SURGICAL ELECTRONIC SOLUTIONS

February 15, 2016

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6
Re: ENSC 440W/305W Functional Specifications for the MYOperator MK 1.0

Dear Dr. Rawicz,

The attached document is the functional specifications for a biomedical device, the *MYOperator MK 1.0*. The objective is to design our ENSC 305W/440W Capstone project based on the functional specifications for this device. 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 functional specification document will have the high level requirements for our device. The specifications for every development stage will be overviewed, as well as the final product. The document is broken down into multiple sections which will cover the three separate components to our device: the Calf Sleeve, the Hip Station and the Base Station. In each of these sections we will cover the physical and electronic descriptions of our product as well as any applicable standards. Furthermore, the research into the safety and sustainability of the device is presented.

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: *Proposal for MYOperator MK 1.0*

SURGICAL ELECTRONIC SOLUTIONS

ENSC 305W/440W CAPSTONE PROJECT

Group 11 Functional Specifications

MYOperator MK 1.0

Project Team: **Darren Zwack**
Gabrijela Mijatovic
Jonathan Feng
Michael Wilkerson
Thomas Newton

Issue Date: **February 15th, 2016**

Contact: **Michael Wilkerson, CEO**
mww3@sfu.ca

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SURGICAL ELECTRONIC SOLUTIONS

EXECUTIVE SUMMARY

The flawless care and attention that a surgeon needs to take while in an operating room is essential to the successful completion of a patient's surgery. Surgeries often require electro-biomedical devices which include hand tools the surgeon controls. The controlling of some of these tools is currently achieved through the use of a wired pedal that is located underneath the operating table. The foot controlled wired pedals are often considered to be tripping hazards and inconvenient, making them non-ideal hardware to have in the operating room. Surgical Electronic Solutions ventures to create a better foot pedal, by removing the pedal all together. It will be a wireless, wearable device, the MYOperator MK 1.0.

This document serves as an overview of the functional specifications for the MYOperator MK 1.0, breaking them down into system components to aid in understanding the overall function of the device. The functional requirements are broken up into four main sections: MYOperator Device, Hip Station, Calf Sleeve, and Base Station. The MYOperator Device section includes specifications that apply to the device as a whole while the sections dedicated to each component cover functions and standards that apply specifically to that component. Within each of the four sections there are three subsections: General Requirements, Physical Requirements and Electrical Requirements. The requirements create a framework for our wearable device to be safe for the user and patient as well as completely functional as a solution to the current wired pedal problem.

When determining the functional specifications, the following criteria were constantly in mind: sustainability, safety, usability and wireless functionality. To create a sustainable product, Surgical Electronic Solutions aims to use minimal energy and the least amount of material possible when designing the MYOperator. To aid in this endeavor, we will use LCA and a C2C design model. When considering safety, it is important to assure the device meets the relevant standards and goes through thorough testing. The functional specifications listed in this document aim to define the functionality of a device which is easy to use and a better alternative to the pedal.

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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]

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

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

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)

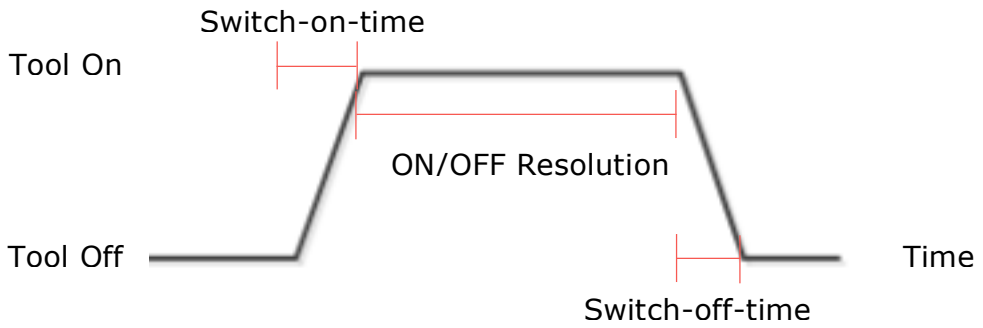

Figure 1 – Tool Timing Diagram

Tool - the cauterizer or whatever we are controlling

ACRONYMS

C2C - Cradle-to-Cradle

CSA - Canadian Standards Association

EMG - Electromyography

ENT - Ear Nose and Throat

HMI - Human Machine Interface

IEC - International Electrotechnical Commision

ISO - International Organization for Standardization

LCA - Life Cycle Analysis

PCBs - Printed Circuit Boards

1. INTRODUCTION

The MYOperator is a wearable biomedical device that acts as a wireless activator for surgical tools. After meeting with a surgeon in Vancouver who is the 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. The Calf Sleeve will have our main sensing circuit, responsible for collecting raw data from the surgeon's muscle movement, using EMG sensing. This circuit will include electrodes to sense small muscle signals that can then be processed and amplified. This will be connected to a circuit board which will communicate with another microcomputer at the Base Station for the majority of the digital signal processing. The Hip Station will act as a user power switch as well as providing sensitivity control. Surgical Electronic Solutions will integrate all of these systems into one and create a wireless solution for a currently wired pedal problem in operating rooms everywhere.

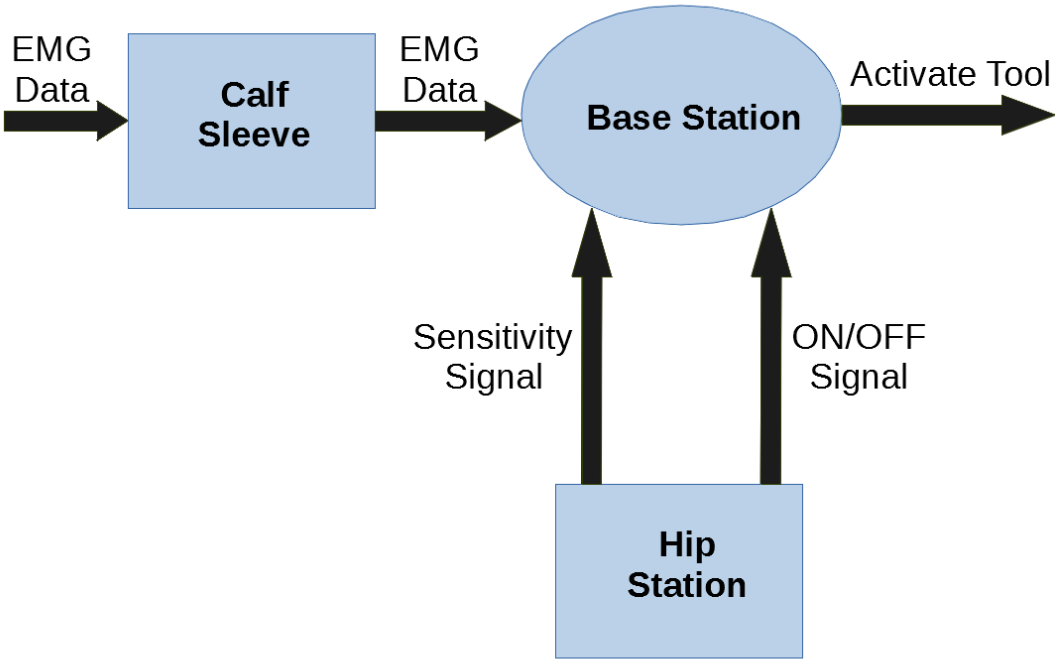

Figure 2 - System Overview

2. REQUIREMENTS OVERVIEW

The requirements are broken up into four main sections: MYOperator Device, Hip Station, Calf Sleeve, and Base Station. The MYOperator Device section includes requirements that apply to the device as a whole while the sections dedicated to each component cover standards that apply specifically to that component.

Within each of the four sections there are three subsections: General Requirements, Physical Requirements and Electrical Requirements.

General Requirements:

The general section focusses on requirements that do not fit into the other categories.

Physical Requirements:

The physical requirements section outlines requirements related to the mechanical properties of the component: size, weight, durability, structure, etc.

Electrical Requirements:

The electrical requirement section deals with requirements pertaining to the acquiring, sending and receiving of data and power.

2.1. Classification of requirements

The following criteria define the priority levels assigned to each requirement: RN-P where N denotes the requirement number as listed in this document and P denotes the priority level (eg. R003-II).

Priority Levels

I - High Priority: This requirement is completed for proof of concept/prototype

II - Medium Priority: This requirement is completed for proof of concept/prototype, time permitting

III - Low Priority: This requirement completed for the final production system

3. REQUIREMENTS

3.1. MYOperator Device

The requirements for the MYOperator device are requirements which pertain to all the components of the device.

3.1.1. General Requirements

R001-I - The device shall allow the user to turn the device ON/OFF

The user needs to be able to turn the device on and off in order to conserve power when the device is not in use.

R002-I - The user shall be able to easily gesture to the tool the ON/OFF commands

The activating gesture made by the user to turn the tool ON/OFF needs to be easy to do and will preferably be similar to the gesture users are already familiar with.

R003-I - In the case that the device fails, it shall always fail into a safe/off state

If the device is being used to control a cauterizer it would be hazardous to both the user and the patient if the device failed and the tool remained on.

R004-I - The device shall allow the user to adjust the sensitivity of the ON/OFF sensing

The surgeon that we consulted regarding our product said that adjusting the sensitivity of the device is a valuable feature.

R005-I - The Calf Sleeve and Hip Station shall sync to the Base Station via wireless communication automatically when switched on

The components of the device only ever need to be synced to each other and never with anything else so there is no need for a manual sync to be done by the user at any time.

R006-R010 In order for the user to feel coordinated with the MYOperator it is important that the there is minimal lag time between the user's gestures and the tool switching on and off. The more comfortable the user is with the timing of the MYOperator, the less likely they are to make a mistake in surgery.

R006-I - The device switch on time shall be less than 0.5 seconds

R007-III - The device switch on time shall be less than 0.25 seconds

R008-I - The device switch off time shall be less than 0.5 seconds

R009-III - The device switch off time shall be less than 0.25 seconds

R010-I - The device shall be able to send a signal to the tool with a minimum on/off resolution of .5 seconds.

R011-R012 The user needs to be able to control on/off functionality of their tool without using their upper body. Certain operations require very fine motor skills and body placement, so the in-operation functionality cannot require the use of the upper body.

R011-I - The device shall be able to be fully operated by the user's lower body

R012-I - The device shall be able to be fully operated by the user in a seated or standing position

R013-III - The device shall be designed in accordance with IEC 62366:2007 [11]

"Medical devices – Application of usability engineering to medical devices"

The advantage of the MYOperator over current surgical footswitches is usability. The design needs to consider all aspects of usability as they

apply to medical devices to that the MYOperator is a competitive device.

3.1.2. Electrical Requirements

R014-I - The device shall be provided with sufficient power to last 30 minutes in constant use

30 minutes provides ample time to demonstrate the prototype.

R015-III - The device shall be provided with sufficient power to last 8 hours in constant use

8 hours provides ample time for the user to perform an operation.

R016-I - Each component shall be able to be powered on and off

Turning the device off is important to conserve power when not needed by the user.

R017-I - The device components shall have enclosures which will not hinder wireless performance and adhere to IEC 60529:2001 [2]

"Degrees of protection provided by enclosures"

R018-I - The device shall be electrically shielded such that in any failure mode it does not deliver a shock to the user

R019-III - The device components shall have push button to pair new devices should replacement components be needed

To provide the user with information on the status of the device components, the following indicators shall be required.

R020-I - The components shall have an on/off indicator light

R021-I - The components shall have a light indicating it is wirelessly connected to the Base Station

R022-R025 In order to be considered as a viable medical device the MYOperator must not interfere with or be affected by other medical device's

wireless signals. This is especially critical in the medical field since many of the devices the MYOperator could interfere with are critical to supporting the patient's life.

R022-III - The device shall not interfere with other wireless and radio signals in the operating room

R023-III - The device shall be immune to other wireless and radio signals in the operating room

R024-III - The device shall be certified to CAN/CSA-C22.2 NO 60601-1-2-08 [1]

> "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests"

R025-III - The device shall be certified to IEC CISPR 11:2010-Ed.5.1 [5]

> "Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement"

R026-R033 There are several medical device standards in Canada that apply to the device. The device must be tested to and meet these standards in order to be used in Canada.

R026-III - The device shall be certified to IEC 62304:2006-Ed.1.0 [6]

> "Medical device software – Software life cycle processes"

R027-III - The Calf Sleeve shall be certified to IEC 61000-4:2008-Ed.2.0 [4]

> "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques"

R028-III - The device shall be certified to CSA-ISO 14971-07

> "Medical devices – Application of risk management to medical devices"

3.2. 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 on/off switch for the user to use during an operation. It is comprised of a circuit board, enclosure and external switches and knobs.

3.2.1. General Requirements

R029-R031 The user will be wearing the Hip Station for the duration of the surgery, therefore the following general requirements apply.

R029-I - The Hip Station shall not inhibit the user's movements during surgery

R030-I - The Hip Station shall have a usability focused HMI

R031-I - The Hip Station controls shall be highly tactile to allow for usability without direct eye contact of the controls

3.2.2. Physical Requirements

R032-I - The circuit board shall have an enclosure

Required to protect it from damage and the user from electric shock.

R033-I - The Hip Station shall have a clip attached to the box

Required so the Hip Station can be easily clipped onto the user's pants.

R034-I - The Hip Station shall have a physical switch

R035-I - The Hip Station shall have a physical sensitivity knob that is easily adjustable with surgical gloves on

The Hip Station is required to be worn on the user's pants for the duration of an operation.

R036-I - The Hip Station shall be light enough to be supported by the drawstring on the user's pants

R037-III - The Hip Station shall be no larger than 11.5 x 11 x 7.5 cm (H x L x W)

R038-III - The Hip Station shall be no heavier than 140g

R039-III - The device shall be certified to ISO 14937:2009 [7]

> "Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices"

3.2.3. Electrical Requirements

R040-I - The Hip Station shall be battery powered so the device is easily mobile

R041-I - The Hip Station shall be able to control the sensitivity of processing EMG data to make it easier or harder for the user to perform tool activation motions

R042-I - The Hip Station shall be able to power on and off the Base Station to prevent unwanted tool activation

R043-III - The Hip Station shall be rechargeable to decrease environmental and financial burden of non rechargeable battery waste

3.3. Calf Sleeve

The primary function of the Calf Sleeve is to detect signals generated from the calf muscles when activated due to foot gestures. These signals will be sent to the Base Station for processing to control the tool. The Calf Sleeve is to 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. It will be worn the entire duration that the user is performing an operation.

3.3.1. Electrical Requirements

R044-I - The Calf Sleeve shall include EMG sensors

R045-I - The Calf Sleeve shall sense the EMG signal of at least one muscle using at least three probes

The circuit board is required for handling the processing and sending of EMG data.

R046-I - The Calf Sleeve shall include a circuit board

R047-I - The circuit board shall have input ports for EMG sensors

R048-I - The circuit board shall be able to send EMG data wirelessly to the Base Station

R049-I - The Calf Sleeve shall be powered by a battery no greater than 9V

The battery is required because the Calf Sleeve is a mobile component.

R050-II - The Calf Sleeve shall include accelerometer

To detect movement to prevent tool activation while walking.

R051-III - The Calf Sleeve batteries shall be rechargeable

3.3.2. Physical Requirements

R052-R056 In order to acquire strong and desired signals the following requirements apply.

R052-I - The Calf Sleeve shall always remain in contact with the user's skin

R053-I - The Calf Sleeve shall be above the ankle and below the knee

R054-I - The Calf Sleeve shall fit securely enough to maintain proper contact and correct positions of the electrodes

R055-II - The Calf Sleeve shall be made of a material that can stretch to fit a wide variety of calf sizes

R056-III - The Calf Sleeve shall be able to fit under hospital scrubs

R057-III - The circuit board and sensors of the Calf Sleeve shall be light enough not to cause unwanted changes in position of the overall Calf Sleeve

R058-R059 Based on similar products on the market the following temperature requirements apply.

R058-I - The Calf Sleeve temperature shall be 10-40C in operating conditions

R059-I - The Calf Sleeve temperature shall be -10-50C in storage conditions

R060-III - The circuit board shall be protected by an enclosure that is able to be opened only by a trained technician

Important to prevent unwanted tampering of the Calf Sleeve by those who might injure themselves if not properly trained.

R061-III - The EMG sensors shall be embedded within the Calf Sleeve

Important to simplify the overall design of the Calf Sleeve and decrease the number of moving parts.

R062-III - The materials of the Calf Sleeve shall be certified to ISO 17664:2004 [12]

"Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices"

R063-III - The Calf Sleeve shall be certified to ISO 14937:2009 [7]

"Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices"

3.4. Base Station

The Base Station is responsible for processing EMG data sent to it from the Calf Sleeve, which it then uses to either turn on or off the tool. The Base Station is also responsible for interpreting the sensitivity signal sent by the Hip Station and whether to turn the tool on or off.

3.4.1. General Requirements

R064-I - The Base Station shall communicate via a wire to the surgeon's tool driving motor

R065-III- The Base Station shall require minimal interaction from the user

The user should be able to get almost all functionality of the device from the Hip Station and Calf Sleeve they are wearing. This will increase usability of the product.

3.4.2. Physical Requirements

R066-I - The Base Station shall have external access to the power input port and tool output port

R067-II - The Base Station enclosure shall have grip on the bottom

It is important for the device to be safe on a cart and therefore grip is required to prevent sliding on surfaces.

R068-R069 To facilitate the addition of the Base Station to the already highly saturated operating room environment, the following size limits are required.

R068-III - The Base Station shall weigh less than 1 Kg

R069-III - The Base Station shall be less than 20 cm x 20 cm x 3 cm (L x W x H)

3.4.3. Electrical Requirements

R070-I - The Base Station shall have a wired power cord for plugging into a wall socket providing 110/120 60Hz AC voltage

R071-I - The Base Station shall process incoming EMG data from the Calf Sleeve

R072-I - The Base Station shall interpret sensitivity and on/off signals provided by the Hip Station

R073-I - The Base Station shall consist of a microcomputer for processing data

R074-I - The Base Station shall be able to activate the tool

R075-III - The Base Station shall be certified to IEC 61000-3-2:2009-Ed.3.2 [3]

> "Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤16 A per phase)"

R076-III - The Base Station shall be certified to IEC 61000-4-5:2005-Ed.2.0 [4]

> "Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test"

4. SUSTAINABILITY

Medical device design is governed by three classical standards: safety, cost and efficacy. In order to create sustainable products, Surgical Electronic Solutions must strive to use minimal energy and the least amount of material possible in our manufacturing process. In a study done by the Bressler Group it was determined that 60-80% of a product's environmental impact is decided right from the concept generation and specification development [2], therefore it is necessary to integrate sustainable design principles right from the beginning of a project.

One of the approaches to creating sustainable design is by using an LCA (Figure 1). This is a systematic way at looking at a product's complete life

cycle, from raw materials, to final disposal of the product [3]. This takes into account the C2C design of products which will also be used to create the MYOperator.

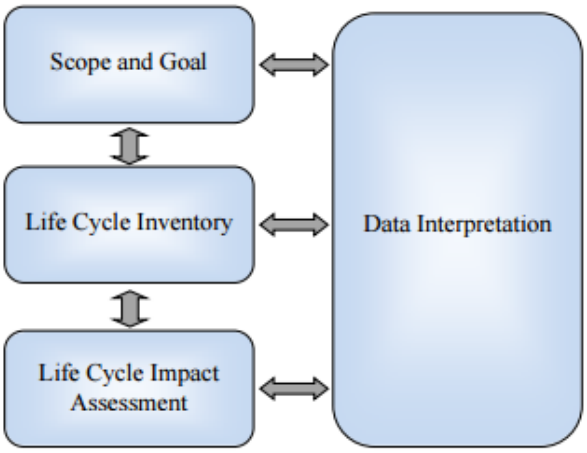

Figure 3 - Phases of a Life Cycle Analysis [3]

In the problem definition stage of an LCA we shall define inputs and outputs of the product (Figure 2).

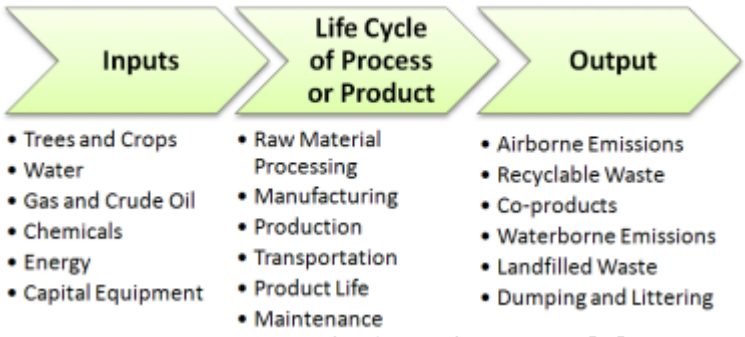

Figure 4 - General Life Cycle Stages [3]

Table 1 defines our expected component lifetimes from our initial research. The lithium ion batteries have had extensive external research performed, and therefore are the only life cycle in the table with a high level of accuracy. We acknowledge that the same level of research is required in order to determine concrete approximate life cycles for the circuit board, microcomputer and EMG sensors. Determining these life cycles becomes

increasingly important as the final design of the product is defined with sustainability in mind.

Table 1 - Component lifetimes based on production level device

Component	Approximate Lifetime
Circuit Boards	7 years
EMG Sensors	5-7 years
Microcomputer	7 years
Batteries (Rechargeable Lithium Ion)	300+ charge/discharge cycles [3]

In creating the MYOperator we shall be using LCA as a tool within the C2C design strategy. C2C is a framework that creates efficient production techniques that are waste free. Within this framework all the material inputs and outputs are seen as either technical or biological nutrients that can either be recycled or consumed [5]. Below in Figure 3 shows a business model called Triple Bottom Line (TBL) which fits into our C2C design framework and will be used to create sustainable products by taking into account the social, environmental and financial impact.

Figure 5 - Triple Bottom Line Business Model [5]

In order to keep the MYOperator environmentally friendly the prototype will be created by reusing components and casings that the team already has. We shall research the most environmentally friendly manufactured electronic

components when needing to purchase new ones. The production level product will have casings made of biodegradable and compostable plastics. The prototype stage uses alkaline batteries that can be recycled, but the production stage product will use rechargeable lithium-ion batteries to be more environmentally conscious. The microcontrollers that will be used in our prototype and their accompanying electronic components, including the EMG sensors, will be chosen such that they have a long usable lifetime. These parts will be chosen from a sustainability-conscious manufacturer and will all have reuse and recycle plans. At production level the microcontrollers will be replaced by PCBs to create less waste and to have a more compact design. Figure 4 shows the Cradle-to-Cradle design principles and all of our components for both the prototype and the final production stage product will fall into either the technosphere recycling (electronics) or the biosphere decomposition (ie. the compostable plastic parts).

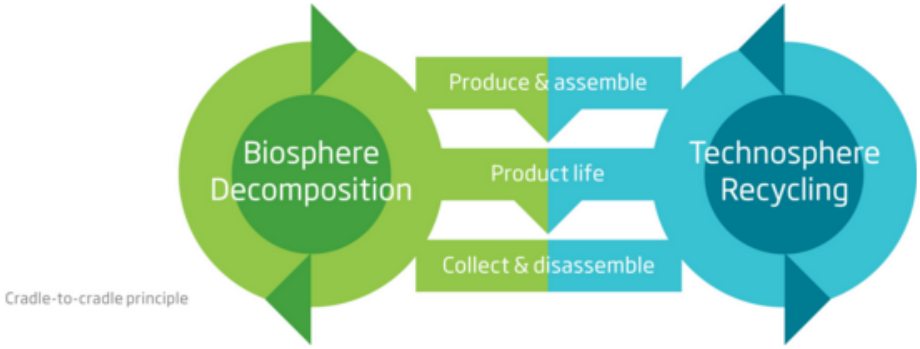

Figure 6 - Graphical Representation of Cradle-to-Cradle Design [6]

5. SAFETY

Surgical Electronic Solutions strives to create products that are of no hazard to users and meticulously follow safety standards and guidelines. We will carefully analyze the safety of our product's features, both electronic and physical, to prevent any risk of hazardous interaction between the end user and the product. The placement of all of our electronic components will be selected such that no wiring will come in contact with the user at the prototype stage, and this potential risk will be eliminated at the production stage by the use of enclosed PCBs. The Calf Sleeve shall be made such that it is comfortable for the user to wear. For the prototype, we have done testing to determine a Calf Sleeve made of soft porous material is comfortable for a

user to wear and does not cause any harm. The end product Calf Sleeve will use soft plastics that have been researched and found to be popular in wearable devices.

The MYOperator will follow applicable technical standards put forth by the CSA, IEC, and ISO. Specific standards are referenced in the requirements section above as they apply to various components in the device.

6. CONCLUSION

At SES we strive to make the surgeon's job easier so that they can focus solely on their patient and not be hindered by the devices they use. A foot pedal is the current power activator for many surgical devices and was brought to SES as a problem to solve by a local ENT surgeon, Dr. Thomas Buonassisi. Eliminating the pedal by creating a wireless wearable device, the MYOperator MK 1.0, is the solution we are designing. Functionally, the device will be comprised of three parts: the Base Station, the Hip Station and the Calf Sleeve. The two wearable parts, the Hip Station and Calf Sleeve, will communicate wirelessly to a Base Station located in the operating theatre, which is another desired functionality brought to us by the ENT. The system as a whole will be highly usable and made sustainably, while follow many internationally set standards to ensure its use is safe.

7. REFERENCES

This is the IEEE referencing for standards

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[2] S. GaleWyrick (2014). *Working Toward Sustainable Medical Device Design* [Online]. Retrieved February 5, 2016 from http://www.bresslergroup.com/blog/sustainable-medical-device-design/

[3] A. S. Williams (2009). *Life Cycle Analysis: A Step By Step Approach* [Online]. Retrieved February 5, 2016 from http://www.istc.illinois.edu/info/library_docs/tr/tr40.pdf

[4] Cadex Electronics (2016). *BU-808: How to Prolong Lithium-Based Batteries* [Online]. Retrieved February 13, 2016 from http://batteryuniversity.com/learn/article/how_to_prolong_lithium_based_batteries

[5] N. Brooks (2013). *Triple Bottom Line - The Modern Business Model* [Online]. Retrieved February 11, 2016 from http://www.powerhousegrowers.com/triple-bottom-line-the-modern-business-model/#prettyPhoto

[6] F. Plast (2011). *Nature sets the standard* [Online]. Retrieved February 11, 2016 from http://www.envirocentre.ie/News.aspx?ID=79D21E24-862B-4685-A66A-2D7059FB72E2&PID=a257bece-c1e7-464a-9cd0-fde10d3a18c3&NID=190c6c89-a2bb-4575-b338-e670cca2b15f&M=2

8. APPENDIX 1 - STANDARDS

[1] Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, CAN/CSA-C22.2 NO 60601-1-2-08, 2008.

[2] Degrees of protection provided by enclosures, IEC 60529:2001-Ed.2.1/Cor.3, 2009.

[3] Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤16 A per phase), IEC 61000-3-2:2009-Ed.3.2, 2009.

[4] Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques, IEC 61000-4:2009-Ed.3.2, 2009.

[5] Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement, IEC CISPR 11:2010-Ed.5.1, 2010.

[6] Medical device software – Software life cycle processes, IEC 62304:2006-Ed.1.0, 2006.

[7] Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices, ISO 14937:2009, 2009.

[8] Degrees of protection provided by enclosures (IP Code), IEC 60529:2001, Ed. 2.1, 2001.

[9] Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement, IEC CISPR 11:2010-Ed.5.1, 2010.

[10] Medical device software – Software life cycle processes, IEC 62304:2006-Ed.1.0, 2006.

[11] Medical devices – Application of usability engineering to medical devices, IEC 62366:2007, 2007.

[12] Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices, ISO 17664:2004, 2004.