January 20, 2016

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
8888 University Drive
Burnaby, BC, V5A 1S6

Re: ENSC 305W Project Functional Specification for OxiTrak-5001

Dear Dr. Rawicz,

Please find attached the Functional Specifications for OxiTrak-5001. Our project aims to revolutionize cardiac and respiratory malfunctions by detecting them in real time using an ear-worn oximeter. Recommended by healthcare professionals to patients with pre-existing respiratory and cardiac conditions, OxiTrak will be able to measure a user's heart rate and blood oxygen levels. This product will provide analyzed feedback along with an emergency algorithm system implemented on a mobile device.

The enclosed document will provide a detailed overview of the system as whole, as well as design specifications and requirements. Overview of the product includes hardware, software and mechanical components of the product development. The three different stages of design are also specified in this document; priorities are given to each requirement according to their design stage.

The motivated OxiTrak team consists of Doasay Igiri, Johnny Chou, Mohammad Ahmad, Shahzada Randhawa and Rasha Abu Alzuluf, five experienced senior engineers in biomedical, electronics, systems and computer fields. This diversity in background ensures a variety in skill set required to cover every aspect of design for successful completion of the project.

Please feel free to contact oxitrak@gmail.com for any inquiries regarding design requirements and specifications.

Sincerely,

Johnny Chou
Chief Executive Officer - OxiTrak

Functional Specifications For OXITRAK-5001

"Track the Rhythm, Keep it Beating"

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Executive Summary

The heart is the main source of life within the human body. A life with a healthy heart is a necessity that some of us take for granted. Many people all over the world are derived from this wonderful gift, and have to deal with life-threatening cardiac conditions. Once an individual is diagnosed with a cardiac or respiratory condition, they will have to deal with it for the rest of their lives. Our device, OxiTrak tries to ensure that such users can monitor their heart rate and blood oxygen level. The device will also implement a notification system that will alert the user, via mobile app, if there is any indication of emergency from the taken readings.

To do this we have split the Project development cycle into following stages:

First Development Stage

- Build the oximeter on breadboard with bare essentials, making sure that sensors are working properly and we are getting accurate readings
- Set up Bluetooth so that the readings can be transferred to cell phone
- UI App development, for data gathering from Bluetooth and emergency triggers

Second Development Stage

- Emergency algorithm addition to the App, for identification of irregular levels of oxygen and heart rate, and following the necessary procedures in case of emergency

Third Development Stage - Production

- PCB of oximeter, printing of the circuitry into a compact and neatly printed out board, replacing the breadboard
- Mechanical packaging of the product, connecting all the components to the PCB and boxing it in a sturdy case
- GPS incorporation and user tracking, using the cell phone GPS to locate the user in crisis and sending the location to the health care professional

OXITRAK

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Glossary

IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
CAN/CSA	Canadian Standard Association
PCB	Printed Circuit Board
GPS	Global Positioning System
QA	Quality Assurance
GUI	Graphical User Interface
LED	Light Emitting Diode

1. Introduction/Background

OxiTrak is a heart rate and oxygen level monitoring device that keeps track of pulse and oxygen saturation in the blood stream. This is achieved through a small wearable product that uses light signals to gather data readings and send the collated data to an Intel Edison microprocessor, which then analyzes and transmits the data to a mobile device. The mobile device visualizes the data and notifies the user of any alarming readings. The continuous tracking and monitoring of a user's pulse rate and oxygen levels contributes to improving the quality of life of patients with cardiovascular problems, and ultimately minimizes the side effects that come with these problems such as high blood pressure, angina and diabetes. OxiTrak indirectly lessens the burden on the healthcare system and the government at large, in terms of hospitalization and post-trauma care costs, by detecting cardiac and breathing problems within seconds and sending immediate information to both patients and caregivers.

1.1 Scope

This document outlines all the important functional requirements for OxiTrak, and the relevant health and safety standards. All the listed requirements are ordered from highest to lowest priority, and they fully describe the specification for our device prototype.

1.2 Audience

This document is to be used by OxiTrak team members to help them with the design process, and development of both electronics and software components of OxiTrak-5001 product. Test plans will not be discussed in this document; however, subsequent plans will be made to ensure that the development/QA team at OxiTrak meets all requirements.

1.3 Classification

The requirements are specified using the following convention,

[Rn-p]

where **R** denotes the requirement and **n** the number of the requirement specified. **P** denotes the priority level of the requirement, which is used based on the three stages of development:

Table 1: Classification of Requirements

I	This requirement is critical to the system and must be met for the **proof-of-concept** stage
II	This requirement should be met for both the **proof-of-concept** stage and the **final product**
III	III. This requirement is not critical to the functionality of the system; it should met for the **final stage** of production

2. System Overview

The application layout has been simplified such that its operation is user-friendly and efficient. It is currently based solely on an android platform, but the OxiTrak team has plans in place to expand to other operating systems, in order to promote cross-functionality. To maximize the efficiency of the application, users will be required to setup accounts consisting of individual profiles that can be updated per discretion, where they will also be able to track blood oxygen level and heart rate components. The application is to be designed in such a way that although healthcare professionals will be able to have access to their patients' data readings in the case of an emergency, all other personal information will only be made available as preauthorized by the account owner. With regards to OxiTrak-5001, an emergency occurs when abnormal health readings occur; alert notifications will be sent out to the user, and in an instance where said user is unresponsive, a geotagged notification will then be sent to his/her registered healthcare professional.

The proof of concept for OxiTrak-5001 integrates all necessary functionality required to demonstrate its feasibility and ability to thrive within the current market. Identification of potential technical and logistical issues that may interfere with the success of already existing oximeters encouraged us to focus on overlooked features such as its aesthetic value – wearability and durability – and simultaneously introduce new features to the application such as a real-time geotag notification system, which will, in turn, give the product its competitive edge.

The system monitors the heart rate and oxygen level through sensors; those reading are filtered and analyzed by the processor and sent to the phone of the user, and then further processed to check for critical levels. If such levels are detected, the processing app will notify the user and user's emergency contact (healthcare professional), with user's location. The level design overview of our system is depicted in the diagram below.

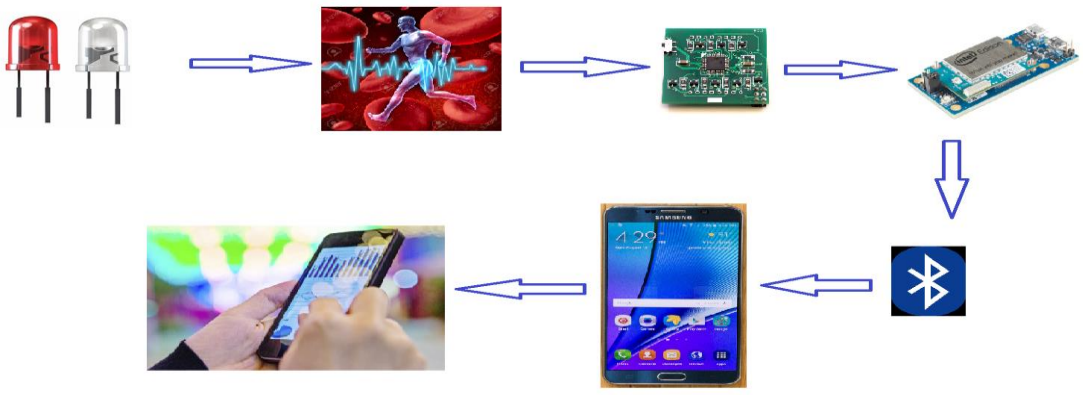

Figure 1: System Overview Block Diagram

The design consists of the following main components:

Packaging**:** This is the enclosure in which the device is fitted into. The packaging is a crucial aspect of our design as this product is aimed at being non-invasive, which means users will be up and about while using it. The packaging will, therefore, have to be a stable fit. The clip, which will be attached to the user's ear, should ideally be mechanically stable and be able to adjust to different users for comfort while still stable enough to provide accurate readings.

Electronics**:** This will be the core of the device; specific light wave (via LED) will be sent through the user's earlobe and detected via a Photo detector. The photo detector contains an instrumentation amplifier, which produces a voltage signal based on the wavelength the sensor receives. This signal must in turn be filtered to eliminate noise to a frequency that is within the range of typical human pulse rates. To further raise the quality of the signal, it must be amplified to suitable level so it can be read by the Intel Edison.

Firmware**:** This section of the design can be referred to the brains of the device. This includes the microprocessor, as well as the software that runs on it. Our design accounts for a single input signal coming from the instrumentation, and three output signals: two signals to control the LEDs and another for the output to be sent via Bluetooth. The internal processing needs to be able to handle the following functions: Heart Rate Detection, SPO_2 Level calculation, control of LED for signal sampling and the transmittal of sound data to the Bluetooth module.

Software**:** The software section of the design includes the Graphical User Interface (GUI), user notification, analysis of data, and emergency use cases. The GUI will have an intuitive interface that will allow the user easy access of the data in innovative ways. For example, tracking history of their SPO_2 levels, detection of trends etc. This ties the analytics part to the software component, where the analysis of this data through automated routines is crucial to the success of this product. Other aspects of the software component include algorithms that will detect dangerous SPO_2 levels in real time, and a built-in tracker to notify emergency services when the user is in distress. These will be intelligent algorithms that can differentiate a real emergency from a false alarm.

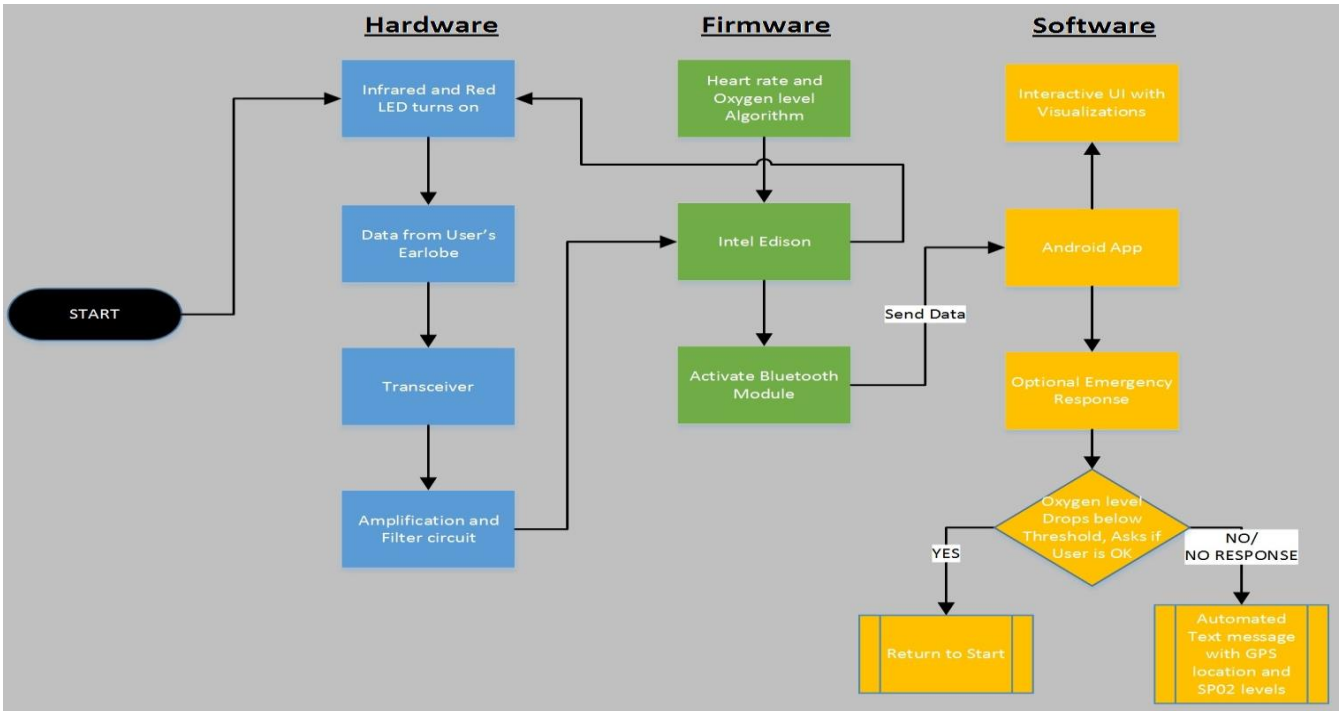

Figure 2: System Design Overview

2.1 Safety Requirements

[R1-II] The device shall not cause bodily harm to the user

[R2-II] The device shall not cause an electrical shock

[R3-III] The device shall be able to detect improper use

[R4-III] The electronic and mechanical components, as well as power connections shall be enclosed

[R5-III] The electronic components of the device shall not cause interference with other devices

2.2 Standards Requirements

[R6-II] The device shall conform to Health Canada Standards

[R7-II] The device shall conform to CSA

2.3 Environmental Requirements

[R8-III] The device shall work over a range of temperatures

[R9-III] The device shall work over a range of humidity levels

[R10-III] The device shall be used both indoors and outdoors

[R11-III] Noise generated during periods of activity shall be minimized

3. Hardware Requirements

The hardware component of this product is comprised of two main categories. The first category is the physical enclosure of the device, which includes a stable casing for the electronics so readings can be taken in a stable environment, as well as a mechanism to attach to the user's ear lobe. This mechanical fitting and enclosure will include sensors, and the electronics of the system.

The second category is the electronics. The electronic design of the system will take a signal from a photo detector and apply proper filtration and amplification parameters to produce a clean signal that can be read by a microprocessor.

A breakdown of the Hardware component is as listed below:

a. Packaging: Enclosure of device in stable enclosure
b. Ear Attachment: Mechanically stable 'clip' that will attach to user's ear
c. Infrared and Red LED circuitry
d. Photo-detection Circuit
e. Amplification and filtration circuitry

3.1 General Requirements

[R12-III] The device should be one size to fit all users
[R13-II] The device should not cost more than $100, in mass production
[R14-II] Device packaging should be waterproof
[R15-I] Data readings should be accurate and not affected by motion
[R16-I] Earpiece clip should not allow external light interference with the oximeter
[R17-II] The device should be comfortable to wear
[R18-I] Earpiece clip should be rightly fitted to each user's earlobe (not too tight to block blood circulation and not too loose to cause inaccurate measurements)
[R19-I] Earpiece clip should be isolated from outside noise

3.2 Physical Requirements

[R20-II] Encasing shall be stable
[R21-I] Packaging should include mechanism to attach to user's ear lobe
[R22-II] Encasing shall cover all electronics
[R23-III] Packaging shall be aesthetically appealing

3.3 Electrical Requirements

[R24-I] Sensor circuit shall be able to pick up RED and INFRARED light waves and output corresponding voltage signals
[R25-I] Photo-detection circuit shall output correct voltage outputs at RED (650nm) and INFRARED (900nm) wavelengths
[R26-I] Filtration component should eliminate noise elements of signal from photo detection output
[R27-I] Bandpass Filter shall extract signal from 0.8 to 3.0 Hz
[R28-I] Amplification Circuit should bring signal to readable value for microprocessor

3.4 Reliability and Durability Requirements

[R29-II] The product (earpiece) shall be waterproof and weather resistant for outdoor use
[R30-II] The product shall not show quick signs of wear and shall be durable for daily use
[R31-II] The product shall not dissipate excessive amounts of heat during wear

4. Firmware Requirements

The Firmware component of the system is crucial in processing the incoming signal from the electronics of the device.

The firmware has four major components to produce a fully functional system. The first is the setup of the LEDs of the device in such a way that the system can sample the sensor circuit and calculate a ratio between the infrared signal and the red signal. To do this we need to ensure that only one of the LEDs is on at certain point for the signal to be sampled correctly.

The next component is pulse rate detection. This component will be achieved by detecting peaks in the sampled signal in order to obtain a pulse, and perform the correct calculations to get the correct rate.

Thirdly, the firmware should be able to take a ratio between the red and infrared LEDs signals and interpolate from a look-up table a correct SPO_2 level.

Lastly, the program needs to be able to communicate the calculated data via Bluetooth.

The Firmware breaks down into the following components:

a) LED Circuitry: Setup of LED on/off signals
b) Heart rate calculation: Level detection of input signal
c) SPO_2 Level calculation: Calculation of ratio of infrared and red signals
d) Bluetooth communication: Transmit calculated data to paired device

4.1 Setup Requirements

[R32-I] Firmware shall turn RED and INFRARED LEDs on and off at correct intervals
[R33-I] Values should be initialized correctly to avoid error

4.2 Heart Rate Detection Requirements

[R34-I] Firmware shall be able to track peaks of signal to detect a pulse
[R35-I] Upon detection of pulses, firmware should be able to calculate an accurate rate

4.3 SPO_2 Calculation Requirements

[R36-I] Firmware shall be able to read voltage signals from RED wavelength signal and INFRARED signal
[R37-I] Firmware should be able to interpolate a ratio between these two signals
[R38-I] Upon calculation of this ratio, firmware should be able to calculate SPO_2 level based on calibrated formulae

4.4 Bluetooth Requirements

[R39-I] Microprocessor shall be able to pair with a smartphone running Oxitrak Software
[R40-I] Microprocessor shall send correct levels of Heart Rate to paired device
[R41-I] Microprocessor shall send correct SPO_2 levels to paired device

5. Software Requirements

The goal of the software unit of the device is to integrate the oximeter with a user-friendly application for data display and notification, along with data forwarding capabilities and geolocation tracking. The real-time emergency unit requires a GPS module for geographical coordinates tracking, and an android device to obtain data via a bluetooth module and transmit information to emergency units and caregivers. The bluetooth module will be implemented on the Intel Edison, and OxiTrak software team will program it such that it can be paired to the hardware, and establish Bluetooth connectivity with the mobile device.

The software unit consists of the following main subunits:

a) Bluetooth Module: For connection to Edison and transfer of readings to mobile device
b) UI App development: To visualize data in forms of graph and meaningful numbers
c) Emergency Algorithm: To detect critical oxygen and pulse rates and trigger the appropriate procedure
d) GPS Module: To locate the user in case of an emergency and send the location to the emergency contact
e) Additional Settings: Extra features such as additional user information; in case of emergency contacts; custom thresholds for pulse and oxygen levels

5.1 General Mobile Application Requirements

[R42-I] The application shall communicate with Edison via Bluetooth
[R43-I] The application shall store the received data
[R44-I] The application shall detect critical heart and oxygen levels from the received data
[R45-II] The application shall be able to alert the emergency contact
[R46-III] The application shall identify user's location via the GPS module, and send location data points to emergency contact

5.2 GUI Requirements

[R47-I] The app shall be designed to be is intuitive and interactive
[R48-I] The registration and login shall occur through a unique username and secure password upon prompt of the app
[R49-I] The system shall validate user login credentials from a directory
[R50-I] The system shall notify user of login failure through an error message, in the case of invalid user credentials
[R51-I] The landing page will include data and diagrams of oxygenated blood levels and heart rate

[R52-I] All plotted data shall be in real-time, and will show real-time intervals for oxygenated blood levels and heart rate
[R53-II] The settings menu icon will be easily recognized and accessed through the main page
[R54-II] Selection of desired settings shall be displayed through an on/off button for each setting
[R55-II] Settings shall include emergency contact registration, emergency text/call notification and geolocation-enabled tracking option

5.3 Analytical Requirements

[R56-II] The application will analyze the received data and trigger the appropriate response e.g. alert the user
[R57-I] Threshold shall be set for critical oxygenated blood levels and heart rate

5.4 Database Requirements

[R58-I] The application may store data for a few days
[R59-I] The application may archive the data on cloud service e.g. dropbox, Google drive
[R60-I] The application may retrieve the archived data
[R61-II] The application may send the gathered data in the form of a report to the health care professional

5.5 Reliability and Durability Requirements

[R62-III] The application will back up data regularly, in case of a crash
[R63-III] The application can recover from a crash
[R64-III] The application will report the crash to the developers
[R65-I] The application shall sync data within seconds
[R66-I] The application will have reliable Bluetooth connection for data transfer
[R67-II] There will be accurate emergency detection and prediction algorithms in place

5.6 GPS Requirements

[R68-III] Accurate location detection of the user via GPS
[R69-III] The app shall display Google or ESRI map with the correct location points
[R70-III] The app shall display last seen location points of the user on the map
[R71- III] The app shall display multiple location points with the option of history location tracking on the map

6. User Documentation

[R72-II] The user manual shall include the company logo, the company's contact email address and website
[R73-II] The manual shall be written in English
[R74-I] The user manual shall sufficiently explain to the layman how to use OxiTrak-5001

7. Engineering Standards

[R75-I] The product shall meet the **CAN/CSA-Z9919-07** requirements [5]
[R76-I] The product shall conform to the **ISO 80601-2-61:2011-Ed.1.0** standards [9]
[R77-I] The product shall meet the **CAN/CSA-C22.2 NO. 601.1B-90** requirements [6]
[R78-I] The product shall conform to the **CAN/CSA-C22.2 NO. 60601-1-4-02** standards [7]
[R79-I] The product shall meet the **CAN/CSA-C22.2 NO. 60601-1-6-05** requirements [8]
[R80-I] The product shall be compatible with **IEC 60601-1-11:2010** standards [10]

8. Sustainability / Safety

For the development of this product, we are going to follow the cradle-to-cradle design to ensure that OxiTrak is sustainable and safe for the users and the environment. We plan to achieve this by a constant recycling process, where we try to reuse the available resources as much as possible, thus reducing waste and the need for unnecessary production of components.

We aim to tackle the five major certification criteria listed below: [1]

1. Material health, i.e. identifying and recognizing the chemical composition of our product
2. Material recycling at the end of their life
3. Energy requirement for production needs to be based on at least 50% renewable energy for all parts (for the highest certification)
4. Water usage and waste quality
5. Social responsibility and fair labour

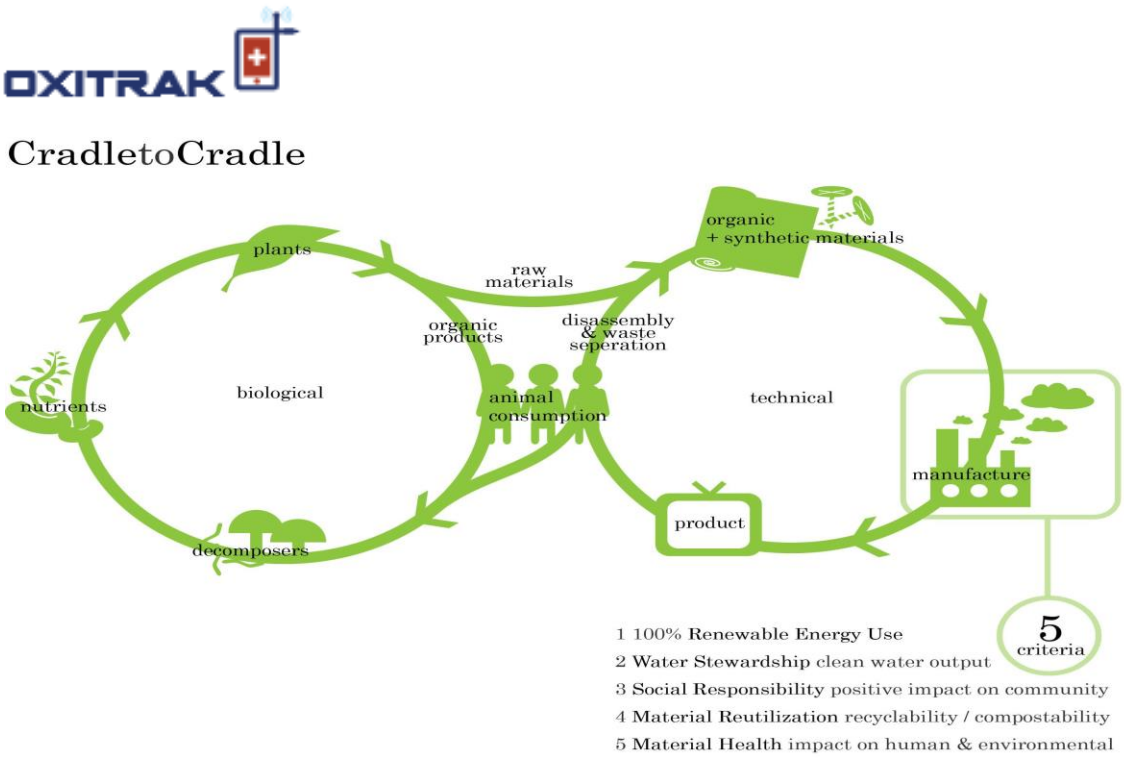

Figure 2: Cradle-to-Cradle Design

The aforementioned criteria shall be met by the following requirements:

[R81-III] The product shall be made of recyclable and eco-friendly materials
[R82-III] The product shall be well insulated to prevent dangers of electric shock
[R83-III] The product shall not have any interference with the brain
[R84-III] The system should be able to withstand extreme usage for at least 10 years
[R85-III] The system shall include full information on the recycling of different components in the user documentation
[R86-III] All electrical and mechanical components must be securely and safely mounted such that they don't inflict any harm to the user

9. Conclusion

The functional requirements have been outlined in this document, along with an overview of system functionality of the device. The outlined requirements, consisting of hardware, software and firmware components, will act as a guideline for OxiTrak team to follow during the process of product development. Each requirement is marked according to its phase and priority level. First phase allows the team to present a proof-of-concept product that can be further developed in the second and third production stages. The expected completion and full presentation of the product is mid April of 2016. The proof-of-concept design is to be completed by the end of February, as stated in the proposal.

10. References

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