July 29th, 2018

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



Re: ENSC 405W Design Specification for NuCare Band

Dear Dr. Rawicz,

The following document contains the Design 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 design of our product. The document consists of a design overview of the NuCare Band, test plans, user interface design and plans for ENSC 440. The document will detail the design 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 design specifications for the NuCare Band. If you have any inquires or concerns regarding our design specification, please contact our Chief Executive Officer, Alfonso Diaz, by email at adiazalo@sfu.ca.

Sincerely,

Alfonso Diaz Chief Executive Officer CardioTech Labs



DESIGN SPECIFICATIONS CARDIAC BIO-SYSTEM MONITORING

Project Team

Younghoon Jee Alfonso Diaz Li Teng Cheok Qassam Yomok Carson Lai

Contact Person Alfonso Diaz - adiazalo@sfu.ca

Submitted to

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

Publish Date July 29, 2018



Hospitals have been using conventional methods that require 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 Labs' 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 number of patients' visits to the hospital for diagnosis after their discharge. [1]

This document outlines all the design specifications and it is intended to be used as a reference for CardioTech Labs team. Design specifications for the project consist of three main components; the hardware design of the wearable device, the algorithm used for abnormality detections and the software design for the Android application.



Table of Contents

Abstrac	t	
Glossar	у	
1. Inti	roduction	7
1.1	Scope	7
1.2	Intended Audience	7
1.3	Design Specification	
1.4	System Overview	
2. Hat	rdware Design Requirement	9
2.1	General Design Requirements	
2.2	Performance Design Requirements	
2.3	Microcontroller Design Requirements	
2.4	Sensors Design Requirements	
2.4	.1 Heart Rate	
2.4	.2 Blood Oxygen Level	
2.4	.3 Blood Pressure	
2.5	Electrical Requirements	
2.6	Weight Design Requirements	
3. Bac	ck-end Design	
3.1	Data Processing	
4. Fro	nt-end Design	
5. Co	nclusion	
6. Ref	ferences	
7. Ap	pendix A – Test Plan	
	pendix B – User Interface	
8.1	Introduction	
8.2	Purpose	
8.3	Scope	
8.4	User Analysis	
8.5	Graphical Presentation	
8.6	Technical Analysis	



		Design Specifications – Cardiac Bio-System Monitoring
8.7	Engineering Standards	
8.8	Analytical Usability Testing	
8.9	Empirical Usability Testing	
8.10	Conclusion	
9. Ap	pendix C – ENSC 440 Plan	
9.1	Introduction	
9.2	Scope	
9.3	Benefits	
9.4	Risks	
9.5	Market & Competition	
9.5	.1 Project Market	
9.5	.2 Possible Competition	
9.6	Project Timeline	
9.7	Cost Analysis	
9.8	Company Organization	
9.8	.1 About Us	
9.8	.2 Our Team	
9.9	Conclusion	

List of Tables

Table 2.1 - General Design Requirements	10
Table 2.2 - Performance Requirements	10
Table 2.3 - Microcontroller Requirements	11
Table 2.4 - Photon Pin Description	12
Table 2.5 - Electron Pin Description	13
Table 2.6 - Fitzpatrick skin type [10]	
Table 2.7 - Electrical Design Specifications	20
Table 4.1 - Software Design Specifications	21
Table 8.1 - Engineering Standards	34
Table 9.1- Current Expenditures	44
Table 9.2 - Expenditures during the prototyping phase	45



List of Figures

Figure 1.1 - Main stages of the system	7
Figure 1.2 - Phases of Product Prototyping	8
Figure 1.3 - System Overview	8
Figure 2.1.1 - Wearing NuCare Band [3]	9
Figure 2.2 - Photon Microcontroller [4]	11
Figure 2.3 - Electron Microcontroller [4]	11
Figure 2.4 - Photon Pin Markings [4]	
Figure 2.5 - Electron Pin Markings (a) front (b) back [4]	
Figure 2.6 - Muscles of the forearm. Palmar and Dorsal views [7]	13
Figure 2.7 - Pulse Sensor [11]	15
Figure 2.8 - MAX30102 Blood Oxygen Level Sensor [13]	15
Figure 2.9 - Oxygenated and deoxygenated hemoglobin profile [14]	
Figure 2.10 - 1000mAh Lithium Ion Battery [19]	
Figure 2.11 - 2000mAh Lithium Ion Battery [20]	
Figure 2.12 - SparkFun Photon Battery Shield [21]	19
Figure 2.13 - SparkFun Photon Battery Shield Pin Marking [21]	19
Figure 3.1 - Back-end Design Diagram	
Figure 8.1 - NuCare Band: Front View	
Figure 8.2 - NuCare Band: Bottom View	30
Figure 8.3 - NuCare Band: Top View	30
Figure 8.4 - NuCare Band: 3D Model	31
Figure 8.5 - Android App Login Page	31
Figure 8.6 - Android App Home Page and BPM Secondary Page	32
Figure 9.1 - Connex Vital Signs Monitor	41
Figure 9.2 - Biovotion Everion	
Figure 9.3 - Embrace	41
Figure 9.4 - Loop	42
Figure 9.5 - Gantt Chart	
Figure 9.6 - Milestones	44

List of Equations

Equation 2.1 - Beer's Lambert Law [17]	16
Equation 2.2 - Hemoglobin Concentration [17]	16
Equation 2.3 - Oxygen Saturation Concentration [17]	16
Equation 2.4 - Photon Battery Time	18
Equation 2.5 - Electron Battery Time	18



Glossary

Bio-System:	A living organism or any complete system of living things that can, directly or indirectly, interact with others.
BPM:	Beats Per Minute
Deep Learning:	Machine learning technique that teaches computers to do what comes naturally to humans.
Firebase Realtime Database:	Cloud-hosted database where data is stored as JSON and synchronized in real time to every connected client.
Hb:	Hemoglobin
IBI	Inter Beat Interval
LED:	Light Emitting Diode. Semiconductor device that emits light when an electric current is passed through it
Microcontroller	Compact integrated circuit designed to govern a specific operation in an embedded system.
PCB:	Printed circuit board.
PPG:	Photoplethysmography
SIM Card	Subscriber identity module card.
SPO ₂ :	Blood Oxygen



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 cardiac 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 which will alert the patient's caregiver immediately in case abnormalities are found in the patient's cardiac profile. The seamless data integration into the healthcare system will enable more efficient cross-boundary care for patients.



Figure 1.1 - Main stages of the system

1.1 Scope

The document will outline the design specifications that will be used during the three development phases of the NuCare Band.

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 design specification the NuCare Band followed, as well as details on the test plan to be followed for the PoC device, the user interface requirements and development plans for ENSC 440 during Fall 2018.



1.3 Design Specification

CardioTech Labs will follow the three phases of product prototyping shown in Figure 1.2:



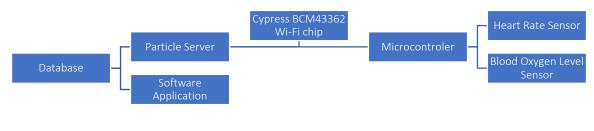
Figure 1.2 - Phases of Product Prototyping

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

Des [Document Section].[Design Requirement Number] - [Product Phase]

1.4 System Overview

The NuCare Band will be focusing on continuous live monitoring of hospital patients in and out of the hospital. This will be achieved through heart rate, 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 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 operation status 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 needed. The button will be easy to press, in case the patient's mobility is difficult. However, it will be covered by a small silicon cover to prevent it from being pressed by mistake.

2. Hardware Design Requirement

The hardware component of our project plays a key role on how the user utilizes and perceives the NuCare Band. We aim to develop a wristband that is comfortable to wear, simple to use, and visually appealing. The focus during Phase I will be mostly aimed at the band's performance when reading the user's vital signs effectively and accurately. This will be accomplished by placing the sensors on the inside part of the user's wrist as shown in Figure 2.1., allowing them to make direct contact with the skin. The diagram showing the placement of the sensors is shown is Figure 2.2.

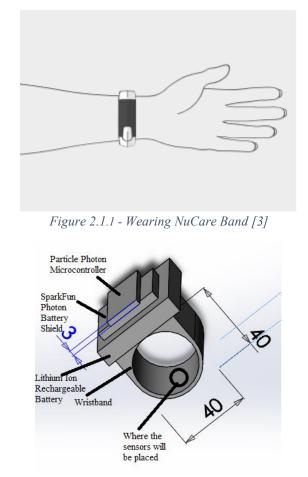


Figure 2.1.2 - Sensors placement and measurements



2.1 General Design Requirements

Table 2.1 shows the general requirements for the NuCare Band. Our CardioTech Labs team is aware of the importance of these requirements since they have the potential to have a negative impact on the wearer as well as the hardware implemented in the design. A concept diagram of the outside of the NuCare Band proposed for the final phase of the project is shown in Figure 2.1.2.

[Des 2.1.1-I]	The sensors and micro-controller shall be placed on the breadboard
[Des 2.1.2-I]	Sensors shall measure vital signs and send the data to micro-controller accurately
[Des 2.1.3-II]	The adjustable device straps shall be made out of Velcro.
[Des 2.1.4-II]	Sensors shall be positioned on the inside of the band strap.
[Des 2.1.5-II]	Only the sensor area shall be exposed to the skin.
[Des 2.1.6-III]	The adjustable device straps shall be made out of soft plastic to enhance users'
	comfort
[Des 2.1.7-III]	The charging pins shall be positioned on the side part of the band.
[Des 2.1.8-III]	The NuCare Band shall have an LED light to indicate the status of the device.
[Des 2.1.9-III]	The LED light shall be positioned on bottom center part of the band.
[Des 2.1.10-III]	The reset button shall be added on the side of the band.

Table 2.1 - General Design Requirements

2.2 Performance Design Requirements

[Des 2.2.1-I]	The microcontroller shall connect and send information to Photon server every 30
	seconds for continuous data monitoring
[Des 2.2.2-I]	Vital signs data received at the Particle server shall be displayed on ThingSpeak.
[Des 2.2.3-II]	Vital signs data received at the Particle server shall be transmitted to firebase
	database and mapped to the patient's cardiac profile.
[Des 2.2.4-II]	Data shall be available for download in plain text format for easy readability.
[Des 2.2.5-III]	A software program shall be used to recognize abnormalities in the patient's
	cardiac profile and be able to send notifications within 3 seconds.
	Table 2.2 Development Development

Table 2.2 - Performance Requirements

2.3 Microcontroller Design Requirements

The Particle Photon micro-controller was initially chosen for Phase 1 development process. Particles platform is open source, providing developers with access to schematics and code. In addition, Particle also provides access to their servers for developing software and processing raw data.

During Phase II, the Photon will be replaced with the Electron micro-controller due to its cellular capability, which will provide the user with constant connectivity even outside of Wi-Fi range.



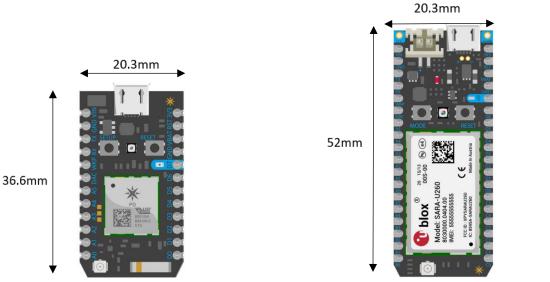


Figure 2.2 - Photon Microcontroller [4]

Figure 2.3 - Electron Microcontroller [4]

[Des 2.3.1-I]	The Photon shown in Fig 2.4 shall be used as the micro-controller and main
	programmable component in the proof of concept prototype.
[Des 2.3.2-II]	The Photon shall be replaced by the Electron shown in Fig 2.5 for its built-in cellular
	capability.

[Des 2.3.3-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

Table 2.3 - Microcontroller Requirements



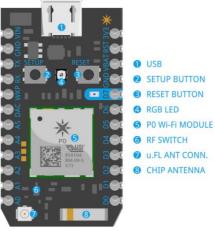
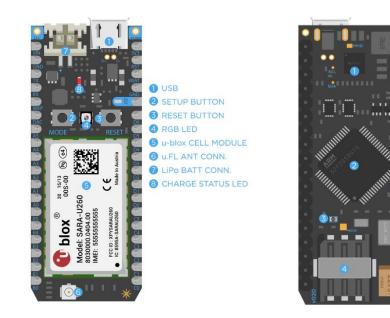


Figure 2.4 - Photon Pin Markings [4]

Pin	Description
VIN	As an input, supply 3.6V to 5.5VDC to power the photon
GND	Ground
D7	Device Status LED
A0	Pulse Sensor Input
A1	Pulse Sensor Output
	Table 2.4 - Photon Pin Description



POWER MGMT IC
 MICROCONTROLLER
 3V3-VBAT JUMPER
 SIM CARD HOLDER



(b) Figure 2.5 - Electron Pin Markings (a) front (b) back [4]



Pin	Description
VIN	As an input, supply 3.6V to 5.5VDC to power the photon
GND	Ground
D7	Device Status LED
A1	Pulse Sensor Output

Table 2.5 - Electron Pin Description

2.4 Sensors Design Requirements

Although blood vessels run through all our body parts, there are some parts that makes the measuring of blood flow data easier. [5] The ear and forehead are the ideal places to measure heart rate since there is no relative motion or noise that can affect the data collection. The wrist and the arm are sometimes used to measure blood flow data; however, large muscles, tendon and ligaments tend to make the area susceptible to some noise due to movement. Commercially available devices and scientific studies have demonstrated to be viable for accurate readings on the forearm and wrist. [6]

Moreover, from consultation with a nurse, we concluded that our sensors should be positioned on the inside part of the wrist and approximately two fingers above the wrist bone, so movement will not be restricted. This area of the forearm is filled with bones and tendons as seen in Figure 2.8; however, the arteries and veins are close to the skin which will allow the optical sensors to provide accurate readings.

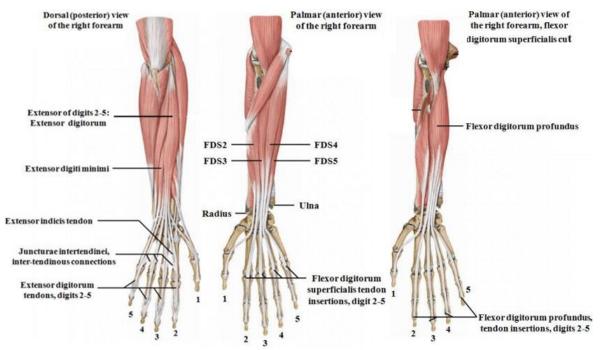


Figure 2.6 - Muscles of the forearm. Palmar and Dorsal views [7]



The optical sensors measure the wavelength of the light refracted from the blood flow. Although the skin pigmentation shown in Table 2.6 play a role in the accuracy of pulse oximetry measurements, as dark skin tone absorbs all color while bright skin tone reflects all, the variations in results are low. [8] [9]

Furthermore, a monitoring device should not be worn too tight as it may interfere with the blood flow. If it is too loose, the space and air can hinder consistent vital sign readings.



Table 2.6 - Fitzpatrick skin type [10]



2.4.1 Heart Rate

The Heart rate sensors used for our prototype is the Pulse Sensor shown in Figure 2.9. This pulse sensor is able to obtain Live Heartbeats and BPM raw data and it is compatible with several DIY platforms such as arduino, Raspberry Pi, Particle and littleBits. [11] This device was chosen for its cross compatibility, its small size and weight specifications.

This pulse sensor uses a photodiode to detect the change in blood refletivity in real time; this data can then be transferred to a microcontroller, where it is processed and translated into BMP. [12]

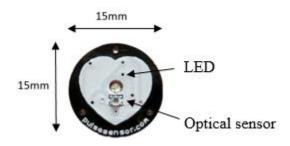


Figure 2.7 - Pulse Sensor [11]

2.4.2 Blood Oxygen Level



Optical sensor for blood oxygen

Figure 2.8 - MAX30102 Blood Oxygen Level Sensor [13]

To measure blood oxygen levels in our prototype, we decided to use the MAX30102 chip since it is compatible with both the Photon and the Electron microcontroller. In addition, the MAX30102 can measure both blood oxygen levels and heart rate; this will be useful in the future when comparing the heart rate data to the pulse sensor's data we are currently using. If development on this chip goes as expected, our team is considering on replacing the heart rate sensor using this chip.



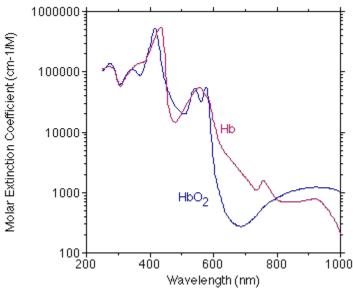


Figure 2.9 - Oxygenated and deoxygenated hemoglobin profile [14]

Pulse oximetry is a medical technique to measure oxygen saturation in humans' blood. The principle is based on absorption difference in oxygenated (HbO₂) and deoxygenated (Hb) hemoglobin. The oxygenated hemoglobin tends to absorb infrared light, which results in red color while deoxygenated hemoglobin absorbs more red light. Consequently, the profile shown in Figure 2.11 shows that HbO₂ has low molar extinction coefficient at a wavelength of 660nm, while Hb has relatively low molar extinction coefficient at 910nm wavelength. [15]

Our blood oxygen sensor measures oxygen saturation using reflectance method where light emitter and photodetectors are adjacent to each other. Light is generated from the emitter, travels through the tissue and bounces back to detector. Our group opted for the reflective mode pulse oximetry sensor as there is more flexible measurements sites. Reflectance method is easily available in the form of watch when measuring blood oxygen. Conversely, a transient-based sensor is thicker and bulkier, which is not optimal for our band-based design. [16]

$$I(z) = I_0 e^{-\mu_a z} e^{-\mu_s z} = I_0 e^{-(\mu_s + \mu_s) z}$$

Equation 2.1 - Beer's Lambert Law [17]

 $C_{Hemoglobin} = C_{Hb} + C_{HbO_2}$

Equation 2.2 - Hemoglobin Concentration [17]

$$S_{O_2} = \frac{C_{HbO_2}}{C_{Hemoglobin}}$$

Equation 2.3 - Oxygen Saturation Concentration [17]



Beer's Lambert law, seen in equation 2.3, states that light absorption is directly proportional to the concentration of light absorbing material. Hence, using Beer's law, the ratio of transmitted red and infrared signals can be calculated to measure oxygen saturation. Oxygen saturation is the ratio of oxygenated hemoglobin concentration over total Hemoglobin concentration as shown in equation 2.2.

Our oximetry sensors use green visible light during the process of photoplethysmography (PPG). PPG encompasses illuminating tissues with optical light and measures absorption coefficient. [18] The reason of choosing green optical light, 540nm in wavelength, for our sensor is that wavelength of visible green light significantly reduces distortions and interferences with other ambient wavelengths generated by other colors. Thus, green light is an ideal color of optical light when measuring pulse rate and blood oxygen level.

2.4.3 Blood Pressure

Blood pressure measurement is a feature that our team would like to implement in the future. However due to lack of sensors that can read this type of data, we have opted to develop our own mechanism which will be compatible with the NuCare Band.

This separate device will be developed using a Photon to ensure compatibility with the band. Workings of the inner mechanism are still in development; however, it will be able to communicate to the server in parallel with the band and it will include an inflation/deflation system which will wrap around the bicep allowing the device to measure the blood pressure of the subject.

2.5 Electrical Requirements

Providing the enough power for the device is essential for its proper functionality. During Phase 1, our team has opted to connect the Photon to a power source via a micro-USB cable. In later stages of the prototype concept, the device will be powered by a Lithium Ion battery. Lithium Ion battery has high energy density, which can provide enough power to the NuCare Band with the battery relatively small size. Another benefit the battery caters is low maintenance. Unlike Ni-Cad cells where periodic discharge is required to preserve cell memory effects, Lithium Ion requires minimal maintenance while ensuring good performance. A 1000 mAh battery is deemed to be an ideal capacity to power photon-based NuCare Band for 8.75 hours. In the meantime, we selected 2000 mAh for electron as cellular enabled micro-controller required more power consumption. Choosing bigger battery capacity ensures relatively solid battery time to be 7.78 hours.



Photon Battery Time = $\frac{Battery Capacity (mAh)}{Average Photon Device Consumption (mA)} \times Consumption Rate$

$$=\frac{1000}{80}\times 0.7$$

= 8.75 *hours*

Equation 2.4 - Photon Battery Time

 $Electron Battery Time = \frac{Battery Capacity (mAh)}{Average Photon Device Consumption (mA)} * Consumption Rate$

$$=\frac{2000}{180} \times 0.7$$

= 7.78 *hours*

Equation 2.5 - Electron Battery Time

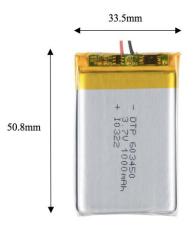


Figure 2.10 - 1000mAh Lithium Ion Battery [19]





Figure 2.11 - 2000mAh Lithium Ion Battery [20]

Photon battery shield has been selected as it supports full compatibility with the Photon microcontroller. Photon battery shield not only allows photon to monitor the Lithium Ion battery, but it can also charge the Lithium Ion battery via USB cable.

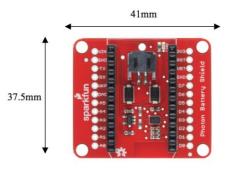


Figure 2.12 - SparkFun Photon Battery Shield [21]

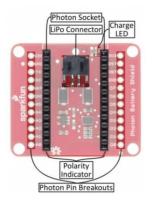


Figure 2.13 - SparkFun Photon Battery Shield Pin Marking [21]



	Design Specifications – Cardiac Bio-System Monitoring
[Des 2.5.1-I]	A Zener diode shall be added to avoid any voltage spikes of Photon.
[Des 2.5.2-I]	NuCare band shall be connected through micro USB to a power source.
[Des 2.5.3-II] [Des 2.5.4-III]	NuCare band shall use photon battery shield to connect rechargeable battery. Wi-Fi enabled NuCare band shall use a rechargeable 1Ah Lithium Polymer battery
[Des 2.5.5-III]	as a power source. Cellular enabled NuCare band shall use a rechargeable Lithium Polymer battery as a power source

Table 2.7 - Electrical Design Specifications

2.6 Weight Design Requirements

Component	Weight (g)
Photon Microcontroller w/Headers	5
Electron Microcontroller w/Headers	10
Pulse Sensor	2
Blood Oxygen Sensor	0.9
Photon Battery Shield	9
1000mAh Lithium Ion Battery	22
2000mAh Lithium Ion Battery	36
Total Mass of Wi-Fi model (Photon)	38.9
Total Mass of Cellular model (Electron)	57.9
Blood Pressure Device	300

Table 2.8 - Weight Design Specifications

3. Back-end Design

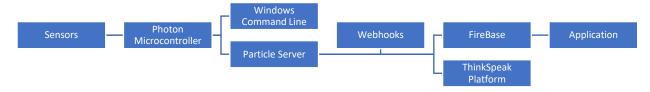


Figure 3.1 - Back-end Design Diagram

3.1 Data Processing

The micro-controller in the NuCare Band will collect the data from the sensors and send it to the Particle server, where it will be processed through our code. The web-hook built-into the Particle servers allows us to send encrypted sensor data automatically to ThinkSpeak platform, where it is securely analyzed and visualized using MATLAB. It is important to note that by default, all websites used in the data processing steps will be using Secure Sockets Layer (SSL) encryption.



During Phase II and III, the Firebase Database will be used for real-time data storage. Firebase is a comprehensive database that allows easy integration of our patients' vital sign data into different mobile platforms.

4. Front-end Design

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 real time data. 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.

[Des 4.0.1-I]	The software application shall display the sensors readings in real time.
[Des 4.0.2-II]	The software application shall be available for Android devices.
[Des 4.0.3-II]	The software application shall have a user-friendly and intuitive interface.
[Des 4.0.4-III]	Patient's health logs available through the application shall be available for view
	and download on a readable format.
[Des 4.0.5-III]	The app shall display three diagrams of all three vital signs with respect to time.
[Des 4.0.6-III]	The software application shall include other diagrams which will allow doctors to
	easily read their patient's data and simplify the diagnosing process.
[Des 4.0.7-III]	The software application shall use machine learning to analyze patient's data and
	recognize abnormal behaviors.
[Des 4.0.8-III]	The software application shall notify doctors in case of abnormalities in the
	readings.

Table 4.1 - Software Design Specifications

5. Conclusion

This document outlines all the design specifications and it is intended to be used as a design reference for CardioTech Labs' team. This document provides a detailed insight about the hardware and software designs required for our product to be intuitive and valuable for the user. The system design specification consists of two major design requirements:

- I. Hardware Design Requirements
 - Micro-controller design:
 - a) Particle Photon will be connected to the cloud by a Wi-Fi module
 - b) Particle Electron will be connected to the cloud by a cellular module
 - Sensors design:
 - a) Pulse sensor will collect BPM/IBI data and send it to the microcontroller
 - b) Blood Oxygen sensor which will collect IR/RED ratio and send it to the micro-controller



- c) Blood pressure sensor will measure the blood pressure and send to the cloud using its own micro-controller
- Electrical design
 - a) Lithium Ion battery will provide power to the NuCare Band and will last approximately 8.75 hours (Photon) and 7.78 hours (Electron)
 - b) Photon battery shield will serve as a bridge between micro-controller, sensors and rechargeable battery
- II. Software Design Requirements
 - Back End design
 - a) NuCare data processing software will be hosted on Particle server and will analyze raw data and preform all the required calculation to obtain accurate measurements
 - b) Web-hooks will connect Particle server to a MATLAB service called ThingSpeak as well as firebase database.
 - c) NodeJS script which will connect the database with the end users' application
 - Front End design
 - a) Android application will be used to display current heart rate and current blood oxygen level.
 - b) Detailed graph information will be available for both heart rate data and blood oxygen level data.
 - c) Application will notify user and doctor of any abnormalities detected.

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.



6. References

- "Medical Tourism," 1 October 2017. [Online]. Available: http://www.medicaltourismmag.com/wearable-medical-devices-transforming-healthcare/. [Accessed 12 June 2018].
- [2] "Health Tech," 2018. [Online]. Available: https://healthtechmagazine.net/media/video/himss-2018-philosophical-underpinningsachieving-connected-healthcare. [Accessed 13 June 2018].
- [3] Mio Global, "Mio Slice Complete User Guide," Mio Global, 2018. [Online]. Available: https://www.mioglobal.com/docs/mio_slice_complete_user_guide_en_v2.pdf. [Accessed 21 May 2018].
- [4] Particle, "Particle Docs," 31 May 2018. [Online]. Available: https://docs.particle.io/datasheets/. [Accessed 13 June 2018].
- [5] M. T. H. I. M. R. H. G. Ethel Tur, "Basal Perfusion of the Cutaneous Microcirculation: Measurements as a Function of Anatomic Position," *J Invest Dermatol*, vol. 81, no. 5, pp. 442-446, 1983.
- [6] H.-S. A. D. M. D. J. M. N. J.-M. L. Sarah E Stahl, "How accurate are the wrist-based heart rate monitors during walking and running activities? Are they accurate enough?," *BMJ Journals*, vol. 2, no. 1, 2016.
- [7] M. Tits, "Development of an optical motion capture setup for feature extraction and statistical analysis of the pianist's expert gestures," *Université de Mons*, 2014.
- [8] R. K. W. A. C. A. M. J. C. K. J. P. a. B. S. Elizabeth E. Foglia, "The Effect of Skin Pigmentation on the Accuracy of Pulse Oximetry in Infants with Hypoxemia," *J Pediatr*, vol. 182, no. 2, pp. 375-377, 2017.
- [9] R. Britt, "Skin tone not a new issue for heart monitors," MarketWatch, 30 Apri 2015.
 [Online]. Available: https://www.marketwatch.com/story/skin-tone-not-a-new-issue-for-heart-monitors-2015-04-30. [Accessed 18 June 2018].
- [10] R. Kraudel, "How to Test Biometric Wearables," Valencell, 20 July 2017. [Online]. Available: https://valencell.com/blog/2017/07/test-biometric-wearables/. [Accessed 10 July 2018].
- [11] "Pulse Sensor," 2018. [Online]. Available: https://pulsesensor.com/. [Accessed 13 June 2018].
- [12] Kickstarter, "Pulse Sensor: an Open Source Heart-rate Sensor that Rocks," 18 July 2011.
 [Online]. Available: https://www.kickstarter.com/projects/1342192419/pulse-sensor-anopen-source-heart-rate-sensor-that/faqs. [Accessed 24 July 2018].
- [13] Ali Express, "Low Power MAX30102 Heart Rate Oxygen Pulse Breakout Borad module Replace MAx30100," 2018. [Online]. Available: https://www.aliexpress.com/item/Low-Power-MAX30102-Heart-Rate-Oxygen-Pulse-Breakout-Borad-module-Replace-MAx30100/32813579402.html. [Accessed 28 July 2018].
- [14] OMLC, "Optical Absorption of Hemoglobin," SAP, 15 December 2009. [Online]. Available: https://omlc.org/spectra/hemoglobin/. [Accessed 27 July 2018].



- [15] Oxymetry, "Principles of Pulse Oximetry Technology," 2006. [Online]. Available: http://www.oximetry.org/pulseox/principles.htm. [Accessed 16 July 2018].
- [16] H. K. J. L. Hooseok Lee, "Reflectance pulse oximetry: Practical issues and limitations," *ICT Express*, vol. 2, no. 4, pp. 195-198, 2016.
- [17] C. Boudoux, Fundamentals of Biomedical Optics, Blurb, 2017.
- [18] A. J, "Photoplethysmography and its application in clinical physiological measurement.," *Physiol Meas.*, vol. 28, no. 3, pp. 1-39, 2007.
- [19] SparkFun Electronics, "Lithium Ion Battery 1Ah," 2018. [Online]. Available: https://www.sparkfun.com/products/13813. [Accessed 20 July 2018].
- [20] SparkFun Electronics, "Lithium Ion Battery 2Ah," 2018. [Online]. Available: https://www.sparkfun.com/products/13855. [Accessed 20 July 2018].
- [21] SparkFun Electronics, "SparkFun Photon Battery Shield," 2018. [Online]. Available: https://www.sparkfun.com/products/13626. [Accessed 21 July 2018].
- [22] D. Norman, 2013. [Online]. Available: http://www.nixdell.com/classes/HCI-and-Design-Spring-2017/The-Design-of-Everyday-Things-Revised-and-Expanded-Edition.pdf. [Accessed 15 July 2018].
- [23] "International Organization for Standarization," March 2018. [Online]. Available: https://www.iso.org/standard/67720.html. [Accessed 18 June 2018].
- [24] "International Organization for Standardization," July 2006. [Online]. Available: https://www.iso.org/standard/37456.html.
- [25] "International Organization for Standardization," July 2006. [Online]. Available: https://www.iso.org/standard/38498.html. [Accessed 15 June 2018].
- [26] "IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components," 6 December 2012. [Online]. Available: https://www.iecee.org/dyn/www/f?p=106:49:0::::FSP_STD_ID:6515. [Accessed 15 June 2018].
- [27] "IEE Standards Association," 2018. [Online]. Available: https://standards.ieee.org/develop/project/360.html. [Accessed 15 June 2018].
- [28] "IEE Standards Association," 2014. [Online]. Available: https://standards.ieee.org/findstds/standard/2700-2017.html. [Accessed 15 June 2018].
- [29] "International Organization for Standardization," September 2009. [Online]. Available: https://www.iso.org/standard/54146.html. [Accessed 15 June 2018].
- [30] I. O. f. Standardization, October 2010. [Online]. Available: https://www.iso.org/standard/44863.html. [Accessed 15 June 2018].
- [31] I. S. Association, 2004. [Online]. Available: https://standards.ieee.org/findstds/standard/11073-10101a-2015.html. [Accessed 15 June 208].
- [32] "IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components," 25 October 2001. [Online]. Available: https://www.iecee.org/dyn/www/f?p=106:49:0::::FSP_STD_ID:18568. [Accessed 15 June 2018].



- [33] "International Organization for Standardization," March 2016. [Online]. Available: https://www.iso.org/standard/59752.html. [Accessed 15 June 2018].
- [34] "International Organization for Standardization," February 2015. [Online]. Available: https://www.iso.org/standard/63179.html. [Accessed 15 June 2018].
- [35] J. Comstock, "MobiHEalthNews," [Online].
- [36] CMA, "2017 CMA Workforce Survey highlights doctors' concern over patient access to care," 2017. [Online]. Available: https://www.cma.ca/En/Pages/2017-CMA-Workforce-Survey-highlights-doctors%E2%80%99-concern-over-patient-access-to-care.aspx. [Accessed 14 June 2018].
- [37] Z. O. Omogbadegun, "Security in Healthcare Information Systems," in 2006 ITI 4th International Conference on Information & Communications Technology, Cairo, Egypt, 2007.
- [38] Geneticdisordersuk.org, "BMA patient discharge," 2018. [Online]. Available: http://www.geneticdisordersuk.org/static/media/up/BMA_patient_discharge.pdf.. [Accessed 29 July 2018].
- [39] Express.co.uk, "Readmission rates raise care fears," [Online]. Available: https://www.express.co.uk/news/uk/376929/Readmission-rates-raise-care-fears. [Accessed 29 July 2018].
- [40] MPO, "The Future of Medical Wearables," 1 July 2017. [Online]. Available: https://www.mpo-mag.com/issues/2017-06-01/view_columns/the-future-of-medicalwearables. [Accessed 29 July 2018].
- [41] Welchallyn.ca, "Connex Vital Sings Monitor," 2018. [Online]. Available: http://www.welchallyn.ca/en/products/categories/patient-monitoring/vital-signsdevices/connex-vital-signs-monitor.html. [Accessed 29 July 2018].
- [42] Biovotion, "Everion," 2018. [Online]. Available: https://www.biovotion.com/everion/. [Accessed 2018 July 29].
- [43] Empatica, "Empatica," 2018. [Online]. Available: https://www.empatica.com/]. . [Accessed 29 July 2018].
- [44] Megadget, "Introducing Loop Vital Signs Wearable Monitor from SpryHealth," 2018. [Online]. Available: https://www.medgadget.com/2017/05/introducing-loop-vital-signswearable-monitor-from-spryhealth.html. [Accessed 29 July 2018].
- [45] J. Comstock, "MobiHealthNews," HIMSS Media, 3 November 2017. [Online]. Available: http://www.mobihealthnews.com/content/five-barriers-wider-clinical-wearable-adoption. [Accessed 2018 May 2018].
- [46] S. Fenske, "Making Medical Wearables Clinically Relevant," MPO, 16 December 2016. [Online]. Available: https://www.mpo-mag.com/contents/view_online-exclusives/2016-12-16/making-medical-wearables-clinically-relevant. [Accessed 29 July 2018].



7. Appendix A – Test Plan

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

- Controller will be powered through a 4.8-V, 2A micro USB power source.
- Data will be transmitted through Wi-Fi.
- Pulse sensor and Blood Oxygen sensor will be attached to 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

Power supply - Microcontroller		
Connect the device to a power source through a micro-USB cable.		
Expected Outcome:		
LED indicator will turn on blue, indicating the micro-controller has been powered on.		
Observed Outcome/Comments:		
Time and Date:Tester:Score:Pass Fail		

Electrical				
Power supply - Se	nsors			
Expected Outcom	e:			
On the inside part of the band, the LED in both oxygen and heart rate sensors will start blinking				
green, indicating the sensors are powered on and working.				
Observed Outcome/Comments:				
Time and Date:	Tester:		Score:	Pass Fail
				1



			Besign speetheutions Curula		in informering
Network					
Device network	connectivity (Wi-Fi)				
Allow 30 seconds	s for the device to estab	olish netw	ork connectivity		
Expected Outcom	me:				
LED indicator wi	ll blink blue, indicating	g the micr	co-controller has connected	d online. I	Blue light
shall continue to blink for the rest of the testing process.					
Observed Outcome/Comments:					
Time and Date:		Tester:		Score:	Pass Fail
		1 050011			1 455 1 411

Performance		
Sensor data transfer		
Fasten the band snugly, about 1-2 finger widths above your wrist bone. The optical sensors should		
make good contact with your skin.		
Expected Outcome:		
Reading from both sensors should display on the online database.		
Observed Outcome/Comments:		
Time and Date:Tester:Score:Pass Fail		



8. Appendix B – User Interface

8.1 Introduction

CardioTech Systems is designing a wearable medical device that would be worn on the user's wrist, thus enabling them or the doctors to monitor the user's vital signs. The design of the hardware component, the NuCare Band, focuses on comfort, familiarity, and appearance. For the mobile application, CardioTech also strives for familiarity, appearance and ease of use.

8.2 Purpose

The purpose of this document is to illustrate the hardware and software UI design of the NuCare Band. It will show why specific choices were made for both the proof of concept and for our prototype design.

8.3 Scope

This document will discuss about four main topics:

- 1. User Analysis
- 2. Technical Analysis
- 3. Engineering Standards
- 4. Usability Testing

8.4 User Analysis

The target audience of the NuCare Band are patients inside the hospital and patients who are newly released from the hospital. In addition, we also target users who are interested in monitoring their own heath conditions. The use of technology today is becoming more and more prevalent. The NuCare Band is designed for ease of use. If users have ever seen or worn a watch or smartwatch, then the NuCare Band will be no different except the main component will be worn on the underside of the wrist instead of on top of the wrist.

For the user to easily wear the device, velcro strips have been added as the wristbands in order to assist with easy removal and installation of the band. This implies that users will need little dexterity when using the NuCare Band.

To observe the data collected from the NuCare Band, users will need to download an Android app designed to display the collected data in a user readable format. The app will also have a different view of physicians allowing them to monitor patients' vitals from the convenience of their smartphones. This app is also necessary in order to first config the NuCare band to connect to a Wi-Fi network in order to transmit its data. Unfortunately, at this time, there are no plans to support IOS devices.



8.5 Graphical Presentation

In Figure 8.1 - 8.4 Shows the Design of the NuCare band by showing its detailed dimensions through its front view, bottom view, side view, and a 3D Model.

In Figure 8.5 and 8.6, we are able to see the proposed UI design of the Android Application. Figure 8.6 shows the collected heart rate data throughout the day which gets plotted nicely onto a live graph. The user is able to adjust the line on the graph to find individual readings of every minute.

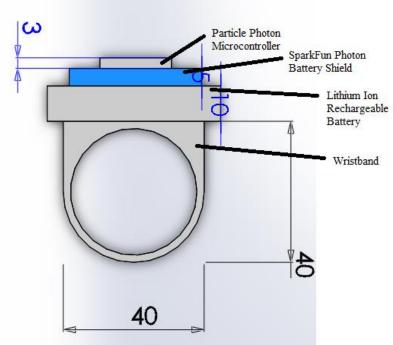


Figure 8.1 - NuCare Band: Front View



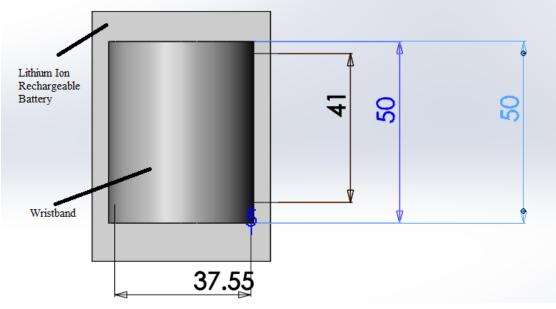


Figure 8.2 - NuCare Band: Bottom View

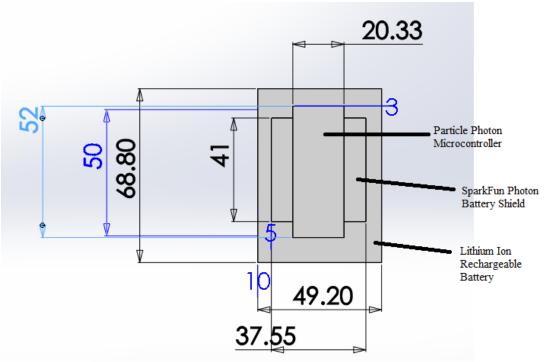


Figure 8.3 - NuCare Band: Top View



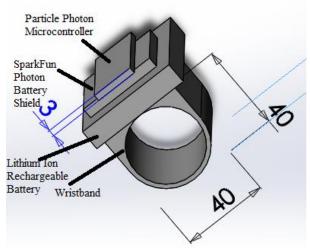


Figure 8.4 - NuCare Band: 3D Model



Figure 8.5 - Android App Login Page



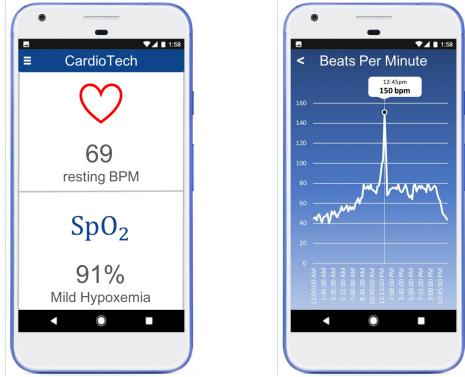


Figure 8.6 - Android App Home Page and BPM Secondary Page

8.6 Technical Analysis

From Don Norman's Book "The Design of Everyday Things" it discusses 7 main criteria for everyday deigns: Discoverability, Feedback, Conceptual Models, Affordance, Signifiers, Mapping, and constraints. [22] Here we will discuss how we have taken these topics into account for our device.

Discoverability

Discoverability aims to create intuitive designs for the user. For our prototype, we will have an app that will display the heart rate data and SpO2 data on the homescreen as seen in Figure 8-2. Clicking into the data on the homescreen will pull up a graph with detailed heart rate and SpO2 information. The app will be designed based on traditional fitness tracker interfaces, so users who own fitness trackers will be more familiar with the layout.

In order to determine the discoverability criteria for the prototype, we analyzed 3 main actions that the user will perform:

- 1. Wear the NuCare Band and adjust until comfy
- 2. Turn on the device with a power switch
- 3. Use Android app to analyze the data collected.



In order to achieve these three main actions:

- 1. The device is in a form of a smart watch/fitness tracker. Allowing users who has used or seen these products to easily put on our device.
- 2. A power switch will be placed on the side of the band, allowing users to easily turn the device on and off.
- 3. The prototype for the application will feature a main menu with the heart rate data and SpO2 data displaying. Pressing on the data will bring the app to a new page with detailed graph information about the two data sets.

Feedback

Feedback is used to inform the user of any changes or issues with the system. For the prototype model, the NuCare Band will include the following:

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

Mobile Application

- When heart rate is pressed on the app main screen, it will display a graph of the detailed heart rate collected throughout the day.
- When SpO2 is pressed on the app main screen, it will display a graph of the detailed SpO2 percentage collected throughout the day.

Conceptual Models

Conceptual models are used to allow users to have a similar experience where possible. In the case of the NuCare Band, it resembles that of a typical watch. In addition, the CardioTech app is designed for easy user navigation with very clear menus. This allows users with experience in using any kind of smart phone application to easily pick up and use the CardioTech app.

Affordance

Affordance makes clear how an object should be used based on its qualities or properties. We have designed a simple app interface that displays the most important information on the main page. In addition, our NuCare Band consists of only one button, to turn the device on and off.

Signifiers

The signifiers of the NuCare Band are similar to those in the feedback section. Most important to keep note of is when the device is turned on, it will have a solid blue LED. While when the device is turned off, no LED will be displayed. In the application, the heart rate will dynamically change according to the current BPM. And the SpO2 level will also change based on percentage.

Mapping

Mapping is very important to allow users to intuitively know the purpose of a control or LED. Therefore, the on off toggle is explicitly labeled with on and off, allowing the user to know when



the device is on or off. In addition, an indication LED placed next to the toggle allows the user to know the status of the device at all times, where solid blue LED is off, and no LED is off.

Constraints

Constraint is the limitation that may restrict a user's interaction with the NuCare Band. User must own a smart phone in order to access their data. No information is available or displayed on the device since there is no screen. Currently only Android users are able to take advantage of the App. However, data can still be logged for users without a smartphone. Users must be familiar with typical smartphone app designs, where the three dashed lines on the top left corner indicates that there are more menu options. They will also need to recognize that clicking on the heart rate data and the SpO2 data will reveal more detailed information. A Hardware constraint will be that the NuCare band must be run on battery. Therefore, users will have to remember to charge their device daily in order to monitor their health throughout the day.

8.7 Engineering Standards

Table 8.1 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 [23]		
ISO 14040:2006			
150 14040:2000	Standard for environmental management Life cycle assessment		
	Principles and framework [24]		
ISO 14044:2006	Environmental management Life cycle assessment Requirements		
	and guidelines [25]		
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.		
IEEE P360	Standard for wearable consumer electronic devices [27]		
IEEE 2700-2017	Standard for Sensor Performance Parameter [28]		
IEC/TR 80002-1:2009	Standard for medical device software [29]		
IEC 80001-1:2010	Standard of risk management for IT-networks incorporating medical		
	devices. [30]		
IEEE Std 11073-	Standard Health informatics -Point-of-care medical device		
10101a-2015			
	communication. [31]		
IEC 60950-1:2001	Standard for rated voltage not exceeding 600V [32]		
ISO 13485:2016	Standard of Medical devices Quality management systems		
	Requirements for regulatory purposes [33]		
IEC 62366-1:2015	Standard of Medical devices Application of usability engineering		
-	to medical devices [34]		

Table 8.1 - Engineering Standards



8.8 Analytical Usability Testing

During the analytical testing stage, the members of CardioTech Labs will review the UI design of the NuCare Band and mobile application. Compiling their own results, which are then brought back to CardioTech Labs research team who will inform our hardware and software division on what needs to be addressed before the final release of the NuCare Band. During the Proof of concept stage, the mobile application is still under development. Therefore, we will only address the testing of the hardware components.

Designer testing

Step by Step instructions for analytical usability testing for Proof of Concept:

- 1. Connect Photon circuit, heart rate sensor, and Blood Oxygen sensor to breadboard
- 2. Connect Photon to computer with the micro USB cable.
- 3. Open CMD and run "particle serial_monitor" command to display current data
- 4. Place finger on heart rate sensor and blood oxygen sensor.
- 5. Open Particle Cloud Console to ensure that Heart Rate data is transmitting
- 6. Open Particle Cloud Console to ensure that Blood Oxygen data is transmitting
- 7. Verify that sensor data is being delivered to the web interface every minute
- 8. Open Thingspeak to verify that data is flowing from WebHook to Thingspeak
- 9. Verify that Thingspeak is graphing the heart rate data.

Heuristic Evaluation

This section analyses the usability problems that users may experience when using the NuCare Band. Members of CardioTech Labs will then use this to ensure that our product will always be meeting the basic needs during the proof of concept and prototyping phases.

For the proof of concept:

- 1. Heart rate sensor is able to detect a person's heart rate when the index finger is placed on the sensor
- 2. Blood Oxygen Level sensor is able to detect a person's Blood Oxygen Level when a finger is placed on the sensor.
- 3. Thingspeak will graph the Heart Rate Data live on the screen
- 4. Particle Cloud will display both Blood Oxygen Level and Heart Rate on its terminal screen.

For the prototype:

- 1. NuCare Band is comfortable to wear
- 2. NuCar Band does not restrict movement
- 3. Sensors are placed in the correct position when the band is closed.
- 4. The device is able to transmit data to the cloud after initial configuration.
- 5. Mobile Application is able to display data collected live on the screen.



8.9 Empirical Usability Testing

Internal Testing

Testing will first occur within the CardioTech team in order to obtain feedback and areas of improvement. The band will be adjusted to fit a specific team members hand, where they will report on size, fitting and comfortability of the device. The main objective will be to place sensors in the correct place when the device is worn. Testing of the sensors accuracy after placement will also take place to ensure that proper placement was achieved. Finally, the final product will include different size wrist bands with the ability to slightly adjust, thus allowing our team to test the device on users with different wrist sizes.

End User Testing

CardioTech labs will enlist help from friends and family with no prior knowledge of the NuCare Band. Users will be asked to use and provide feedback on the product in order to help improve on the final design of the NuCare Band.

Ending User Testing – Survey: These questions will be reworded into a user-friendly feedback form consisting of fillable bubbles from 1-10, allowing users to rate each category.

- 1. Was the device easy to wear?
- 2. Was the device easy to setup?
- 3. Was the device comfortable to wear for long periods of time?
- 4. What was your first impressions of the device?
- 5. Would this be something you are willing to wear every day? If not, why?
- 6. Was the App intuitive to use? If not, what could be done to improve it?
- 7. Would you recommend the NuCare Band to other? Explain.

Additional Survey Questions for Heath Practitioners:

- 1. Would this be something you could see your patients using after being released from the hospital?
- 2. Would you use this in order to help monitor your patient's health data?



User Feedback Form

Questions:12345678910First Impression of the NuCare Band00<	Rating Scale: 1-10 (1: Bad and 10: Excellent)										
Ease of Wearability 0	Questions:	1	2	3	4	5	6	7	8	9	10
Ease of Setup 0 <	First Impression of the NuCare Band	0	0	0	0	0	0	0	0	0	0
Comfortability000<	Ease of Wearability	0	0	0	0	0	0	0	0	0	0
Would you wear the device daily?OOO <th< td=""><td>Ease of Setup</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></th<>	Ease of Setup	0	0	0	0	0	0	0	0	0	0
Would you wear the device daily to have a better diagnosis?OO <t< td=""><td>Comfortability</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></t<>	Comfortability	0	0	0	0	0	0	0	0	0	0
better diagnosis?000 <td>Would you wear the device daily?</td> <td>0</td>	Would you wear the device daily?	0	0	0	0	0	0	0	0	0	0
How intuitive was the Android application?		0	0	0	0	0	0	0	0	0	0
For Heath Practitioners only: How likely will you recommend this device to your patients? O <td>How intuitive was it to use the device?</td> <td>0</td>	How intuitive was it to use the device?	0	0	0	0	0	0	0	0	0	0
How likely will you recommend this device to your patients? 0<	How intuitive was the Android application?	0	0	0	0	0	0	0	0	0	0
your patients? 0	For Heath Practitioners only:										
		0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0





8.10 Conclusion

User Interface Design is a very important aspect of product. It will enable users to either easily learn and use the product or make it difficult to a point where they will not want to use it. The UI Appendix help to illustrate the necessary UI components in order for users to experience comfort, ease of use and familiarity. Though the analysis of the seven fundamental principles of UI design, CardioTech Labs has been able to reach our goal in providing users with a comfortable wrist band, an intuitive mobile application, and a device that is similar in design to current fitness trackers and smartwatches. To ensure that both the hardware device and the mobile application works as intended, CardioTech Labs will work closely with users, collecting feedback and test results which will enable us to perform design improvements. For the proof of concept design, we aim on providing on a minimalistic design, while showing the basic functionalities of all sensors and display data. For the prototype version, CardioTech Labs will strive to meet our goals of comfort, ease of use and familiarity.



9. Appendix C – ENSC 440 Plan

9.1 Introduction

CardioTech Systems is designing a wearable medical device that would be worn on the user's wrist, thus enabling them or the doctors to monitor their vital signs. From the Health Conference on 2017, doctors are showing concern over the health of newly released patients. [35] NuCare Band would then allow doctors to monitor their patient's condition through a cloud wirelessly. Also, for users who aren't patients, it allows them to understand their health condition through the app which will be connected to NuCare Band.

In order to keep our planning on track, the following sections will discuss more about the scope analyses, market research, time management and the cost estimations of the project. This would then reduce slippage or any risk that might delay our project.

9.2 Scope

NuCare Band is a wearable, non-invasive device that allows doctors to monitor their patients' vital signs and help them before it's too late. The blood oxygen and the pulse sensor are embedded in the wearable band on the wrist on the user. A microcontroller is used to transmit the data to a smart device through Wi-Fi. An application will process the information and display the data on a cloud. The user has the option to receive feedback on their condition and for the doctors to analyze the users' or patient's condition. The primary demographic of NuCare Band is the newly-released patients that just got released from the hospital. This appendix outlines the development and process of the Nu-Band prototype.

9.3 Benefits

It's critical for hospitals and medical facilities to monitor the patients' recovery condition outside the hospital via remote monitoring. A new survey released by the Canadian Medical Association (CMA) shows physicians are very concerned over Canadian's patients' access to care. [36] Our proposed device allows doctors to track and monitor their patients' condition wirelessly using NuCare Band, regardless of their location. This will also improve hospitals' quality of care overall. Patients themselves will be able to better understand their own health through the app.

This product can be further improved upon for a vast range of potentials, such as medical wearable device for the public who are interested in understanding one's body and health.



9.4 Risks

Health wearables are still most commonly associated with fitness devices that are worn on a person's wrist to count their steps or monitor some level of their body's biometrics. The biggest problem with these devices is the accuracy. As information gathered through the NuCare Band would be shared with the doctors, this may negatively affect the doctor's analysis of the patient's wellness. This could result in doctors providing inaccurate analysis of the patient, not detecting a heart condition (false negative). CardioTech Labs plans to test with other sensors to improve the accuracy of the device. Accuracy can also depend on the location where the wearable is worn. As for now, CardioTech Labs has implemented the pulse rate and oxygen level sensor to be measured on the wrist. CardioTech Labs will be testing different sensor positioning on the wrist to improve accuracy.

With long operating hours, dissipated heat in combination with a high temperature may cause NuCare Band's components to exceed their maximum operating temperatures. CardioTech Labs will carry out extensive tests to ensure that this will not happen as it might cause harm to the user's skin. CardioTech Labs will also ensure that the device will be fabricated well through the testing of multiple materials.

Another potential risk is the failure to transmit data using the Particle Photon. Our proposed design collects large amounts of information every single day. Essentially, all the information is fed into one server. With these collected medical information, NuCare Band can be used to accurately analyze things, like diagnostic trends and disease outbreaks. Failing to transmit data would result in doctors not being able to keep track of their patients' wellness. Also, data security is essential when dealing with medical facilities' information. [37] To prevent data to be hacked, CardioTech plans to have our device encrypted.

9.5 Market & Competition

9.5.1 Project Market

Hospital discharge can be a challenging process for healthcare professionals, patients, family members and caretakers. It is crucial that patients are not in hospitals for unnecessary amount of time. Therefore, the involvement of patients and their families is crucial to successful and timely discharge planning. [38] According to an article, the 28-day readmission rate for older people has double from 103,000 in 2001–02 to 201,000 in 2010–11, suggesting that the health condition of these patients should be monitored. [39]

As of right now, CardioTech Labs focuses on providing aid for doctors to monitor newly discharged patients; however, we plan on providing public access to our device as wearables are becoming widely used by the public. According to a Cision article, the wearable medical devices market is estimated to reach USD 14.41 Billion by 2022 from USD 6.22 Billion in 2017, at a



Design Specifications - Cardiac Bio-System Monitoring

CAGR of 18.3% during the forecast period. [40] It is believed using a wearable device to collect data allows the public to understand their health and body's condition.

Eventually, CardioTech Labs would like to help improve the accuracy of the device to aid the users in monitoring their health conditions. CardioTech Labs would like to help the patients and the public in monitoring and improving their health conditions.

9.5.2 Possible Competition

Connex Vital Signs Monitor



Figure 9.1 - Connex Vital Signs Monitor

Everion



Figure 9.2 - Biovotion Everion



Figure 9.3 - Embrace

The Connex Vital Signs Monitor is a touchscreen monitor that is designed by Welch Allyn to monitor patients who are suffering in low-acuity care areas. The monitor measures pulse oximetry, non-invasive blood pressure, temperature, EtCo2, respiration and more. The monitor sends vital information wirelessly whenever and wherever clinicians need it. [41]

Biovotion Everion is a non-invasive wearable device that is designed to measure vital signs with multiple sensors. The vital signs measured using Everion that would be collected continuously are heart rate, skin temperature, respiratory rate, oxygen blood level. Everion also collects and records real time data continuously. Right now, there are two versions of the device available, the fitness and medical version. However, the medical version is currently not available in all markets. [42]

The company Empatica, has developed a device capable of identifying seizures using machine learning and notifying the patient's caregivers. The device, Embrace, which has been FDA approved, monitors the sympathetic nervous systems through the skin and analysis the electrothermal activity. [43]



Loop



Spry Health is designing Loop, which is a non-invasive wearable device that measures blood pressure, heart rate, oxygen saturation, CO2 levels and respirations. Data from Loop will be combined with an analytic platform for medical facilities to easily analyze their data. Loop is designed to improve health conditions through the measuring of vital signs continuously and early detection of clinical deterioration. [44]

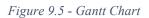
9.6 Project Timeline

Figure 9.5 shows the Gantt Chart for NuCare Band as well as document deadlines for ENSC 405W. It includes four main categories, consisting of: Pre-Alpha Phase, Alpha Phase, Beta Phase and Final and Integration Phase, which consists of hardware, software and testing tasks. In addition, below in Figure 9.6, it shows the Milestones of NuCare Band and the deadlines that we have set as a company. A contingency of at least 5 days is added to each category.

CardioTech Labs

Design Specifications -	 Cardiac B 	Bio-System I	Monitoring
Besign speemeations	Curaine D	no bybtemi	, ionicoring

Pre-Alpha Phase 25	days	Aug 1	5 - Sep 18			
HW: Blood pressure sensor construction—10	days 🔚 🖉 A	Aug 15 - Aug 28				
HW:Test the blood pressure sensor independent	ently—6 days 📘	Aug 29 - Sep 5				
HW: Test integration of all sensors	6 d	ays 📰 Sep 6 - Se	ep 13			
SW: Build Database using Firebase	8 days	Aug 29 - Sep	p 9			
SW:Connect photon to the blood pressure set	nsor 9 d	ays 📰 Sep 6	- Sep 18			
SW: Creation of App for mobile platforms —		7 days 📰 Sep 1	0 - Sep 18			
Alpha Phase		—23 days	Sep	o 19 - Oct 20		
HW: Positioning of sensors			Sep 19 - Sep 28			
HW: Power Shield Photon arrives		——4 days 📰 Se	ep 19 - Sep 24			
HW: Incorporation of LED and buttons		8 days 📘	Sep 24 - Oct 3			
HW: Improve band's comfortability & placem	ent	7 d	ays 📰 Oct 4 - C	Oct 12		
HW: Implementation of rechargeable battery			—5 days 📰 Oct	t 13 - Oct 20		
SW: Transfer functionality from Photon to Ele	ctron	—10 days	Sep 19 - Oct 2			
SW: Test functionality after migration		6 da	ys 🔜 Oct 3 - Oc	rt 10		
SW: Available for Android			-7 days 🗾 Oct	t 11 - Oct 20		
Beta Phase			——————————————————————————————————————	Oct 21 - N	ov 7	
Construction of the Band's Shell			——————————————————————————————————————	Oct 21 - N	ov 7	
Data Storage			——-13 days 📘	Oct 21 - N	ov 7	
Final Integration and Testing			;	20 days	Nov 8 - Dec 5	
Test data accuracy and no corruption				20 days	Nov 8 - Dec 5	
Test on end users			;	20 days	Nov 8 - Dec 5	
Using machine learning to analyze data				20 days	Nov 8 - Dec 5	
20	018					
A	ug	Sep	Oct	Nov	Dec	2018



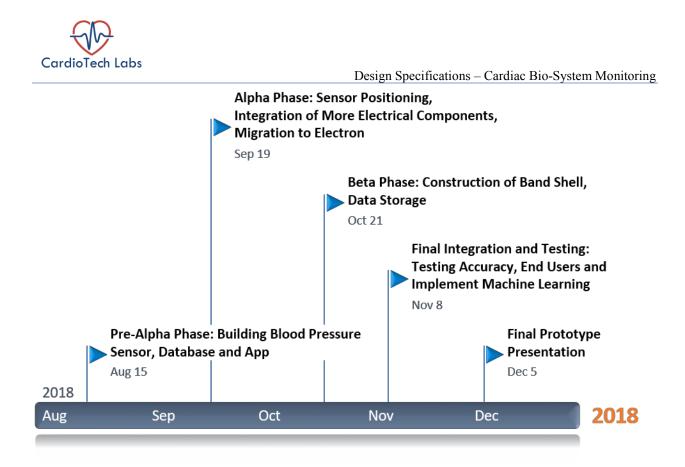


Figure 9.6 - Milestones

9.7 Cost Analysis

Current expenditures:

Materials	Quantity	Cost (USD) – Tax and Shipping
Particle Photon Microcontroller	2	\$38
Pulse Sensor	1	\$24.99
MAX30100 Pulse Oximeter Heart Rate Sensor	1	\$12.99
ICStation Heartbeat Sensor	1	\$12.95
Shipping & Tax		\$30
Contingency Fund		\$100
		Total: \$119

Table 9.1- Current Expenditures



Expenditures during the prototyping phase:

Materials	Quantity	Cost (USD) – Tax and Shipping
Components to build the blood Pressure Sensor	1	\$50
Lithium Ion Rechargeable Battery - 2000mAh	1	\$12.95
Lithium Ion Rechargeable Battery - 1000mAh	1	\$9.95
SparkFun Photon Battery Shield	2	\$25.9
Particle Electron Chip + SIM Card Package	2	\$49
Shipping + Tax		\$30
Contingency Fund		\$100
		Total: \$277.8

Table 9.2 - Expenditures during the prototyping phase

In order to fund the NuCare Band, we have decided to apply for both the Wighton Engineering Development Fund, and the Engineering Science Student Endowment Fund. However, these applications will not be available until our final prototype design in ENSC 440. Therefore, the founding members of CardioTech Labs will split payment equally until a source of funding is secured. In the case that funding is declined, members of Cardio Tech Labs have agreed to fund the project upwards of \$100 each, giving a grand total of \$500.

Currently, we have spent just over \$180 on 2 photon controllers, 1 pulse sensor and 3 oxygen sensors, which can be seen in Table 9.1. We had to buy several blood oxygen sensors as one of the blood oxygen level sensors - MAX 300 level - wasn't compatible with our microcontroller. For our prototype phase, we will be purchasing blood pressure sensor, 1000mAh and 2000mAh Lithium Ion batteries, photon battery shield, and Particle Electron microcontroller. The expenditure of Wi-fi and cellular models including shipping and tax will be \$177.8. We have also included a contingency fund of \$100; thus, the total will be \$277.8 in USD.



9.8 Company Organization

9.8.1 About Us

CardioTech Labs was created with the mission to provide accurate data to doctors and nurses for efficient care and treatment to patients.

The NuCare Band offers a non-intrusive way to monitor cardiovascular patterns which will be logged at the hospital's database as well as allowing caregivers live access to the data.

The band allows the continuous monitoring of patient's condition after hospital discharge, and daily response to treatments.



9.8.2 Our Team



Alfonso Diaz adiazalo@sfu.ca Chief Executive Officer

Alfonso is a fourth year Electronics Engineering student currently doing research at the Communication Networks Laboratory. He is interested on smart DIY projects and machine learning. As the Chief Executive Officer, he possesses the experience to organise the objective and plan of actions to be followed. He is also in charge of hardware integration of the device.



Carson Lai ckl41@sfu.ca Chief Technology Officer

Carson is a fifth-year Computer Engineering student at Simon Fraser University. Having previously worked at Ritchie Bros. Auctioneers, Carson specializes in Information Technology Support. As the Chief Technology Officer, he is quick in adapting and changing to any technological obstacles or challenges he faces. He also contributes his software knowledge to our project



Li Teng Cheok lcheok@sfu.ca Chief Information Officer

Li Teng is a fifth-year System Engineering student at Simon Fraser University. She has just completed 4 months at PerfectMind as a Quality Assurance Analyst where she took part in testing the accounting aspect of the software. As the Chief Information Officer, she is responsible for gathering technology information to achieve the purpose of the product. She is also in charge of the testing and data analysis of the product.



Qassam Yomok qyomok@sfu.ca Chief Product Officer

Qassam is a fourth-year Computer Engineering student at Simon Fraser University. Qassam's primary interests are in machine learning and FPGA design flow. He worked as a software developer at Binary Stream where he developed a software to facilitate firms billing process. During his work, Qassam gained a solid understanding about Agile development cycle and team work. He is also in charge of the software integration of the project.



Younghoo Jee yjee@sfu.ca Chief Operating Officer

Younghoon Jee is a fifth-year Electronic Engineering student at Simon Fraser University. He worked as quality assurance and embedded system developer at T2 systems where he fixed many software test cases using gtest. With his knowledge of development workflow and hardware testing, he is part of the hardware team.



9.9 Conclusion

Medical wearable technology is changing the healthcare industry, as doctors and medical professionals are trying to get their hands on these devices to obtain accurate, real-time information about their patients. [1] The purpose of the project was to design a device that would benefit doctors and users to monitor health conditions. Researching more about the market have provided us a better understanding of the benefits and potential risks of NuCare Band. CardioTech has also proposed project timelines and milestones that the team plans to achieve by December 2018. Furthermore, our target budget gives us a good grasp on what parts we expect to obtain and keeps us aware of how we will manage funding.