June 21, 2018

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

CardioTech Labs

Re: ENSC 405W Requirements Specification for NuCare Band

Dear Dr. Rawicz,

The following document contains the Requirement Specifications for the NuCare Band. Our device is aimed to consistently monitor patients' vitals and allow doctors to follow up with their patients. We believe that our medical wearable allows medical professions to reliably process and manage patients' data both more effectively and efficiently. Hence, caregivers can cater prompt and proper care to patients whenever needed.

The purpose of this document is to provide detailed specifications for the requirements of our product. The document consists of a system overview, system requirements, engineering standards, safety, and sustainability requirements. The document will detail the requirements necessary for the proof of concept, prototype, and our production model.

CardioTech Labs is composed of five perseverant engineering students: Younghoon Jee, Carson Lai, Liteng Cheok, Alfonso Diaz, and Qassam Yomok. Every team member is competent and possesses different skill sets from extensive hardware and software experiences gained from industry and school.

Thank you for the time to review our requirement specifications for the NuCare Band. If you have any inquires or concerns regarding our requiremets specification, please contact our Chief Executive Officer, Alfonso Diaz, by email at adiazalo@sfu.ca.

Sincerely,

Alfonso Diaz
Chief Executive Officer
CardioTech Labs

CardioTech Labs

REQUIREMENTS SPECIFICATION

CARDIAC BIO-SYSTEM MONITORING

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Submitted to
Dr. Andrew Rawicz & Prof. Steve Whitmore
School of Engineering Science
Simon Fraser University

Publish Date
June 21, 2018

Abstract

Hospitals have been using conventional methods that required complicated and invasive methods to monitor patients' vital signs. [1] The use of medical wearable devices has been increasing significantly as the device has potential for it to be non-invasive and the ability for information to be transmitted wirelessly. CardioTech's goal is to manufacture a non-invasive medical wearable device that monitors the user's vital signs, which includes the measurement of pulse rate, oxygen levels and blood pressure.

Currently, the main concern for hospitals and medical facilities are the patients' health condition after their leave from the hospital. [2] With the integration of our hardware, software and electrical sections, NuCare Band allows medical professionals to have access to patients' vital signs wirelessly, using a cloud. With the information transmitted to the cloud, doctors are able to analyze their patients according to their needs and conditions. Also, this would reduce the amount of patients' visits to the hospital for diagnosis after their discharge. [1]

This document outlines all the functional specifications and it's intended to be used as a functional reference for CardioTech Labs team. This document provides a detail insight about the hardware and the software functionalities required for our product to function as designed. Our product should also meet all the engineering, safety and sustainability standards. The three development stages for NuCare Band are the following: Proof of Concept, Prototype and the Final Design. CardioTech aims to complete the construction of our Proof of Concept design by August 2018 and our final product by December 2018.

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Glossary

Bio-System:	A living organism or any complete system of living things that can, directly or indirectly, interact with others. [3]
Firebase Realtime Database:	Cloud-hosted database where data is stored as JSON and synchronized in real time to every connected client. [4]
Microcontroller:	Compact integrated circuit designed to govern a specific operation in an embedded system. [5]
LED:	Light Emitting Diode. Semiconductor device that emits light when an electric current is passed through it. [6]
SIM Card:	Subscriber identity module card.
Machine Learning:	Method of data analysis that automates analytical model building. [7]
Deep Learning:	Machine learning technique that teaches computers to do what comes naturally to humans. [8]
PCB:	Printed circuit board.

1. Introduction

Vital sign monitoring is a fundamental component of patient care. It allows caregivers to quickly assess basic patients' health and to retain critical information needed to facilitate treatment decision. Even though medical devices become more capable, many of them lack core features. The major setback of current vital sign monitoring devices are lack of portability and poor workflow integration and expensive cost.

CardioTech Labs introduces a cardiac profile monitoring wearable, NuCare band, to address obstacles that current medical devices have. NuCare band is a comprehensive vital sign monitoring system that connects clinicians to their patients. The primary aim of NuCare band is to measure the medical parameters such as heart rate, oxygen levels in blood and blood pressure. It will then transmit the data wirelessly to our database so that patients' health data can be monitored anytime. Moreover, CardioTech Labs will implement notification features that if vital signs appear abnormal, it will alert the patient's health care provider immediately. This feature may also reduce the need for post-discharge patients to physically visit doctors for diagnoses. The seamless data integration into healthcare system enables more effective cross-boundary care. Hence, patients can receive quality care while they are in and out of hospitals.

1.1 Scope

The outline of the specifications and requirements of the NuCare Band will consist of the following points. The format of the requirements that will be used throughout the document will be provided; then an overview of the features of the band will be outlined as well as what issues this technology will address. The requirements will be listed in this order of sequences:

- General Requirements
- Performance Requirements
- Hardware Requirements
- Electrical Requirements
- Software Requirements
- Engineering Standards
- Safety Requirements
- Sustainability Requirements

1.2 Intended Audience

The intended audience of this document is Dr. Andrew Rawicz and Prof. Steve Whitmore; as well as the members of CardioTech Labs. In the future, this document will serve for anyone who is interested on the requirements the NuCare Band followed, as well as its compliance with imposed engineering standards.

1.3 Requirement Specification

CardioTech Labs will follow the three phases of product prototyping shown in Figure 1.1:

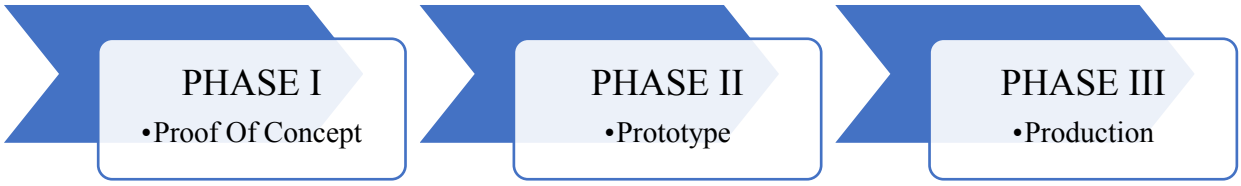

Figure 1.1 Phases of Product Prototyping

The format used in this document as requirement classification will have the following scheme:

Req [Document Section].[Requirement Number] - [Product Prototyping Phase]

2. System Overview

The NuCare Band will be focused on continuous live monitoring of hospital patients in and out of the hospital. This will be achieved through heartrate, blood oxygen and blood pressure sensors incorporated in a rechargeable, reusable, and recyclable bracelet.

The device will use WI-FI technology to connect to our server, from which doctors will be able to view a log and live feed of the patient's cardiac profile. The logs will allow for a more accurate diagnosis; and along with the live feed, will provide relevant information to caregivers.

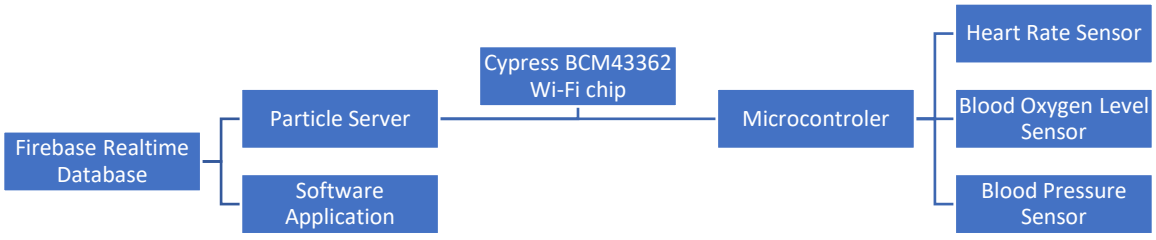

Figure 2.1 System Overview

Figure 2.1 provides an overview of the system to be implemented in Phase I, the PoC (Proof of Concept) stage. The NuCare Band will be directly connected to the sensors, through the Photon microcontroller; which will connect to the Particle Server through its built in Wi-Fi chip. All the information read by the sensors will then be sent to the Firebase Realtime Database. The Android software application will be able to pull the information and display it to the user.

If the microcontroller needs troubleshooting, an LED will be added to indicate status of operation of the photon. This simple feedback mechanism will be able to tell the user if something is wrong with the device.

A small reset button will also be added to restart the device if need be. The button will be easy to press in case the patient's mobility is difficult. However, to prevent it from being pressed by mistake it will be covered by a small silicon cover.

3. System Requirements

The overall requirement that the NuCare band will meet is to be able to help doctors and nurses in the hospital have a more complete view of their patient's cardiac profile over long periods of time. This means that the patient will be using the band constantly; after which the band will be taken by the hospital to be prepared to be given to another patient. These issues are being taken in to account in Table 3.1.

The performance requirements outlined in Table 3.2, encompass the basic capabilities of the NuCare Band at each phase of product prototyping. These requirements will be the baseline of the design and our team's key end goal for each phase.

Table 3.3 and Table 3.4 show the hardware and electrical requirements for the NuCare Band. Our team at CardioTech Labs understand the importance of these requirements since they have the potential to have negative impact on the wearer as well as the hardware implemented in the design. Deeper assessment on how we plan to protect the user is provided in section 5.1.

3.1 General Requirements

[3.1.1-I]	The microcontroller along with connected sensors shall be small enough to wear on a wristband.
[3.1.2-II]	Wristband shall be comfortable to wear for long periods of time and small enough to not restrict wrist movements.
[3.1.3-II]	Wristband shall adapt to different wrist sizes. Small / 5.5"–6.5" / 14.0 cm–16.5 cm Large / 6.5"–7.7" / 16.5 cm–19.6 cm X Large / 7.7"–8.9" / 19.6 cm–22.6 cm
[3.1.4-III]	Device shall be reusable and recyclable.

Table 3.1 General Requirements

3.2 Performance Requirements

[3.2.1-I]	The microcontroller shall connect and send information to server every 30 seconds.
[3.2.2-II]	The user's software application shall retrieve data from firebase database and display it within 30 milliseconds.
[3.2.3-III]	The device shall recognize abnormalities in the patient's cardiac profile and be able to send notifications within 3 seconds.

Table 3.2 Performance Requirements

3.3 Hardware Requirements

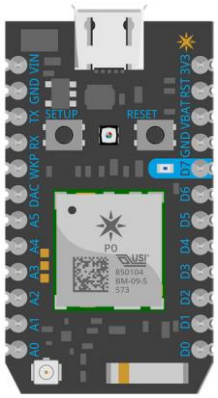

Figure 3.1 Photon Microcontroller **[9]**

Figure 3.2 Electron Microcontroller **[9]**

[3.3.1-I]	The Photon shown in Figure 3.1 shall be used as the microcontroller and main programable component in the proof of concept prototype.
[3.3.2-I]	The Photon microcontroller shall collect data from sensors.
[3.3.3-I]	The Photon microcontroller shall connect to the server though Wi-Fi.
[3.3.4-II]	The Photon shall be replaced by the Electron shown in Figure 3.2 for its built in cellular capability.
[3.3.5-II]	The Electron shall connect to the server though a mobile network using a SIM card.
[3.3.6-II]	An LED shall be incorporated to the circuit to provide a status of the device. ▪ Blue (*solid*) - Device is On ▪ Blue (*blinking*) - Device is On and connected online ▪ Green (*solid*) - Battery is fully charged ▪ Green (*blinking*) – Device is charging ▪ Red (*solid*) – Device failure ▪ Red (*blinking*) – Device is ON with battery less than 10% ▪ Off – Device is OFF
[3.3.7-III]	Reset button shall be added to restart device in case of failure.
[3.3.8-III]	Vibrating or sound notification shall alert user of abnormal readings.

Table 3.3 Hardware Requirements

3.4 Electrical Requirements

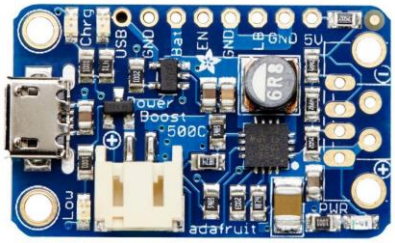

Figure 3.3 Power Boost 500 Charger

[3.4.1-I]	Photon microcontroller shall use wired connection, through a micro USB cable as a power source.
[3.4.2-I]	Photon microcontroller shall use wired connection, through a micro USB cable as a power source.
[3.4.3-I]	A 5.1V Zener diode shall be added to avoid any voltage spikes of Photon.
[3.4.4-I]	Voltage range between 3.3V and 5V shall be used to power MAX30105 to operate.
[3.4.5-I]	Pulse sensor shall be operated between 3V to 5.5V.
[3.4.6-II]	The device shall use a replaceable battery as a power source.
[3.4.7-II]	The battery shall provide a minimum voltage of 3.6V and a maximum of 5.5V. [9]
[3.4.8-II]	Electron microcontroller shall be connected to Lithium Polymer (LiPo) battery at all times when powered from a traditional USB port to compensate for power consumption peaks.
[3.4.9-II]	Input voltage of electron microcontroller shall be between 3.9V DC to 12V DC at VIN pin
[3.4.10-III]	The device shall use a rechargeable battery as a power source.
[3.4.11-III]	The rechargeable battery shall last for at least 24 hours per single charge.
[3.4.12-III]	TPS61090 shall be operated with input voltage within 1.8V to 5.5V.

Table 3.4 Electrical Requirements

3.5 Software Requirements

NuCare band software system will be divided into two components. The first component is the NuCare application. The application will be written in Java and will be connected to Firebase database using Nodejs which will allow the software to display patient's data in real time. The second component is the data analysis software, this software will be written in C and will be hosted on the Particle Photon server. We will be using machine learning and deep learning concepts to analyze patient's data and determine abnormalities.

[3.5.1-I]	The software application shall display the sensors readings in real time.
[3.5.2-II]	The software application shall be available for Android devices.
[3.5.3-II]	The software application shall have a user-friendly and intuitive interface.
[3.5.4-III]	Patient's health logs available through the application shall be available for view and download on a readable format.

[3.5.5-III]	The app shall display three diagrams of all three vital signs with respect to time.
[3.5.6-III]	The software application shall include other diagrams which will allow doctors to easily read their patient's data and simplify the diagnosing process.
[3.5.7-III]	The software application shall use machine learning to analyze patient's data and recognize abnormal behaviors.
[3.5.8-III]	The software application shall notify doctors in case of abnormalities in the readings.

Table 3.5 Software Requirements

4. Engineering Standards

Table 4.1 shows the Engineering standards chosen for the NuCare Band. The left-hand column represents the Standard ID given by the following Engineering standards organizations: IEC, ISO, and IEEE.

IEC 80601-2-49:2018	Standard for medical electrical equipment: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment [10]
ISO 14040:2006	Standard for environmental management -- Life cycle assessment -- Principles and framework [11]
ISO 14044:2006	Environmental management -- Life cycle assessment -- Requirements and guidelines [12]
IEC 62133:2012	Standard for the safe operation of portable sealed secondary cells and batteries (other than button) containing alkaline or other non-acid electrolyte, under intended use and reasonably foreseeable misuse. [13]
IEEE P360	Standard for wearable consumer electronic devices [14]
IEEE 2700-2017	Standard for Sensor Performance Parameter [15]
IEC/TR 80002-1:2009	Standard for medical device software [16]
IEC 80001-1:2010	Standard of risk management for IT-networks incorporating medical devices. [17]
IEEE Std 11073-10101a-2015	Standard Health informatics--Point-of-care medical device communication. [18]
IEC 60950-1:2001	Standard for rated voltage not exceeding 600V [19]
ISO 13485:2016	Standard of Medical devices -- Quality management systems -- Requirements for regulatory purposes [20]
IEC 62366-1:2015	Standard of Medical devices -- Application of usability engineering to medical devices [21]

Table 4.1 Engineering Standards

5. Safety and Sustainability

5.1 Safety

CardioTech aims to ensure that the product will be safe for users to use as they will be wearing it for a long period of time. The following safety requirements, which can be seen in Table 5.1, address multiple concerns that could be a potential risk for the user.

[5.1.1-I]	CardioTech Labs shall ensure that the user doesn't get shocked by limiting the amount of current to be equal or less than 10mA. [22]
[5.1.2-I]	The temperature of the components in the device shall be limited. [23]
[5.1.3-II]	The construction of the device shall not contain any chemicals or hazardous materials.
[5.1.4-II]	Electrical components shall not come into contact with the user's skin.
[5.1.5-III]	The materials used for this design shall not cause allergic reactions or skin irritations.
[5.1.6-III]	The exterior of the product shall be free of any sharp edges to prevent the user from getting hurt.
[5.1.7-III]	Security measures shall be taken to protect personal data.
[5.1.8-III]	NuCare Band shall be water-resistant to protect the band a prevent the user from getting hurt in case of malfunction.

Table 5.1 Safety Standards

5.2 Sustainability

CardioTech aims to produce a device according to the cradle-to cradle criteria to prevent the use of harmful materials or chemicals to our users and the environment. Cradle-to-Cradle refers to the idea where all of the materials that are being used when manufacturing a product are able to be brought back into the development cycle to be re-used. [24]. Following criteria would allow us to reduce the amount of waste and encourage the recycling of materials. [25]

Our proof of concept will be consisting of several electronic parts, such as a microcontroller, some wiring components, breadboard, electronic components and the sensors. All of these components can be reused and recycled for future purposes. The materials that will be part of our prototype design includes replaceable batteries, a PCB, electric components, sensors, and microcontroller. After finishing up on the prototype design, the sensors and microcontroller can be used again; however, the replaceable batteries and PCB have to be dealt with. Any excess materials, scraps or unwanted electronics, like the replaceable batteries, PCB or non-working electric components, will be handed to the electronic recycling location. [26] We are considering to contact and locate the closest Return-It Electronics location to return these parts. [27] As for our final product, we will be including rechargeable batteries into our product design. For medical devices, where reliability and longevity are most important, the preferred power source is rechargeable battery, especially

Lithium-ions. [28] Having to use rechargeable batteries would reduce the amount of batteries being disposed. There are multiple sites in British Columbia that collects different type of batteries for recycling. [29]

CardioTech hopes to decrease the amount of waste used by recycling and reusing the materials. Also, the individual components should be dissembled accordingly, without destructing the product itself. According to the Cradle-to-Cradle criteria, CardioTech is looking forward to applying the suggested approaches to help build a sustainable product.

[5.2.1-II]	Individual parts of the product shall be handled carefully when dissembling it to avoid damaging the components.
[5.2.2-II]	Excess and broken electronic components shall be brought to electronic recycling sites to ensure parts are returned accordingly. [26] [27]
[5.2.3-III]	NuCare Band shall be powered by rechargeable batteries.
[5.2.4-III]	The device shall be designed to be recyclable and reusable by different patients.

Table 5.2 Sustainability Standards

6. Conclusion

This document outlines all the functional specifications and it's intended to be used as a functional reference for CardioTech Labs' team. This document provides a detailed insight about the hardware and the software functionalities required for our product to function as designed. It also includes all the engineering standards required to make NuCare band safe and sustainable. The system specification consists of five major requirements:

1. Hardware Requirements
    i. The Photon shown in Figure 3.1 shall be used as the microcontroller and main programable component in the proof of concept prototype.
    ii. The Photon shall be replaced by the Electron shown in Figure 3.2 for its built in cellular capability.
    iii. An LED shall be incorporated to the circuit to provide a status of the device.
2. Electrical Requirements
    i. The rechargeable battery shall last for at least 24 hours per single charge
3. Software Requirements
    i. The software application shall display the sensors readings in real time.
    ii. The software application shall use machine learning to analyze patient's data and recognize abnormal behaviors.
    iii. The software application shall notify doctors in case of abnormalities in the readings.
4. Engineering Standards
    i. CardioTech Labs' team shall commit to the engineering standards published by all the organizations mentioned in this document.
5. Safety and Sustainability
    i. The construction of the device shall follow the engineering standards to ensure a safe design for the user.
    ii. Security measures shall be taken to protect personal data.
    iii. NuCare band shall be designed to be recyclable and reusable by different patients.

At CardioTech Labs, we understand the need to fill the market gap with a portable and accurate medical device. This project aims to be one of the first steps to aid doctors, nurses and patients by continue modernizing hospitals and the healthcare system. This document will be our guide during the three phases of our implementation process. However, the specification details in this document may be slightly modify as the project progresses.

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8. Appendix A – Proof of Concept

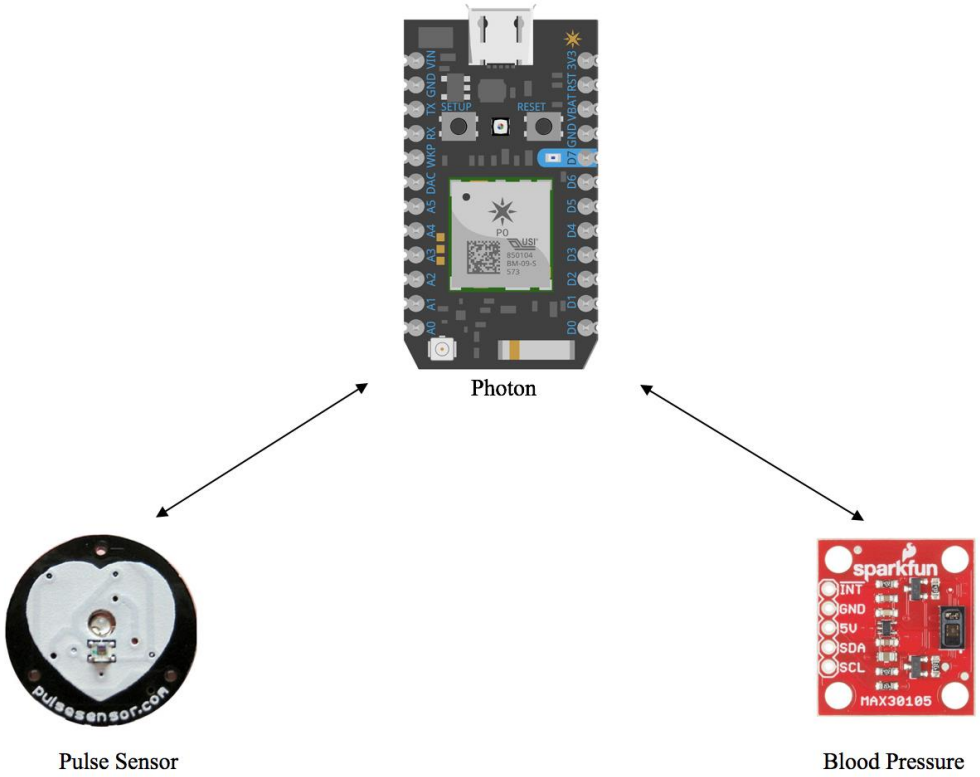

Figure A.1 System Overview of Nucare band [7] [28] [29]

Our deliverable for the proof of concept for the NuCare Band is as follows:

- Pulse sensor will be attached to the main controller (Photon) and be able to transmit data to the cloud.
- Blood Oxygen sensor will be attached the main controller (Photon) and be able to transmit data to the cloud.
- Data will be able to be viewed live from a web console
- Controller will be powered through a 4.8-V, 2A micro USB power source.
- Data will be transmitted through Wi-Fi.
- The device will have LED indicator lights to display status.

Table A.1 shows the final requirements we have compiled for our proof of concept device.

[3.1.1-I]	The microcontroller along with connected sensors shall be small enough to wear on a wristband.
[3.2.1-I]	The microcontroller shall connect and send information to server every 30 seconds.
[3.3.1-I]	The Photon shown in Figure 3.1 shall be used as the microcontroller and main programable component in our prototype.
[3.3.2-I]	The Photon microcontroller shall collect data from sensors.
[3.3.3-I]	The Photon microcontroller shall connect to the server though Wi-Fi.
[3.4.1-I]	Photon microcontroller shall use wired connection, through a micro USB cable as a power source.
[3.4.2-I]	Photon microcontroller shall use wired connection, through a micro USB cable as a power source.
[3.4.3-I]	A 5.1V Zener diode shall be added to avoid any voltage spikes of Photon.
[3.4.4-I]	Voltage range between 3.3V and 5V shall be used to power MAX30105 to operate.
[3.4.5-I]	Pulse sensor shall be operated between 3V to 5.5V.
[3.5.1-I]	The software application shall display the sensors readings in real time.
[5.1.1-I]	CardioTech Labs shall ensure that the user doesn't get shocked by limiting the amount of current to be equal or less than 10mA. [22]
[5.1.2-I]	The temperature of the components in the device shall be limited. [23]

Table A.1 Summary of Requirements used in Phase I.