SURGICAL ELECTRONIC SOLUTIONS

January 25, 2016

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

Re: ENSC 440W/305W Project Proposal for the MYOperator MK 1.0

Dear Dr. Rawicz,

The attached document is the proposal for a biomedical device, the *MYOperator MK 1.0*. This document outlines our ENSC 440 Capstone Project on this device. It is our goal to design and implement this wireless device as a replacement for a current activating pedal that is used in all operating rooms. We hope to create a unique solution for the existing problem of mobility restriction that surgeons face.

This proposal will provide a detailed overview of our product and its place in the field, with an analysis of the market. There is also an outline of our design specifications, an anticipated budget with funding sources as well as a summary of our timeline goals for the completion of a prototype for the MYOperator MK 1.0.

Surgical Electronic Solutions is comprised of five founding partners, Michael Wilkerson, Thomas Newton, Gabrijela Mijatovic, Darren Zwack, and Jonathan Feng. We are a group of senior engineering students who would like to thank you for your interest in our proposal. You can contact us at 604-992-9667 or mww3@sfu.ca for any questions or concerns.

Sincerely,

Michael Wilkerson
CEO
Surgical Electronic Solutions

Enclosed: *Proposal for MYOperator MK 1.0*

ENSC 305W/440W CAPSTONE PROJECT

Group 11 Project Proposal

MYOperator MK 1.0

Project Team: **Darren Zwack**

Gabrijela Mijatovic

Jonathan Feng

Michael Wilkerson

Thomas Newton

Issue Date: **January 25th, 2016**

Revision Number: **2.0**

EXECUTIVE SUMMARY

An operating room is a place of high stress and high risk. During any surgery there are many general complications that arise just from the procedure itself - regardless of any human errors. There are often many doctors and nurses present for any given operation poses even more of a possibility for problems. The complexity of the operating room sets the stage for an environment in need of simplicity.

The flawless care and attention that a surgeon needs to take while in an operating room is what is essential to the successful completion of a patient's surgery. Often there is need for cauterization during surgeries and this requires a machine that has a hand tool that the surgeon controls. The controlling of the tool is currently through a wired pedal that is located underneath the operating table. These wired pedals, which are controlled by the feet, are often considered to be tripping hazards and not the most ideal hardware to have in the operating room. Surgical Electronic Solutions ventures to create a better foot pedal, which is not even a pedal at all, it will be a wireless, wearable device, the MYOperator MK 1.0.

The current wired solution for tool power control is what our product will rival, as well as wireless foot pedal devices. The main approach to creating a functioning medical device that would be appropriate was to use electromyography (EMG) sensing to eliminate the foot pedal and Bluetooth as a way to keep the system wireless. EMG sensing uses the electric potential from one's muscle contraction to produce a desired result. Our approach is to take the data collected from the surgeon's calf muscle. The foot gesture the surgeon will do to create a desired electric potential will be something they already know because of the existing use of a pedal, therefore the transition to our product will not be difficult.

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1.0 INTRODUCTION

"Primum non nocerum. (First do no harm)" — **Hippocrates**

An operating room (OR) is where a surgeon needs to feel completely comfortable and it is of utmost importance that they can perform their job without error. The basic workplace needs of surgeons are similar to almost all other occupations - they must be able to work safely and effectively. The operating theatre is a place where the patient might not realize the amount of people involved. For any given surgery there are about nine surgical staff. This includes the primary surgeon, who will perform your surgery and is responsible for your care as a whole. There will also be a secondary surgeon assisting the primary as well as a surgical assistant and technician (often a nurse). Also present in the OR will be an anaesthesiologist and a nurse anesthetist who helps administer the anesthesia. Along with all of these essential people there will also be a handful of nurses who help with all tasks. There are scrub nurses who assist surgeons at the operating table with the passing of sterile tools and completion of sterile tasks. The scrub nurse has a complement position which is called the circulating nurse and she deals with all of the non-sterile procedures. With so many technological advances being integrated into these rooms the amount of people and equipment also keeps increasing.

Figure 1 - Operating Suite at St. Joseph Mercy Oakland [1]

In a study from 2003, 40 Australian surgeons were asked about how they would change the OR if they could [3]. Many of the problems that they identified in the study were not surprising, such as equipment, lighting and the overall layout and design of the room itself. The results of the study were a collection of 349 comments which then got organized into 12 sections that were ranked in importance. The category that got the most complaints was equipment, which included problems with the operating table as well as different bulky monitors and components that were too complex and had a steep learning curve. The category with the third most complaints was about cables and tubing. More specifically these can tangle and obstruct the movability of equipment. Another more obvious problem here is it becomes a safety hazard for anyone in the area needing to move around. Moving down to the sixth category which is the most important to our cause, foot pedals. The surgeons complained that they had trouble feeling the pedals and that finding them posed to be a major distraction from the operation at hand. These pedals often move from the position originally placed, because of their long cable associated with their function. Another complaint was about their unusual and undesirable size, often too small, as well as being unergonomic. From a study aimed at creating new ergonomic rules for the design of foot pedals they found that during the surgical procedure 91% of their 45 subjects occasionally lost contact with their foot pedal and 56% of those found it annoying and a hinderance [3]. All of the candidates found that the foot pedals impeded their freedom to move and incidentally made them hit the wrong switch. As one can imagine, hitting the wrong switch during a surgery could be a deadly mistake. Another common complaint amongst foot pedal using surgeons is that they end up causing physical discomfort in their legs and feet. This is caused by unergonomic designs as well as long term use, as some surgeries can last hours and use of the pedal can be very frequent and/or constant. The problems seem endless with the current foot pedal design, and Surgical Electronic Solutions endeavors to revolutionize operating room suites with an answer to all of these issues.

Foot pedals have been long-established in the field of medicine as simple switches. One of the main medical practices that currently relies on a foot pedal for its power is cautery. Cauterization is a procedure where part of a patient’s tissue is burned in order to close it, often to stop bleeding. Electrocauterization specifically will cut through tissue using heat conduction from a tool that is heated by electric current [4]. Electrocautery applies high frequency alternating current and is administered with a metal probe and can also be used to stop bleeds.

Surgical Electronic Solutions has corresponded personally with a number of surgeons in Vancouver who have all identified that the use of a pedal was a major annoyance when performing surgeries. These surgeons will remain as informants throughout our project and have assured us in the merit of our product.

The objective of this project is to create a wearable device that will replace the current foot pedal solution. The wearable device, the MYOperator MK 1.0, will be essentially a wireless activator for surgical devices. Biomedical engineering is a growing field, and more specifically there are technological advances that can be made with the use of bioelectric sensors. The device will consist of electromyography (EMG) sensors connected to an Arduino on the surgeon's calf which will communicate via Bluetooth to an Arduino attached at the surgeon's hip. There will be a Raspberry Pi as a base station that will receive an activation signal from the hip Arduino and will then tell a motor controlling a surgical tool, ie. the cautery probe to turn on. The design will be explained in further detail within this document.

The sensing involved in our project corresponds to the evaluation and recording of the electrical activity that is produced by a body's skeletal muscles. Our use of EMG involves using multiple electrodes that are connected to the surgeon's calf. The raw data collected is the detection of electrical potential that was generated by muscle cells which have been electrically or neurologically activated.

The scope of the project will discuss further in detail the proposed solution and alternative solution to the problem at hand. Furthermore the potential risks involved with our project and benefits that could be reaped from it will also be outlined. There will be an explanation of market analysis and competition for our product. From there we will discuss the structure of our company, Surgical Electronic Solutions, and continue onto the planning of the making of the MYOperator MK 1.0 and its cost considerations where we look into a realistic estimation of expenditure.

2.0 SCOPE/RISKS/BENEFITS

2.1 Scope

The end goal of our product, MYOperator MK 1.0, is to eliminate the need for the wired pedals currently being used in operating rooms. The wired pedals occasionally get misplaced and distract the surgeon when they need the tool to be on or off. By introducing a wireless solution that is always with the surgeon, they are able to switch on and off the tool by moving their foot, which will activate the calf muscles. If our product is accepted by the medical industry, there will definitely be an increase in safety and decrease in distractions while in the operating theatre. Other solutions on the market are wireless pedals that the surgeons physically step on that communicate with a base station via infrared or radio frequency. We decided to implement an EMG solution because we want to get rid of the pedal altogether. By utilizing the EMG sensors in our device, we will be detecting the difference in voltage of the two major calf muscles.

The calf sleeve is where the EMG kit, and importantly, the leg Arduino will be held in a form that is easily wearable and unobtrusive to the surgeon. This is where the EMG data collection and first later of signal processing will take place, all housed in one unit. The EMG kit is comprised of three electrodes that are connected to a board which will be wired to an Arduino (all within the calf sleeve). This Arduino will send the data at 25 mb/s through Bluetooth to another Arduino board, which will communicate with the Raspberry Pi through Bluetooth. This Arduino at the hip of the surgeon is to act as a master switch and to adjust the sensitivity of the EMG sensors. The following figure shows how the sensors, microcontrollers, and microprocessor will turn on the surgical tool.

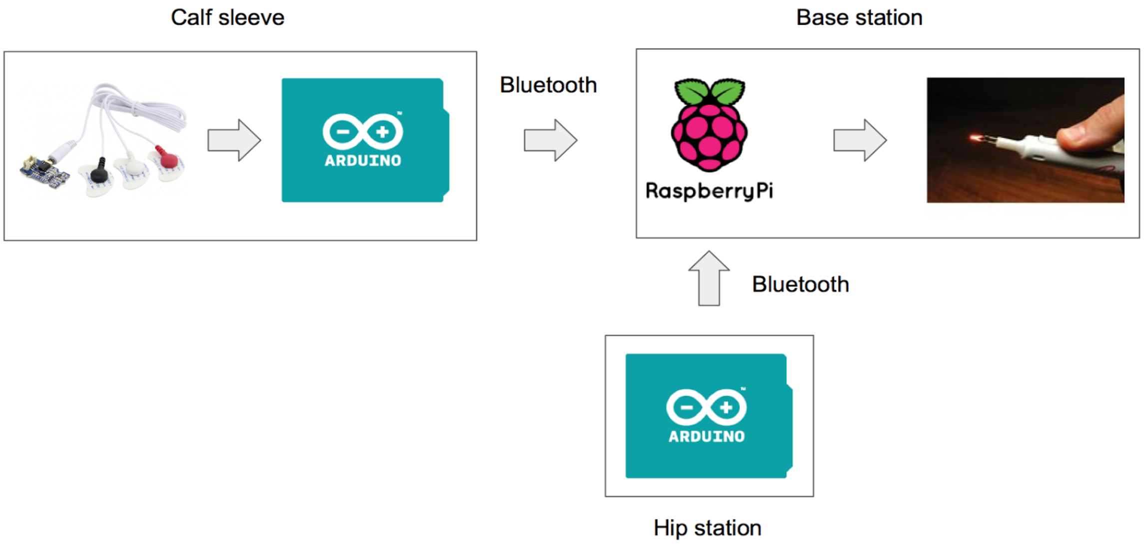

Figure 2 – MYOperator MK 1.0 System Design [2]

The Bluetooth event data that will be sent by the Hip Station will then be dealt with by the Raspberry Pi base station, which will do all of the message passing. The following is a state machine diagram for the base station as well as a legend for it.

Table 1– Legend for State Machine Diagram

SO - Idle	**E0 -** Wait	**E5 –** ON Received
S1 – Process Data	**E1 –** Data Received	**E6 –** Change Sensitivity
S2 – Activate Motor	**E2 –** Data Processed	**E7 –** Arduino ON
S3 – Send On/Off to Arduinos	**E3 –** Motor Activated	**E8 –** Arduino OFF
S4 – Send Sensitivity	**E4 –** OFF Received	**E9 –** System OFF

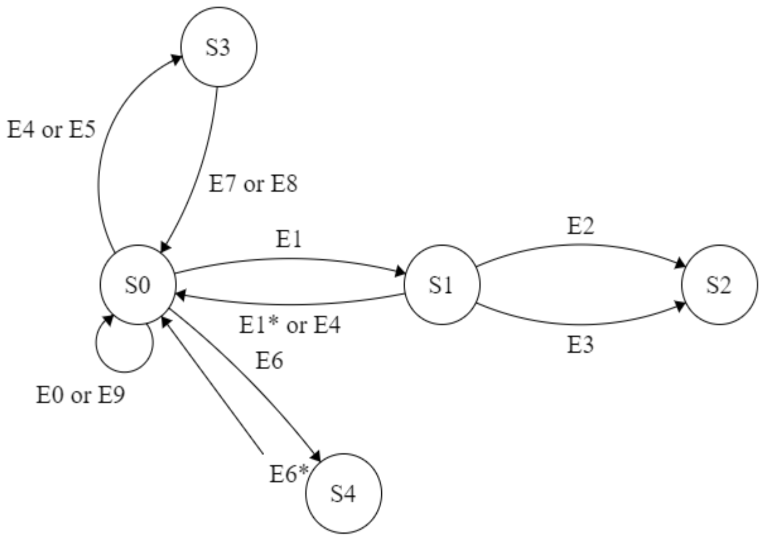

Figure 3 - State Machine Diagram for Raspberry Pi Base Station

2.2 Risks

Since the MYOperator MK 1.0 will be used while performing a surgery, there is concern for sanitation. Although we are currently using a neoprene sleeve to wear the EMG sensor, in the future, we plan to rubber or similar material to attach to the calf for faster and effective cleaning of the device. In the event that the operating tool is behaving differently from expected, a failsafe will be implemented to turn off the machine to not cause further damage. Being a wireless device, the risk of possible interference from other devices is always a factor. However, since the device will be communicating via Bluetooth, it will only be interacting with one device at a time. While working on the device, a possible risk is electrostatic discharge (ESD) because we are not working in an ESD safe environment. We will have to be careful while working with the device as to not do any accidental discharges and render the device unusable.

Other risks that we face are the time we have available to complete the project. We have roughly two months to complete the project before demonstrating its capabilities, which can be tough since all members of the group have other classes and one member is currently on a work term. We also face a financial risk since the project has not yet been fully funded. SES has currently only received about 45% of our full funding and we will have to look for other investors or other funds to support the project. As for expertise risks, we do not have any member of the team who specializes in biomedical engineering or a biomedical related field. We have also little experience working with EMG sensors and are learning as the project progresses. Given all these risks, we will try our very best to minimize the impact they will have on the overall result of the project.

2.3 Benefits

Surgical foot switches are one of the top things that surgeon's want improved out of all of their equipment. The main reason that current footswitches are so poorly regarded are the cords that run along the floor of the operating room, and the inherent difficulty of finding the footswitch with your foot while it is under the operating table and the surgeon can't move their arms. The MYOperator solves both of those problems by being entirely wireless and wearable. Taking advantage of electromyography, a calf sleeve containing sensors can detect foot gestures that can be used to control the on/off power of surgical tools being used. This increases the efficiency of the operating procedure because time is not wasted finding the foot pedal, or positioning it in the right place since with our solution the functionality of the foot pedal will be with the surgeon at all times.

3.0 MARKET/COMPETITON

3.1 Market

Electrosurgical devices are a growing industry with worldwide sales expected to grow at Compound Annual Growth Rate (CAGR) of 5.9% to a total of $4 billion (USD) by 2019 [5]. According to a report by "Markets and Markets" the growth is expected due to development of advanced energy based electrosurgical devices, rising demand of minimally invasive surgical procedures, and worldwide rise in the aging population [5]. In the same report "Market and Markets" states that as of 2014, North America holds the largest share of the global electrosurgery market, and Europe is the next largest market. The Asia-Pacific market is expected to grow the most between 2014 and 2019 with a CAGR of about 8% because of rising government efforts to increase the population access to elective surgery, healthcare infrastructure, and because of the growing popularity of cosmetic surgery [5].

The $4 billion (USD) electrosurgery market is split into three main categories, with each category contributing to the $4 billion (USD) total. The three categories are:

- *Electrosurgical generators,*
- *Electrosurgical instruments and accessories, and*
- *Argon and smoke management systems.*

The MYOperator fits into the "electrosurgical instruments and accessories" category. We had to work with incomplete information since the "Markets and Markets" report was not affordable, but from a sample of the report we were able to find that in 2013 accessories were a $122.6 million (USD) market in global sales, and in 2014 all of electrosurgery was a $2.791 billion market [6], so assuming global sales were relatively similar in 2013, accessories make up about 4.4% of the electrosurgery market. If you assume that as the electrosurgery market grows to $4 billion (USD) the accessories sales will increase proportionally, the global market for electrosurgery accessories to be approximately $160 million (USD) by 2019.

The main products that make up the "electrosurgical and instrument accessories" are patient return electrodes, cords, cables, adapters, and others (foot switches, carts, and tip cleaners) [5]. Since the category contains so many different products it is difficult to know how much of the $160 million (USD) would be from foot switches, but since foot switches are some of the most expensive products in the group and they are ubiquitous in the electrosurgical field it is safe to assume they make up at least 10% of the $160 million (USD) and perhaps much more. The report containing more detailed information cost $4500 (CAD) so we could not get more detail.

3.2 Competition

The current leader in the foot switch market is Linemaster who claim "more than 90% of the world's largest original equipment manufacturers turn to Linemaster for their medical grade foot controls [7]." The goal of Surgical Electronic Solutions is to produce a product that outperforms any product offered by Linemaster so that we can cut into their sales and generate contracts with major electrosurgical device manufacturers so they use our switches instead of Linemaster's. The goal is attainable because Linemaster currently does not sell any type of wearable switch and we will, the MYOperator. Linemaster makes wireless foot switches, but since the MYOperator is also wireless, what was once an advantage for Linemaster over the competition will not be an advantage over the MYOperator.

The major electrosurgical equipment manufacturers that we would be looking to sell our product to are [5]:

- *Covidien plc (Ireland),*
- *Ethicon (U.S.),*
- *Olympus Corporation (Japan),*
- *CONMED Corporation (U.S.),*
- *ERBE Elektromedizin GmbH (Germany),*
- *B. Braun Melsungen AG (Germany),*
- *Bovie Medical Corporation (U.S.), and*
- *BOWA-electronic GmbH Co. KG (Germany).*

CONMED Corporation is the only one of these manufacturers that currently sells their devices with a wireless footswitch, the Zen Wireless 3-pedal footswitch [8]. The MYOperator will be able to outperform the Zen Wireless 3-pedal footswitch because of its wearable design, which allows the surgeon to move his feet without worrying where the pedal is located, therefore creating a more ergonomic work station for the surgeon.

4.0 COMPANY DETAILS

Michael Wilkerson - Chief Executive Officer (CEO)

Michael is a sixth year Systems Engineering student at Simon Fraser University. Currently a Software Engineer Co-Op at MDA, he has gained skills in C++ programming and in designing professional level software detailed designs. At MDA, he is responsible for both software design and development of test cases assuring that his code is up to the high standards MDA strives for. A natural leader, Michael is able to see the full-scale of a project and break it down into smaller, more manageable pieces. He is able to efficiently lead his team and complete tasks to achieve the overall goal.

Darren Zwack - Chief Technical Officer (CTO)

Darren is a sixth year Systems Engineering student at Simon Fraser University. His work experience includes working for Global Container Terminals (GCT) as a project engineer and at Spot Solutions as a quality assurance specialist. From GCT Darren brings project management skills, as well as experience setting up a wireless communication system. At Spot Solutions Darren gained experience detecting, tracking, and monitoring software issues. He is a highly motivated individual that excels in a fast working pace environment.

Jonathan Feng - Chief Financial Officer (CFO)

Jonathan is a fifth year Computer Engineering student at Simon Fraser University. His previous work experience includes being at BlackBerry as a Software Test Associate. While he was there he has tested multiple versions of the BlackBerry operating system BB10. His skills include hardware testing and programming skills such as C++, Python, HTML/CSS, and JavaScript. His interest includes software development and testing as well as hardware development and testing.

Gabrijela Mijatovic - Chief Operations Officer (COO)

Gabrijela is a fifth year Systems Engineering student at Simon Fraser University. She has experience with C/C++ as well as VHDL and Python. She has technical experience with designing and implementing circuits along with a background using lab equipment. She also has experience with the Microsoft Office, Solidworks and Matlab with Simulink design. She is self-driven and a motivated individual who has excellent interpersonal communication skills and excels in team working environments.

Thomas Newton – Chief Quality Officer (CQO)

Thomas is a sixth year Systems Engineering student at Simon Fraser University. During his time at Kardium Inc. as an Electrical Engineer Co-op student he gained a lot of hands on electronics skills with FPGAs and PCBs. He was responsible for investigating bugs and often had to diagnose timing issues in complex circuits using an oscilloscope and other diagnostic tools. As the Engineering Technical Coordinator at E-Comm 9-1-1 Thomas gained project management skills and was heavily involved during all phases of a $200,000 DC power system project.

5.0 PROJECT PLANNING

Figure 4 below is a Gantt chart outlining our tentative documentation and product development schedule. The documentation final dates are those outlined on the course website. Below the Gantt chart is Table 2 that depicts our milestones for completing each document. We have set a completion date for each document to be one day prior to the actual document deadline. This allows us an extra day to complete any given document given unforeseen circumstances that didn't allow us to reach our milestone. Table 3 defines our milestone dates relative to product development. We have separated our final product into three main components so that different team members can develop each component congruently, which once all complete we can integrate to build the final product. Note that our schedule was developed with the earliest possible presentation in mind, Friday, April 1st.

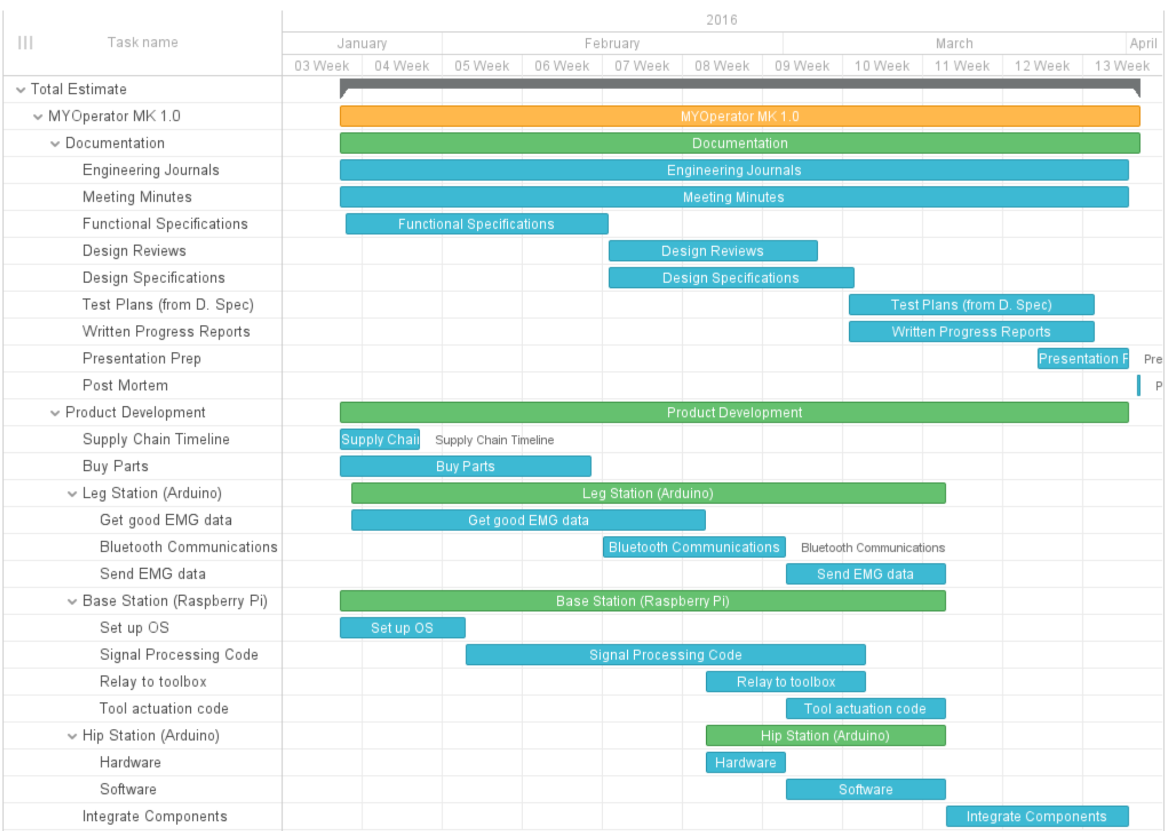

Figure 4 - Gant Chart

Table 2- Documentation Milestones

Milestone	Date Completed By
Functional Specifications	Sun, Feb 14th
Design Specifications	Sun, Mar 6th
Test Plans	Sun, Mar 27th
Written Progress Reports	Sun, Mar 27th
Engineering Journals	Fri, Apr 1st
Post-Mortem	Fri, Apr 1st

Table 3- Product Milestones

Milestone	Date Completed By
Leg Station	Tue, Mar 15th
Base Station	Tue, Mar 15th
Hip Station	Tue, Mar 15th
Final Product	Thu, Mar 31st

6.0 COST CONSIDERATIONS

7.1 Budget

Table 4 lists the components needed to complete our project. We have decided on two options to implement the calf sensor. The first option is to build our own device using EMG sensors attached to an Arduino. The second option for the calf sensor is to use the MYO to communicate with the base station if the one we built cannot be completed within the timeframe. We have allotted 10% contingency to account for shipping and handling as well as unforeseen price increases due to the falling Canadian dollar.

Table 4– Budget Breakdown

Component	Cost ($ CAD)
EMG Electrodes Kit	185.00
Arduino Starter Kit	130.00

Arduino Uno R3	33.00
Arduino Bluetooth Shield (x2)	70.00
Arduino 9 Axes Motion Shield	55.00
Arduino Relay Shield	25.00
Raspberry Pi 2 Model B	60.00
3D Printing (estimated)	200.00
MYO EMG Sensor	280.00
Miscellaneous parts (batteries, extra electrodes, charging cables, sleeve, etc.)	217.00
10% Contingency	125.50
TOTAL:	1380.50

7.2 Funding and Resources

Surgical Electronic Solutions has confirmed funding from the Engineering Science Student Endowment Fund (ESSEF) $626.00 CAD. We hope to receive the remaining amount for our budget from the Wighton Engineering Development Fund towards the end of the project. If the Wighton Fund and ESSEF do not fully cover the project, the members of SES agree to equally share the remaining amount.

7.0 CONCLUSION

At Surgical Electronic Solutions, we strive to help make surgeons' jobs easier so they can focus more on saving the life in front of them while in the operating room. By eliminating little distractions such as finding the pedal, we are able to help increase productivity and decrease the risk to the patient. We have spoken to a few medical professionals and they have all agreed that the pedal is a major concern during surgery. The MYOperator MK 1.0 will be the only wireless, wearable pedal solution, so we are confident that our product will appeal to surgeons around the world. Around 45% of our funding has already been guaranteed, so we will keep searching for further support from different sources to help make this project a reality. We look forward to making all operating rooms a safer and more productive environment.

8.0 REFERENCES

8.1 Vendors

BestBuy Canada: www.bestbuy.ca

DigiKey Electronics: www.digikey.ca

Lee's Electronic Store: www.leeselectronic.com

8.2 Figures

[1] Operating Room Image:
http://americajr.com/news/stjosephpavilion0927.html

[2] Grove EMG Detector Image:

http://www.robotshop.com/media/catalog/product/cache/7/image/800x800/9df78eab33525d08d6e5fb8d27136e95/s/e/seeedstudio-grove-emg-detector.jpg

Arduino Logo:

https://www.arduino.cc/new_home/assets/illu_what_is-board.png

RPI Logo:

http://www.volkanaktas.com/wp-content/uploads/2014/05/RaspberryPi_Logo-194x150.png

Cautery Tool Image:

http://ecx.images-amazon.com/images/I/41Q8LYXGocL._AC_UL160_SR160,160_.jpg

8.3 Information

[3] "Improvement of foot pedals used during surgery based on new ergonomic guidelines" in Surg Endosc. Epub 2003 May 6. Retrieved January 24, 2016, from http://www.ncbi.nlm.nih.gov/pubmed/12728372

[4] Cauterization [Online]. Retrieved January 24, 2016, from https://en.wikipedia.org/wiki/Cauterization

[5] Electrosurgery Market by Product - Generator, Electrosurgical Instruments (Vessel Sealing, Bipolar Forceps, Electrode, Suction Coagulator), Accessories, Surgery (General, Gynecology, Orthopedic, Cardiovascular, Cosmetic) - Global Forecasts to 2019. (2014, April). Retrieved January 22, 2016, from http://www.marketsandmarkets.com/Market-Reports/electrosurgery-market-142006761.html

[6] IQ4I Research & Consulting Pvt. Ltd.,"Electrosurgical Devices Global Market," IQ4I Research & Consulting Pvt. 2015.

[7] Linemaster Switch Corporation. "Linemaster Expertise," Linemaster Switch Corporation. Woodstock, CT. 2015. http://cdn.thomasnet.com/ccp/00469908/52374.pdf

[8] CONMED. (n.d.). Retrieved January 25, 2016, from http://www.conmed.com/