Axolo METRICS

Dear Dr. Rawicz,

Please find Axolo Metrics' ProsthetiSense Functional Specification enclosed for our 440W capstone project. ProsthetiSense is a tool to be used by prosthetists that identify pressure points and shear forces within a prosthetic socket. ProsthetiSense ensures patients have the most comfortable fit to their prosthesis, and consequently avoids skin breakdown in the case of unwanted forces within the socket.

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The enclosed document includes a comprehensive collection of requirements and specifications that ultimately define a roadmap for the ProsthetiSense project. Priority classifications have been assigned to each respective requirement to provide further guidance when Axolo Metrics proceeds with the project. The priority classifications also split the ProsthetiSense project into two phases; one being a proof of concept to be completed this term, and the other being a market ready product. Requirements have also been broken down by category for clarity and easy referral. With the enclosed functional specification document, Axolo Metrics will be able to remain focused on creating a robust, safe, and purposeful device to advance prothetic technology.

Axolo Metrics is comprised of five hard working and knowledgable fourth year engineering students: Daniel Dixon, Joshua Barrett, Kirill Shestakov, Tanner Frison, and Vijay Parameswaran. If you have any further questions, please do not hesitate to contact me by phone at 778-384-0335 or by email at drdixon@sfu.ca.

Thank you for taking the time to read our proposal.

Sincerely,

Daniel Dixon
CEO Axolo Metrics

ProsthetiSENSE

Prosthetic Socket Pressure Sensor Array

Functional Specification

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GLOSSARY

CSA	CSA Group. Formerly known as Canadian Standards Association. A not-for-profit organization which publishes various standards.
EPEAT	Electronic Product Environmental Assessment Tool. Electronic products that are registered meet environmental measures defined by specific criteria.
FSR	Force sensitive resistor. The resistance of this sensor changes when a force or pressure is applied.
IC	Integrated circuit
IEEE	Institute of Electrical and Electronics Engineers. An association which, among other things, publishes various standards in the electrical and electronics engineering field.
ISO	International Organization for Standardization. An international group comprised of various national standards associations that sets standards for various fields.
LiPo	Lithium-Ion Polymer. A type of battery.
mA	Milliamperes. A unit of electrical current.
MCU	Microcontroller unit. A small computer on a chip that can be programmed to control inputs and outputs.
PCB	Printed Circuit Board
RoHS	Restriction of Use of Hazardous Substances. These regulations limit or ban specific substances in electronic equipment.
UL	UL LLC. A safety certification and consulting company.
V	Voltage. A measure of electric potential.

EXECUTIVE SUMMARY

Prosthetic technology has been constantly evolving over the past many years, and modern prosthetics gives those amputees the ability to live life to the fullest. While amputees have access to very advanced prosthetics, if they don't fit perfectly to their body, they cannot take full advantage of their prosthesis. Improper fitting can lead to discomfort to the patient, and skin breakdown in some cases. [1]

Axolo Metrics is advancing the prosthetic fitting process by creating a pressure sensing system that will be able to measure the forces between the patient and their prosthetic socket. Being able to analyze and pinpoint problem areas will greatly help the prosthetist ensure a perfect fit. Axolo Metrics' ProsthetiSense device will be the ideal solution for prosthetists and patients alike. By placing our pressure sensor material between the patient and the socket, ProsthetiSense will wirelessly transmit its data to a mobile application, from where a 3D pressure map will be generated. Quantitative, real-time feedback will be invaluable in the prosthetic fitting process, ultimately leading to a much improved fit, and reducing patient discomfort.

Axolo Metrics will be developing ProsthetiSense in stages. First, a proof of concept that will demonstrate features vital to the basic operation of the device, which includes the sensors detecting accurate readings, and the application displaying those results in a graphical manner. A second phase will be focused on getting ProsthetiSense market ready, including generating a full 3D model of the socket, and obtaining the required medical and electrical certifications to be used by the market.

For further granularity, requirements have assigned priority classifications. These priorities ensure development can be easily scheduled and benchmarked. Priority 0, I and II are all related to the ProsthetiSense proof of concept. The specificity of the proof of concept is a consequence of Axolo Metrics currently working on this phase of the project. It will be complete this phase in early April 2016.

All of Axolo Metrics' requirements were made with quality, safety, and sustainability in mind. ProsthetiSense's foundation will come from the requirements defined here, creating a roadmap for a useful, safe, and robust medical device that will advance prosthetics and ultimately improve the lives of amputees.

1. INTRODUCTION

Axolo Metrics is designing and implementing a new sensor array system, ProsthetiSense, for measuring pressure and shear forces exerted by prosthetic sockets on residual limbs of below-knee amputees. The ProsthetiSense system will help prosthetists customize prosthetic sockets for amputees in order to create a better fit and improve the quality of life for many. Functional limbs are an extremely important part of every person's daily life, and their loss is undeniably tragic as it can create unbearable difficulties. The task of fitting a prosthetic socket onto an amputee's residual limb can be very challenging for the prosthetist as well as the amputees themselves. An improper fit dramatically increases the risk of developing significant skin problems due to high normal and shear forces on the amputee's residual limb. These skin problems sometimes lead to further amputations. Additionally, an amputee's subjective feedback is not adequate to customize a prosthetic socket mold because the response is often too general and can be limited due to the nerve damage in the residual limb [1]. Axolo Metrics is committed to empowering prosthetists with a device that will objectively determine where pressure and forces are too high and show them which areas pose considerable health risks for below-knee amputees.

The ProsthetiSense system will be placed inside the prosthetic socket, and will use a controller with wireless communication capabilities in order to transmit data obtained from the sensors to a prosthetist's mobile device, and display the relevant pressure map in the mobile application [1].

1.1 Scope

The purpose of this document is to outline certain functional requirements that Axolo Metrics set for the ProthetiSense product. This document will describe the functionality of the complete system, as well as individual components such the sensor array, controller with wireless connectivity, and a custom mobile application. These requirements and functional specifications will determine the necessary and desirable features for both proof-of-concept and the final product, and will be a guiding roadmap to our design process to ensure that the product can be relied on by the prosthetists to deliver on the stated promises.

1.2 Intended Audience

The document is intended to be used by all members of Axolo Metrics team at the development, testing, and implementation stages of the ProsthetiSense project. Our team will use the document in order to have a clear vision of the action items required and the functionality of the proof-of-concept as well as the final product.

1.3 Classification

To represent the priority of functionalities listed in this document, the following classification method is used:

[FS(#)- (P#)],

where **FS(#)** is the specification number, and (**P#)** is the specification priority, which are ordered as shown below:

[FS(#) - 0] (Priority 0) - Functions with this priority are considered basic and foundational functions. More complex functions can either rely on or derive from these functions. These are absolutely required to demonstrate the proof-of-concept.

[FS(#) - I] (Priority I) - Functions with this priority are slightly more complex functions required to demonstrate the proof of concept.

[FS(#) - II] (Priority II) - Functions with this priority are recommended to be ready to demonstrate with the proof-of-concept if time permits, but are required for the final product.

[FS(#) - III] (Priority III) - Functions with this priority are only projected to be implemented in the final product.

2. Device Requirements

2.1 System Overview

The ProsthetiSense sensor array delivers accurate information about the distribution of pressure forces within lower limb prosthetic sockets. The device has four core functional components:

i. Sensor Array

ii. Power Electronics

iii. Controller with Device Firmware

iv. Mobile Application

A map of the device operation comprising these four components is shown in **figure 1.**

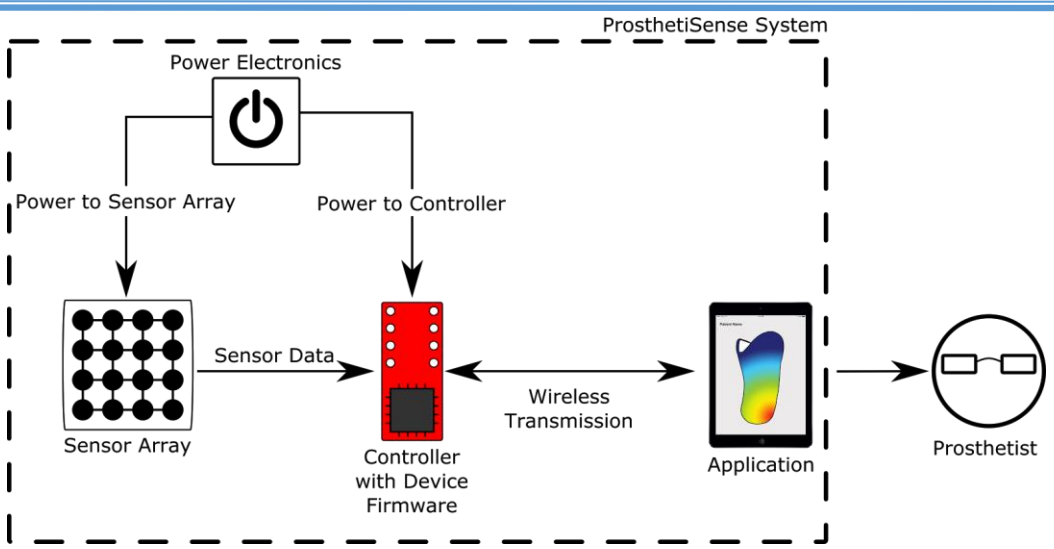

Figure 1 – A high level overview of the ProsthetiSense System

The ProsthetiSense system is made to be intuitive and easy-to-use for prosthetists, while at the same time providing accurate and useful information.

The sensor array will comprise of pressure sensing elements as well as contour detecting elements. The array sheet will be attached to the amputee's residual limb, which will then be inserted into the prosthetic socket. The array will wirelessly transmit sensor information to a mobile application. The mobile application will use the sensor information to generate a real-time two-dimensional and a three-dimensional pressure map.

2.1.1 Device General Requirements

The general requirements are primarily composed of requirements of setup and interaction times between amputees and prosthetist. These requirements exist to ensure the ProsthetiSense system's convenience prosthetists and amputees. If setup or operation is cumbersome and complex, prosthetists will likely resort to more traditional methods [1].
A device that is quick to setup will allow the prosthetist to quickly and efficiently diagnose critical areas on an amputee's residual limb. Discussions with prosthetists indicate that an ideal setup time is around two minutes [1].

[FS(1)- II]	The pressure sensing process shall happen in real time, less than 300ms
[FS(2)- III]	The device setup time between amputee and device shall take under 2 minutes
[FS(3)- III]	The device shall be reusable from patient to patient
[FS(4)- III]	The device shall be shipped in recyclable cardboard packaging
[FS(5)- III]	The device shall not weigh over 500 grams

2.1.2 Safety Requirements

[FS(6)- 0] All electrically conductive components in the device shall be shielded from human contact

[FS(7)- III] The final product shall be RoHS Compliant [2]

2.1.3 Environmental Requirements

The environmental requirements outline various external influences necessary for ProsthetiSense to function normally. **Table 1** describes the operating temperature ranges for the key components of our system. From these operating temperature ranges we can formulate our environmental requirements as follows.

Table 1- Operating temperature ranges of the major hardware blocks. The limiting component is bolded.

Suitable Component	Operating temperature range (°C)
Multiplexer IC [4]	-55 to 125
Atmel MCU [5]	-40 to 85
7.4V LiPo Battery [3]	**-25 to 60**
Interlink FSR [6]	-40 to 85

[FS(8)- 0] The system should function perfectly under room temperature conditions (i.e. between 19-24 degrees Celsius)

[FS(9)- I] Operating temperature of the system will be between -25 and 60 degrees Celsius as limited by the batteries [3]

[FS(10)- III] Assembly and soldering of any electronics that will come into near contact with patients and prosthetists should be carried out with lead-free processes

2.1.4 User Manual Requirements

Although intuitive and easy-to-use, the ProsthetiSense system will ship with a user manual outlining proper operating procedures for both hardware and software components of the system. This user manual will be written in plain language and supplemented with diagrams. The user manual will not be completed until the final product is at the end of its development to ensure the most accurate instructions are described.

[FS(11)- III] The device shall come with a user manual defining operating practices and basic troubleshooting techniques

[FS(12)- III] The user manual shall also be made available online in pdf format

[FS(13)- III] The user manual shall be written in language that is easy to understand for the prosthetist

[FS(14)- III] The user manual shall include visual instructions for installing the sensor array

[FS(15)- III] Include visual instructions how to operate the mobile application

[FS(16)- III] The user manual shall written in both English and French for U.S. and Canadian Market

[FS(17)- III] The user manual will include liability clauses and other relevant legal information

2.2 Hardware Requirements

Hardware components comprise the bulk of the core functionalities of the ProsthetiSense system: The sensor array, power electronics, and the hardware aspects of the controller components. The power electronics enable both the sensors and controller to perform essential functions. The sensor array gathers information on pressure on the amputee's residual limb and the shape of the residual limb. The controller hardware reads the sensor data, and wirelessly transmits it to be read by the application.

2.2.1 Sensor Array

The device's sensor array is the prime functional component of the entire system. The sensor array detects pressure and shear forces acting on the amputee's residual limb alongside detecting the shape of the limb to provide the system with the information needed to build a three dimensional pressure map. While both information on pressure and shear forces are informative for prosthetists, pressure is the value of greater interest [1]. Knowing the movements of high pressure points would also allow prosthetists to determine where shear forces may be acting.

The sensors must also be compact and flexible enough for the amputee to maintain comfort during testing of the socket, but at the same time, must have a high enough resolution to provide useful data. Custom fabrication is required to obtain a high resolution sensor array for the commercialized product.

General Requirements

[FS(18)- 0] The sensor array shall sense pressure at various points on the residual limb

[FS(19)- 0] The sensor array shall be comprised of off-the-shelf sensors that can be reused in future prototyping stages

[FS(20)- II] The sensor array shall detect the contours of the residual limb

[FS(21)- III] The sensor array shall be able give readings for pressures greater than 0.83 kilograms per square centimeter [7]

[FS(22)- III] The resolution of the sensor array shall be one sensor per square centimeter [1]

[FS(23)- III] The sensor array shall detect shear forces on the residual limb

[FS(24)- III] The sensor array shall be custom fabricated

[FS(25)- III] The sensor array shall be reusable from patient to patient

Safety Requirements

[FS(26)- II] The sensor array shall not have any sharp points that could damage an amputee's residual limb liner or residual limb

[FS(27)- II] When in use, the sensor array temperature must not rise over 20 degrees Celsius [8]

[FS(28)- III] The sensor array shall not cause discomfort when being used on an amputee

[FS(29)- III] The sensor array shall not exert additional forces on the amputee's residual limb when being used

Physical Requirements

[FS(30)- I] The sensor array must be embedded in a flexible fabric

[FS(31)- I] The sensor array shall be such that it wraps around the length of the amputee's residual limb

[FS(32)- II] The sensor array must be thin enough so as to not worsen the current fit of the amputee's socket

[FS(33)- II] The sensor array must be embedded in a mildly stretchable fabric

[FS(34)- III] The sensor array shall be resistant to sweat released from the amputee's residual limb

[FS(35)- III] The sensor array shall be implemented in a modular design - Users can add and remove sheets as desired depending on the size and coverage required to obtain useful testing results

[FS(36)- III] The fabric for sensor sheet shall be resistant to tears

Electrical Requirements

[FS(37)- 0] The sensor array shall operate at 3.3-5V

[FS(38)- II] The sensor array shall draw a maximum of 500 mA

2.2.2 Controller

The controller acts as the bridge between the data reading operation of the sensor and the data processing operation of the mobile application. The controller reads the sensor data, and wirelessly transmits it to be processed by the application.

General Requirements

[FS(39)- 0] The controller shall be have USB power and data transmission capabilities

[FS(40)- I] The controller shall have wireless transmission capabilities

Physical Requirements

[FS(41)- II] The controller shall be attached to the outside of the prosthetic socket

[FS(42)- II] The controller circuitry shall be assembled on a PCB

[FS(43)- III] The controller circuitry shall be enclosed in a case along with the power electronics

Electrical Requirements

[FS(44) - 0] The controller shall operate at 3.3-5V

[FS(45) - 0] The controller shall be capable reading analog signals

[FS(46) - 0] The controller shall be capable of outputting digital signals

[FS(47) - 0] The controller shall be properly grounded

[FS(48) - I] The controller shall draw a maximum of 500 mA

2.2.3 Power Electronics

The power electronics enable the sensor electronics and controller to perform their essential functions. This component allows the ProsthetiSense system to be completely self-contained at the most basic level, with all power requirements being satisfied from an on-board battery. This allows for the system to be light and portable. The power electronics component can be expanded to include more complex functions such as battery recharging and level identification.

General Requirements

[FS(49)- 0] The power electronics shall provide adequate power to the sensors and controller

[FS(50)- 0] The power electronics shall never supply voltage or current levels that will damage any electrical circuit or component in the system

[FS(51)- III] Power supply should be such that the device can operate for 6 hours of constant use without recharge

Safety Requirements

[FS(52)- 0] The batteries in the power electronics should not be subjected to conditions that would present fire or explosive hazard

Physical Requirements

[FS(53)- II] The power electronics shall be assembled on a PCB

[FS(54)- III] The power electronics components shall be attached to the outside of the prosthesis socket

[FS(55)- III] The power electronics shall be enclosed in a case along with the controller circuitry

Electrical Requirements

[FS(56)- 0] The power electronics shall supply 3.3-5V to the controller unit

[FS(57)- 0] The power electronics shall supply no more than 500 mA to the controller unit

[FS(58)- 0] The power electronics shall supply 3.3-5V to the sensor array

[FS(59)- 0] The power electronics shall supply no more than 500 mA to the Sensor Array

[FS(60)- 0] Power the microcontroller unit via USB power to ensure functionality of the proof-of-concept

[FS(61)- I] The controller shall be properly grounded

[FS(62)- II] Use rechargeable batteries to supply power to the system

[FS(63)- III] System should be self-contained and function entirely off battery power

[FS(64)- III] The power electronics shall incorporate battery recharging circuitry

2.3 Software Requirements

Another large component of the ProsthetiSense system is the software components. Software is split into two categories: Firmware and Mobile Application. Firmware is used to manipulate measured sensor values into usable data, and send this data to the mobile application. The mobile application receives this data, interprets it, and displays it to the user.

2.3.1 Device Firmware

Device firmware is used to process the data received from the sensors and send this data to the mobile applications. In addition, the device firmware must be able to accomplish these tasks in a reasonable time frame in order accomplish the system's real time requirements. To provide convenience to the prosthetist the firmware should generate data which can be transmitted wirelessly.

General Requirements

[FS(65)- I] The device firmware shall complete its processing so as to maintain real-time constraints

[FS(66)- II] The device firmware shall be able to stop reading data from specified sensors based on user specification

Transmission Requirements

[FS(67)- 0] The device firmware shall read data from sensors

[FS(68)- I] The device firmware shall generate data which can be transmitted wirelessly

[FS(69)- II] The data shall be transmitted in real time with a transmission delay below 300 ms

2.3.2 Mobile Application

The mobile application will be used to receive the processed data and display this data in an intuitive way. In early iterations it will be created for iOS platforms as this is the native platform of the prosthetists. Wireless connectivity will be implemented to provide convenience to the

prosthetists. The display will display data in the form of a pressure map to ensure practical feedback.

General Requirements

[FS(70)- I] Application will exist on iOS platform

[FS(71)- II] The mobile application shall be able to disable column(s) of sensors to vary detection area to accommodate different stump sizes

[FS(72)- III] Application will exist on Android, Mac OS X, and Windows

Connectivity Requirements

[FS(73)- III] The mobile application shall connect wirelessly to the device

Display Requirements

[FS(74)- I] The mobile application shall construct a two dimensional pressure map from sensor information

[FS(75)- III] The mobile application shall construct a three dimensional pressure map from sensor information

[FS(76)- III] The mobile application shall store previous data and have the ability to playback on demand

[FS(77)- III] The mobile application shall record corresponding video with dynamic capture movement to examine gait

[FS(78)- III] The mobile application shall be able to store patient profiles

2.4 Standards

This section will outline various requirements which relate to existing engineering standards. The ProsthetiSense sensor array in it's final iteration will conform to the standards set by the IEEE, ISO and CSA [9, 10, 11]. In particular, the standards set in place by the ISO for documentation and the standards recognized by Health Canada for medical devices [12,13]. These specific standards are listed below as requirements. The documentation standards will be used so that any medical staff will be able to easily interpret user manuals. The Health Canada recognized standards are used to ensure that the final device shall be usable in Canadian medical facilities. The device in its final iteration shall also carry certification marks from UL and CSA [11,14,15]. Finally, the device will be made to comply with certain sustainability standards to ensure that it is environmentally sustainable. The sensors will meet the EPEAT Gold standard for environmental sustainability and the other components will meet the UL and CSA sustainability standards [14,15,16,17].

2.4.1 ISO Documentation Standards

[FS(79)- III] ISO 8548-2:1993 - Method of Describing lower limb amputation stumps [13]

[FS(80)- III] ISO 8549-2:1989 - Terms relating to external limb prostheses and wearers of these prostheses [13]

[FS(81)- III] ISO 13405-2:2015 - Description of lower limb prosthetic components [13]

2.4.2 Health Canada Standards

[FS(82)- III] CAN/CSA-C22.2 NO 60601-1-08 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance [12]

[FS(83)- III] IEC 62366:2007 - Medical devices – Application of usability engineering to medical devices [18]

[FS(84)- III] ISO 14971:2007 - Medical devices – Application of risk management to medical devices [10]

2.4.3 Sustainability Standards

[FS(85)- III] EPEAT Gold standard for environmental sustainability [17]

[FS(86)- III] UL and CSA sustainability standards such as GREENGUARD and ECOLOGO [14,15,16]

2.4.4 Necessary Certifications

[FS(87)- III] The device shall have UL Certification

[FS(88)- III] The device shall have CSA Certification

[FS(89)- III] The device shall have RoHS Certification

3. SAFETY AND SUSTAINABILITY

Axolo Metrics is committed to creating a product which is safe to use and environmentally sustainable. During the development of the proof-of-concept and prototypes environmental sustainability is not a major concern, however it becomes a larger concern at the production level. Meanwhile safety hazards are important during early development and become even more important during the production level. This section outlines what steps have and will be taken to ensure safety and sustainability.

3.1 Safety

The primary concerns with regard to safety have to do with the hardware components of the ProsthetiSense system. As a result, many of the requirements to do with safety can be found in the general, sensor array, and power electronics sections of this document. In addition to following these requirements, safety will be ensured by following Health Canada standards and various certifications.

In general, voltages and currents used in any of the electrical components of the device will be safe for potential contacts with the skin of the amputee. In early iterations of the product such as the proof-of-concept and prototype this general requirement will be sufficient to ensure that no engineers or potential test subjects are harmed. As ProsthetiSense moves toward production the standards set in place by Health Canada for medical electrical devices must be followed. Specifically, standard NO 60601-1-08 set in place by the CSA and standard 14971-07 set in place by the ISO [10,12]. These two standards will be followed to ensure basic safety, essential performance, and risk management of the device.

There are safety concerns in regard to the physical aspect of the sensor array in addition to those of the general system. These are addressed by the safety requirements in the sensor array section. In later iterations of development when more thorough testing is taking place these requirements become more relevant. In particular, the sensor array should not have any sharp or protruding elements which may cause further damage to the residual limb. In later iterations it is also of paramount importance that the sensor array not exert additional forces on the limb. If the sensor array exerted additional forces it may have a chance of causing skin breakdown. It also would result in incorrect measurements of forces causing the prosthetist to incorrectly modify the socket, which in turn could cause extreme cases of skin breakdown.

ProsthetiSense is a product aimed at helping prosthetists provide a better standard of living for their patients. As such, Axolo Metrics will do everything in their power to ensure the utmost levels of safety for their clients. Failure to do so would result in a product which causes discomfort for the amputees, the exact opposite of the company's goals.

3.2 Sustainability

In addition to producing a safe product, Axolo Metrics is committed to producing an environmentally sustainable product. A high degree of sustainability will be achieved for early iterations of the product and, more importantly, during final production.

In earlier iterations sustainability is not of particular large concern. Nevertheless, Axolo Metrics is committed to sustainability at all stages of development. Before obtaining parts for proof-of-concept designs, extensive research is conducted to ensure that only necessary parts are purchased to minimize the production of waste. In addition, this extensive research will allow for the purchase and usage of parts which comply with the cradle-to-cradle philosophy of technical nutrients [19]. This will ensure that parts used in the proof-of-concept will be able to be used again in any later prototyping models, thereby minimizing waste produced. Fabrics used will either be able to be reused and repurposed in later iterations or will be biodegradable and able to be disposed of ecologically.

In later iterations, environmental sustainability becomes more challenging. The three major areas of the product which must be produced sustainably are the electrical components, any fabrics associated with the sensor array, and packaging. The electrical components will be limited to non-toxic, non-harmful synthetic materials that can be recycled at various electronic depots. In order to ensure these components meet their requirements, the sensors will be subject to the EPEAT Gold standard for environmental sustainability and the rest will be subject to UL and CSA sustainability standards [14,15,16,17]. Fabrics will be produced similar to those used in the early product iterations and will consist of materials which are either recyclable or compostable. Finally, packaging must also be produced in a sustainable manner. Fortunately, ProsthetiSense is targeted at a niche market, as such customers will likely be ordering online. Because the majority of sales are done online, packaging can consist of easily recycled materials such as light cardboards or recycled pulp boxes.

In following these requirements and standards from early development through to production ProsthetiSense will be an environmentally sustainable product. In addition, Axolo Metric's pursuit of a high quality product will result in ProsthetiSense having durable hardware components. This means that the majority of updates will only apply to software components, further reducing any negative environmental impact.

4. CONCLUSION

The functional specification outlines deliverables and their relative priorities that Axolo Metrics will use in the ProsthetiSense product development. The document draws distinctions between the proof of concept currently in development, and the market ready product for future reference. Requirement priority classifications will also be used in project scheduling, ensuring benchmarks are met throughout development. All Priority 0 and Priority I requirements will be completed by early April 2016.

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