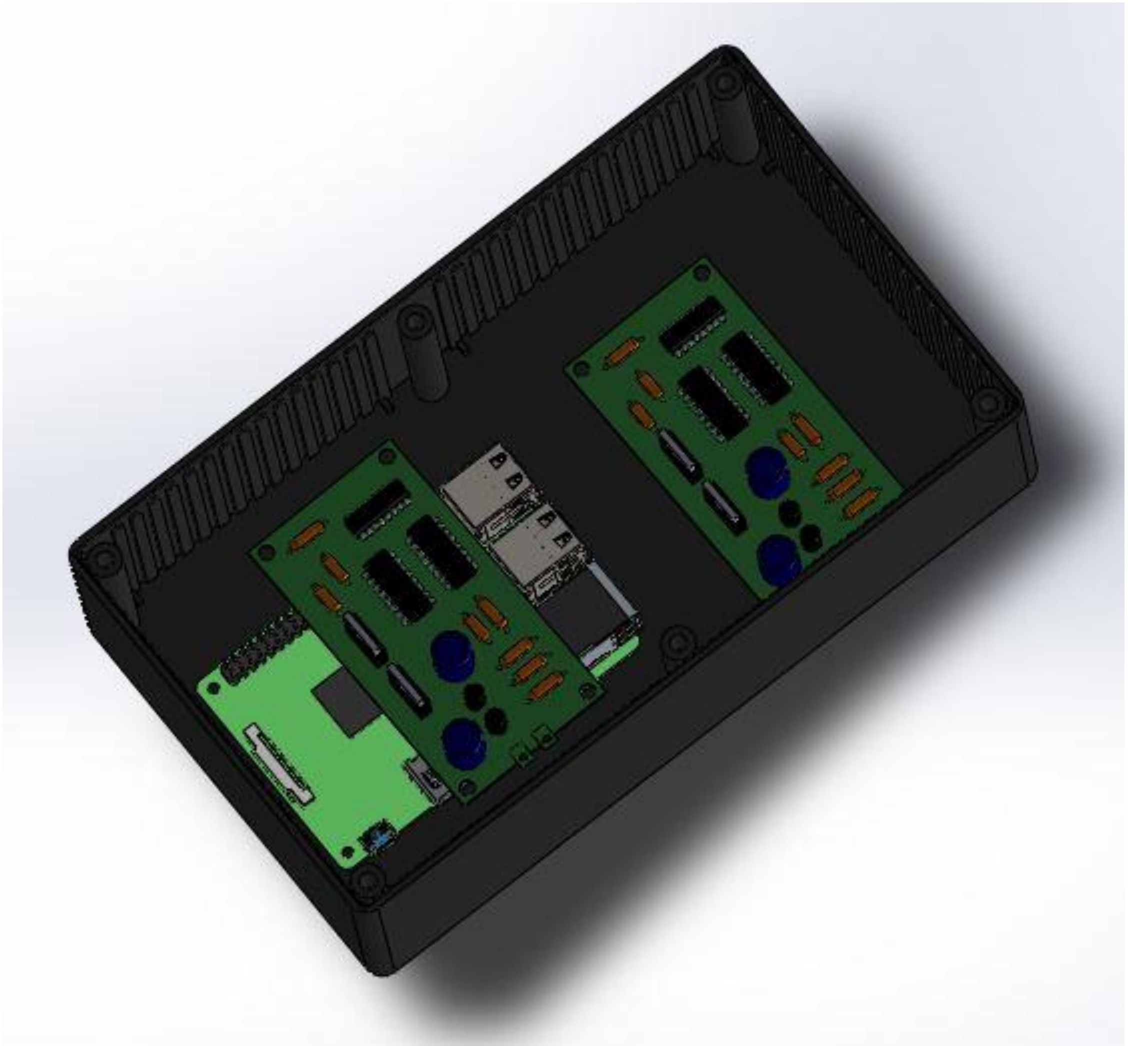


Figure 12 - Solidworks of the Base Station

3.3.1. Electrical Design

The Base Station will be powered via a micro-usb cord plugged into a 5V, 2A wall adapter. The electrical design of the base station will consist mainly of the Raspberry Pi 2's GPIO pins and a relay circuit to activate the tool. The relay requires 5V at 40 mA to activate, so the 5V rail of the Raspberry Pi will be used. Due to this rail being always on, the controllable 3.3V GPIO pin will activate an NPN transistor, allowing current from the 5V rail to flow through the relay, allowing for The Tool to be activated. The 5V rail of the Raspberry Pi can only supply about 37 mA of current, so with the 3.3V GPIO pin supplying the remaining 3 mA, it will activate the coil within the relay and flip the switch to turn on The Tool.

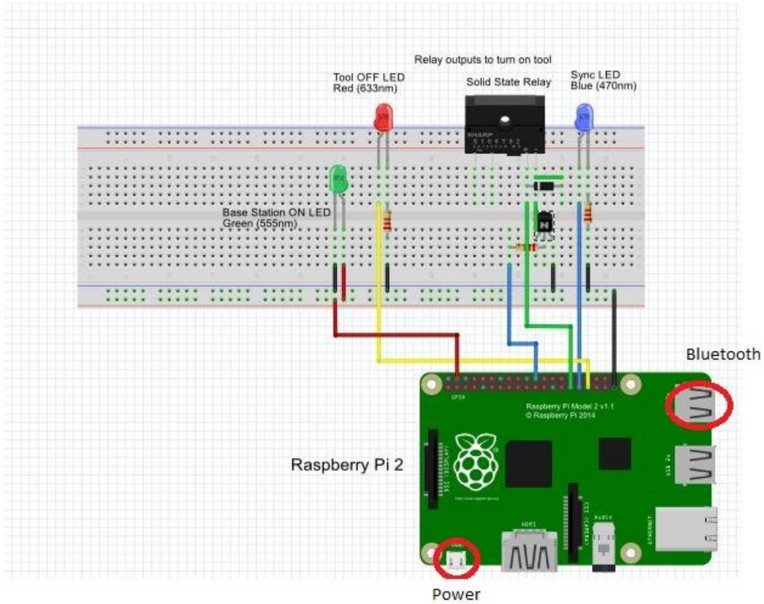


Figure 13 - Base Station Hardware Design

3.3.2. Mechanical Design

The Base Station enclosure is 19 x 11 x 5.5 cm. The Base Station is stationary during use and would be placed on a table so the size of the Base Station in our prototype is not as important as it is for our other components, therefore the interior of the Base Station has some extra space.

The Base Station has two prototype boards inside its enclosure along with a Raspberry Pi. The Raspberry Pi is mounted on the bottom of the enclosure with one prototype board beside it. The prototype board mounted on the bottom of the enclosure contains a relay that triggers a demonstration tool for our Final Capstone Presentation. The demonstration tool is a DC motor that we are going to use during our demonstration to show that the MYOperator works.

We built a shelf inside the Base Station enclosure that holds the second prototype board above the Raspberry Pi. The shelf was made using plastic L-shaped mounts that were glued to the enclosure.

3.4. Design Aspects Common Across All Three Components

This section describes certain aspects of the MYOperator design that are common across the Base Station, Hip Station, and Calf Sleeve.

3.4.1. Electrical Design

Three LED's are used to provide feedback to The User. A green LED to indicate the device is powered on, a blue LED to indicate that the devices are synced over Bluetooth, and a red LED to indicate that The Tool is enabled by using the Calf Sleeve.

For our Bluetooth connections between the Hip Station, Base Station, and Calf Sleeve we used two Sparkfun Bluetooth Mate Silver boards as transmitters and one CSR-4 Bluetooth dongle as a receiver at the Base Station. The Sparkfun Bluetooth Mate Silver is capable of speeds of 2400 bits per second to 115200 bits per second. The boards is FCC approved, capable of operating in RF environments containing WiFi signals, encrypted, and has a range of up to 20 meters. The board is powered by 3.3V to 6V and has a typical power consumption of 25 mA.

The Calf Sleeve and the Hip Station will both be battery powered. The Hip Station just needs enough power for an Arduino. The Arduino requires 25 mA at 9V for a total power consumption of 225 mW. The Calf Sleeve needs enough power for an Arduino, 225 mW, plus the power required to run the signal conditioning circuit, which requires 0.6 mA at 9V for a total of 5.4 mW. Typical Alkaline 9V batteries have a capacity of 550 mAh, which is more than enough to power our Calf Sleeve at 230.4 mW for 30 minutes.

3.4.2. Mechanical Design

For our Base Station, Hip Station, and Calf Sleeve we chose various sizes of polystyrene enclosures. The material is certified to UL94-V0, and is RoHS compliant. RP Electronics had a wide variety of sizes so we were able to choose enclosures that most tightly fit our prototype electronics. Another option was to use metallic enclosures, but Bluetooth signals are easily blocked by metallic materials. All enclosures will have three 3 mm slots for the red, green and blue LED's to be mounted in.

All of our components utilize prototyping boards for our customized hardware. The boards are made of FR4 glass epoxy which is robust and provides a long life. The through-hole connections are laid out in the same configuration as a breadboard which allowed us to replicate our exact design from our breadboard prototypes on our soldered prototypes. The boards we purchased are lead-free and RoHS compliant.

4. SOFTWARE DESIGN

4.1. Windows Remote Arduino Background

The Windows Remote Arduino library is an open source Windows Runtime Component library [4]. It allows the Arduino to be controlled using the windows runtime language [4] which includes C++/CX, python and C#. Windows Remote Arduino allows for communication over wifi, bluetooth and USB and is built on top of the Firmata protocol [4] which is designed for communicating with microcontrollers using software on a standard computer [4].

We chose to use Windows Remote Arduino because it allows for the wireless controlling of an Arduino Uno over Bluetooth by a Raspberry Pi 2 running Windows IoT. When the standard Firmata sketch it loaded on the Arduino it enables the Raspberry Pi to issue commands and access information on the Arduino's GPIO pins. This couples the substantial processing power of the Raspberry Pi with the excellent information gathering capabilities of the highly mobile Arduino.

4.2. Overall Design

The Raspberry pi 2, the main component of our Base Station, will run the windows IoT operating system, allowing the pi to run a single dedicated application for interacting with the other components. The base station will use C++/CX, a language based heavily on C++ with some unique features such as its own garbage collector, similar to Java [4]. Coupling the Raspberry Pi's Windows Remote Arduino library [5] with the standard Firmata sketch [3] loaded on the Arduinos, the Base Station will be able to communicate with the Arduinos over Bluetooth.

When the Raspberry Pi 2 boots up, it will load the MYOperator app and start the main Startup class beginning the Run() function as seen in figure 14. This function will initialize the Hip Station, Calf Sleeve and Base Station objects utilizing the MYO_RPI and MYO_ARDUINO classes depending on which board is used in the component. These classes handle all setting and getting of the Arduino and Raspberry Pi GPIO pins. The Run() function also initializes the Bluetooth Connection object and creates an event handler for when connection to the Bluetooth devices occurs. As seen in figure 14, should the connection events trigger, the InitGPIO() and InitGPIOCalf() functions will be called, initializing the appropriate GPIO pins required for the MYOperator device. The InitGPIO() function will also wait for the Calf Sleeve to finish initializing before proceeding to call the ProcessManager() function, responsible for handling all thread creation.

The MYOperator app Startup class will include three threads: HandlerBTCheck, HandlerEMGData and HandlerSwitch. The HandlerBTCheck thread constantly checks whether all devices are connected, and turns off the tool permanently should the connections fail. The HandlerEMGData thread will read in EMG data from the Calf Sleeve's analog pin, load these values into a buffer, average twenty values, and compare the overall mean to a threshold to turn on or off the tool. Finally, the HandlerSwitch collects information from the sensitivity and tool enable switches and determines both the EMG threshold and whether EMG processing occurs at all, respectively. These three threads will use thread pool timers and will be called in the event that these timers run out. The timer values can be seen in the bottom of Figure 14, and in accordance with WinRT timer format, the values provided are in 100 nanosecond units. The threads will operate in parallel so that the EMG data will be processed fast enough to achieve an on signal within ½ a second of flexing the tibialis anterior. See Appendix 1 for more information on how these threads will operate.

The overall design of the software was created to fulfill the following Functional Specification Requirements: R064, R065, R071, R072, R073, R074.

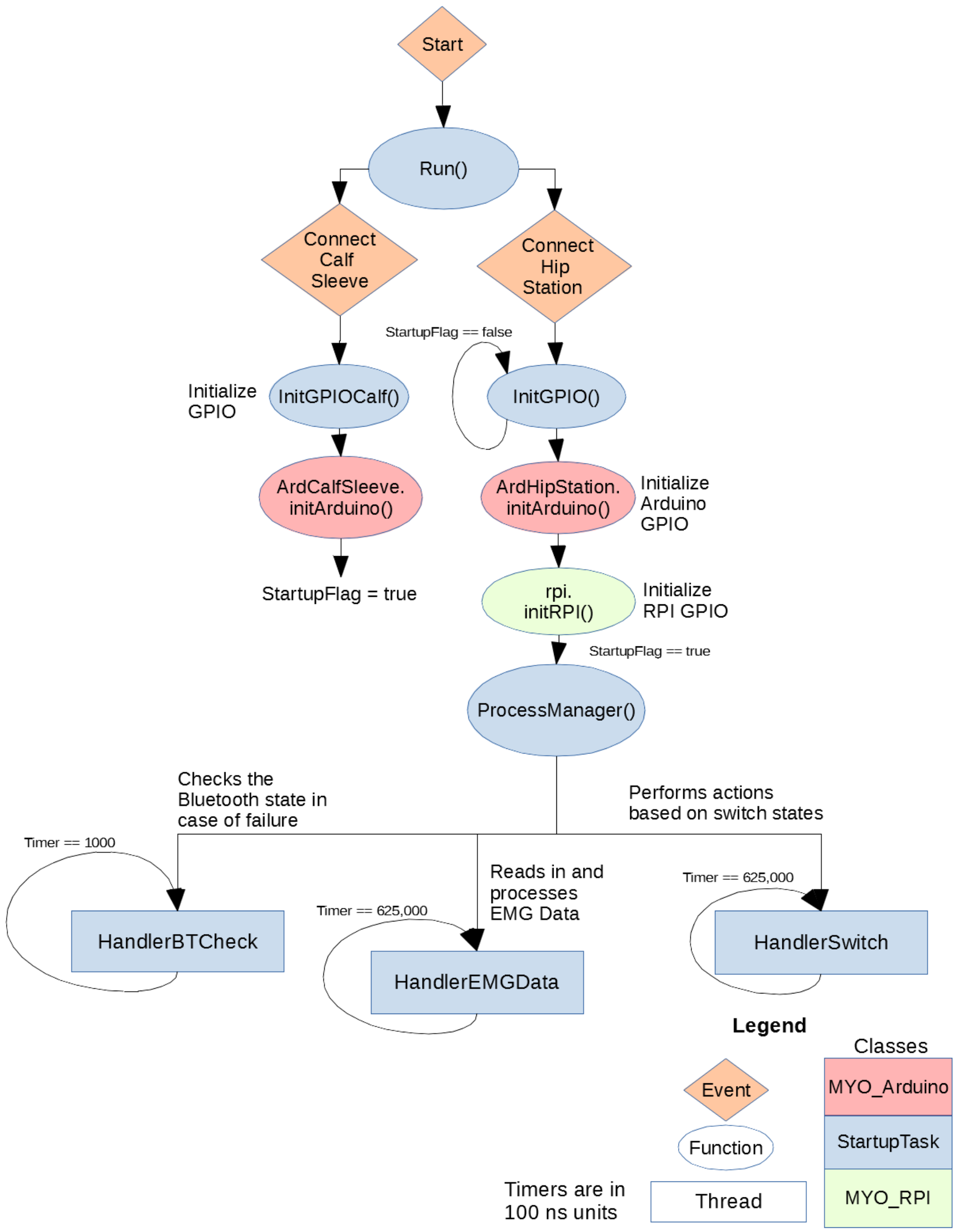


Figure 14 - Main Software Flow Chart

5. CONCLUSION

At SES we strive to make the surgeon's job easier so they can focus solely on their patient and not be hindered by the devices they use. We have identified foot pedals as an area that can be improved in the medical industry. We hope that our injection of creative design and new technology to an old device will solve the main problems with current foot pedals. The MYOperator is a wearable and wireless solution that solves surgeon's complaints about foot pedals being hard to find with your foot and the tripping hazard caused by pedal's cord. The prototype we have designed needs a lot of improvements before it would be ready to be used in an operating room, but we think we have designed a prototype that will demonstrate how useful the MYOperator will be.

REFERENCES

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[2] Electromyography. (n.d.) *Mosby's Medical Dictionary, 8th edition*.(2009). Retrieved February 15 2016 from http://medical-dictionary.thefreedictionary.com/electromyography

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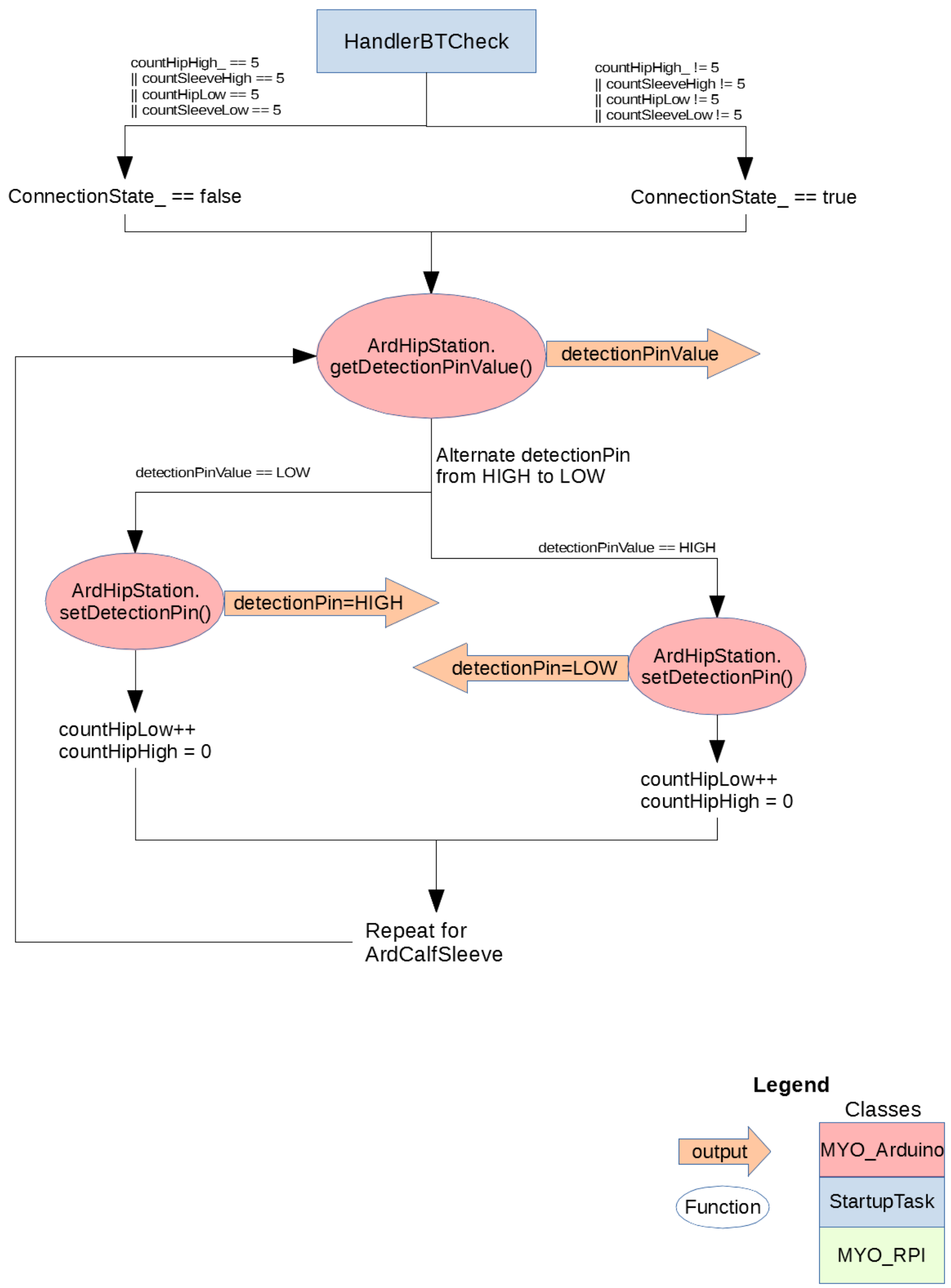
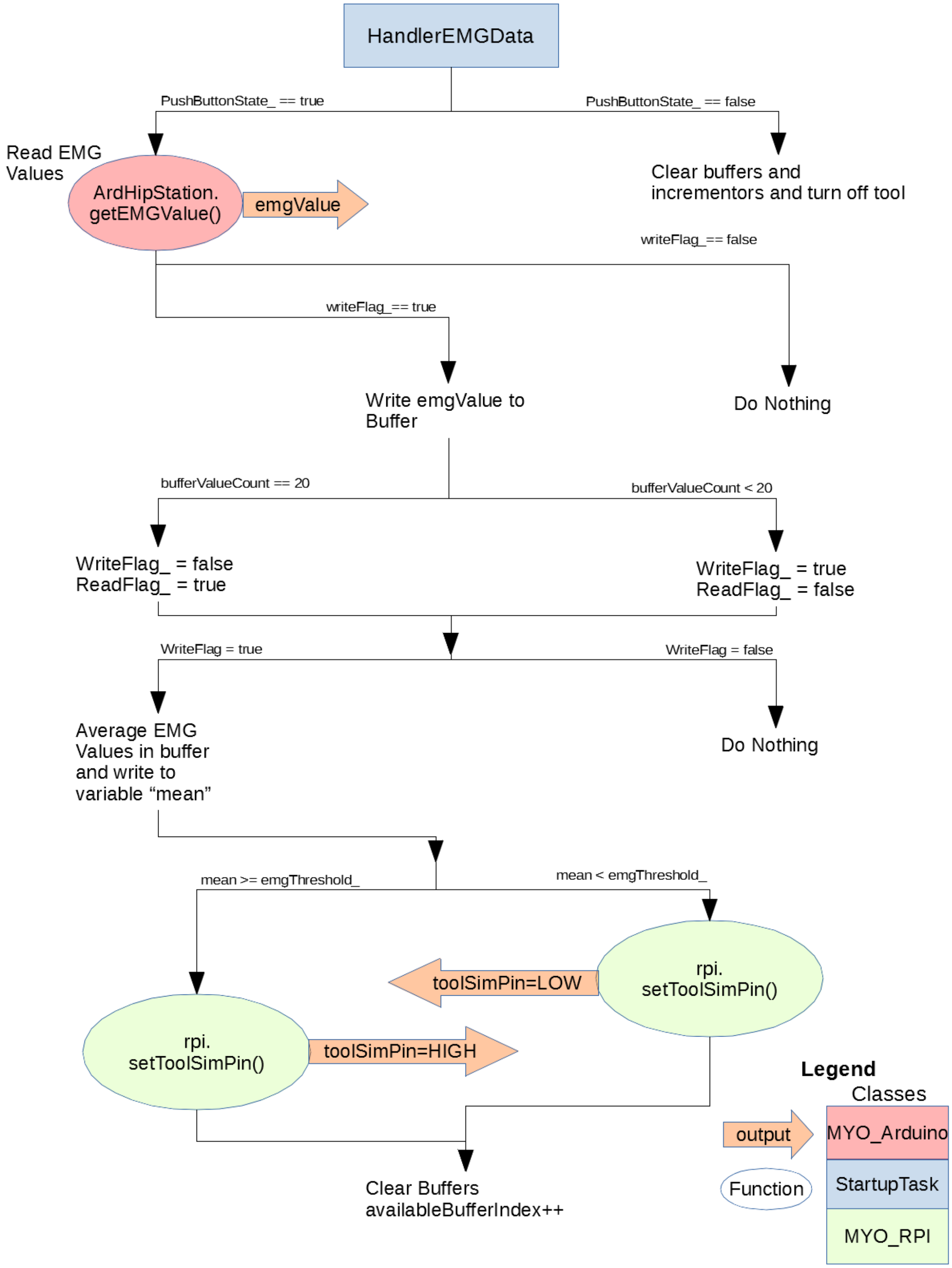
[6] *Bodypictures.org*, 2016. [Online]. Available: http://bodypictures.org/large/4/Body-Pictures-4.jpg. [Accessed: 14- Apr-2016].

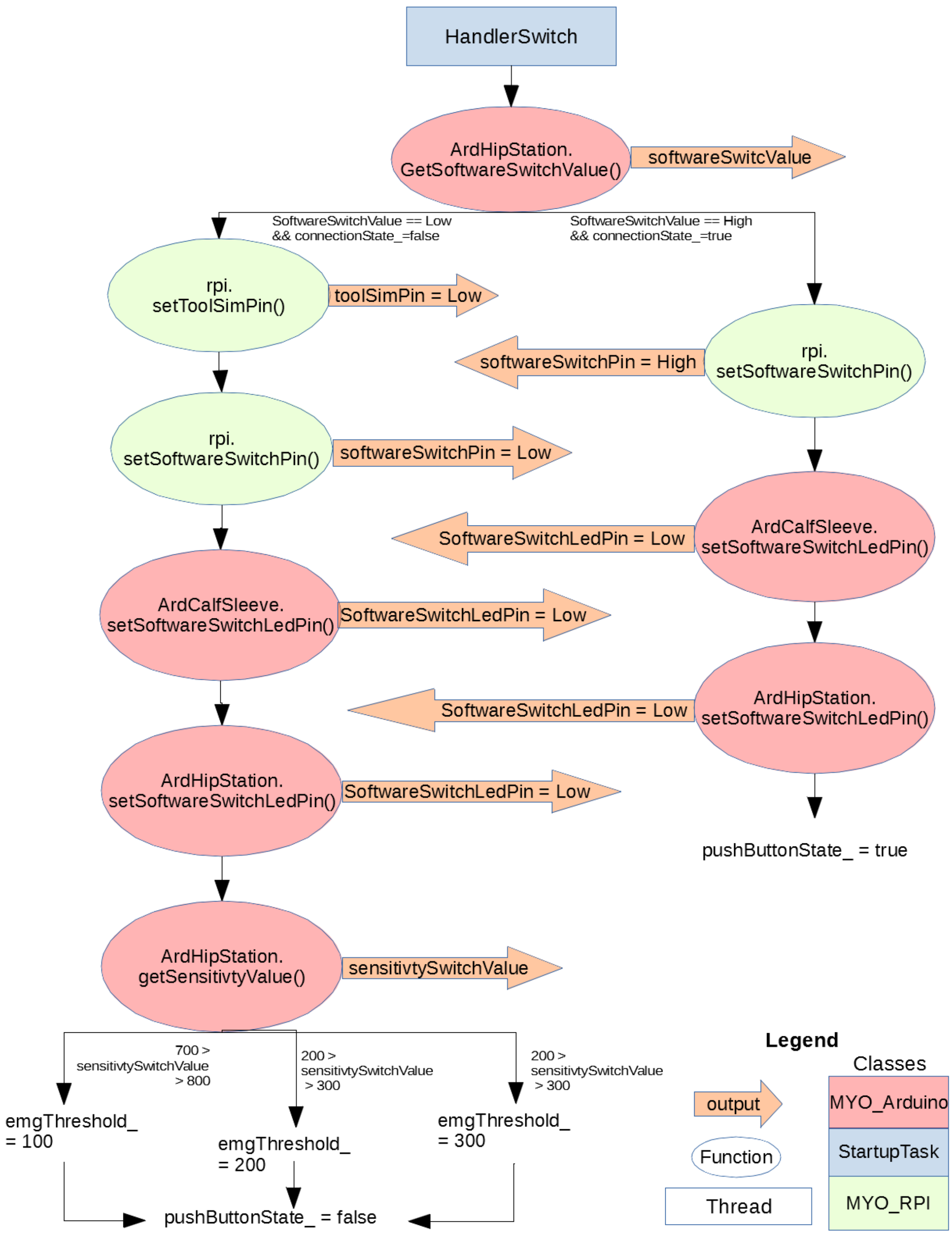
APPENDIX 1 – THREAD FLOW CHARTS



SES
SURGICAL ELECTRONIC SOLUTIONS



SES
SURGICAL ELECTRONIC SOLUTIONS



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APPENDIX 2 – TEST PLAN

The following document is a test plan that ensures that the final MYOperator meets the key requirements of our functional and design specifications. The reliability of our product will be ensured through multiple tests which include operational tests and standard tests. The testing of our product is broken down into three stages: initialization testing, functionality testing and failure testing.

Initialization Testing

Test	Procedure	Verification	Pass/Fail	Comments
Hip Station and Calf Sleeve Power	1. Turn switches on Hip Station and Calf Sleeve to ON	- Green LED turns ON		
Base Station Power	1. Turn Base Station On	- Green LED turns ON		
Bluetooth Pairing	1. Turn Base Station On	- Blue LEDs on all components turn ON		

In order to move on to the second stage of testing, for functionality, it is a requirement that all of the Initialization tests have passed.

Functionality Testing

Test	Procedure	Verification	Pass/Fail	Comments
Calf Sleeve Placement	1. Put on Calf Sleeve according to indicator symbols 2. Walk around	- Sleeve stays on calf and indicator symbols are still aligned		
Sensitivity Knob	1.Turn knob to low and	- Increasing the sensitivity knob level requires		

	flex until tool turns ON 2. Turn knob to middle and flex until tool turns ON 3. Turn knob to high and flex until tool turns ON	decreasing amounts of muscle flexion to turn the tool ON		
EMG data acquisition	1. Flex calf muscle	- Tool turns ON		

Once the initialization and functionality tests have all been passed the third stage of testing begins: failure testing.

Failure Testing

Test	Procedure	Verification	Pass/Fail	Comments
Switch Failure	1. Turn Hip Station switch to OFF 2. Flex calf and hold flex	- Data is no longer passed - The red LED is ON - Tool does not turn ON		
Sensitivity Failure	1. Turn Hip Station switch to ON 2. Turn sensitivity knob to middle level 3. Shift weight from toes to heels and back	- Tool does not turn on		
False On Failure	1. Turn Hip Station switch to OFF 2. Walk around	- Tool does not turn on		