



March 03, 2016

Dr. Andrew Rawicz
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Simon Fraser University
8888 University Drive
Burnaby, BC, V5A 1S6

Re: ENSC 305W Project Design Specs for OxiTrak-5001

Dear Dr. Rawicz,

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

The enclosed document will provide a detailed overview of the system as whole as well as design specifications and requirements based on the recently compiled functional specifications. This document will also include a thorough analysis of the hardware, software and mechanical components of our product, as well as a detailed test plan to ensure that the product meets all stated requirements.

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

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

Sincerely,

Johnny Chou
Chief Executive Officer - OxiTrak

Design Specifications for OXITRAK- 5001

“Track the
Rhythm,
Keep it
Beating”

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Abstract

Design specifications have been outlined in this document for a real-time emergency notification oximeter. OxiTrak is a real-time oximeter recommended by healthcare professionals to patients with pre-existing respiratory and cardiac conditions. This device will be able to measure a user's heart rate and blood oxygen levels, and provide analyzed feedback along with an emergency algorithm system implemented on a mobile device. The outlined design specifications consist of the following main components:

- Infrared wave detection circuit
- Filter and amplification circuit
- Intel Edison microprocessor
- Bluetooth module
- Smartphone signal processing application
- User interface

The design of each listed component is described according to their development stage priority. The discussed designs for each hardware, firmware and software parts are based on technical work and extensive scientific research in order to meet the functional specifications document. Moreover, detailed test plans for each component are covered for future evaluation and testing of the product.



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Glossary

IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
CAN/CSA	Canadian Standard Association
PCB	Printed Circuit Board
GPS	Global Positioning System
QA	Quality Assurance
MCU	Microcontroller Unit
IOT	Internet of Things
GUI	Graphical User Interface
SPO2	Saturation Percentage of Oxygen
Hb	Haemoglobin
LED	Light Emitting Diode
IR	Infrared
GPIO	General-purpose input/output
I2C	Inter-Integrated Circuit Communication
SCL	Synchronous Clock
SDA	Synchronous Data
FIFO	First In – First Out
SPP	Serial Port Profile
ABS	Acrylonitrile butadiene styrene



1. Introduction / Background

OxiTrak helps people with respiratory and heart conditions to keep track of their heart rate and oxygen saturation level. It takes these readings with the help of an oximeter, which transmits the read signals to a microprocessor, from where the processed signal is then sent to a companion app. The app visualises the data into human readable form; in case of any alarming readings, the app queries the user about their well-being and in case the user doesn't responds promptly a health care professional is contacted. This ensures immediate help can be reached in a timely manner.

1.1 Scope

This document specifies the design of OxiTrak-5001 and explains how the design meets the functional requirements described in *Functional Specification for OxiTrak-5001* [9]. Furthermore, the design specifications will outline the necessary modules to achieve a proof-of-concept for OxiTrak-5001 by incorporating all the basic features of the Functional Specification.

The notation [Rn-p] references the functional specification where R denotes the requirement and n denotes the number of the requirement specified. P denotes the priority level of the requirement, which is used based on the three stages of development:

- I. Proof-of-concept
- II. Proof-of-concept and Final Product
- III. Final stage of production

Since we will be focusing mainly on the proof-of-concept system, only design considerations pertaining to the functional requirements marked I or II will be explicitly discussed.

1.2 Audience

The target audience for this document is aimed at the OxiTrak team members to help them with the design process, development and implementation of the hardware and software components of OxiTrak-5001. It is also aimed at all TA's and professors privy to this project, to achieve a documented reference for the design of this device. Test plans will be discussed and created in this document to ensure that all requirements are met by the development and QA team at OxiTrak, and the technical details and measurement data will be used as benchmarks for development.



2. System Overview

The main goal of OxiTrak is to provide a real-time notification system that will alert both the user and his/her caregiver in the case of an emergency, via an Android Application.

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

The proof of concept for OxiTrak-5001 integrates all necessary functionality required to demonstrate its feasibility and ability to thrive within the current market. Identification of potential technical and logistical issues that may interfere with the success of already existing oximeters encouraged us to focus on overlooked features such as its aesthetic value – wearability and durability – and simultaneously introduce new features to the application such as a real-time geotag notification system, which will, in turn, give the product its competitive edge. The system monitors the heart rate and oxygen level through sensors; those reading are filtered and analyzed by the processor and sent to the phone of the user, and then further processed to check for critical levels. If such levels are detected, the processing app will notify the user and user's emergency contact (healthcare professional), with user's location. The design overview of our system is depicted in the diagram below:

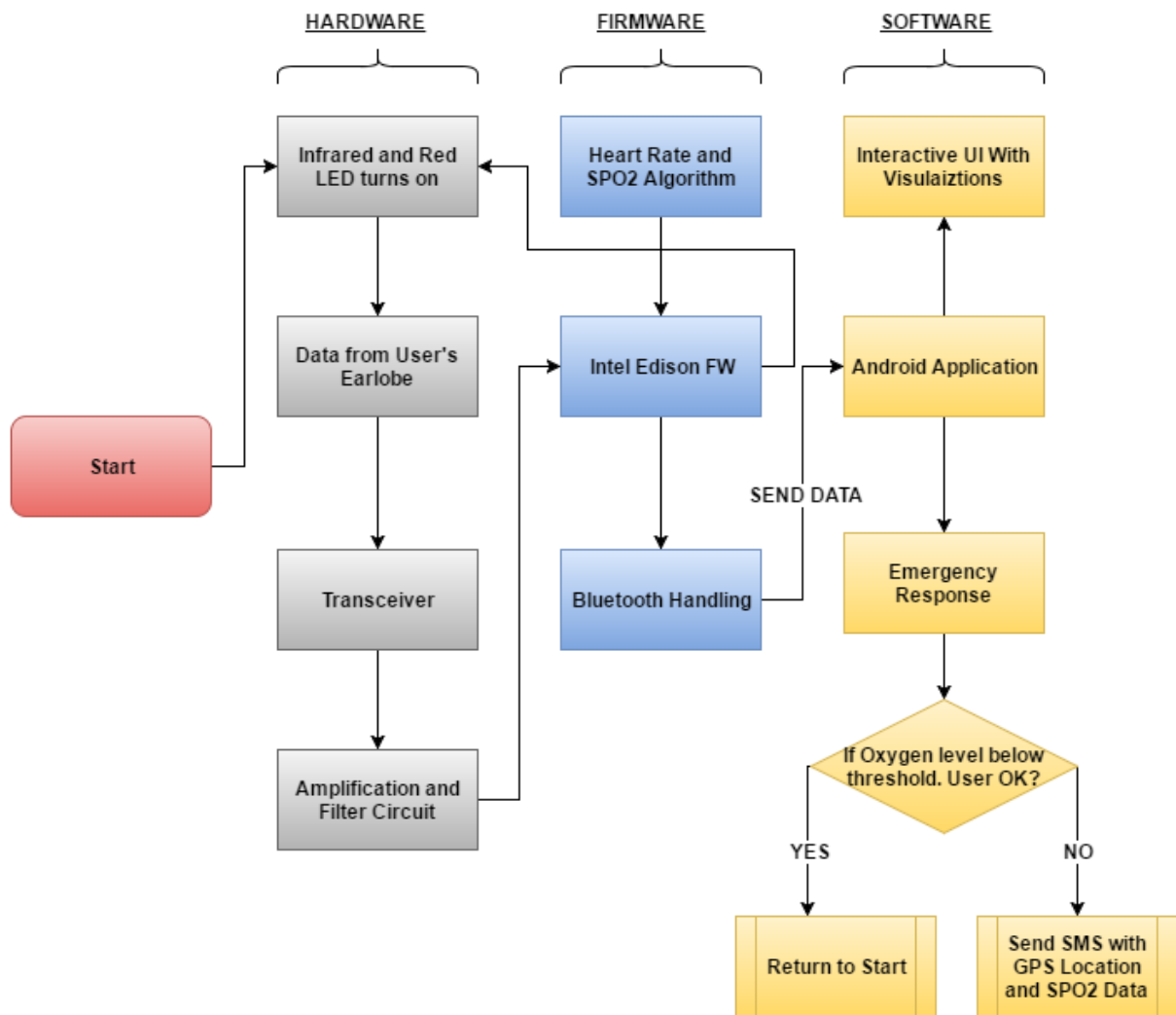


Figure 1: System Block Diagram

3. SPO₂ Theory

Pulse oximeters measure how much of the hemoglobin in the blood is carrying oxygen, measuring the oxygen saturation. By shining lights through certain areas of the body (fingers and earlobe), the photodiode will be able to detect some light while the body absorbs the rest. The amount of light absorbed by the body depends on three things [11]:

- 1) Concentration of the light absorbing substance; the more haemoglobin, the more light is absorbed
- 2) Length of the light path; the width of the surface area where the light crosses
- 3) Oxyhemoglobin and deoxyhemoglobin (explained below)

Figure 2 shows spectroscopic and absorptive properties of oxyhemoglobin (HbO₂) and deoxyhemoglobin (Hb). Oxyhemoglobin absorbs more infrared light, while deoxyhemoglobin absorbs more red light.

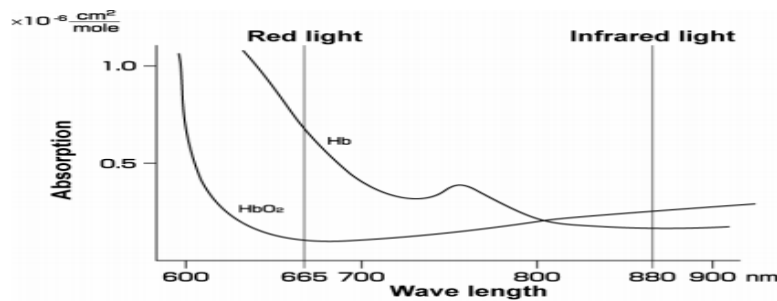


Figure 2: Absorption of Oxygenated and Deoxygenated Blood Levels

The percentage of HbO₂ and Hb is determined by measuring the ratio of infrared and red light detected by the pulse oximeter. To show the worst case and best-case scenarios, we included both graphs where the oxygen level is at 100% and 0%. For any % in between, the graph will be within the cases presented.

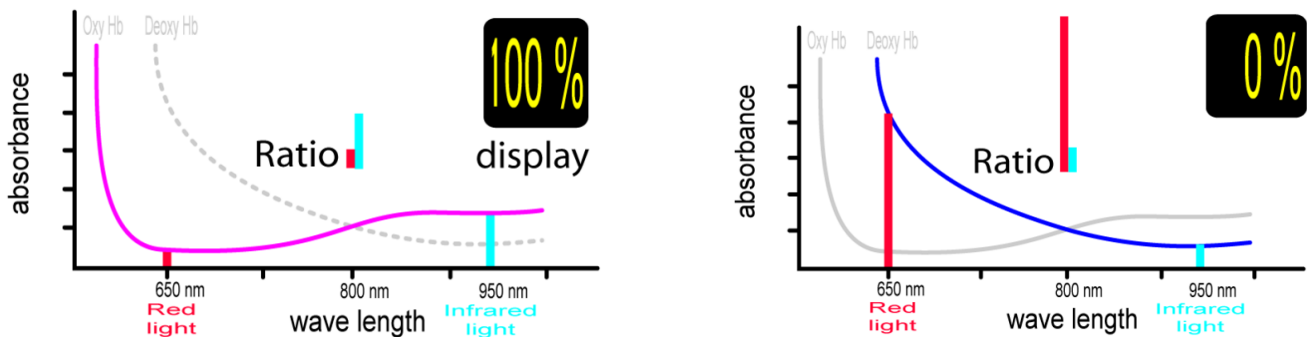


Figure 3: Ratio for 100% and 0% Oxygen Saturation

4. Hardware Design

The hardware component of this product can be split into mechanical design and electronics. The mechanical design refers to the physical enclosure of the device, which includes a stable casing for the electronics so readings can be taken accurately, as well as a mechanism to attach to the user's ear lobe. The electronics design of the system will process the signals from a photodetector and send it to the microprocessor, Intel Edison. In order for the design to filter 0.8Hz to 3.2Hz [R27-I], amplify the signal [R28-I], and block external light from interfering with the readings [R16-I], the two categories must work together to successfully satisfy some of the critical requirement for the proof-of-concept stage. **Figure 4** shows the high level block diagram for electronics design.

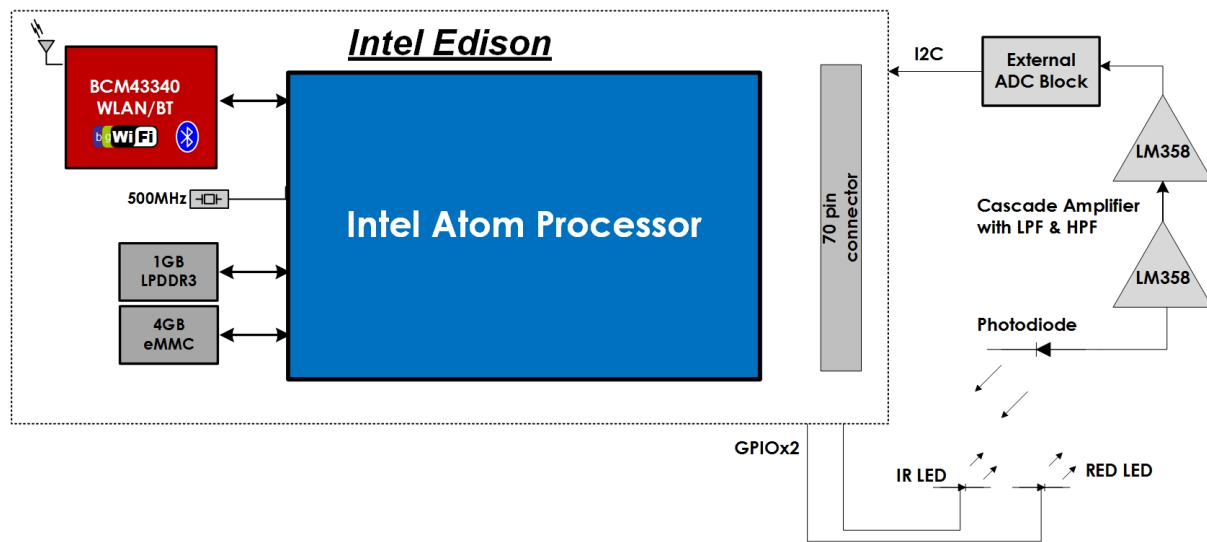


Figure 4: High Level Hardware Electronics Design

4.1 LED, Transceiver and Circuitry

In order to measure heart rate and SPO_2 levels, as per [R24-I], we need to use a red and infrared LED; there will be a photodiode that converts the light into current. The current will go through a transimpedance amplifier, then through a cascade amplifier with high pass and low pass filter. This is accordance with [R27-I] and [R28-I]. **Figure 5** shows stage 1 filter:

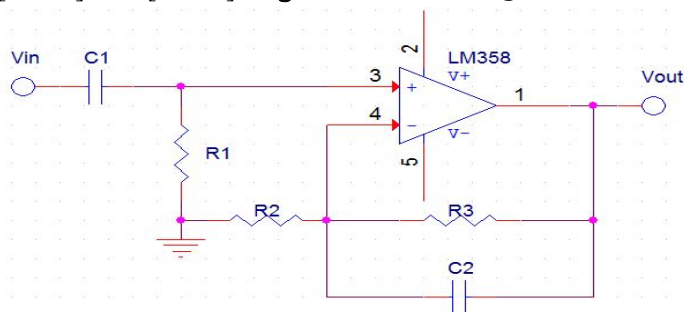


Figure 5: Schematic for Amplifier with Bandpass Filter

First, we derive the transfer function of the filter:

$$\frac{V_{OUT}}{V_{IN}} = \left(\frac{R_2 + R_3}{R_2}\right) \frac{SC_1R_1\left(1 + \frac{SR_2R_3C_2}{R_2 + R_3}\right)}{(1 + SR_3C_2)(1 + SR_1C_1)}$$

From this equation, we know the gain, two poles and two zeros:

$$Gain = \frac{R_2+R_3}{R_2}, \omega_{p1} = \frac{1}{R_3C_2}, \omega_{p2} = \frac{1}{R_1C_1}, \omega_{z1} = 0, \omega_{z2} = \frac{R_2+R_3}{R_2R_3C_2}$$

By choosing $R_1=20k\Omega$, $C_1=10\mu F$, $R_2=330\Omega$, $C_2=1 \mu F$ and $R_3=50k\Omega$, we have a bandpass filter of 0.79 – 3.18Hz and a total gain of 43.6dB

After the filter and amplification, we then need to feed it through an Edison ADC block in order for Edison to read the signal through the I2C line. We have implemented this to meet [R28-I] of the functional specifications.

Theoretically, the calculations and numbers are correct, but with the excessive noise we receive and not being able to filter them out, we were not able to produce clean enough signals to use for Edison. We looked into different solution, and came across MAX30100, which is a “Pulse Oximeter and Heart-Rate Sensor” IC. We chose this IC because it has all the components we stated above, and most importantly, it has ambient light cancellation. Above all, this chip is 6mm x 3mm, which will allow us to save a lot of board space. It also is still in compliance with all requirements we have designed for and referenced above. The pinout and block diagram of MAX30100 are shown in

Figure 6:

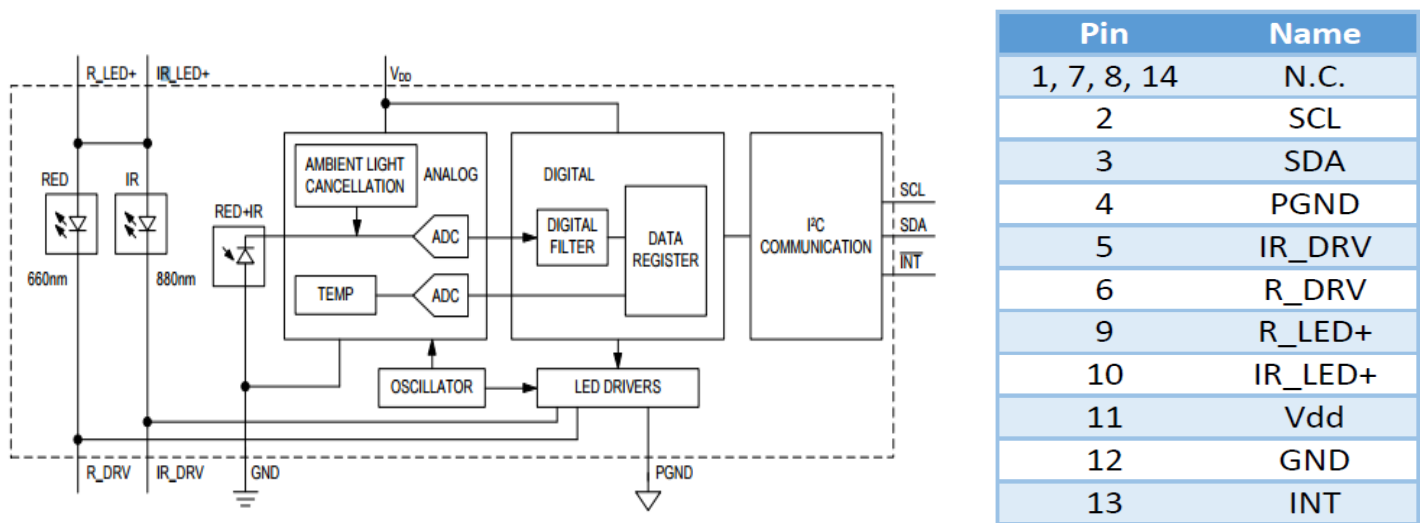


Figure 6: Block Diagram and Pinout of MAX30100

MAX30100 requires a breakout board therefore we purchased a Heart Rate Click, **Figure 7**, which brings out the SCL, SDA and INT pins of the IC. **Figure 8** displays how the IC works mechanically, which is different than the typical oximeter where the LED and receiver are on the opposite sides.

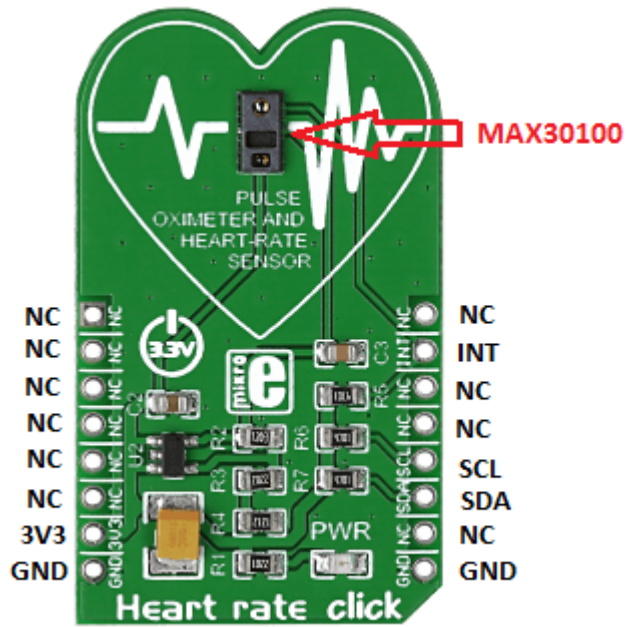


Figure 7: Heart Rate Click with MAX3010

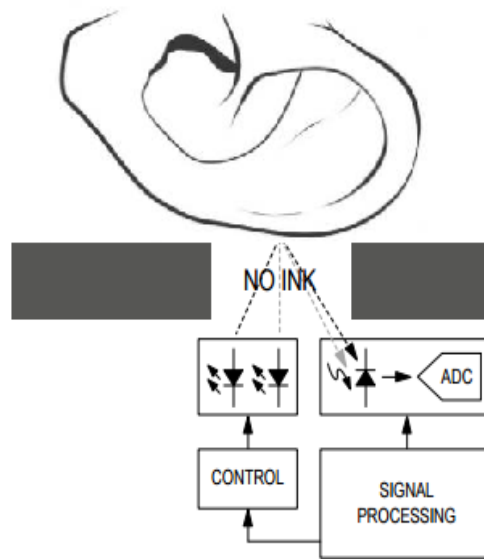


Figure 8: Functionality of MAX30100

The schematic of the breakout board is displayed in **Figure 9**:

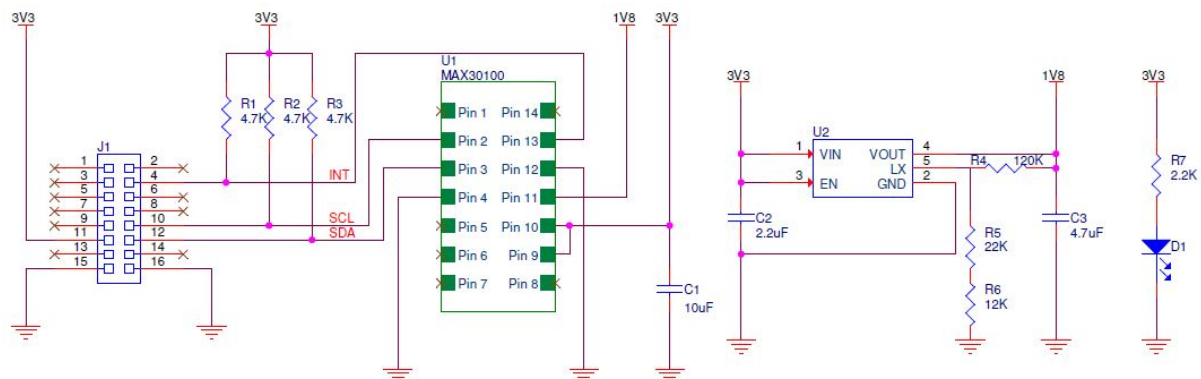


Figure 9: Schematic of Heart Rate Click

4.2 Intel Edison

Prior to making the decision of using Edison for our project, we compared other competitors such as Arduino Uno and Raspberry Pi. The following table lists some of the key features to help us determine which one is most suitable.

Categories	Arduino Uno	Raspberry Pi	Intel Edison
Price	\$30	\$35	\$75
Size	7.5x1.9x6.4cm	8.5x5.6x1.7cm	3.5x2.5x0.39cm
Memory	0.002MB	512MB	1GB
Onboard Network	None	10/100 Ethernet socket	Dual-band (2.4&5 GHz) Wifi, BT 4.0
External BT Module Cost	\$25	\$25	-
Input voltage	7-12V	5V	3.3-4.5V
Flash Memory	32KB	Micro SD Card	4GB eMMC
Operating System	None	Linux	Yocto Linux v1.6
Integrated Development Environment (IDE)	Arduino IDE	Scratch, IDLE, anything with Linux	Arduino IDE, Eclipse, Intel XDK

Table 1: Specification Comparison for Arduino Uno, Raspberry Pi and Intel Edison

Immediately, you can see that Edison costs twice as much as its competitors, which deterred us away from it. Further research indicated that in order for us to have wireless connectivity in accordance to [R39-I], we would need to buy Bluetooth module that costs \$25. This automatically brings the price point of all three options with BT closer. The larger memory size of Intel’s MCU also gives us more option for our software. For example, if Edison isn’t connected to any device wirelessly, we can temporarily store offline data on it until it pairs with a device. The biggest factor for us to go with Edison is definitely the size of the MCU. With Edison being just a fraction of it’s competitors size, it can easily be integrated into our design of a wearable technology.

In order for Edison to communicate MAX30100, it uses the I2C bus, which includes the SCL and SDA pins. There is also an interrupt (INT) pin, which can trigger the oximeter for different options.

Figure 10 shows the communication between the MCU and IC.

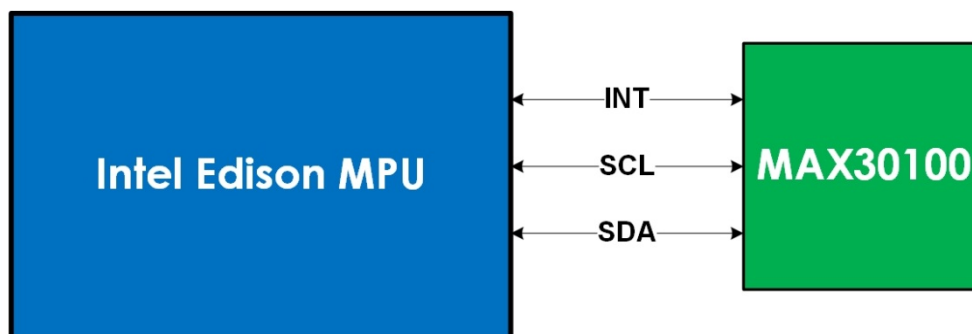


Figure 10: Communication between Edison and MAX30100

4.3 Packaging

Figures 12 and 13 below depict the prototype design for the Intel Edison case and the ear clip, created using AutoCAD software. The designs were created in accordance with the requirements as stated in the *Functional Specification for OxiTrak-5001* [9]. Some of these include:

- **Physical Requirements**
 - Stability: Both the casing and the ear clip have been designed to be stable (as per [R20-II]) when worn by the user, such that external vibrations can be spread evenly across the device so as not to affect readings or measurements being taken ([R15-I]).
 - Wearability and Aesthetics: In accordance with [R22-II], the Intel Edison casing has been designed to completely cover the hardware, leaving openings where necessary for easy access to wires and buttons. The ear clip will implement a spring open-and-close component, so that it can be adjusted to fit each user comfortably ([R21-I]). Overall, we have kept both designs simple, compact and portable, making them aesthetically pleasing as stated in requirement [R23-II].

- **Reliability and Durability Requirements**
 - For testing purposes, we have opted to 3D print the Intel Edison case and earclip using a sustainable and ecofriendly material, ABS Plastic. This plastic is durable, water resistant and recyclable ([R29-II], [R81-III]).

It is essential to note that since this is only the first prototype, the proposed designs are subject to change as requirements dictate.

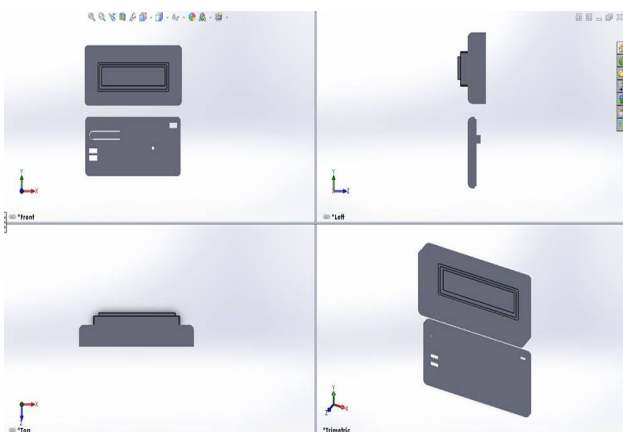


Figure 11: Edison Case

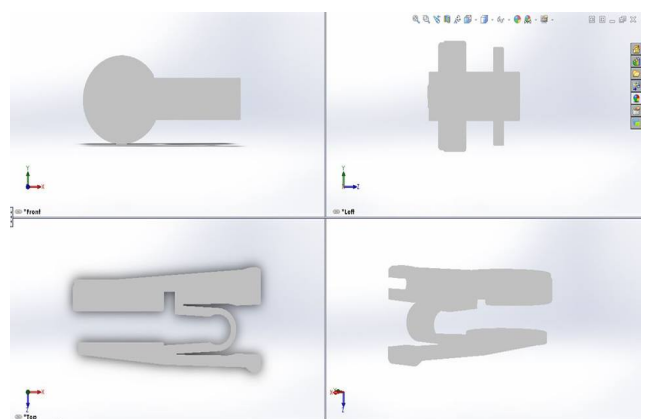


Figure 12: Ear Clip

5. Firmware Design

Below is the high-level firmware design of the Oxitrak-5001. This is the implementation of the software that will run on the Intel Edison Microprocessor itself. The software must coherently drive the sensor LEDs, read the incoming samples, process the data and send it to a Bluetooth socket to be in accordance with [R32-I], [R36-I], and [R41-I] respectively from the Oxitrak-5001 Functional Specifications. The Intel Edison runs a full Linux image and contains useful application interfaces that make development for IoT devices a more complete process. We have taken advantage of the full embedded system on the Edison with the use of shell scripts and Linux services to configure our device to handle our software. Also through the use of python scripts we have utilised many internal libraries that come with the Edison. In this section we will discuss the use of the Linux Image on the Edison, the Bluetooth software design, as well as the GPIO drivers implemented.

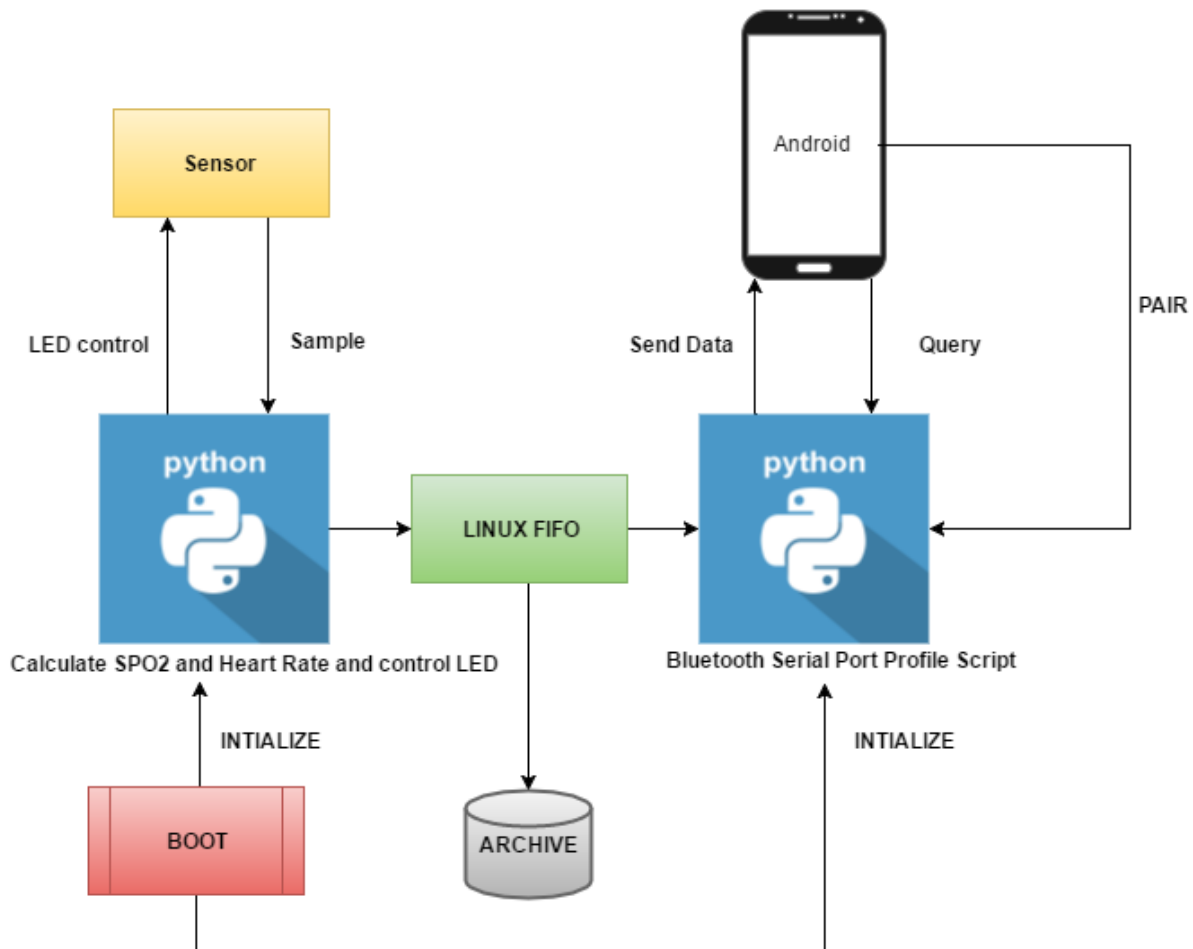


Figure 13: Overall Software Implementation on Edison

5.1 Yocto Linux Image

The power of the Intel edison comes to full force with the Yocto Linux image. This is an open source project that brings together many tools and processes specifically designed for customized Linux based embedded systems. Below is the Yocto Linux program stack implemented on the Edison ^[10]

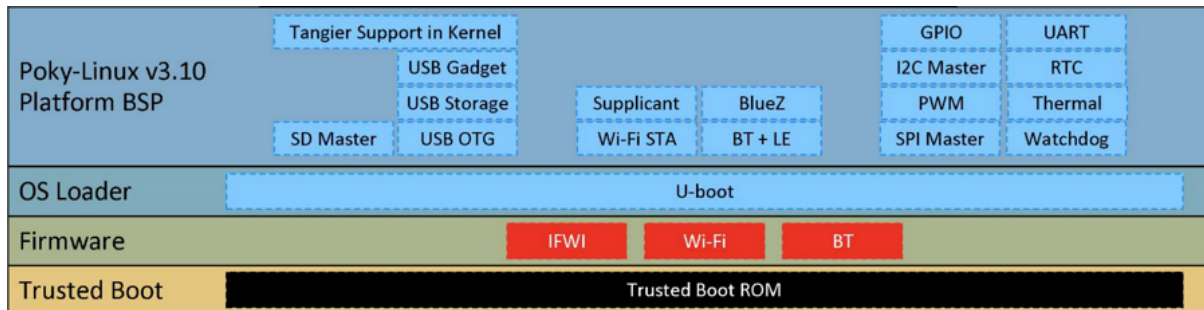


Figure 14: Yocto Linux Program Stack

We have particularly focused on customizing and utilizing the OS Loader, Bluetooth (BT), BlueZ, and GPIO components of the program stack.

5.2 Image Customizations

The OS Loader is a program that runs when the Edison is booted up. This is a crucial program as we want the device to be configured in a specific way on Boot-up. More specifically we want the device to have the Bluetooth Module enabled and discoverable as well as ensure our python script handling the serial connection is initiated. We implemented this with a shell script that is called by a service file that is read during Boot up by the OS loader. This is to meet the [R33-I] requirement of the functional specifications.

The bluetooth module is interfaced through the BlueZ component of the Linux image. BlueZ is the official Bluetooth stack of Linux devices. Through this program stack we can create a customized “Serial Profile” that will have its own unique identifier on the device and will send data upon a certain “Query Event” from a paired device. Below is the implementation of the BlueZ stack on the Intel Edison. We primarily have implemented our design on the application layer under “BlueZ” python scripts, however we have also taken advantage of the “bluetoothctl” and “rfkill” interfaces to set up our profile.

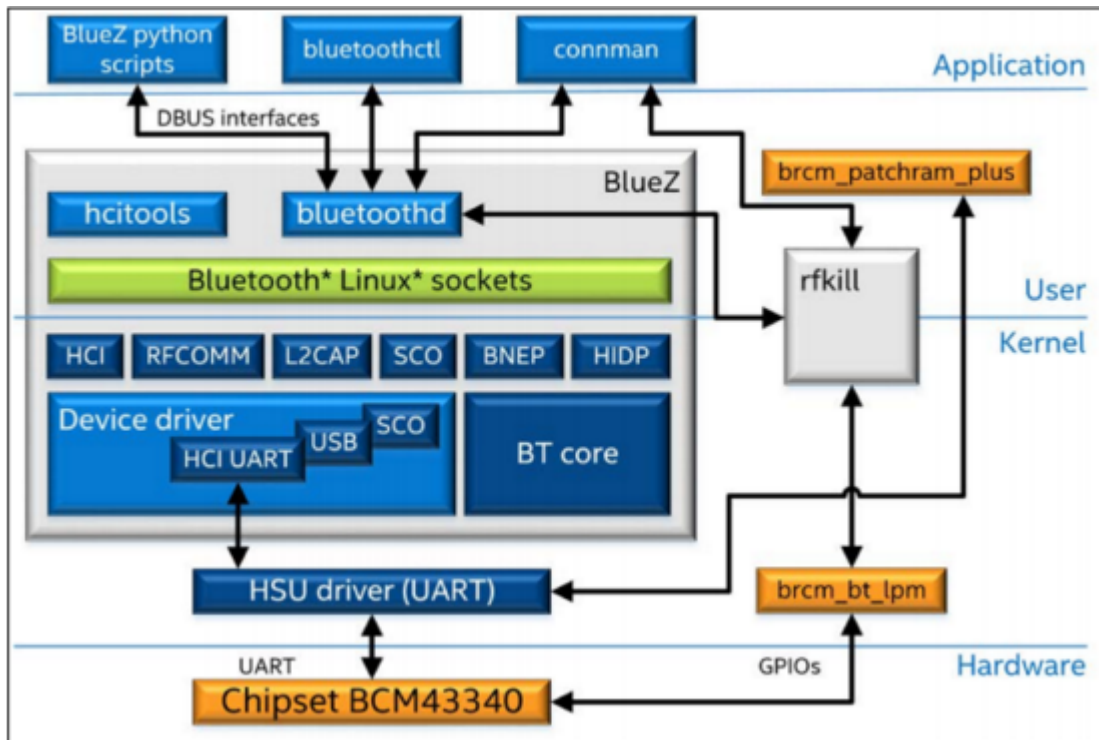


Figure 15: Linux Bluetooth Program Stack [7]

Our application of this stack initially creates a “Serial Profile.” It then waits for connection to be established which initiates our Serial data transfer routine. We have implemented this in accordance with [R39-I] requirement set out in the functional specification, which details the device should be able to establish a connection with a smartphone. This routine waits for an “event” to occur, which is the reception of a query from our paired android device. Upon reception of this query the script will call a “Hook” script, which read from a FIFO buffer. This buffer will contain SPO2 data being read from the sensor. Which satisfies requirement [R40-I] and [R41-I] that state the device must send correct data over the bluetooth interface. The entire implementation from Boot-up to transfer of data is described in the diagram below.

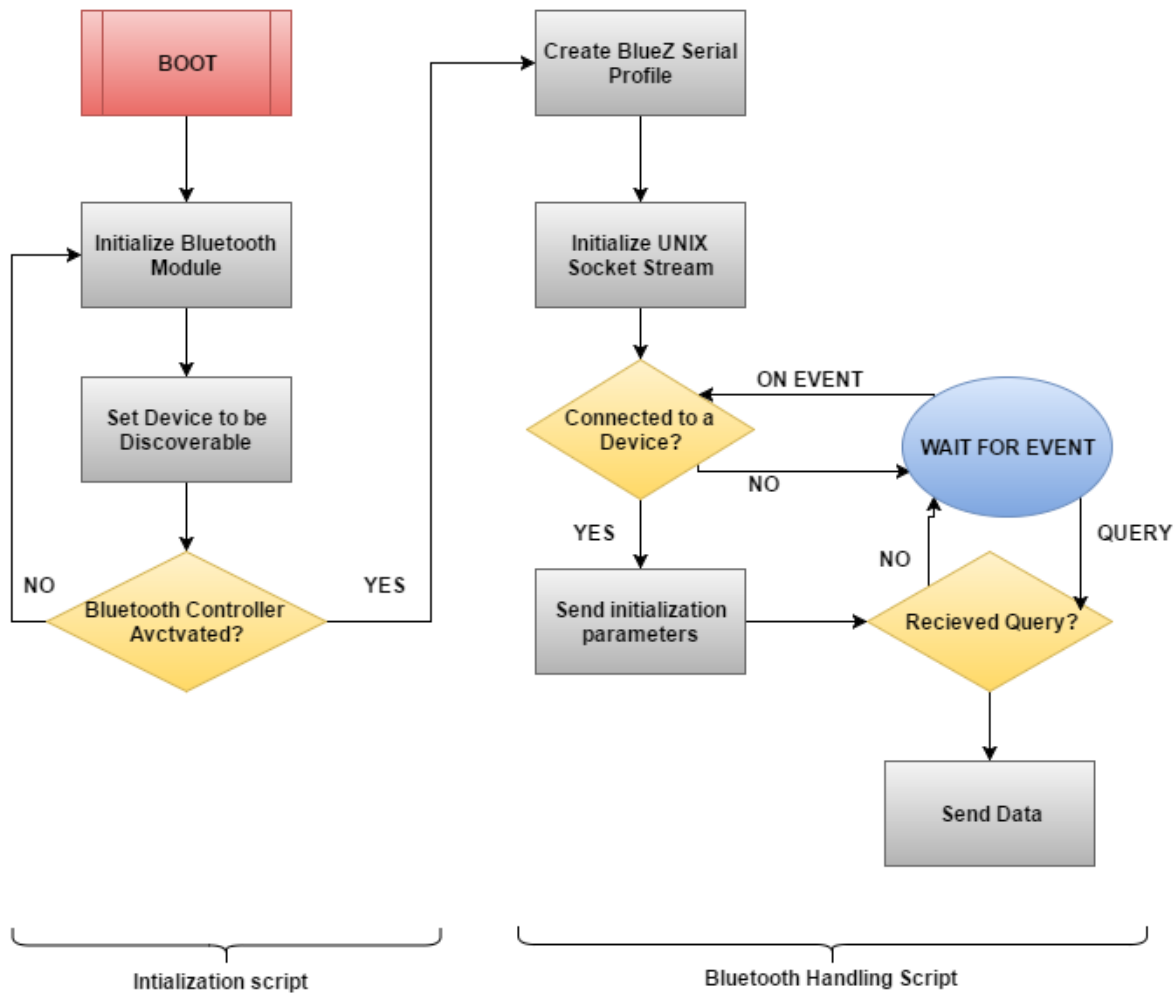


Figure 16: Bluetooth Handling Implementation

We can see the result of this script through manually checking the status of the Bluetooth Controller through Linux OS. After booting up the device we simply call the “bluetoothctl” program as detailed in the above diagram of the bluetooth stack. We see that controller is initialized. Upon checking the controller's status, we see all sockets and applications running within the stack and in it we see the “Serial” profile we created through our Bluetooth handling script. We can see this in Shell screenshot below:

```

root@oxitrak5001:~# bluetoothctl
[NEW] Controller 98:4F:EE:04:1A:78 oxitrak5001 [default]
[NEW] Device A4:E4:B8:06:55:43 BLACKBERRY-51EB
[bluetooth]# show
Controller 98:4F:EE:04:1A:78
  Name: oxitrak5001
  Alias: oxitrak5001
  Class: 0x3c0110
  Powered: yes
  Discoverable: yes
  Pairable: yes
  UUID: PnP Information (00001200-0000-1000-8000-00805f9b34fb)
  UUID: Generic Access Profile (00001800-0000-1000-8000-00805f9b34fb)
  UUID: Generic Attribute Profile (00001801-0000-1000-8000-00805f9b34fb)
  UUID: A/V Remote Control (0000110e-0000-1000-8000-00805f9b34fb)
  UUID: A/V Remote Control Target (0000110c-0000-1000-8000-00805f9b34fb)
  UUID: Handsfree (0000111e-0000-1000-8000-00805f9b34fb)
  UUID: Audio Source (0000110a-0000-1000-8000-00805f9b34fb)
  UUID: Audio Sink (0000110b-0000-1000-8000-00805f9b34fb)
  UUID: Message Notification Se.. (00001133-0000-1000-8000-00805f9b34fb)
  UUID: Phonebook Access Server (0000112f-0000-1000-8000-00805f9b34fb)
  UUID: IrMC Sync (00001104-0000-1000-8000-00805f9b34fb)
  UUID: OBEX File Transfer (00001106-0000-1000-8000-00805f9b34fb)
  UUID: OBEX Object Push (00001105-0000-1000-8000-00805f9b34fb)
  UUID: Vendor specific (00005005-0000-1000-8000-0002ee000001)
  UUID: Serial Port (00001101-0000-1000-8000-00805f9b34fb)
  Modalias: usb:v1D6Bp0246d0518

```

Figure 17: Intel Edison Shell Bluetooth CTL Status Query

5.3 Sensor Interface

To interface with our sensor, we need to be able to control the Red and Infrared LEDs of the device as well as read the incoming data as per [R31-I]. To do this we take advantage of the GPIO pins of the Edison. We can access these pins from our python scripts using the “MRAA” library, which is a Low Level Skeleton Library for IO Communication on GNU/Linux platforms. The documentation for this library provides pin mappings [8].

We are particularly interested in the I2C Pins as the MAX30100 Sensor utilizes I2C communication. I2C or Inter-Integrated Circuit Communication is a widely used protocol for communication between integrated circuits as the name implies. Using this protocol we can send commands to the Sensor to change its mode to sense heart rate or to turn LEDs on or off. More importantly we can also read the data from FIFO buffer on the sensor itself. As specified in the Hardware section the sensor will sample data and through a simple digital processor place the sample values in a buffer for us to read.

The MAX30100 provides a more detailed explanation of a single byte is transferred via I2C Communication in its Datasheet. From here it is apparent we need to specify a device address as well ensure our program points to the correct FIFO buffer address. The buffer will contain infrared and red LED samples that will need to be processed. The buffer is a register, which stores 16-bit

samples. This implies we will need to complete 2 cycles of the I2C protocol above to read an entire sample.

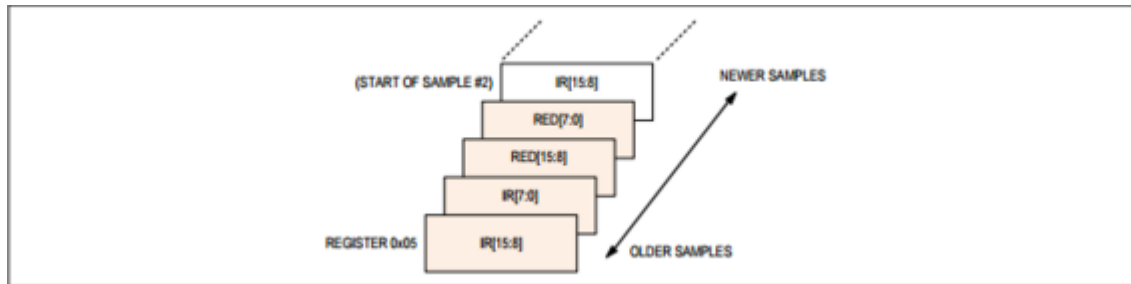


Figure 18: FIFO Data Structure Datasheet

The overall implementation to read sampled data from the sensor will follow the algorithm below. This algorithm has been designed to meet requirements [R37-I], [R38-I] and [R35-I] where the device controls the LEDs and calculates the correct metrics based on the given samples. The implemented script will calculate a ratio between infrared and red samples and store the calculated value in FIFO buffer on the Edison to be collected by a Hook script which will be called by the main Bluetooth handling script.

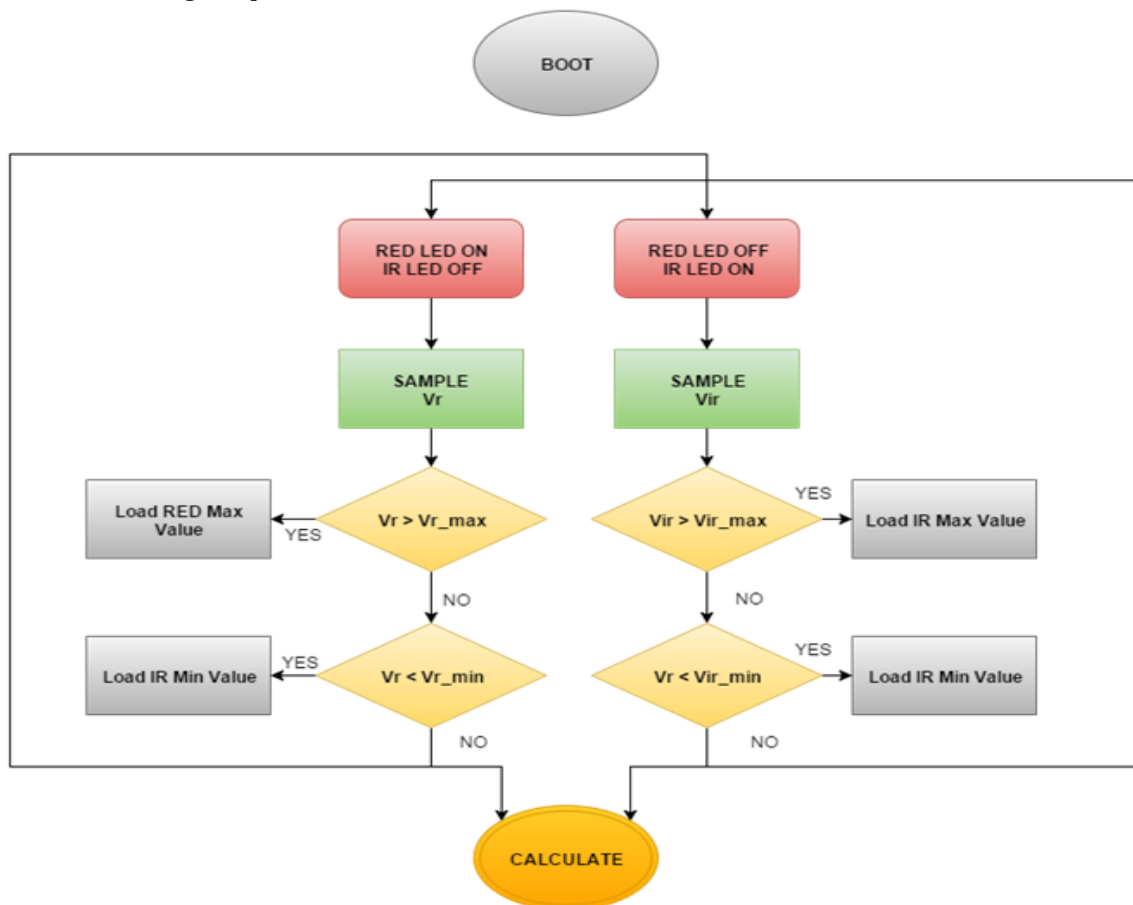


Figure 19: SPO2 and Heart Rate Calculation Algorithm

6. Software Design

6.1 Mobile Application

The designed mobile application is the main platform for system/user interaction and is intuitive and reliable as required by [R47-I], which is essential for instant information provision and emergency notification. The software will receive data from the sensors via Bluetooth and display user health information on the software application. OxiTrak application stores history of user data on their device and help the user understand and improve their health conditions over time. It is an android-based application and is not compatible with IOS platform yet, but future plans will include the availability of OxiTrak app in apple store.

As stated in requirement [R48-I], user interface allows the user to set up a new account and login with their credentials. Navigation to the landing page will be direct after the user's credentials are verified ([R49-I]). The main page includes SPO₂ diagrams and a settings menu ([R51-I]). Settings menu consist of geolocation and emergency notification options, which are only activated with the permission of the user and could be turned off anytime upon preference.

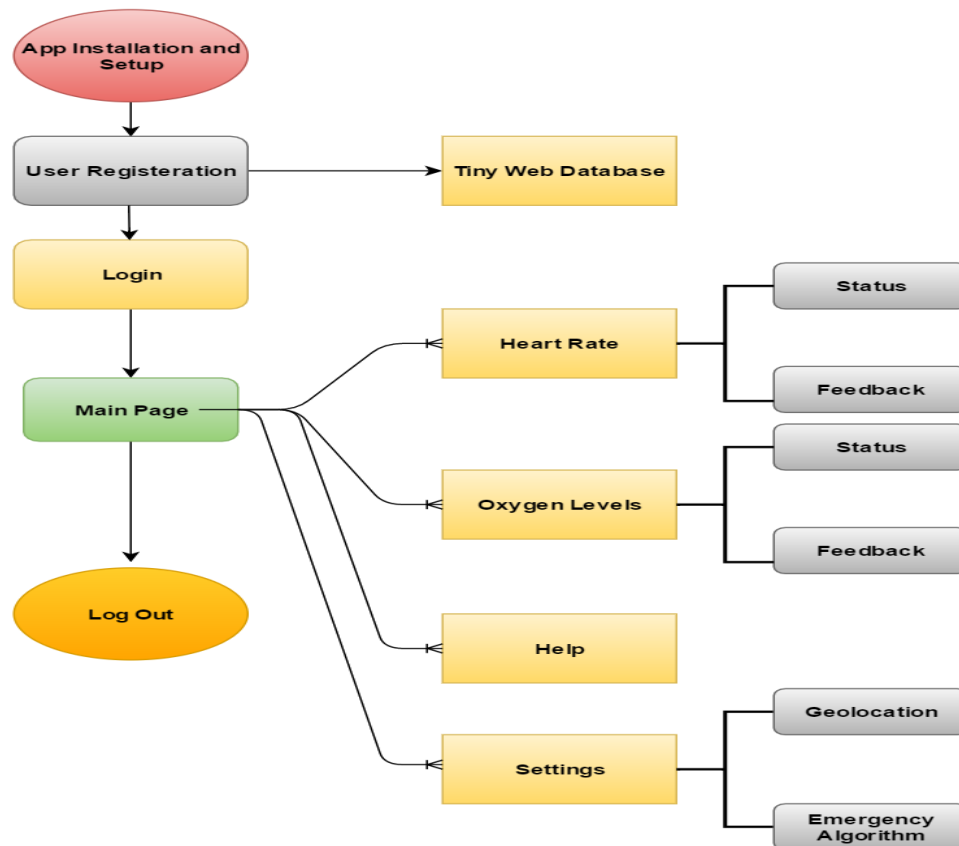


Figure 20: Flowchart of OxiTrak Android Application

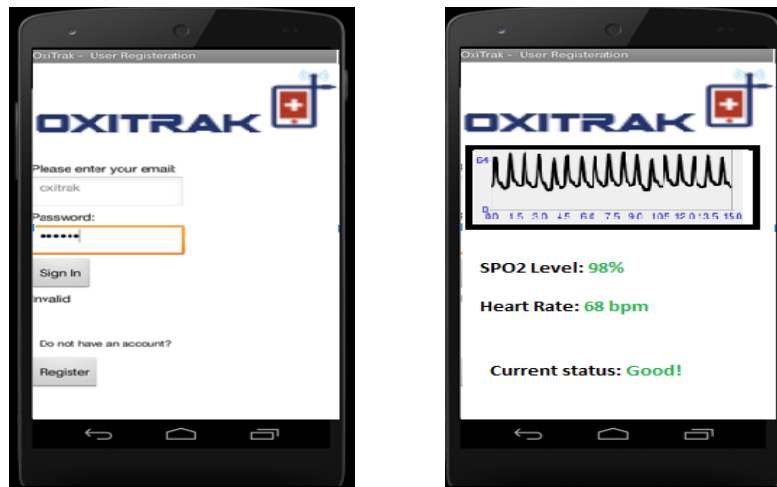


Figure 21: Screenshot of User Registration and Main Page

6.2 Bluetooth

Bluetooth is used to connect Edison to the companion app. The connection verification following requirements [R42-I] and [R66-I] from the functional specification [9] is explained by the following flow chart:

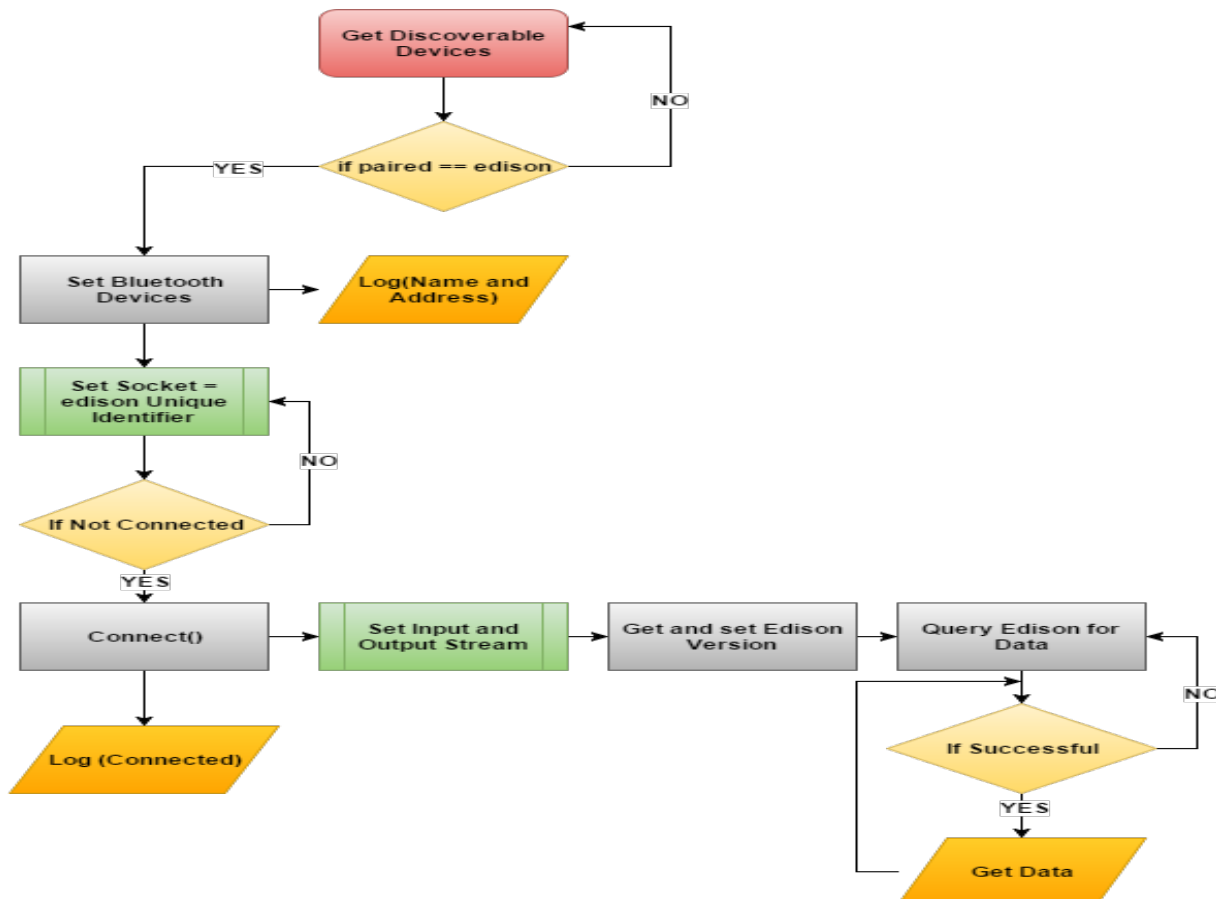


Figure 22: Bluetooth Connection JAVA Algorithm



6.3 Analysis of Data

Once the data is received, it is run through the emergency algorithm (discussed in the next section), which determines the viability of the data in respect to the benchmark conditions that are pre-set. If the data is deemed valid it is further analysed to check for any anomalies that might indicate a medical emergency, in which case the user, and if need be user's emergency contact, is notified.

6.4 Emergency Algorithm

Emergency algorithm ([R67-II]), which is an essential part of OxiTrak-5001, helps analyze the incoming data and the appropriate response for the results. It does so by the help of conditions stated in requirements [R56-II] and [R57-I], that are put in place to check if the user's heart rate or oxygen level is abnormal. The validity of these readings is checked by the parameters that compare these values to those that are considered acceptable by medical professionals.

This procedure is continuous. If the readings are within an acceptable range then no action is needed, but when the readings are alarming the first step is to inquire the user by a notification, asking them if they are ok or in need of assistance. If the user selects ok, then the app resumes back to its normal function, until it detects the next emergency. If the user selects in need of assistance or fails to respond within 30 seconds, a notification is sent to the user's emergency contact, along with user's identification info and location, so that help can be sent to the user immediately.

In the event of an emergency, OxiTrak app will ask the user "Are you okay? Emergency algorithm implementation will consist of the following options:

- Respond by pressing "Y" for yes or "N" for no using your Android device:
 - Pressing "Y" will avoid contacting emergency caregiver and will continue to monitor vital signs of SPO2 levels.
 - Pressing "N" will immediately contact your emergency caregiver
- No response will automatically contact emergency care givers.

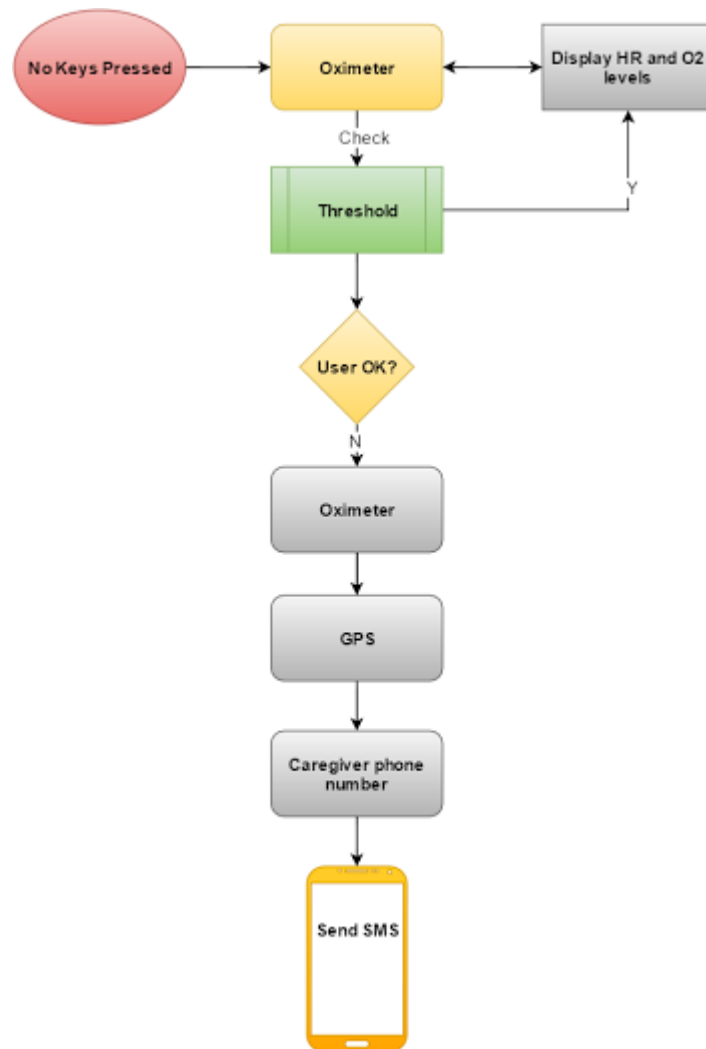


Figure 23: Vital Sign Monitoring Algorithm Flowchart

7. System Test Plan

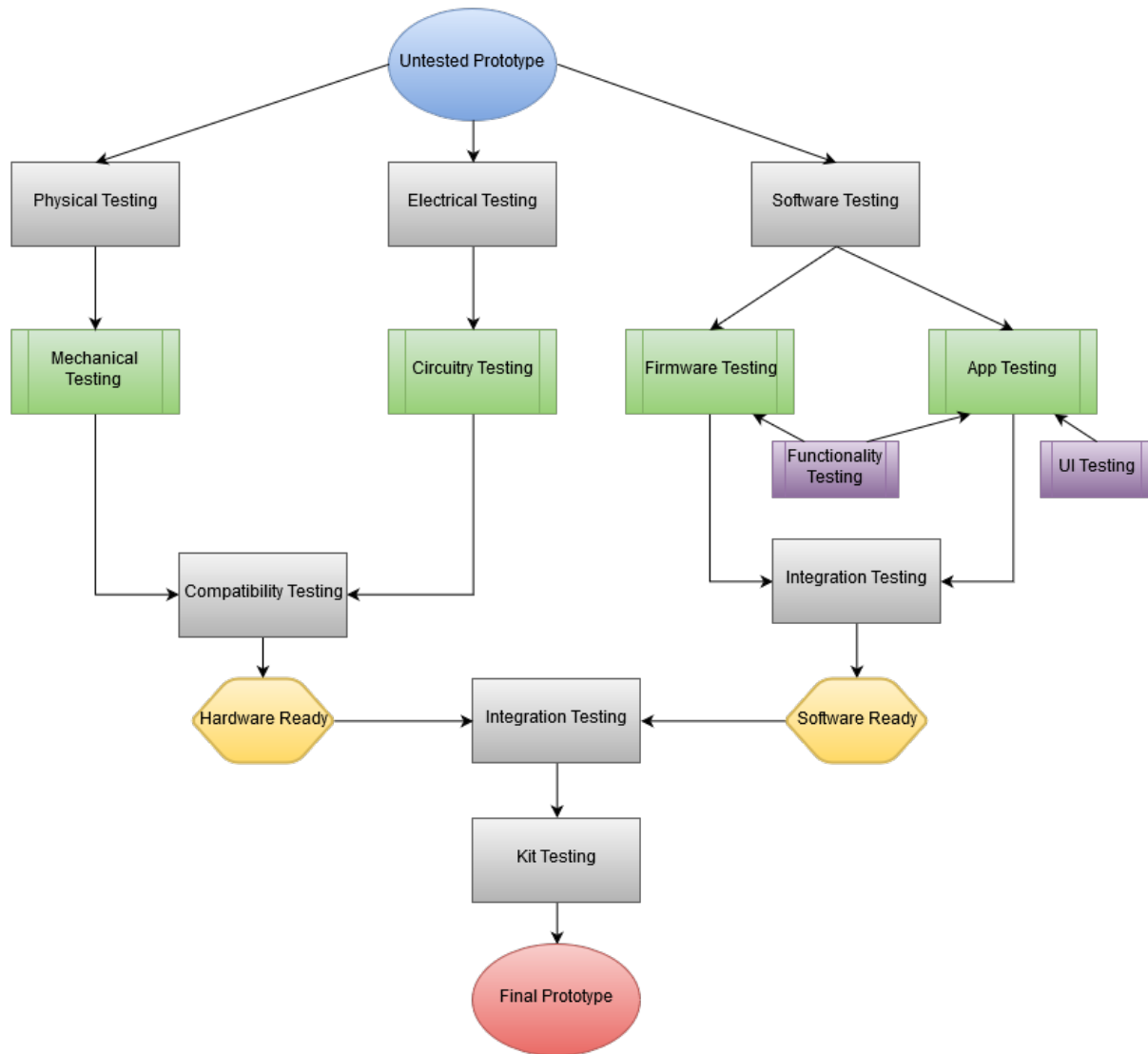


Figure 24: Flowchart of System Test Plan

A series of unit tests will be conducted at different stages of development of OxiTrak-5001, in order to help with the debugging process and error detection, and eventually to ensure overall efficient performance of the product. After the first stage of development, rigorous tests will be carried out to ensure that the features implemented work as desired; otherwise, major bugs should be caught and fixed before commencement, including replacing hardware parts and creating upgraded versions of the products software. By the second stage of development, the whole systems should be working efficiently and without glitch.

Some of the tests that could be conducted are as follows:



7.1 Hardware Test Plan

This section will be testing categories ranging from the stable encasing of the electronics to ensure accuracy of readings, to photo detection and signal filtration and amplification.

A. Mechanical Requirements

- a. Earpiece clip should not allow external light interference with the oximeter
- b. Earpiece clip should be tightly fitted to each user's earlobe (not too tight to block blood circulation and not too loose to cause inaccurate measurements)
- c. Earpiece clip should be isolated from outside noise
- d. Packaging should include mechanism to attach to user's ear lobe

B. Electrical Requirement

- a. Sensor circuit shall be able to pick up RED and INFRARED light waves and output corresponding voltage signals
- b. Photo-detection circuit shall output correct voltage outputs at RED (650nm) and INFRARED (900nm) wavelengths
- c. Filtration component should eliminate noise elements of signal from photo detection output
- d. Bandpass Filter shall extract signal from 0.8 to 3.0 Hz
- e. Amplification Circuit should bring signal to a readable value for microprocessor

7.2 Firmware Test Plan

The Firmware component of the system is crucial in processing the incoming signal from the electronics of the device. For a fully functional system, there are four steps to be tested:

A. LED Circuitry

- a. Firmware shall turn RED and INFRARED LEDs on and off at correct intervals
- b. Values should be initialized correctly to avoid error

B. Heart Rate Detection

- a. Firmware shall be able to track peaks of signal to detect a pulse
- b. Upon detection of pulses, firmware should be able to calculate an accurate rate

C. SPO₂ Level Detection

- a. Firmware shall be able to read voltage signals from RED wavelength signal and INFRARED signal
- b. Firmware should be able to interpolate a ratio between these two signals
- c. Upon calculation of this ratio, firmware should be able to calculate SPO₂ level based on calibrated formulae

D. Bluetooth Communication

- a. Microprocessor shall be able to pair with a smartphone running OxiTrak Software
- b. Microprocessor shall send correct levels of Heart Rate to paired device
- c. Microprocessor shall send correct SPO₂ levels to paired device



7.3 Software Test Plan

The goal of the software unit of the device is to integrate the oximeter with a user-friendly application for data display and notification, along with data forwarding capabilities and Bluetooth connectivity. The Bluetooth module will be implemented on the Intel Edison, and OxiTrak software team will program it such that it can be paired to the hardware, and establish Bluetooth connectivity with the mobile device.

A. Bluetooth Module

- a. The application shall communicate with Edison via Bluetooth
- b. The application will have reliable Bluetooth connection for data transfer

B. UI App Test

- a. The app shall be designed to be intuitive and interactive
- b. The registration and login shall occur through a unique username and secure password upon prompt of the app
- c. The system shall notify user of login failure through an error message, in the case of invalid user credentials
- d. The landing page will include data and diagrams of oxygenated blood levels and heart rate
- e. The settings menu icon will be easily recognized and accessed through the main page

C. Emergency Algorithm

- a. The application shall detect critical heart and oxygen levels from the received data
- b. Threshold shall be set for critical oxygenated blood levels and heart rate

D. Storage and Database Requirements

- a. The system shall validate user login credentials from a directory

E. Regression Test

- a. Implementation of additional features such as Geolocation tracking and Emergency notification does not introduce new bugs in the system

F. White Box Test

- a. Program structure is logical
- b. System features behave according to expectations

7.4 Overall System Testing

Pending successful testing of hardware, firmware and software components of OxiTrak, overall system testing will be conducted by comparison between data obtained from a standard hospital oximeter and OxiTrak. Both devices will be placed on an individual's earlobe and standard deviation of results will be calculated and considered. Results are expected to be fairly similar within limits.



8. Conclusion

This document encloses detailed design methods and procedures of the real-time emergency oximeter, OxiTrak. Combined with functional specifications document, it provides a detailed overview of the design of our product based on extensive scientific research. All three main components of the document have been detailed in terms of design, which are hardware, firmware and software.

9. Appendix

Hardware Test Plan Checklist			
Tested By		Date	
Procedure/ Expected result	Pass/Fail (P/F)	Actual Results	Comments
A - Mechanical Requirements			
a. No external light allowed			
b. Correct fitting of earlobe piece			
c. Earclip piece isolated from outside environment			
d. Packaged clip attaches to user's earlobe			
B - Electrical Requirements			
a. Sensor circuit picks up infrared and red light			
b. Photo detection circuit outputs correct voltage			
c. Noise eliminated from photo detection output			
d. Bandpass filter extracts signal from 0.8 - 3.0 Hz			
e. Amplification circuit outputs readable value			

Firmware Test Plan Checklist			
Tested By		Date	
Procedure/ Expected result	Pass/Fail (P/F)	Actual Results	Comments
A - LED Circuitry			
a. LEDs turned on and off at correct intervals			
b. Values initialized correctly			
B - Heart Rate Detection			
a. Firmware tracks peaks of signal and detects pulse			
b. Firmware calculates accurate rate of pulse			
C - SPO₂ Level Detection			
a. Firmware reads voltage signals from INFRARED and RED wavelengths signal			
b. Firmware interpolates signals between these two signals			
c. SPO ₂ levels calculated based on calibrated formula			
D - Bluetooth Communication			
a. Microprocessor pairs with OxiTrak app			
b. Microprocessor sends correct levels of heart rate			

c. Microprocessor sends correct SPO2 levels			
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Software Test Plan Checklist			
Tested By			Date
Procedure/ Expected result	Pass/Fail (P/F)	Actual Results	Comments
A - Bluetooth Module			
a. App communicates with Edison via Bluetooth			
b. App has reliable Bluetooth connection			
B - UI App Test			
a. App intuitive and interactive			
b. Unique user registration and login credentials			
c. Verification and notification of user credentials			
d. Landing page include diagrams of heart rate and oxygenated blood levels			
e. Settings menu icon easily recognized and accessed			
C - Emergency Algorithm			
a. App detects critical heart rate and oxygenated levels from data			

b. Threshold set for critical levels			
D – Storage and Database Requirements			
a. App stores the received data			
b. App stores data for few days			
c. User credentials validated from directory			
E – Regression Test			
a. No bugs introduced from additional emergency notification and geolocation features			
F – White Box Test			
a. Program structure is logical			
b. System features behave according to expectation			

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