June 9, 2019

LumoAnalytics

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

RE: ENSC405/440 Requirement Specification: Pulse Tracer

Dear Dr. Rawicz,

Please see attached the Requirements Specifications for the Pulse Tracer by LumoAnalytics. Our goal for this device is to use photoplethysmography (PPG) to remotely monitor the heart and respiratory rates of stationary patients who are typically left unattended. We hope to provide a means of accurately measuring these metrics without the use of wearable technology in an attempt to reduce levels of discomfort seen by patients. With this technology, we can allow individuals to live independently while still assuring they are safe to do so.

The attached document will provide detailed specifications for the functions and requirements of the Pulse Tracer at three design stages, specifically the Proof of Concept, Prototype, and Final Product. The document will provide an overview of the device and list the specific requirements of the system. The document will also outline various engineering standards that the Pulse Tracer must conform to and will discuss safety and sustainability concerns of the product.

LumoAnalytics is comprised of a team of five engineering students: Winsey Chui, Wenpei Li, Huy thong Bui, Corey Myrdal, and Brittany Hewitson. Our team members come from a range of engineering concentrations, each bringing a particular skill set to the team that we believe will contribute to the success of the project.

Thank you in advance for taking the time to review our requirements specifications. If you have any questions or concerns, please feel free to contact our Chief Communications Officer, Huy thong Bui, by email at htbui@sfu.ca.

Sincerely,

Brittany Hewitson
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LumoAnalytics

Requirements Specifications for
Pulse Tracer

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Abstract

This document outlines the requirements specifications for Pulse Tracer, a patient monitoring system aimed towards tracking the heart and respiratory rates of immobile elderly patients. The device consists of three main components:

- **Hardware System**
  An imaging system responsible for remotely capturing the raw heart rate data from the patient's skin in the form of videos.
- **Image Processing System**
  Responsible for automatically detecting regions of interest from the image data collected by the hardware system and determining the heart rate and respiratory rates of the patient.
- **User Interface**
  An application that allows the patients and their approved caregiver to interact with the data by viewing historical and real-time heart rate and respiratory rates. It also allows the ability for users to flag significant changes in heart rate and respiratory rates as periods of exercise or other known causes.

This document will begin by providing a system overview of Pulse Tracer, describing the high-level functionality of the device. Next, the functional requirements for each of the above components will be detailed and sub-categorized according to which of the design phases they correspond to. The project is expected to consist of three design phases, including a proof of concept, engineering prototype, and the final product.

In addition to the functional requirements of each component, this document will also discuss the non-functional requirements for Pulse Tracer, highlighting the engineering standards the device must conform to and address sustainability and safety considerations. This document will also include an acceptance test plan in Appendix A.

Table of Contents

List of Tables

List of Figures

Glossary

PPG: Photoplethysmography is a simple and low-cost optical technique that can be used to detect blood volume changes in the microvasculature in a bed of tissue

PCB: a printed circuit board

LED: A light-emitting diode is a semiconductor light source that emits light when current flows through it

Respiratory Rate: The number of breaths per minute

Nyquist Rate: The Nyquist rate is twice the bandwidth of a bandlimited function or a bandlimited channel.

Sleep apnea: A potentially serious sleep disorder in which breathing repeatedly stops and starts.

Arrhythmias: A problem with the rate or rhythm of the heartbeat

Oxyhemoglobin: The form of hemoglobin after binding with oxygen.

Deoxyhemoglobin: The form of hemoglobin without oxygen.

SD: Secure Digital is a proprietary non-volatile memory card format developed by the SD Card Association for use in portable devices.

Raspberry Pi: A series of small single-board computers developed by the Raspberry Pi Foundation

FDA: The Food and Drug Administration

1 Introduction

1.1 Background

With improvements in healthcare technologies, the life expectancy in Canada is continuing to increase [2]. However, with this increase comes the need to provide more health care services for the aging population. This can prove to be problematic, as nursing homes and other health care facilities can become crowded and unable to take additional patients. This leads to the elderly living at home with little to no regular supervision from caregivers.

With Pulse Tracer, LumoAnalytics hopes to provide patients the ability to be independent in their own home while still ensuring a professional caregiver can monitor their health. The Pulse Tracer accomplishes this through the use of photoplethysmography (PPG) to remotely monitor the heart and respiratory rates of patients [3]. Using this data, Pulse Tracer is able to determine baseline heart and respiratory rates and detect when significant changes from these values occur. Professional caregivers are then able to view this data to determine if the patient may have any emerging health conditions, as well as to monitor patients living with conditions such as sleep apnea and arrhythmias [4]. Pulse Tracer can also be used to detect behavioural changes in the patient, such as predicting when a patient is encountering periods of stress that could potentially lead to medical emergencies such as a heart attack [5].

1.2 Scope

This specifications document will provide a system overview for Pulse Tracer and specify the functional requirements of the device. The requirements have been grouped by their related system components and have been sub-categorized according to which stage of design they correspond to. This document will also outline the non-functional requirements of Pulse Tracer, including compliance with engineering standards as well as sustainability and safety considerations.

1.3 Intended Audience

This document is intended to be reviewed by the members of LumoAnalytics, Dr. Craig Scratchley, Dr. Andrew Rawicz, the teaching assistants for ENSC 405W/440, and any potential customers and partners interested in the device.

1.4 Requirements Classification

The requirements classification used in this document will be as follows:

Req {section code}.{subsection code}.{requirement number}-{phase number}

The section and subsection codes map the requirement to its corresponding category, while the phase number indicates which stage of the design the requirement will be met. The following table shows the three design stages in this project.

Design Stage	Description
Phase 1	Proof of Concept
Phase 2	Engineering Prototype
Phase 3	Final Product

Table 1.1: Design Stages

The proof of concept stage will be completed at the end of ENSC 405W, the engineering prototype will be completed in ENSC 440, and the final product represents the functions of the product once its in production.

2 System Overview

Pulse Tracer is an unobtrusive monitoring device designed to monitor the heart and respiratory rates of immobile patients. Through the use of near-infrared light, information is captured from the subject and processed to calculate heart rate and respiratory rates. The device is split into three main components: a hardware component to capture data, a software component for processing, and a user interface to view the data. These components will be described in further detail in the subsections below.

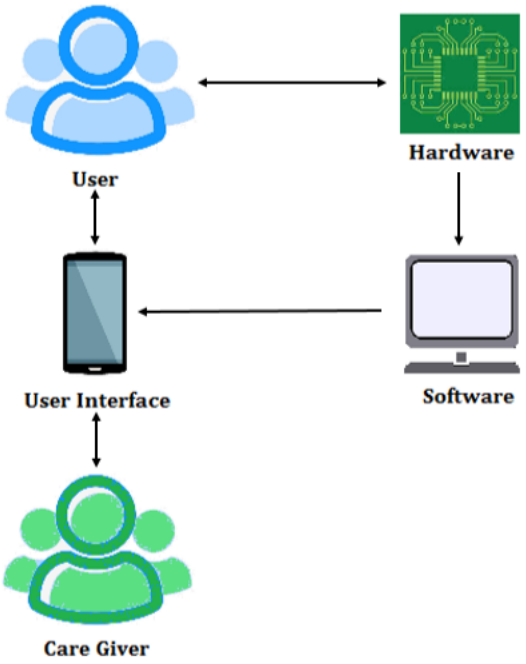

Figure 2.1: Conceptual Diagram of Pulse Tracer

2.1 Hardware Design Overview

Optical properties of near-infrared light in living human tissue state that while most tissue is nearly transparent to the light waves, absorption and scattering can be caused by optical pigments, such as oxyhemoglobin and deoxyhemoglobin [6]. As such, the reflection of hemoglobin can be caught and used to provide information about a subject's heart rate and blood oxygen levels. Because of this, near-infrared LEDs are attached to a custom PCB board with regulated current and voltage, and

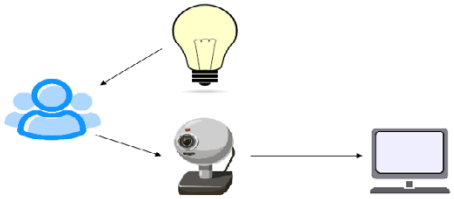

Figure 2.2: Overview of Hardware System.

are used to illuminate the patient for data collection. Light is reflected from the patient according to principles of blood absorption described earlier, and the reflection will be captured with a webcam. This data is sent to a single board computer for data processing. A conceptual relationship between each hardware component is shown in Figure 2.2.

2.2 Software Design Overview

Each frame of video footage captured by the camera is processed to find the average intensity within several automatically-found regions of interest. Each region of interest is then compared to find the best quality of data. The time series of selected average intensities is passed through data analysis in the form of filtering, motion correction and mathematical analysis to calculate a final output of heart rate and respiratory rate. This information is then stored in an encrypted database for user access. The process described in this section is detailed in the figure below.

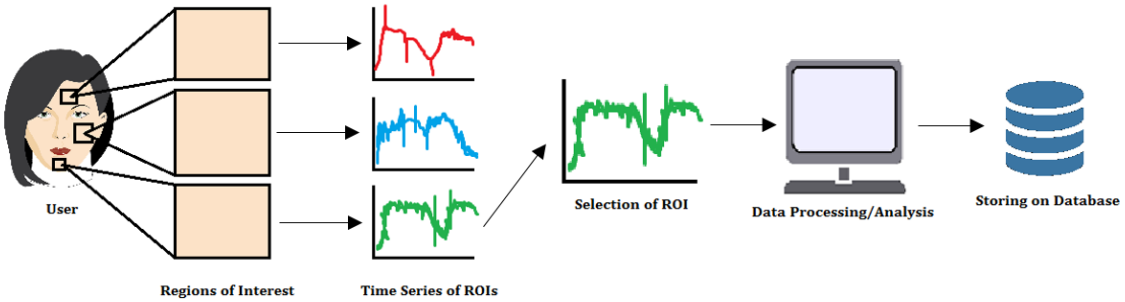

Figure 2.3: Overview of Software Design

2.3 User Interface Design Overview

Pulse Tracer is paired with a simple, easy-to-use application that is used by both the patient as well as caregivers. The app has different settings depending on whether the user is the patient or caregiver. However, both settings allow the user to wirelessly view real time heart rate and respiratory rate measurements, as well as previous heart rate and respiratory rate measurements stored on the database.

On the patient setting, a notification is sent to the user to check on their status during periods where heart rate or respiratory rate exceed a pre-determined threshold. Patients have the option of flagging their data for periods of exercise, or other times where heart rate or respiratory rate may be elevated or slowed due to a known cause.

On the caretaker setting, a list will be given of all patients under their care to select from. Caregivers will not be able to interact with the data beyond viewing it.

3 General Requirements

Pulse Tracer aims to remotely track the heart and respiratory rates of patients such as the elderly and those with sleep apnea, for the purpose of providing more independence without the need for regular supervision from caregivers. In order to achieve this, the device must be placed in a convenient, unobtrusive location in the patient's home in order to be able to remotely and accurately collect and analyze data, as well as adjust for external noise. Pulse Tracer also provides a viewing platform for the data, which will notify the patient and possible caregivers of possible abnormalities in the data. The following sections will detail the general functional, system and performance requirements.

3.1 Functional

Requirement ID	Requirement Description
Req 3.1.1 - I	The device must accurately identify a patient's heart rate
Req 3.1.2 - I	The device must accurately identify a patient's respiratory rate
Req 3.1.3 - I	The device must be non-contact
Req 3.1.4 - I	The device must work at a distance of approximately arm's reach
Req 3.1.5 - II	The device must send heart rate data to a database to be analyzed
Req 3.1.6 - II	The device must send respiratory data to a database to be analyzed
Req 3.1.7 - II	The device shall incorporate hardware to allow for blood oxygen level measurements
Req 3.1.8 - II	The device must be able to identify abnormal changes in heart rate and respiratory rate
Req 3.1.9 - II	The device must be able to notify the patient of abnormal changes in heart rate and respiratory rate
Req 3.1.10 - II	The device must have an user interface
Req 3.1.11 - II	The device must allow caregivers and patients the ability to view data on the interface
Req 3.1.12 - III	The device must increase tracking distance to 1m or more
Req 3.1.13 - III	The device must include motorized facial tracking

Table 3.1: Functional Requirements

3.2 System

Requirement ID	Requirement Description
Req 3.2.1 - I	The device is intended to be used on humans
Req 3.2.2 - I	The device is intended to be used on immobile patients
Req 3.2.3 - I	The device is intended for indoor use
Req 3.2.4 - II	The device must have the ability to be mounted depending on the user application
Req 3.2.5 - II	The device must be in an enclosed container
Req 3.2.6 - II	The device must work on patients of all skin colours
Req 3.2.7 - III	The device is intended for both mobile and immobile patients
Req 3.2.8 - III	The device is intended for use both indoors and outdoors

Table 3.2: System Requirements

3.3 Performance

Requirement ID	Requirement Description
Req 3.3.1 - I	The detector must sample light at a rate fast enough to provide an adequate number of data points
Req 3.3.2 - I	The system must be able to provide real time results without a large time delay
Req 3.3.3 - I	The system must provide accurate measurements within reasonable error tolerances

Table 3.3: Performance Requirements

4 Hardware Requirements

As stated in Section 2.1 Hardware Design Overview, Pulse Tracer uses biophotonics to calculate heart rate and respiratory rate, and thus require a near-infrared light source of several LEDs operating at the same irradiance to avoid uneven illumination. The reflected light is caught by a detector, followed by connection to a processing unit. Because the hardware component contains several electrical aspects, a custom PCB will be designed so Pulse Tracer can be completely enclosed to avoid contact with electrical components and fully grounded. Given that the final version of Pulse Tracer is intended for both mobile and immobile patients, the device is equipped with a rechargeable battery for the purpose of easy movement.

In terms of the processing unit, the average heart rate of a patient is approximately 1.3Hz [7]. Given this, the Nyquist rate is 2.6Hz, and thus will need a minimum sampling rate of 5.2Hz. Because of this, we require the clocking speed of our Raspberry Pi to be above this. From here, data analysis will be completed and sent wirelessly to the database.

4.1 General

Requirement ID	Requirement Description
Req 4.1.1 - I	The system must include a light source
Req 4.1.2 - I	The system must include a camera to detect light
Req 4.1.3 - I	The system must be connected to a power source
Req 4.1.4 - I	The system will include a Raspberry Pi
Req 4.1.5 - I	The camera must be able to connect to the Raspberry Pi
Req 4.1.6 - I	The Raspberry Pi must have five I/O ports
Req 4.1.7 - I	The system must include an SD card
Req 4.1.8 - I	The operating clock speed on the Raspberry Pi will be at a minimum of 100 Hz
Req 4.1.9 - I	The system must include a switch to power the device on and off
Req 4.1.10 - II	The Raspberry Pi must connect to WiFi
Req 4.1.11 - II	The hardware components must be confined to an enclosed space with openings for the camera lens, LEDs, and any wires that leave the system
Req 4.1.12 - II	The system must be able to be powered on and off through the user interface
Req 4.1.13 - III	The microcontroller must be customized for the device

Table 4.1: General Hardware Requirements

4.2 Electrical

Requirement ID	Requirement Description
Req 4.2.1 - I	The system must include a PCB
Req 4.2.2 - I	All wires should be insulated and grounded for safety
Req 4.2.3 - I	The input current must not exceed LED current limits
Req 4.2.4 - I	The system must contain multiple LEDs placed strategically on the PCB
Req 4.2.5 - I	The LEDs will be attached to the PCB for power supply and current limiting
Req 4.2.6 - I	The Raspberry Pi will have an operating voltage of approximately 5V [8]
Req 4.2.7 - I	The Raspberry Pi will have an input current of approximately 2A [8]
Req 4.2.8 - I	The PCB must be compatible with the microcontroller
Req 4.2.9 - II	The PCB will be customized for the circuit
Req 4.2.10 - II	The custom PCB must be compatible with the microcontroller
Req 4.2.11 - II	The device must be battery-powered
Req 4.2.12 - II	The device must be protected from power surges
Req 4.2.13 - II	The battery must be rechargeable
Req 4.2.14 - III	The PCB will be designed as compact as possible

Table 4.2: Electrical Requirements

4.3 Optical

Requirement ID	Requirement Description
Req 4.3.1 - I	The LEDs must emit the same irradiance
Req 4.3.2 - I	The LEDs must have a wavelength in the near-infrared range
Req 4.3.3 - I	The LEDs must sufficiently illuminate the region of interest
Req 4.3.4 - I	The LEDs shoule be able to operate continuously
Req 4.3.5 - II	The LEDs must be properly housed for effective illumination
Req 4.3.6 - II	The LEDs must be as unobtrusive as possible
Req 4.3.7 - II	The system must be able to include additional LEDs operating at a shorter wavelength to allow for pulse oximetry wavelength
Req 4.3.8 - III	The LEDs should be reliable over long term usage

Table 4.3: Optical Requirements

5 Software Requirements

The goal of Pulse Tracer is to identify the heart and respiratory rates of a patient from image data. Therefore, the system will need to include an image processing algorithm to detect changes in the intensity of light reaching the detector. This algorithm will first need to be able to detect a region of interest on the patient's face in order to compare the light intensity at the same location over time. This will ensure the changes in intensity result from the change in blood volume within the patient rather than the result of comparing light intensities at different locations on the patient. The algorithm will also need to account for changes in illumination in the room where the patient resides. This is important for distinguishing changes in light intensity that correspond to the heart rate of the patient compared to changes in intensity that result from varying illumination in the room.

Pulse Tracer will also need to include a user interface to give users the ability to view heart and respiratory rates. This will initially be in the form of a web application for phase 2, and then a phone application in phase 3 to allow users the ability to easily access their data. In order to encourage adoption of the device in the elderly population, the Pulse Tracer will need to address the biggest concerns those over the age of 60 have with using technology. This includes ensuring the collected data is secure such that only the user and their professional care givers can access the data [9].

The following tables outline the requirements addressing these concerns.

5.1 Data Analysis

Requirement ID	Requirement Description
Req 5.1.1 - I	The software must include an algorithm to extract heart rate from detected light intensity
Req 5.1.2 - I	The software must include an algorithm to detect respiratory rate
Req 5.1.3 - I	The software must automatically select the region of interest on a patient
Req 5.1.4 - I	The software must accommodate changes in illumination
Req 5.1.5 - II	The software must be able to identify significant changes in heart rate over time
Req 5.1.6 - II	The software must be able to identify significant changes in respiratory rate over time
Req 5.1.7 - II	The data must be compressed into average values for days and weeks
Req 5.1.8 - II	The software will identify additional regions of interest on the face for increased accuracy
Req 5.1.9 - III	The software must include facial tracking
Req 5.1.10 - III	The software will be able to identify regions of interest aside from on the face

Table 5.1: Data Analysis Requirements

5.2 User Interface

Requirement ID	Requirement Description
Req 5.2.1 - I	The processed data will be viewed on a monitor
Req 5.2.2 - II	The system must include an application for users to view heart rate data
Req 5.2.3 - II	The user interface of the application should be simple and easy to use
Req 5.2.4 - II	The application must include a database to store heart rate data over time
Req 5.2.5 - II	The application should alert users when heart rate or respiratory rate stray from their average values
Req 5.2.6 - II	Data stored in the application must be secure and not shared with anyone other than the patient and associated caregiver(s)
Req 5.2.7 - II	The application must be able to connect wirelessly to the patient data
Req 5.2.8 - II	The users must be able to flag data through the application
Req 5.2.9 - III	The application must work on Android, IOS, and Windows operating systems
Req 5.2.10 - III	The application will include data encryption for security measures
Req 5.2.11 - III	The database must be able to accommodate multiple users

Table 5.2: User Interface Requirements

6 Engineering Standards

Medical device development is an industry where following the proper standards is especially important. In order to guide the development as well as to ensure the safety and effectiveness of the system, the following standards shall be followed. Standards for the US FDA are mentioned instead of Canadian standards as seeking approval with the FDA will allow the product to be exposed to a larger market.

6.1 General System Standards

Requirement ID	Requirement Description
Req 6.1.1	The system and company shall comply with ISO 13485 which outlines the structure of a quality management system to provide an outline for development of the device as well as a method to prove the safety and effectiveness of the product [10]
Req 6.1.2	The system and company shall comply with ISO 14971 which specifies the application of risk management to medical devices which allows the company to determine the safety of the device [11]
Req 6.1.3	The system shall comply with IEC 80601-2-49 which provides requirements for the basic safety and performance of multifunction patient monitoring equipment[12]
Req 6.1.3	The system shall comply with IEC 62366, which details the standard for application of usability engineering in medical devices [13]
Req 6.1.4	The system and company shall comply with 21 CFR 820 which outlines the specific requirements for a quality management system with various controls such as design and document controls that is valid for the US market [14]
Req 6.1.5	The system shall be classified as specified in 21 CFR 860 which provides several device classes outlining the risks and approval process for different kinds of medical devices [15]
Req 6.1.6	The system shall comply with 21 CFR 880 which provides requirements for general hospital and personal use devices for both their safety and effectiveness [16]

Table 6.1: General System Standards

6.2 Hardware System Standards

Requirement ID	Requirement Description
Req 6.2.1	The system shall comply with IEC 60601-1 which specifies the general requirements for basic safety and essential performance of medical electrical equipment [17]
Req 6.2.2	The system shall comply with IEC 60601-2-57 which specifies the particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic or monitoring use [18]
Req 6.2.3	The system shall comply with IEC 60950-1, which is the safety standard of battery-powered information technology equipment with a rated voltage not exceeding 600V [19]
Req 6.2.4	The system shall comply with IEC 62133 which outlines requirements and tests for the safe operation of lithium and other non-acid portable batteries[20]
Req 6.2.5	The system shall comply with 21 CFR 1010 which outlines standards for electronic products mostly related to emitted EM radiation and proper grounding of such products [21]
Req 6.2.6	The system shall comply with 21 CFR 1040 which specifies limits for light-emitting products such that they are safe for human use [22]

Table 6.2: General System Standards

6.3 Software System Standards

Requirement ID	Requirement Description
Req 6.3.1	The system software shall comply with IEC 62304 which contains requirements for the development of medical software and the software within medical devices [23]
Req 6.3.2	The system shall comply with IEEE 802.11 which provides requirements for devices using wireless LAN communication [24]
Req 6.3.3	The system shall comply with IEEE 1074, which is the standard for developing a software project life cycle process [25]
Req 6.3.4	The system shall comply with IEEE 11073, which details the standard for personal health medical device communication [26]

Table 6.3: General System Standards

7 Safety and Sustainability

7.1 Safety

Requirement ID	Requirement Description
Req 7.1.1 - I	The device will not be built using any toxic materials
Req 7.1.2 - I	The heating in the system should not overheat or harm customers skin.
Req 7.1.3 - II	The electronics will be fully enclosed and under normal operating conditions will not pose an electrical hazard
Req 7.1.4 - II	The battery and circuitry will not pose a flame or explosion hazard under normal room conditions
Req 7.1.5 - II	The database system should ensure that the customers information be secured. .
Req 7.1.6 - III	The device will turn off automatically in the event where any components overheat.
Req 7.1.7 - III	The device of will display warning for electrical hazard

Table 7.1: Safety Requirements

Besides the ultimate goal of Pulse Tracer, which is providing an accurate and non-invasive method for heart rate and respiratory rate measurement, the safety and sustainability of the product is also considered a top priority. LumoAnalytics strives to provide a product that will pose limited risks to the end user. As such, LumoAnalytics will ensure all circuitry in Pulse Tracer will be contained in insulated packaging and the optical components will not operate in ranges that can cause overheating or damage to the patient's tissue. Additionally, the database used to store collected data will be secure as to protect the data from being viewed by anyone other than those with authorized access.

7.2 Sustainability

Requirement ID	Requirement Description
Req 7.2.1 - I	The device shall use recyclable materials where possible.
Req 7.2.2 - I	The individual components, if cannot be recyclable, must not contain components that are toxic for the environment.
Req 7.2.3 - II	The device will rely on rechargeable power sources in place of non-rechargeable products where possible.
Req 7.2.4 - II	The individual components of the device will not be damaged upon disassembly.
Req 7.2.5 - II	The device should operate with minimal power consumption.

Table 7.2: Sustainability Requirements

In addition to producing a reliable and safe product, LumoAnalytics is also dedicated to making Pulse Tracer as green as possible. Though Pulse Tracer is currently designed for immobile patients in its proof-of-concept stages, the future of this device is intended for patients that are mobile in every aspect, including sleeping babies. As such, the preservation of the environment, something that is important to all intended users of this device at every age and stage of life, is a crucial aspect in designing this device.

With that in mind, a cradle-to-cradle (C2C) design will be used for Pulse Tracer. That is, the design will take into consideration how Pulse Tracers components could be reused or discarded by applying cradle-to-cradle approach [1]. The C2C design will also ensure no toxic or chemical products will be used in the design of the device.

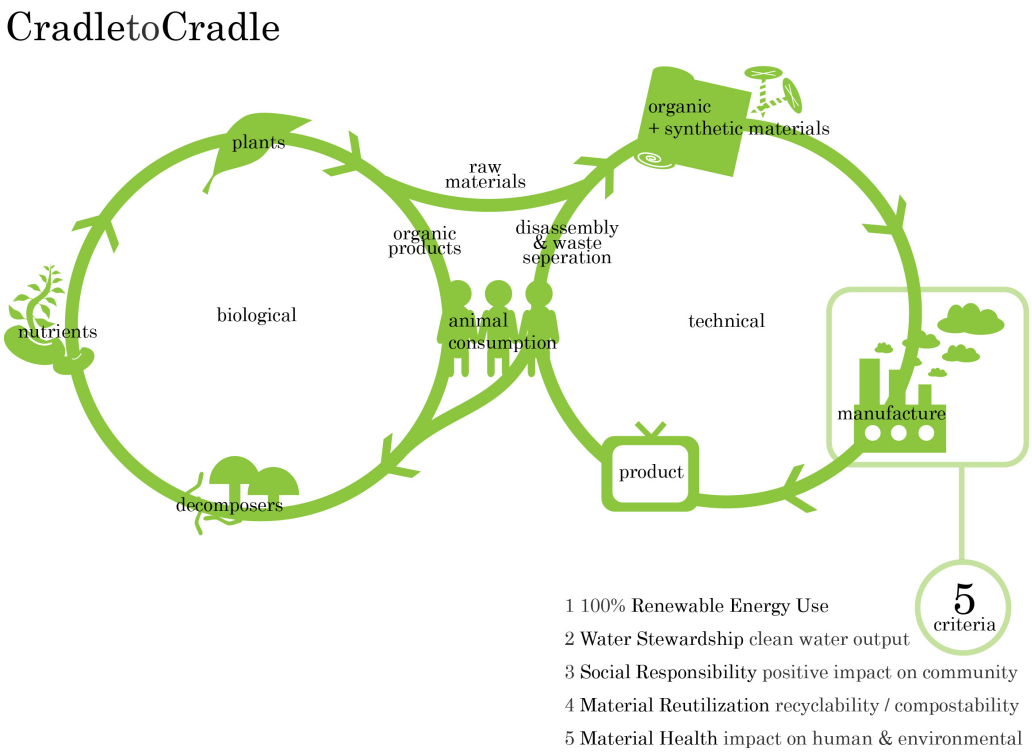

Figure 7.1: Conceptual Design of C2C [1]

7.2.1 Hardware Component

Because the hardware component of Pulse Tracer makes the bulk of its physical presence, it is important to ensure all materials that go into the hardware component can be recycled or reused in some way.

Phase 1 of the project includes use of light sources, a camera and a microcontroller. The camera and microcontrollers can easily be reprogrammed and reused for other purposes. Although LEDs are not reusable after burning out, they are easily recyclable, along with other components such as wires [27].

In the prototype phase of Pulse Tracer, a custom PCB board will be used, as well as a rechargeable battery and an enclosure for the device. A rechargeable battery will ensure that fewer products are introduced to the environment by reducing the need for disposable batteries. The PCB contains many different types of metals that can be extracted and reused, and can be sent for recycling at companies such as M.I.S Electronics Inc., which is based in Ontario, Canada [28].

7.2.2 Software Component

In terms of the software aspect, Pulse Tracer is focused on minimal energy consumption in all its components, whether in the data analysis, storing, or viewing the data.

During phase 1 of Pulse Tracer, a Raspberry Pi is used for processing and a simple monitor to view the data. Energy consumption of the Raspberry Pi can be done in multiple ways, whether by switching off the USB ports or disabling on-board LEDs [29].

In the second phase of the project, Pulse Tracer will contain an on-off switch as well as a cloud-based database to store data. The on-off switch will prove invaluable for saving power when the device is not in use. As for the database, it is intended to be deployed on a cloud service that is eco-friendly, with consideration to its energy and resource efficiency. Cloud-based databases are steadily becoming more popular due to their sustainable practices, which include having better infrastructure, higher utilization rates, reduced electricity use, and reducted climate impact [30]. A simple example of a cloud that is eco-friendly is Google Cloud [31].

8 Conclusion

Pulse Tracer is a patient monitoring system intended to provide patients the opportunity to live in their own home while still ensuring their health is closely monitored by professional caregivers. The device showcases the applications of remote PPG by detecting heart and respiratory rates of patients without the use of wearable technology. The secure and easy-to-use web application allows patients and caregivers the ability to view trends in the patient's data, which can be indicative of emerging health conditions.

This document has provided a high-level overview of the components of Pulse Tracer and what each needs to include in order to ensure the success of the device. It has also detailed the functional and non-functional requirements of the device at each of the three design phases. The proof of concept phase is slated to be completed by August of this year, with the engineering prototype concluding in December. The final product will include improvements to the physical appearance and miniaturization of the device. This document has also outlined the relevant engineering standards the device must conform to, as well as safety concerns to ensure Pulse Tracer causes no harm to the users. Finally, sustainability considerations have been explored to produce an environmentally-friendly device by reducing environmental waste, utilizing sustainable materials, and considering the power-efficiency of its components.

The engineers involved in the design of the Pulse Tracer at LumoAnalytics hope to combine their diverse knowledge and skill sets to create a patient monitoring system aimed towards improving the early detection of health conditions related to the heart and respiratory rates. With the requirements detailed in this document, LumoAnalytics hopes to realize this idea into Pulse Tracer.

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Appendix A: Acceptance Test Plan

The following tables outline various tests to verify and validate the proof of concept prototype. They are numbered according to their related category and test number as follows:

Test.{category number}.{test number}

The following table identifies the category numbers.

Category Number	Category Description
3.1	General Function
3.2	System
3.3	Performance
4.1	General Hardware
4.2	Electrical
4.3	Optical
5.1	Data Analysis
5.2	User Interface

Table 8.1: Category Numbers

Once the system has test the passed, a check mark can be added to the last column of the table.

Test ID	Component Under Test	Test Description	Acceptance Condition	Passed
Test 4.1.1	Camera	Ensure camera functions under ambient light by recording video of an object	Video shows the object accurately	
Test 4.1.2	Camera	Ensure camera functions while viewing reflected NIR light by recording video of an object while NIR LEDs are turned on	Video shows the object accurately using NIR light	
Test 4.1.3	Camera	Ensure camera can adjust for change in focus under NIR light by moving object towards and away the camera	Video remains in focus at various object positions	
Test 4.1.4	Camera	Ensure camera can record a persons face under NIR light	Video shows the face accurately	
Test 4.1.5	Camera	Ensure camera can record a persons face under NIR light and adjust for change in focus	Video shows the face accurately and in focus	
Test 4.2.1	NIR LED	Ensure NIR LEDs can be powered and begin emitting	NIR light can be seen with camera	
Test 4.2.2	NIR LED	Ensure NIR LEDs can fully illuminate a face	Face can be illuminated and seen with camera	
Test 4.2.3	NIR LED	Ensure NIR LEDs can operate continuously for at least 10 minutes	NIR light can be seen with camera for at least 10 minutes	
Test 4.3.1	Raspberry PI	Ensure Raspberry PI can be turned on and controlled after connecting to a monitor and keyboard	Raspberry PI reaches desktop and applications can be used	
Test 4.3.2	Raspberry PI	Ensure Raspberry PI can receive video from the camera	Raspberry PI can receive and save the video	
Test 4.3.3	Raspberry PI	Ensure Raspberry PI can run the software for analysis of the video	Raspberry PI can run the software and produce the desired results	

Table 8.2: Acceptance Test Plan for Hardware

Test ID	Component Under Test	Test Description	Acceptance Condition	Passed
Test 5.1.1	Heart Rate Algorithm	Ensure the software can extract the heart rate from a stationary subjects face	Software analyzes video and produces a heart rate close to the actual heart rate of the subject	
Test 5.1.2	Heart Rate Algorithm	Ensure the software can extract the heart rate from a subjects face that is slightly moving	Software analyzes video and is able to track the region of interest to produce an accurate heart rate	
Test 5.1.3	Heart Rate Algorithm	Ensure the software can extract the heart rate from subjects face under bright ambient light	Software analyzes the video and produces an accurate heart rate	
Test 5.1.4	Heart Rate Algorithm	Ensure the software can extract the heart rate from subjects face under dark ambient light	Software analyzes the video and produces an accurate heart rate	
Test 5.2.1	Respiratory Rate Algorithm	Ensure the software can extract the respiratory rate from a stationary subjects face	Software analyzes video and produces a respiratory rate close to the actual respiratory rate of the subject	
Test 5.2.2	Respiratory Rate Algorithm	Ensure the software can extract the respiratory rate from a subjects face that is slightly moving	Software analyzes video and is able to track the region of interest to produce an accurate respiratory rate	
Test 5.2.3	Respiratory Rate Algorithm	Ensure the software can extract the respiratory rate from subjects face under bright ambient light	Software analyzes the video and produces an accurate respiratory rate	
Test 5.2.4	Respiratory Rate Algorithm	Ensure the software can extract the respiratory rate from subjects face under dark ambient light	Software analyzes the video and produces an accurate respiratory rate	
Test 5.3.1	Display and Communication	Ensure the software displays the current respiratory and heart rate on the monitor	Software produces a visualization of the respiratory and heart rate on the monitor connected to the raspberry PI	

Table 8.3: Acceptance Test Plan for Software