

March 26, 2021

Dr. Craig Scratchley
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Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405W Design Specification for Harp Blood Pressure Monitor

Dear Craig Scratchley,

The following document contains the design specification for the Harp Blood Pressure Monitor. Our goal is to construct a non-invasive device that can measure diastolic blood pressure continuously. The device is intended to be comfortable enough to be worn throughout the day and be usable during most daily activities.

The design specification will provide a software specification, including the workflow, functions and data processing; the hardware specification, including our sensors, microcontroller and circuit design; the test plan, and UI specification of this device.

Thank you for taking the time to review our functional specification for the Harp Blood Pressure Monitor. If you have any questions or concerns regarding our document, please contact Khalil Ammar, our Chief Executive Officer.

Sincerely

A handwritten signature in black ink, appearing to read 'Khalil Ammar', written over a horizontal line.

Khalil Ammar
Chief Executive Officer
Chiron Solutions Inc.



Design Specification

Harp Blood Pressure Monitor

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Abstract

This document presents the design specification for the Harp Blood Pressure Monitor in detail. The product is composed of 2 main modules:

- Hardware module: The hardware module contains 3 sensors to collect ECG, SCG and PPG data, an Arduino microcontroller and a Bluetooth module to interface with the software module
- Software module: A mobile application that receives the sensor data from the hardware module and processes it to calculate the user's blood pressure in real-time and displays it in a user-friendly format.

The Harp Blood Pressure Monitor aims to provide users with a portable and easy to use continuous blood pressure monitor that has minimal interference with their day-to-day lives. Therefore, the design decisions outlined in this document are mostly dictated by the need to minimize the size while maximizing the battery life of our product. The design specifications outlined in this document fit our needs and abide by the aforementioned constraints.

The document also includes appendices that provide an overview of our product's appearance and software UI as well as a comprehensive test plan to ensure that our implementation covers all the requirements.

Table of Contents

Abstract	i
List of Tables	iii
List of Figures	iv
Glossary	v
1. Introduction	1
1.1 Background	1
1.2 Scope	1
1.3 Intended Audience	1
1.4 Design Specification Format	2
2. Software Specification	2
2.1 Platform	2
2.2 Functionality	2
2.3 Data Collection	6
2.3.1 ECG	6
2.3.2 PPG	6
2.3.3 Accelerometer (for SCG)	6
2.4 Data Transmission	7
2.5 Data Processing	8
2.5.1 Pre-Processing	8
2.5.2 Blood Pressure Calculation	9
2.5.3 User-Specific Parameter Calibration	10
3 Blood Pressure Monitoring System	12
3.1 Sensor specification	12
3.2 Lead Heart Rate Monitor	13
3.3 Accelerometer	13
3.4 Pulse Oximeter and Heart Rate Sensor	14
4 Hardware Specification	16
4.1 Microcontroller	17

Harp Blood Pressure Monitor - Design Specifications

4.2 Power consumption of ATmega328	18
4.3 System design connection	19
4.4 Communication Methods	20
4.4.1 I2C	21
4.4.2 UART	22
4.5 Workflow	22
4.6 Circuit design	23
4.7 Power Supply	24
4.8 Other components	24
4.8.1 Electrodes	24
4.8.2 Bluetooth	24
4.9 Design alternatives	25
Conclusion	25
References	27
Appendix A – Acceptance Test plan	30
A.1 Introduction	30
A.2 Hardware Testing	30
A.3 Software Testing	31
A.4 User Testing	32
Appendix B – User Interface	33
B.1 Introduction	33
B.1.1 Purpose	33
B.1.2 Scope	33
B.2 Graphical Representation	33
B.3 User Analysis	37
B.4 Technical Analysis	38
B.4.1 Discoverability	38
B.4.2 Feedback	38
B.4.3 Conceptual Models	38
B.4.4 Affordance	39
B.4.5 Signifiers	39

Harp Blood Pressure Monitor - Design Specifications

B.4.6 Mapping	39
B.4.7 Constraints	39
B.5 Engineering Standards	39
B.6 Usability Testing	39
B.6.1 Analytical Usability Testing	39
B.6.1.1 Harp Blood Pressure Monitor	40
B.6.1.2 Mobile Application	40
B.6.2 Empirical Usability Testing	40
B.6.2.1 Harp Blood Pressure Monitor	40
B.6.2.2 Mobile Application	41
B.7 Conclusion	41
B.8 References	41
Appendix C - Design Choice Justification	42
C.1 Software Design	42
C.2 Hardware Design	43
References	44

List of Tables

Table 1: Glossary Table	7
Table 2: Design specifications for mobile application platform	2
Table 3: Design specifications for software application	5
Table 4: Design specifications for Data Collection	5
Table 5: Design specifications for Data Transmission	6
Table 6: Design specifications for calibration	12
Table 7: Sensor specification	12
Table 8: AD8232 working environment[2]	13
Table 9: MMA8452Q working environment [3]	14
Table 10: MAX30101 working environment[4]	15
Table 11: MAX32664 working environment[5]	16
Table 12: Hardware specification	19
Table 13: microcontroller working data [6]	20
Table 14: Sensor connections	20
Table 15: Test Plan for Hardware Testing	31
Table 16: Test Plan for Software Testing	32
Table 17: Test Plan for Hardware Testing	33
Table 18: List of Engineering Standards	41
Table 19: Software design choices justification	44
Table 20: Hardware design choices justification	45

List of Figures

Figure 0: System overview	2
Figure 1: Home Screen Example	3
Figure 2: BP Graph example	4
Figure 4: Bluetooth Low Energy (BLE) Service profile internal-view	7
Figure 5: : PEP and PTT from ECG(green), SCG(Blue), and PPG(Orange) data	10
Figure 6: Steps for Linear Regression Method	11
Figure 7: Calibration steps using oPTP, mPTP, and fPTP	11
Figure 8: Lead Heart Rate Monitor (AD8232)	13
Figure 9: AD8232 PIN configuration [2]	13
Figure 10: Accelerometer (MMA8452Q)	14
Figure 11: MMA8452Q PIN configuration[3]	14
Figure 12: Pulse Oximeter and Heart Rate Sensor(MAX30101&MAX32664)	15
Figure 13: PIN diagram of sensor (MAX30101)	15
Figure 14: PIN diagram of analysis	16
Figure 15: SparkFun RedBoard Qwiic[8]	17
Figure 16: Block diagram of ATmega328 [6]	18
Figure 17: Microcontroller layout and PIN layout of SparkFun RedBoard Qwiic[6]	21
Figure 18: I2C protocol [9]	21
Figure 19: System simple block diagram	22
Figure 20: Circuit Layout	23
Figure 21: Electrodes (with 3-connector pad cables)[18][19]	24
Figure 22: ESP32- WROOM (Bluetooth module)[20]	24
Figure 23: Android App - Issues Page	35
Figure 24: Android App - 4 variations of the Homepage	36
Figure 25: Android App - Statistics with three slides Pages	36
Figure 26: Android App - Settings Page	37
Figure 27: Front View of the Module	38
Figure 28: Top View of the Module	38

Glossary

Term	Definition
DBP (Diastolic Blood Pressure)	The lowest/minimum arterial pressure occurring each heartbeat.
ECG (Electrocardiogram)	A graph of voltage versus time of the electrical activity of the heart using electrodes placed on the skin.
PEP (Pre-Ejection Period)	The time period between the onset of left ventricular depolarization (the onset of QRS complex on electrocardiogram (ECG), and in particular the ECG Q wave when available) and the opening of the aortic valve.
PPG (Photoplethysmography)	Optical technique used to detect volumetric changes in blood in peripheral circulation
PTP (Point-to-Point)	A type of calibration of cuff-less blood pressure (BP) measurement.
PTT (Pulse Travel/Transit Time)	The time it takes a pulse wave to travel between two arterial sites.
SBP (Systolic Blood Pressure)	The highest/maximum arterial pressure occurs in each heartbeat.
SCG (Seismocardiography)	The non-invasive measurement of accelerations in the chest wall produced by myocardial movement
oPTP (one Point-To-Point)	Calibration method using one sample
mPTP (mean Point-To-Point)	Calibration method through averaging
fPTP (factor Point-To-Point)	Calibration method through introducing a penalty factor

Table 1: Glossary Table

1. Introduction

1.1 Background

About 14.4% of the global population suffers from hypertension, and many more are at risk of developing blood-pressure-related diseases at a later stage in their lives [1]. That is why it is very important for individuals, whether healthy or not, to constantly keep an eye on their blood pressure and share these trends with their doctors to prevent developing such diseases [2].

Unfortunately, current solutions to measure blood pressure are not ideal. The go-to solution for anyone who wishes to measure their blood pressure from the comfort of their own home is the cuff-based blood pressure monitors. These monitors are bulky, uncomfortable, and they make it hard for the user from doing anything else while measuring[3].

That is where our device, the Harp Blood Pressure Monitor, comes in. Our product is a small module that attaches to the user's chest with the help of a comfortable strap. The module connects to a mobile application where the user can see their blood pressure amongst other vital signs in real-time. Harp Blood Pressure Monitor is portable, comfortable to use, and provides continuous readings of the user's blood pressure.

1.2 Scope

This document outlines the design specifications for our product as dictated by the requirement specifications document. The document will describe the design choices that were made for each module and submodule in detail and provide justification for each choice in "Appendix C". The scope of this document covers mostly the proof of concept but some design options for the engineering prototype and the final product will be discussed as well.

Furthermore, the appearance of the mobile application and the hardware module for the Harp Blood Pressure Monitor, as well as a detailed step-by-step test plan will be provided in the attached appendices.

1.3 Intended Audience

The intended audience for this document is the entirety of the R&D team of Chiron Solutions Inc. The following document will be used as a guideline for the developers working on bringing the Harp Blood Pressure Monitor to market. The design specifications will be used to ensure the product's compliance with the requirements outlined in the Requirements Specifications document.

1.4 Design Specification Format

For the sake of clarity and consistency, we will be using a standardized format to refer to our design specifications:

D.[Section].[Subsection].[Specification Number]-[Design Stage]

Where “Design Stage” should be one of the following:

- A: Alpha stage (proof of concept)
- B: Beta stage (engineering prototype)
- F: Final product

1.5 System overview

The system use consists of a sensor with a belt, the sensor measures the ESG,PPG and SCG data and transfers it to the APP through Bluetooth. Then the APP can represent all data.

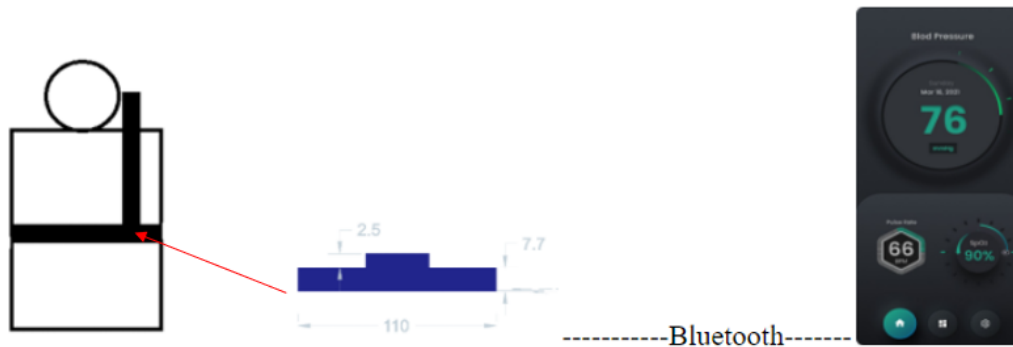


Figure 0: System overview

2. Software Specification

2.1 Platform

There are many reasons as to why our product requires a mobile app. First, the Arduino microcontroller does not have enough processing power to handle the complex data analysis that is required in real-time. Second, the user needs an easy and convenient way to interface with the product and a smartphone app is the best way to do that since almost everyone carries a smartphone nowadays.

Harp Blood Pressure Monitor - Design Specifications

The mobile platform on which we will develop our app will be Android for two reasons. The main reason is that Android controls a large share of the mobile market with 79.63% of users being Android users so building an Android app would allow our app to reach a much bigger user base than if we were to develop an iOS app [4]. The other reason is that our members do not have the hardware required to build an iOS app. The app will support Android 10 since it holds the highest share of users with 45.29% compared to other versions [5].

D.2.1.1-B	The mobile app shall support Android 10
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Table 2: Design specifications for mobile application platform

2.2 Functionality

The mobile application will allow the user to interface with the hardware module by providing simplified data visualization while abstracting the complex mathematical formulas that are used to calculate the blood pressure. This abstraction allows us to reach a broader customer base, especially considering that the majority of our target audience are not tech-savvy. The app will be simplified in such a way that the user can visualize their blood pressure from the home screen without requiring much setup as is shown in **Figure 1** and **Figure 2**. Further customization features will be included in the app but are not required to make use of its basic functionality.

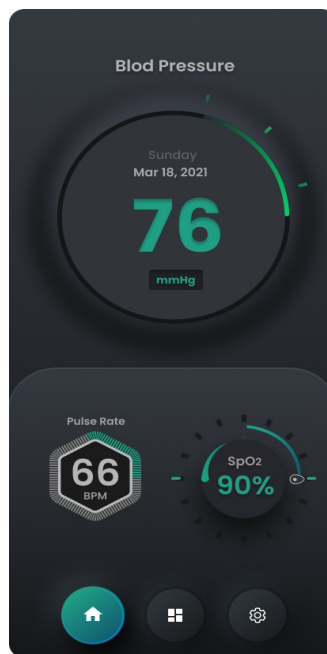


Figure 1: Home Screen Example

Harp Blood Pressure Monitor - Design Specifications



Figure 2: BP Graph example

D.2.2.1-B	The app shall allow the user to select the frequency of data visualization.
D.2.2.2-B	The app shall provide the user with different ways of visualizing the data
D.2.2.2.1-B	The app shall have an option to view the data in graph form
D.2.2.2.2-B	The app shall have an option to view the data points in real-time
D.2.2.3-B	The app shall have an alert feature

D.2.2.3.1-B	The app shall provide the user with the option to select the threshold value for the alert
D.2.2.3.2-B	The app shall allow the user to turn on/off the alert feature
D.2.2.4-B	The app shall allow the user to send the data by email
D.2.2.4.1-B	The user shall be able to convert the data to csv or JPEG format before sending the e-mail
D.2.2.5-B	The app shall allow the user to create/edit his health profile
D.2.2.5.1-B	The health profile shall include the name, age, gender, medication, and medical history of the user
D.2.2.6-B	The app shall allow the user to choose how far back in time his data can be accessed
D.2.2.6.1-B	This period shall not exceed 30 days
D.2.2.7-B	The app shall communicate with the hardware using the BLE protocol.

Table 3: Design specifications for software application

2.3 Data Collection

D.2.3.1-A	The sensors shall be able to communicate with the microcontroller (arduino).
-----------	--

Harp Blood Pressure Monitor - Design Specifications

D.2.3.2-B	The arduino shall process the data to scale the signal.
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Table 4: Design specifications for Data Collection

Data is collected in analog format (for ECG and PPG) and digital format (for accelerometer) by the sensors, passed on to the analog or digital pins of the microcontroller (arduino) where we must first denoise this data and scale it based on the operation mode (power supplied to the circuit). In particular:

2.3.1 ECG

The Heart rate monitor (AD8232) can be connected to the arduino's analog pins and using the function `analogread()`, we can take readings and put them in an array or similar data structure for temporary storage.

2.3.2 PPG

The PPG sensor (MAX30101/MAX32664) can be connected through Sparkfun's "Qwiic" interface cable to their redboard (arduino based) or using analog pins with any arduino. Then, using the "<SparkFun_Bio_Sensor_Hub_Library.h>" library and the custom classes, we can easily take readings related to blood pressure and blood oxygen levels, these readings will again be put in a suitable data structure (array) for temporary storage.

2.3.3 Accelerometer (for SCG)

The accelerometer (MMA8452Q) is used to estimate SCG. The sensor can be connected to the SCL and SDA lines of the arduino. Then, using the `wires.h` library and driver functions from sparkfun, we can collect readings and access advanced features such as tap, orientation, and interrupts. The data will be put in a suitable data structure (array) for temporary storage.

2.4 Data Transmission

D.2.2.1-B	The mode of transmission shall not consume too much power.
D.2.2.2-B	The transmission protocol shall allow both inbound and outbound traffic.
D.2.2.3-B	The mode of transmission shall retain the accuracy of the data as collected by the sensors.

Table 5: Design specifications for Data Transmission

Harp Blood Pressure Monitor - Design Specifications

We have chosen Bluetooth Low Energy (BLE) as our mode of transmission. It uses Generic Attributes hierarchical data structure or GATT standard, which defines the abstract interface over which two BLE devices can communicate with each other and an abstract model is shown below in **Figure 4**. The server will be the arduino module in this scheme and the application will be the client.

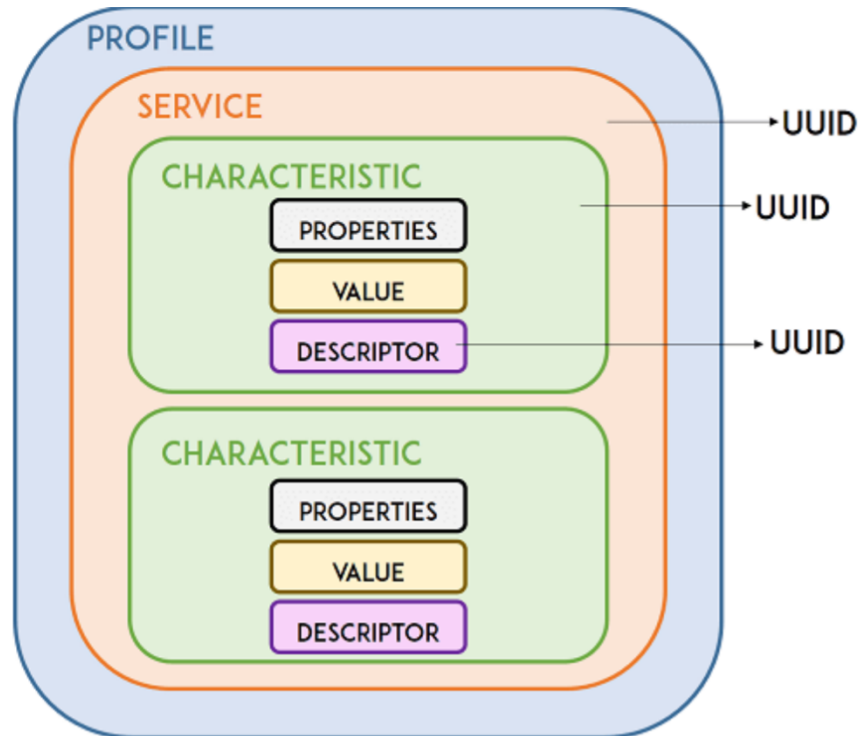


Figure 4: Bluetooth Low Energy (BLE) Service profile internal-view [6]

Basically, to transmit data, we must use certain predefined characteristic services such as: Heart Rate Measurement (UUID 0x2A37) and Body Sensor Location (UUID 0x2A38) but will also be implementing more characteristics to transfer Accelerometer data, personalization settings from the app, as well as any other heart rate data that can not fit in the Heart rate measurement characteristic.

For each one of these characteristics, we will also assign the read property (for the client) for the sensor readings, which will allow the application (client) to read sensor values and write property for the settings, so the client can send updated user preferences and the arduino can receive these updated settings from the client. As for the implementation of this structure in our application, we can use the BluetoothGatt class from the Android API for development on android, and the CoreBluetooth APIs from Apple for development on iOS, these APIs handle

Harp Blood Pressure Monitor - Design Specifications

interactions with BLE devices from the phone, such as searching, connecting and transferring data to and from a BLE GATT server (arduino in our case).

Explanation: We chose BLE over Bluetooth because it allows for lower power consumption by going to sleep instead of keeping an active connection.

2.5 Data Processing

Once the raw data has been received by the phone over BLE, it is firstly saved on the phone in a compatible format (CSV) so it can be kept for record keeping and the .csv file can be exported out if the patient desires. This csv file can also be readily exported from the app to upload to any cloud services or transfer via email. This can facilitate sharing the user's health status with his doctors and/or caregivers.

2.5.1 Pre-Processing

Before the raw data can be utilized in the blood pressure calculation algorithm, it needs to be pre-processed to remove external noise, unwanted frequencies and to smooth the data to increase accuracy and reduce the algorithm's susceptibility to motion artifacts.

To avoid spending too much time experimenting with different methods to pre-process the raw data, we used pre-processing steps mentioned in one of the research papers on which our design is based [7].

The raw ECG data will be amplified by a factor of 200 then passed through a high pass filter with a cutoff frequency of 0.3 Hz to remove unwanted low-frequency components. The output of the high-pass filter will be passed through a second order butterworth low-pass filter with a cutoff frequency of 40 Hz [7].

The raw PPG data will be "passed through a passive high-pass filter with a cutoff frequency of 0.3 Hz, followed by a second-order Butterworth low-pass filter with a cutoff frequency of 20 Hz." Since the PPG and ECG data provided by the sensor is analog, we would first need to pass them through an ADC before pre-processing [7].

The raw accelerometer data for the SCG measurement will be configured "with a sensitivity of 420 mV/g, followed by a passive first-order low-pass filter with a cutoff frequency of 22 Hz". The only axis we are interested in is the z-axis (the axis going through the body of the user) otherwise known as the anteroposterior axis[7].

2.5.2 Blood Pressure Calculation

Once all the raw individual data has been pre-processed, it is ready to be processed by the algorithm from the paper, we can estimate the Pulse Pressure using the following equation:

$$PP \approx \beta_1 \cdot \frac{PEP}{PTT^2} + \beta_2 \cdot \frac{1}{PTT^2} + \beta_0.$$

Where β_0 , β_1 , and β_2 are subject-specific parameters, the PTT = Pulse Transit Time and PEP = pre-ejection period can be both extracted from the ECG, PPG and SCG waveforms as shown in Figure x. The DBP can be calculated using the following equation, where α_0 and α_1 are subject-specific parameters:

$$BP = \frac{\alpha_1}{PTT} + \alpha_0.$$

From this, we can also calculate the systolic pressure:

$$SBP = DBP + PP$$

Once these values are calculated, they will update the main console and graphs. Based on the user's settings, it can also notify the user about a new reading or alert the user about the reading being above or below a threshold.

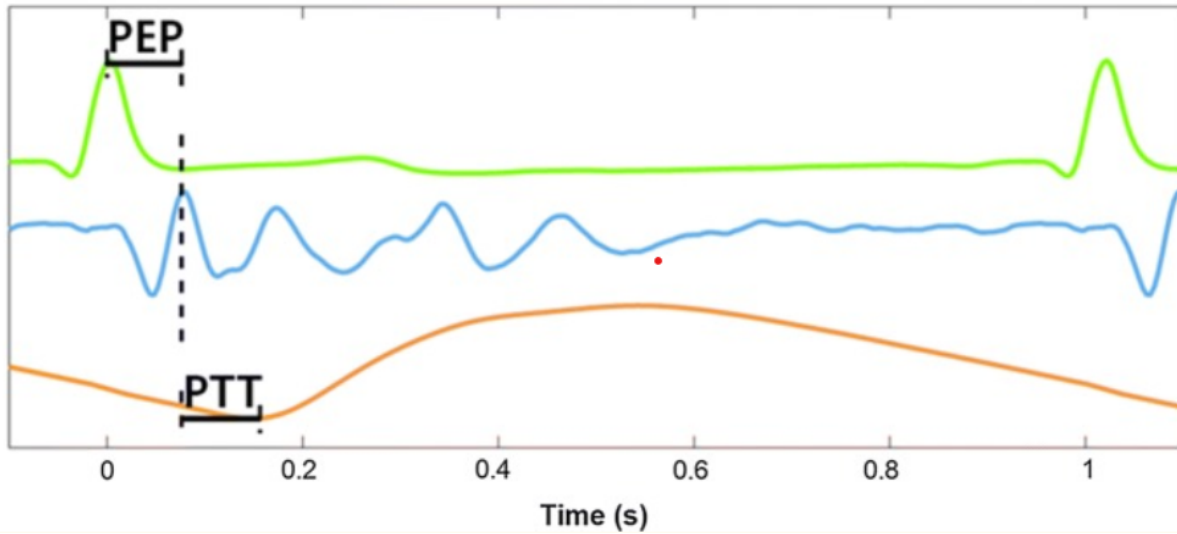


Figure 5: : PEP and PTT from ECG(green), SCG(Blue), and PPG(Orange) data [7]

2.5.3 User-Specific Parameter Calibration

The Harp Blood Pressure Monitor uses the algorithm mentioned in the previous section to calculate the user's blood pressure in real-time based on the PTT and PEP extracted from the sensor data. However, these values vary from individual to another due to differences in physiological parameters such as artery elasticity [7].

Therefore, to provide accurate readings, each user will need to calibrate their device using BP readings from a cuff monitor. This calibration is only needed before the first use and every few months depending on the medications taken by the user. Each user is encouraged to consult with their doctor to find out how frequently they need to calibrate their device.

There are various methods that we can use to calculate the user-specific parameters such as using the least-squares regression coupled with one Point-To-Point (oPTP) method or employing more complex methods such as mean PTP (mPTP), or factor PTP (fPTP) which are harder to implement but provide a more robust calibration experience and reduce the frequency of required calibration [8].

Employing the least-squares regression method and oPTP would provide sufficient results for our proof of concept. The purpose of least-squares regression is to find the best linear fit given a set of data points N . This method can therefore be applied to our linear models introduced in the previous section. The steps to calculate the best linear fit as well as the steps to calibrate the device using the various Point-To-Point methods are outlined in Figure 6 and Figure 7 respectively [8][9].

Harp Blood Pressure Monitor - Design Specifications

Step 1: For each (x,y) point calculate x^2 and xy

Step 2: Sum all x , y , x^2 and xy , which gives us Σx , Σy , Σx^2 and Σxy (Σ means "sum up")

Step 3: Calculate Slope **m**:

$$m = \frac{N \Sigma(xy) - \Sigma x \Sigma y}{N \Sigma(x^2) - (\Sigma x)^2}$$

(N is the number of points.)

Step 4: Calculate Intercept **b**:

$$b = \frac{\Sigma y - m \Sigma x}{N}$$

Step 5: Assemble the equation of a line

$$y = mx + b$$

Figure 6: Steps for Linear Regression Method[8]

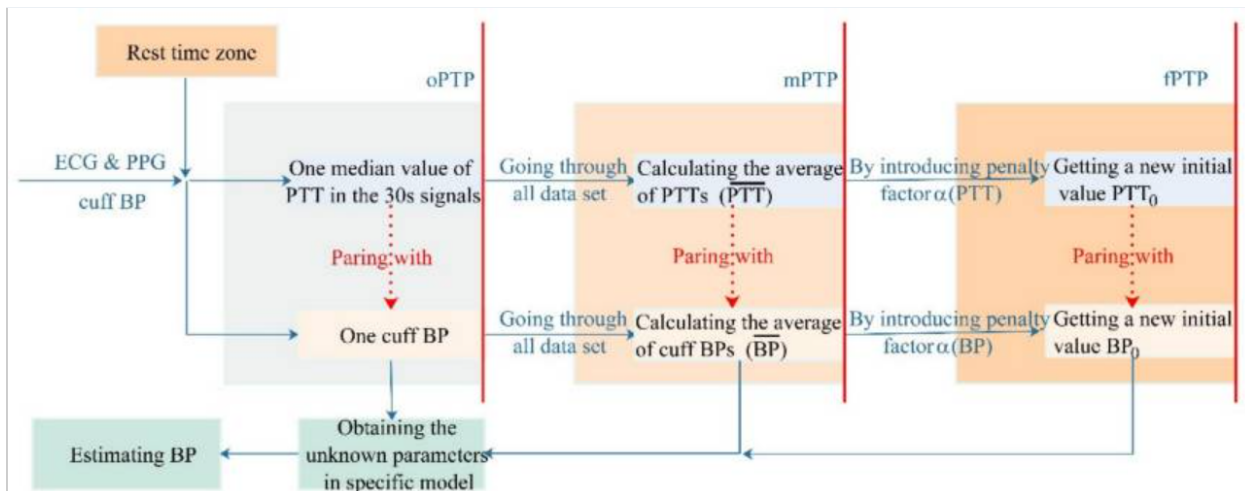


Figure 7: Calibration steps using oPTP, mPTP, and fPTP[9]

D.2.5.3.1-A	The device shall require the user to perform a calibration before the first use
D.2.5.3.2-A	The calibration for the proof of concept shall utilize the Least-Squares regression method and oPTP
D.2.5.3.3-B	The engineering prototype shall utilize at least the mPTP calibration method

Table 6: Design specifications for calibration

3 Blood Pressure Monitoring System

3.1 Sensor specification

Our product contains 3 sensors to measure the ECG, SCG and PPG from the users to analyze their blood pressure. The SCG and PPG sensors are using I2C to communicate with the microcontroller, and the ECG sensor is using UART to and transfer digital signals directly to the microcontroller.

Sensor specification	
D.3.1.1-A	All sensors shall communicate with the microcontroller with the proper protocol
D.3.1.2-A	The Lead Heart Rate Monitor shall measure the ECG
D.3.1.3-A	The accelerometer shall collect the data for SCG and transfer it to the microcontroller
D.3.1.4-A	Pulse Oximeter and Heart Rate Sensor contains 2 components and shall measure and analyze pulse oximeter for PPG.

Table 7: Sensor specification

3.2 Lead Heart Rate Monitor

Lead Heart Rate Monitor (AD8232) can collect the electrical activities through the electrodes from the body. The collected electrical activities will be transferred to the microcontroller, and processed for charting the ECG.[19]

Supply Voltage	-0.3V to 3.6V
Storage Temperature Range	-65°C to +125°C
Operating Temperature Range	-40°C to +85°C
Voltage on each pin	-0.3V to Vs+0.3V

Table 8: AD8232 working environment

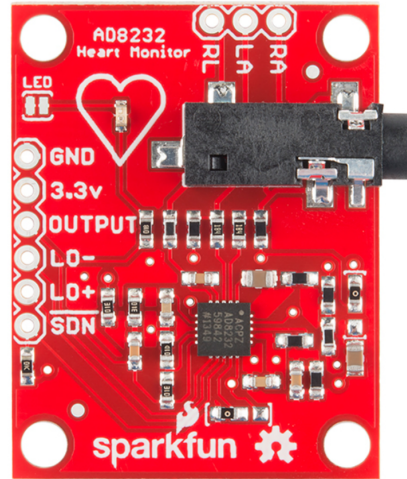


Figure 8: Lead Heart Rate Monitor (AD8232)

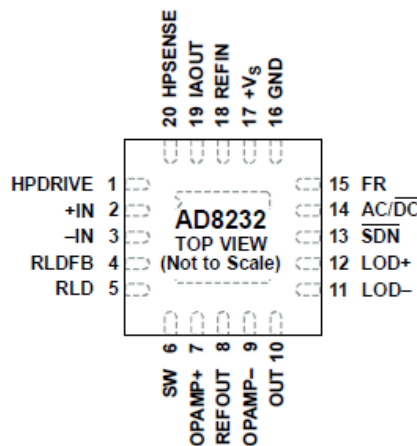


Figure 9: AD8232 PIN configuration [10]

3.3 Accelerometer

MMA8452Q is a 3-axis accelerometer. In the product, it will be used to collect the data for SCG and transfer it to the microcontroller. The accelerometer will just be against the skin, it will measure the vibrations in the blood vessels in terms of acceleration. The the data MMA8452Q collected is the SCG data[24]

Supply Voltage	-0.3V to 3.6V
Storage Temperature Range	-40°C to +125°C
Operating Temperature Range	-40°C to +85°C
Voltage on each pin	-0.3V to Vs+0.3V
Maximum Acceleration (all axes, 100 μ s)	5000g

Table 9: MMA8452Q working environment [11]

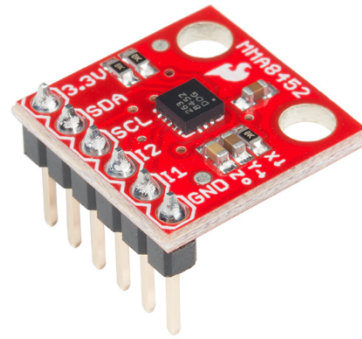


Figure 10: Accelerometer (MMA8452Q)

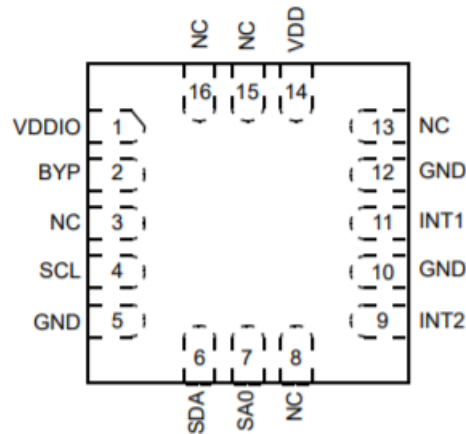


Figure 11: MMA8452Q PIN configuration[11]

3.4 Pulse Oximeter and Heart Rate Sensor

Pulse Oximeter and Heart Rate Sensor has two functions: pulse oximeter for PPG and Heart rate for ECG. It contains components on the board: MAX30101 and MAX32664. MAX30101 is the sensor, it will collect the data through shining different light such as red, infrared, and green light through your skin. Then it will read the light without being absorbed by skin. And the light will be sent to the biometric sensor hub of MAX32664, and it will analyze the data from the sensor and send the data to the microcontroller. In this case, MAX30101 & MAX32664 will collect both ECG and PPG data when it is working.[19 - 25]

Harp Blood Pressure Monitor - Design Specifications

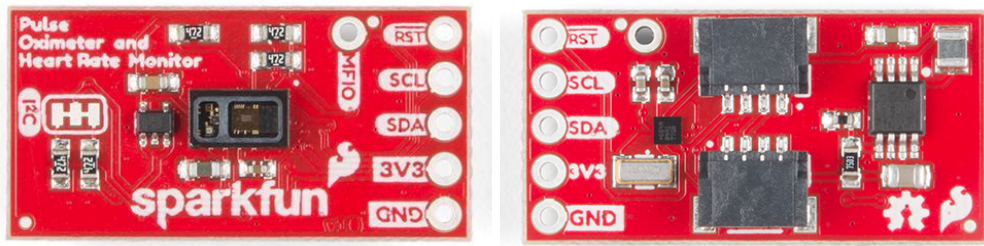


Figure 12: Pulse Oximeter and Heart Rate Sensor(MAX30101&MAX32664)

Supply Voltage	-0.3V to 3.6V
Storage Temperature Range	-40°C to +125°C
Operating Temperature Range	-40°C to +85°C
Voltage on each pin	-0.3V to Vs+0.3V

Table 10: MAX30101 working environment[12]

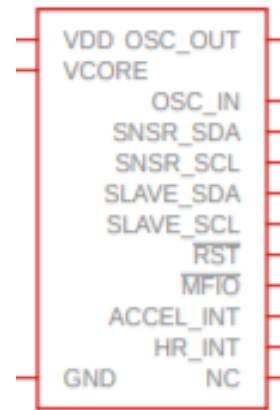


Figure 13: PIN diagram of sensor (MAX30101)

Supply Voltage	-0.3V to 3.6V
Storage Temperature Range	-40°C to +125°C
Operating Temperature Range	-40°C to +85°C
Voltage on each pin	-0.3V to Vs+0.3V

Table 11: MAX32664 working environment[13]

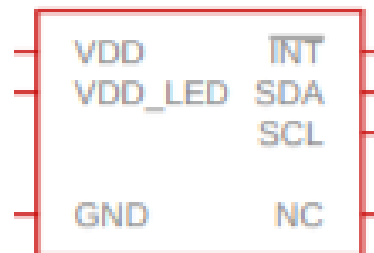


Figure 14: PIN diagram of analysis

Note: MAX30101 and MAX32664 are on the two side of the same board, so their parameters are the same

4 Hardware Specification

4.1 Microcontroller

We use SparkFun RedBoard Qwiic[16] in the current phase, the microcontroller of RedBoard is ATmega328 on Arduino pro mini 328. Arduino pro mini 328 is a 3.3V Arduino running the 8MHz bootloader. The support voltage of the RedBoard is 7-15V. The new feature we applied in this project is Qwiic connector[16]. And here are the hardware peripherals we may use in the blood pressure monitoring system: 20 Digital I/O pins with 6 PWM pins, UART, SPI and external interrupts[16].

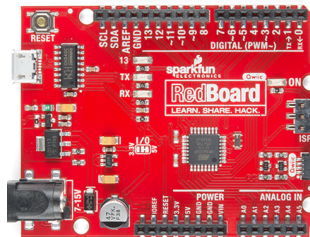


Figure 15: SparkFun RedBoard Qwiic[16]

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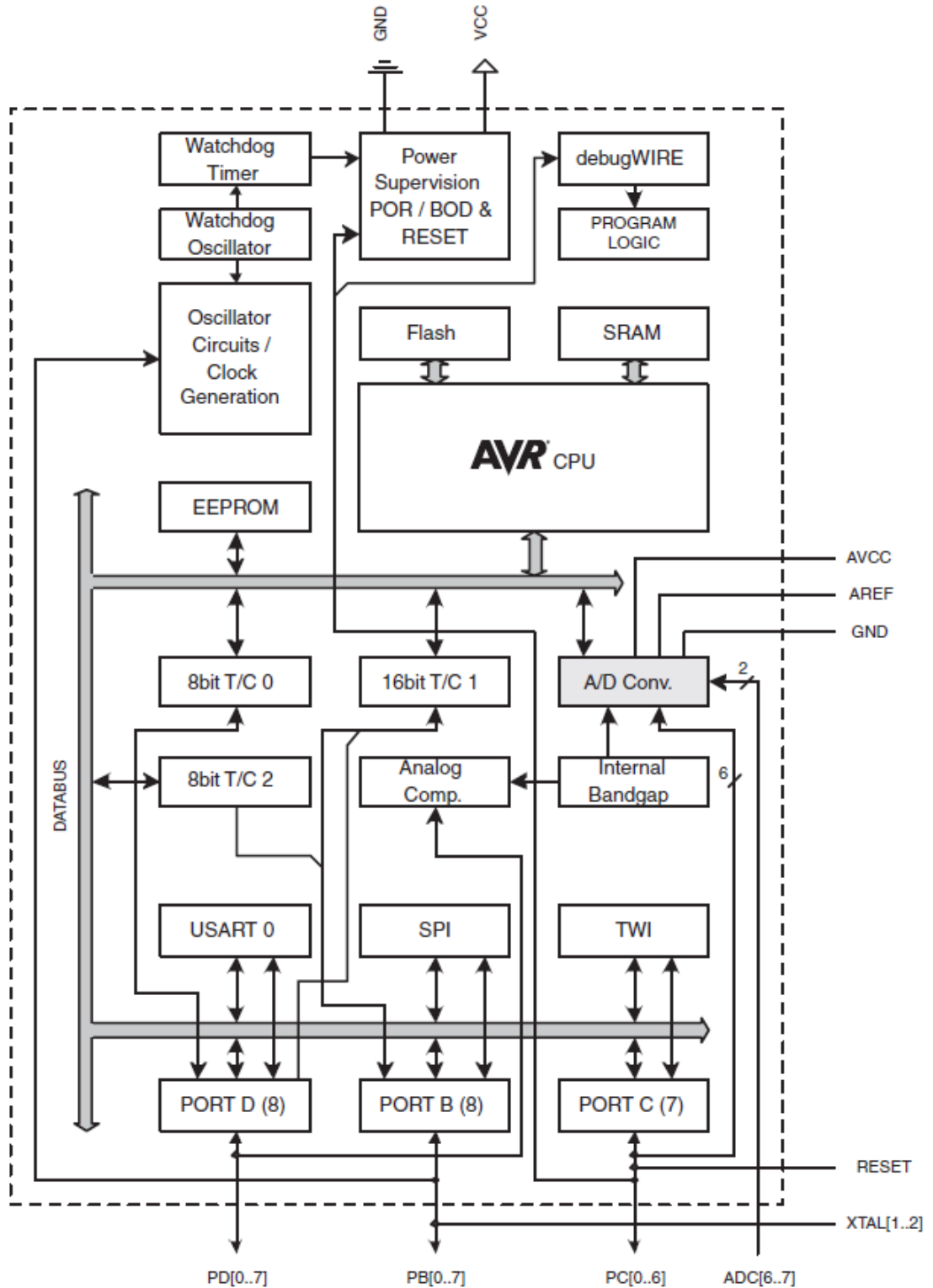


Figure 16: Block diagram of ATmega328 [14]

Hardware specification	
D.4.1.1-A	The RedBoard Qwiic shall be our microcontroller.
D.4.1.2-A	There shall be 3 sensors that transfer the data to the microcontroller through PINs and
D.4.1.3-A	The work voltage of the system shall be 3.3 volts.
D.4.1.4-A	The accelerometer and the Oximeter shall transfer the data to the microcontroller with I2C
D.4.1.5-A	The Heart Rate Monitor shall transfer the data to the microcontroller with UART
D.4.1.6-A	There shall be 10 PINs used to drive the system
D.4.1.7-B	The board shall work with a 5V 180mAh battery and the lifetime should be at least 30 hours
D.4.1.8-A	The circuit shall connect the microcontroller and the sensors
D.4.1.9-B	The circuit shall use ESP32 as the bluetooth module

Table 12: Hardware specification

4.2 Power consumption of ATmega328

According to the manual, there are a few different values of current under different conditions. (We use condition 25 C (room temperature) as a general condition). In this case, we pick 3V as our input voltage, then in the active mode, we have $f = 4\text{MHz}$, $V = 3\text{V}$, and the normal current is 1.2 mA, maximum current is 2.5 mA [14].

Mode	Frequency(MHz)	Voltage (V)	typical current (mA)	maximum current(mA)
Active	1	2	0.2	0.5
	4	3	1.2	2.5

Harp Blood Pressure Monitor - Design Specifications

	8	5	4.2	9
Idle	1	2	0.03	0.15
	4	3	0.2	0.7
	8	5	0.9	2.7

Table 13: microcontroller working data [14]

4.3 System design connection

The RedBroad Qwiic has a variety of pins, here are what we used for each sensor:

“Output”, “LO+” and “LO-” of single lead heart rate monitor(AD8232) are connected to the PIN “A0”, “10” and “11” of RedBoard respectively. “SCL” and “SDA” of (MMA8454Q)

Note: we use the pin labels on RedBroad Qwiic not ATmega328, because ATmega328 does not have “QWIIC”.

Sensor	Function	Name	Type	ADC	PIN
AD8232	Analog output	Output	I/O	ADC0	A0
	Leads-off Detect +	LO+	I/O	N/A	10
	Leads-off Detect -	LO-	I/O	N/A	11
MMA8452Q	Clock	SCL	I/O	N/A	SCL
	Data	SDA	I/O	N/A	SDA
MAX30101 & MAX32664	Data & Clock	QWIIC	I/O	N/A	QWIIC
	Muti IO	MFIO	I/O	N/A	5
	Reset	RST	I/O	N/A	4

Table 14: Sensor connections

Note: other connections like “3.3V”, “GND” do not represent in the table.

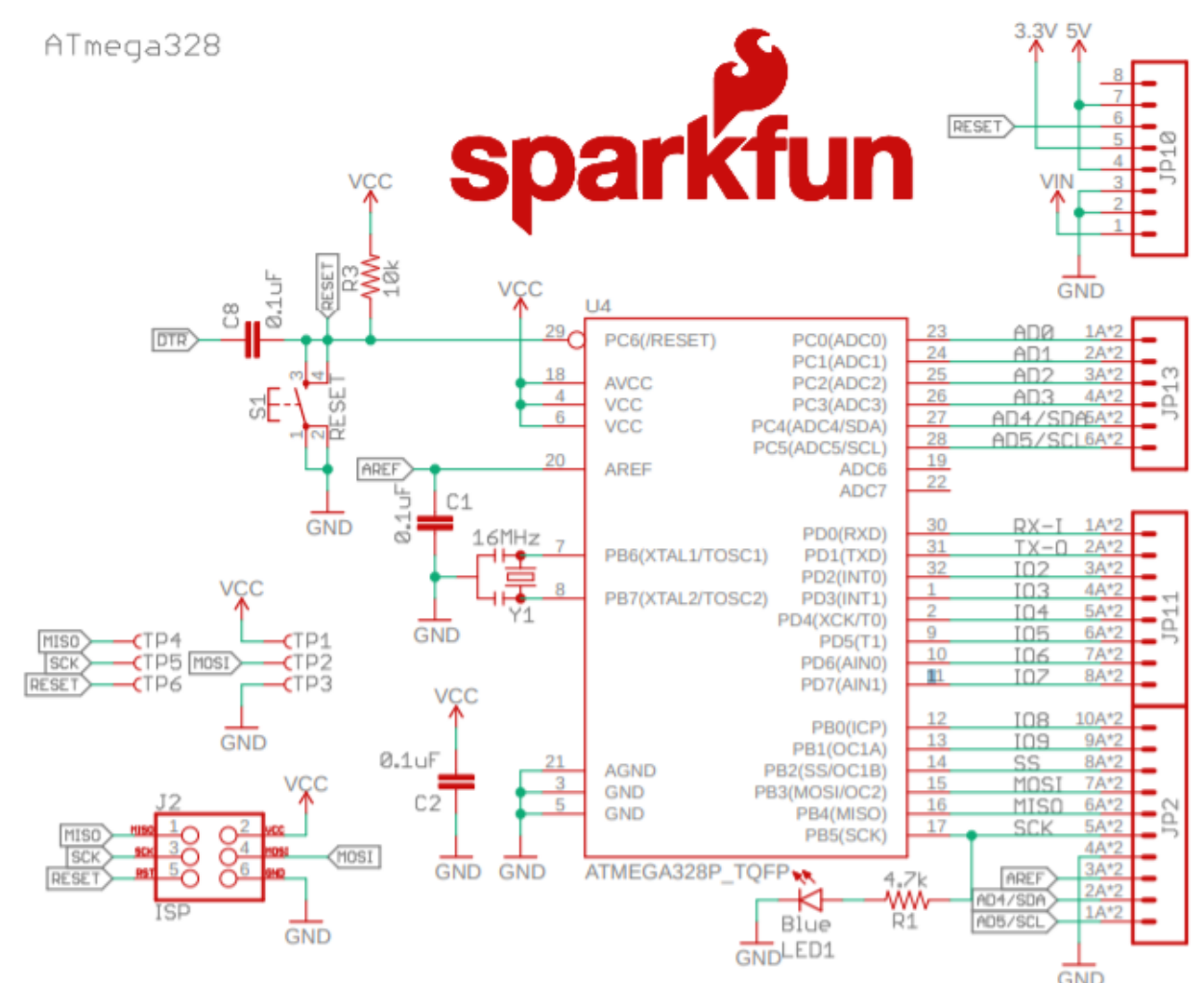


Figure 17: Microcontroller layout and PIN layout of SparkFun RedBoard Qwiic[14]

4.4 Communication Methods

4.4.1 I2C

In the project, the MMA8452Q and MAX30101 & MAX32664 use I2C. The I2C bus is a two-way two-wire synchronous serial bus developed by Philips[17]. It can use two wires to transfer data between devices connected to the bus[17].

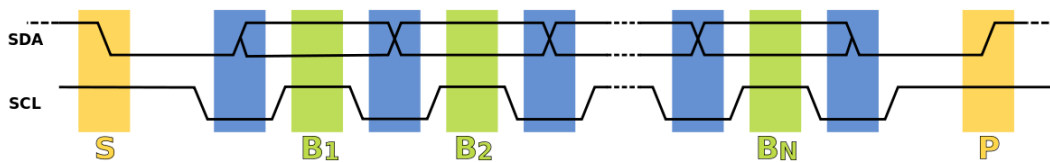


Figure 18: I2C protocol [17]

4.4.2 UART

AD8232 uses UART. UART’s full name is “universal asynchronous receiver-transmitter”. It is a universal serial data bus used for asynchronous communication. This bus has two-way communication, which can realize full-duplex transmission and reception [18].

4.5 Workflow

- In the Figure below, it shows the workflow between sensors and microcontroller. AD8232 sends the ECG data to the PIN A0 of RedBoard Qwiic through UART. “Leads-off Detect +”, “Leads-off Detect -” will transfer leads-off signals to the microcontroller together. “Leads-off Detect +” send data to PIN 10, and “Lead-off Detect -” send data to PIN 11.
- In the MMA8452Q, it receives clock data from PIN SCL, and it sends data to PIN SDA. Both of them use I2C to complete transmission.
- In MAX30101 & MAX32664, it sends ECG & SCG data to RedBoard Qwiic as well as receives a clock from it. It uses I2C to complete transmission, and the name of the port is “QWIIC”. MFIO and Reset connect to PIN 5 and PIN 4 respectively, they determine whether the sensor enters data collection mode.

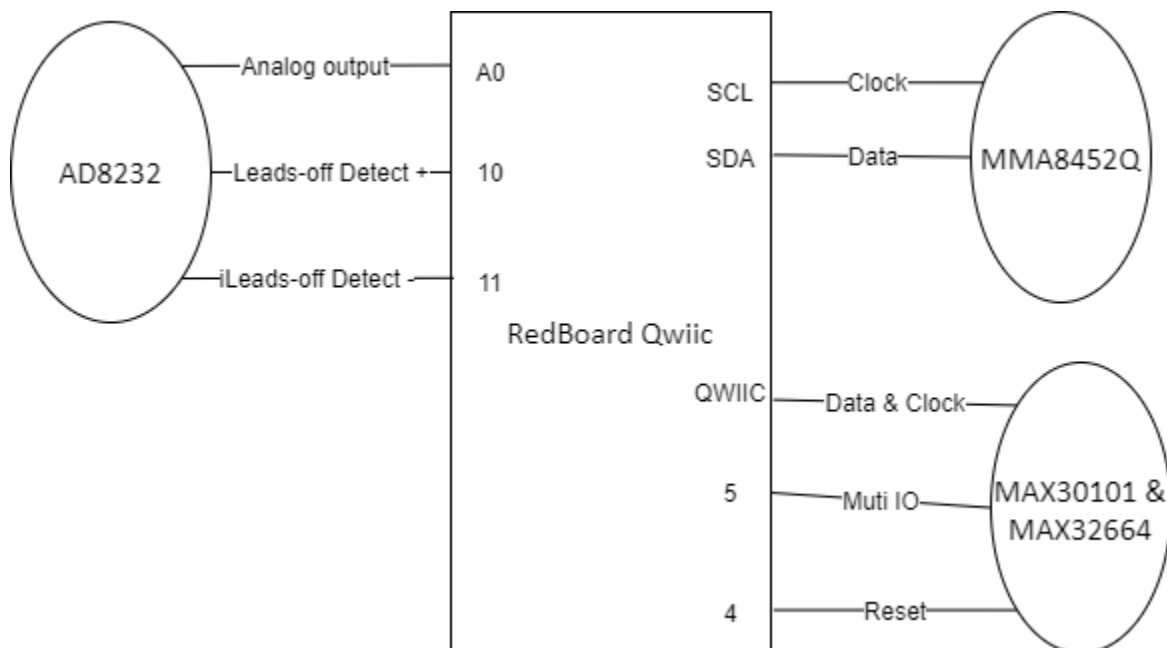
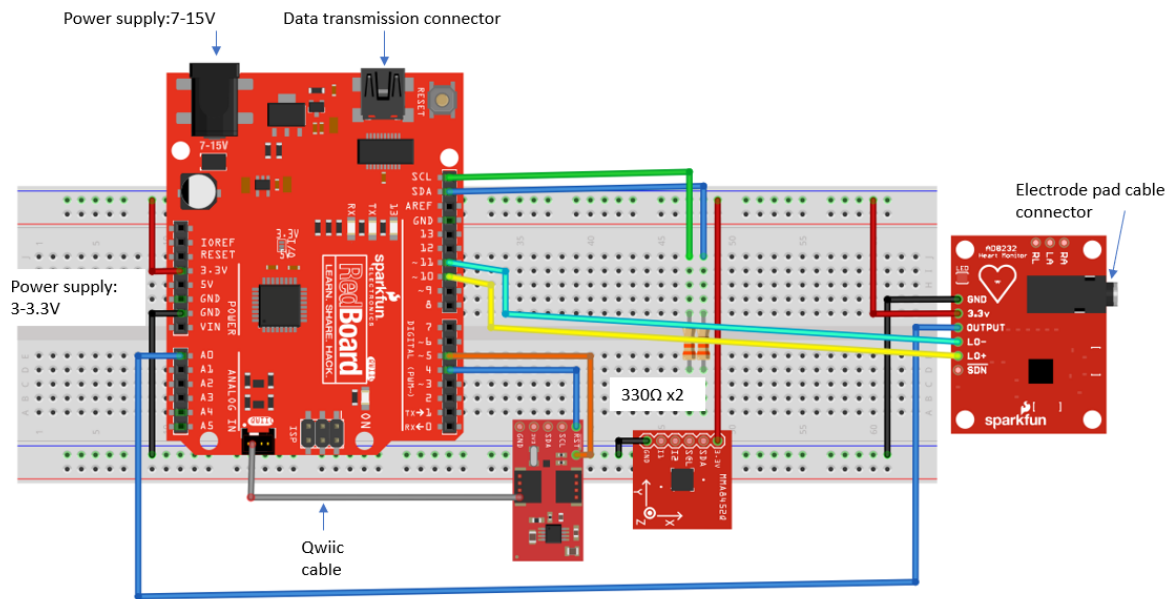


Figure 19: System simple block diagram

4.6 Circuit design

We have 3 sensors for collecting 3 different types of data. Each sensor has its own initial circuit with their own microcontroller[19][20][21]. In this case, we aim to gather all of them into one microcontroller. The power supply of RedBoard is 7-15V directly. And the RedBoard will output 3.3 V to each sensor as input voltage.



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Figure 20: Circuit Layout

Note: In the figure above, the gray cable means Qwiic cable

The accelerometer needs resistance for transferring SCL and SDA[20]. The Pulse Oximeter and heart rate monitor does not need to connect the power[21]. The “Electrode pad cable connector” will connect electrodes. The “data transmission connector” will connect a cable to transfer collected data to the other device. The power supply of RedBoard is 7-15V, and the RedBoard will provide 3-3.3 voltage to sensors. The circuit does not include the power, electrodes, and bluetooth module, they will be described in the following sections.

4.7 Power Supply

According to the manual of ATmega238 [14] and Figure 20 above. The worst case of the current supply of each pin in ATmega238 when $V_{cc} = 3V$ and $F = 4MHz$ is $61.8 \mu A$. In the circuit, we have 7 pins and one Qwiic are connected to different sensors. In this case, the power supply of each sensor is $3.3V$.

The total current of each pin:

$$\text{Energy} = (8 * 61.8 \mu A + 0.2 \text{mA}) * 3.3 \text{ V} * 1 \text{ h} = 1.63 \text{ mWh}$$

$$Q = \text{Energy}/V = 1.63 \text{ mWh}/3.3V = 0.494 \text{ mAh}$$

With a li-ion battery with 180 mAh , it can last up to $180/0.494 = 364.37$ hours on a single charge.

4.8 Other components

Here are other components for this system

4.8.1 Electrodes

Electrodes will be attached to the skin of the chest, and it will transfer electrical signals to the lead heart rate monitor as ECG data. For the product, the electrodes are connected to the AD8232 for ECG collection.

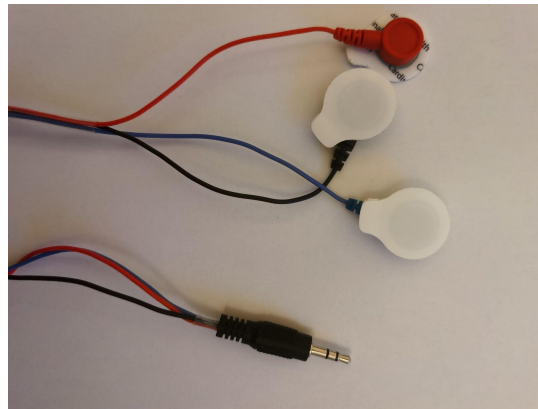


Figure 21: Electrodes (with 3-connector pad cables)[26][27]

4.8.2 Bluetooth

In Figure 20, all data was transferred to the PC/mobile device through the cable. It will use ESP32 bluetooth module to replace the connector of cable. The current ESP32 module is

Harp Blood Pressure Monitor - Design Specifications

RSP32-WROOM. It uses the ESP32-D0WDQ6 core, and supports I2C, URAT. In the product, we will use it to replace the cable data transmission connect in the Figure 20.

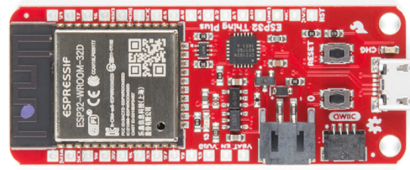


Figure 22: ESP32- WROOM (Bluetooth module)[28]

4.9 Design alternatives

In the sensor, “Pulse Oximeter and Heart Rate sensor”(MAX30101 & MAX32664). When it is working, it can measure and transfer both ECG and PPG data. In the current design, we only pick and process the PPG data in the software part. We are testing the performance of each sensor, if the data of ECG comes from “Pulse Oximeter and Heart Rate sensor” is the same accurate as, or more accurate than “Single Lead Heart Rate Monitor”(AD8232), then we may consider removing AD8232 in the final product for reducing the size and power consumption.

In the bluetooth module, since we do not use ESP32 microcontroller directly, we may change other bluetooth such as “BLE Link Bee”, “JY-MCU”, “BLE Mini”, and other types of “ESP32” module.

5 Conclusion

This document outlines all the design specifications and is intended to be used as a guideline and data reference when constructing the prototype blood pressure measurement device. The document provides details about software and hardware designs, as well as the working requirements, workflows and required knowledge.

These details include hardware specifications. In these specifications, there are details and working conditions of the sensors we chose, Lead Heart Rate Monitor (AD8232), Accelerometer (MMA8452Q), and Pulse Oximeter and Heart Rate Sensor(MAX30101&MAX32664). There are also details about the microcontroller of this product, RedBoard Qwiic. Besides, there are external components of the design, electrodes, the ESP32 as our bluetooth module, and the

Harp Blood Pressure Monitor - Design Specifications

power supply of 5V, 180mAh. We also talk about the protocol the sensors use to communicate with the microcontroller, I2C and UART.

The software section included design specifications for the companion application, which will be developed to run on android due to our team's extended experience in this domain and android OS's mass appeal. Secondly, the application should allow the user to create and edit their own health profile and visualize the collected data in the form of graphs or view real-time data points. The application will also alert the user based on their alert preferences and will allow the user to export their collected data in either csv or jpeg format. Finally, the application will also allow the user to configure how long the application should store their data, which at maximum can be set to 30 days. For the interface between the Arduino and the application, Bluetooth Low Energy (BLE) was chosen over Bluetooth, due to its lower power consumption.

In addition to these system requirements, UI requirements are also listed in the appendix, examples of software and hardware UI. Besides, engineering standards from IEEE, IEC, and ISO which are relevant to the development of the device are listed.

The specifications listed in this document are only meant to be used as guidelines when developing the prototype and the starting of the final product, therefore as development progresses on the devices, there may be changes to the details in this document, and requirements may be slightly modified to fit the updated needs.

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Appendix A – Acceptance Test plan

A.1 Introduction

This appendix document will contain the necessary information to conduct an acceptance test for the proof of concept, prototype and the final product.

The goal of the proof-of-concept will be:

- Read ECG data and store temporarily in the microcontroller
- Read PPG data and store temporarily in the microcontroller
- Read accelerometer data and store temporarily in the microcontroller
- Bundle the data together and transfer to PC/mobile device most likely with a cable
- Verify that with the collected data that some sort of blood pressure measurement can be calculated
- The process of collect data and transfer to device should be 1 minute

The goal of the prototype will be:

- All of the above
- The device should power itself and not need external power cable
- Bundle the data together and transfer over BLE to a mobile phone
- Verify that the collected data can, to a degree of accuracy, calculate the diastolic blood pressure of patient continuously over time
- A functioning mobile application that can store and display the user information in real time

A.2 Hardware Testing

Table 15 is a hardware test plan for the prototype.

Test Case	Expected Result	Pass/Fail (circle)	Observation & Comments
Turn the device on and off, observe the Green LED	Green LED is on when the device is on and off when the device is off	P/F	
Turn the device on and leave it on, observe the Yellow LED	The Yellow LED should turn on when the device is low on power	P/F	
Start the device AD8232 and	Verify that the ECG data is collected in the	P/F	

Harp Blood Pressure Monitor - Design Specifications

proceed to collect ECG	microcontroller		
Start the device MAX30101&MAX32664 and proceed to collect PPG	Verify that the PPG data is collected in the microcontroller and transferred to PC through cable	P/F	
Start the device MMA8452Q and proceed to collect accelerometer	Verify that the accelerometer data is collected in the microcontroller and transferred to PC through cable	P/F	
Connect and integrate the 3 sensors into one RedBroad and process ECG,PPG and accelerometer data	Verify that the ECG, PPG and accelerometer data can be connected to one microcontroller synchronously and transferred to PC through cable	P/F	
Bluetooth test. Replace the cable connector to bluetooth. Repeat the previous test case	Verify that the ECG, PPG and accelerometer data can be transferred to PC/APP/other device through bluetooth synchronously	P/F	

Table 15: Test Plan for Hardware Testing

A.3 Software Testing

Table 16 is a software test plan for the prototype.

Test Case	Expected Result	Pass/Fail (circle)	Observation & Comments
Open the mobile application	Verify there should be a prompt to connect through bluetooth to the device	P/F	

Harp Blood Pressure Monitor - Design Specifications

Connect the device through bluetooth	Verify that the prompt for bluetooth goes away	P/F	
Navigate through the different pages	Verify the user can navigate through the different pages using the navigation menu	P/F	
Navigate to the data view page	Verify data for the user should be displayed accordingly such as the blood pressure numbers	P/F	
Navigate to the settings page	Verify that there should be personal information, privacy & security, help, and about pages	P/F	

Table 16: Test Plan for Software Testing

A.4 User Testing

Table 17 is a user test plan for the prototype.

Test Case	Expected Result	Pass/Fail (circle)	Observation & Comments
Have a test user turn on the device and strap it on across the chest as instructed	Verify the user can turn on the device and strap it without any problems	P/F	
Have the test user open the mobile application and connect the device through the bluetooth	Verify the user can open the mobile application and follow the prompt to connect the device	P/F	
Have the test user sit for several minutes to allow the data to collect	Verify that the data is in real time being collected and displayed to the user on the mobile application	P/F	

Table 17: Test Plan for Hardware Testing

Appendix B – User Interface

B.1 Introduction

Chiron Solutions Inc. is designing a casual wearable medical measurement device that will be placed on the patient's chest while transmitting the measurements to the patient's phone via Bluetooth. For the software application, we were trying to pursue the app's familiarity, pleasant design, and ease of use. The hardware part will be made according to all the Engineering Standards and Safety Requirements. The hardware module consists of ECG, SCG, PPG sensors, and Bluetooth modules, its shape looks like a small box and uses a belt to fix on the chest.

B.1.1 Purpose

The purpose of this document is to demonstrate the main components' User Interface designs of our product. This document will demonstrate the specific decisions that were made in designing the product.

B.1.2 Scope

This document will discuss four major topics: User Analysis, Technical Analysis, Engineering Standards, and Usability Testing.

B.2 Graphical Representation

Figures 23 – 28 demonstrate the proposed UI design for the Android Application.

Figure 23 is the window that will pop up if the Bluetooth or module are not connected properly.

After the module and Bluetooth connection are adjusted by the user, this window will disappear.

Figure 24 shows the variations of the Homepage, which is proposed by the colour of the Blood Pressure display. The reason for changeable colour will be explained later in Technical Analysis.

Figure 25 displays three slides that are containing the statistics graph for the last 5 hours, and average results for all time, last month, and last week. The three slides of statistics are including the Blood Pressure, Pulse Rate, and %SpO2 on the 1st, 2nd, and 3rd slides respectively. Figure 26

is demonstrating the basic Setting Page that is containing Personal Information about the user.

Figures 27 and 28 demonstrate the approximate hardware design parameters and how will it look like.

The dimensions of the prototype should be- Length: 110 mm, W: 72 mm, H: 7.7 mm. The hardware will include the ECG and PPG sensors in it, and the exact Top View and Front View are shown in Figures 27 and 28.

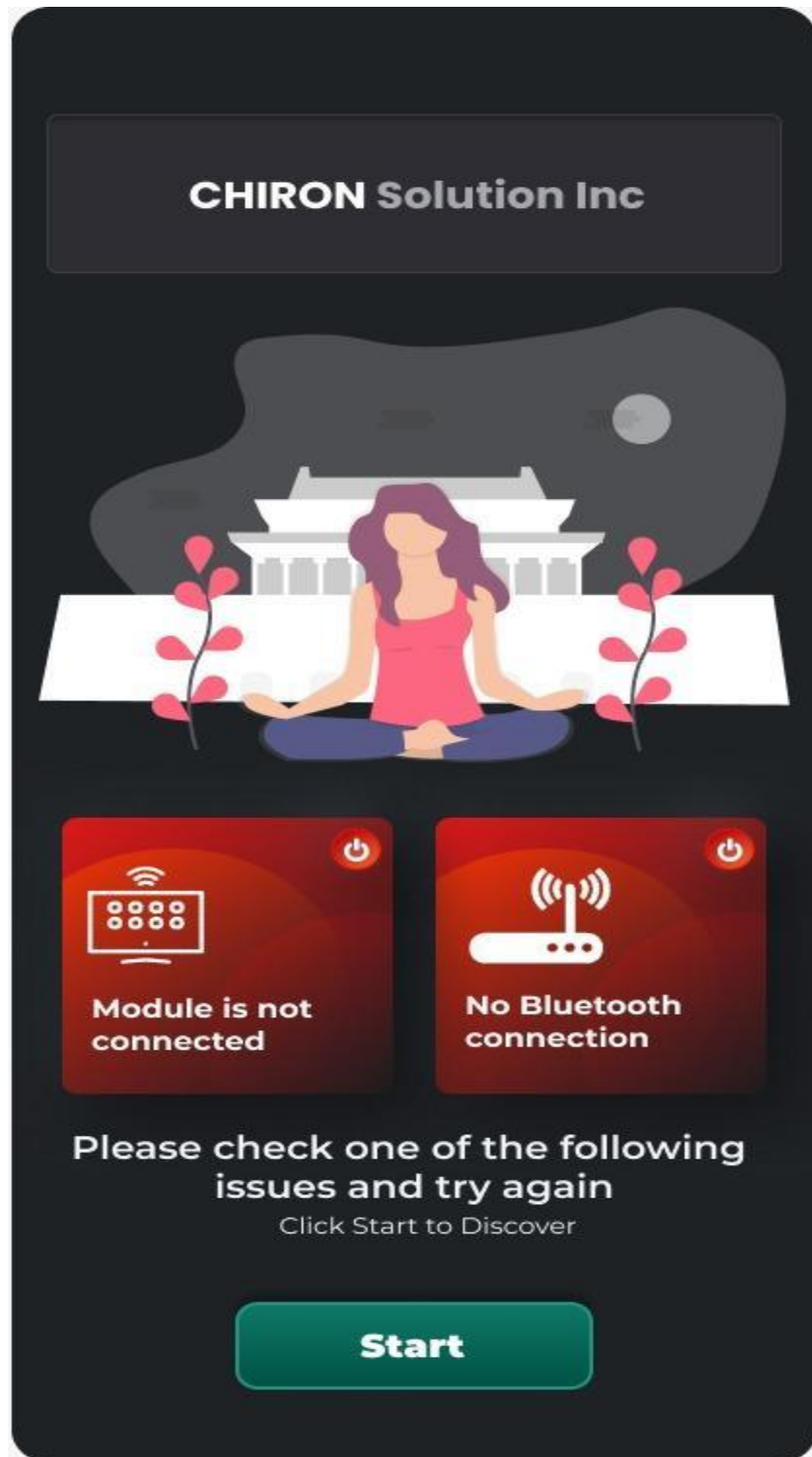


Figure 23: Android App - Issues Page

Harp Blood Pressure Monitor - Design Specifications



Figure 24: Android App - 4 variations of the Homepage

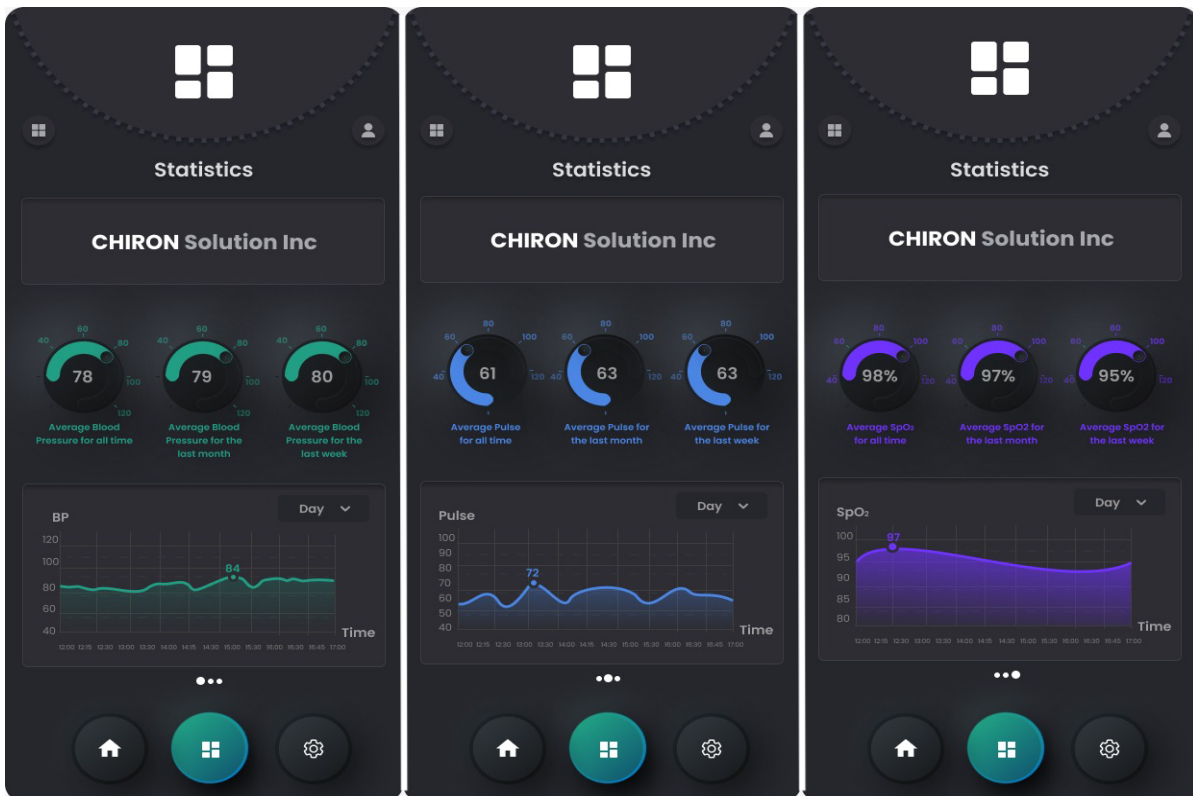


Figure 25: Android App - Statistics with three slides Pages

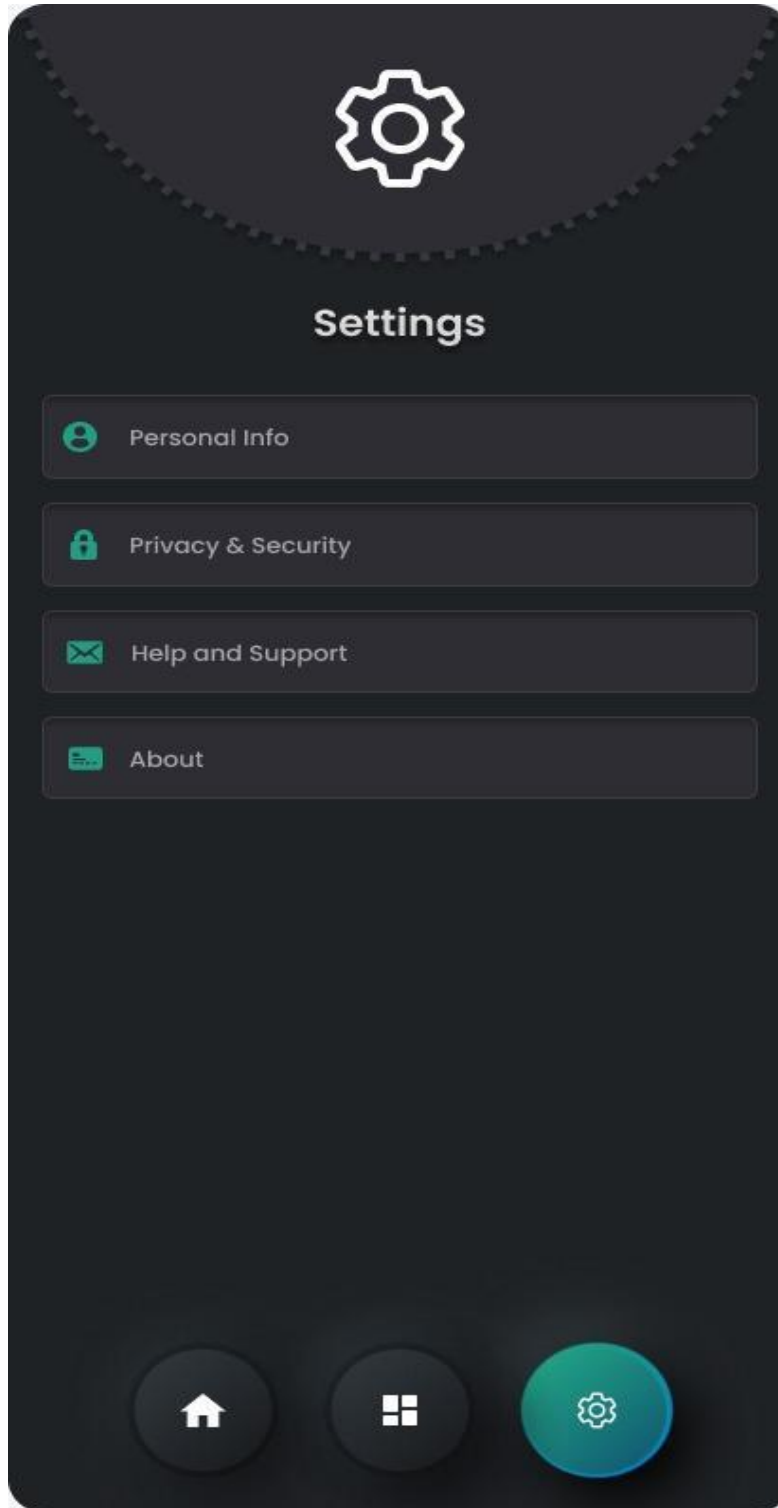


Figure 26: Android App - Settings Page

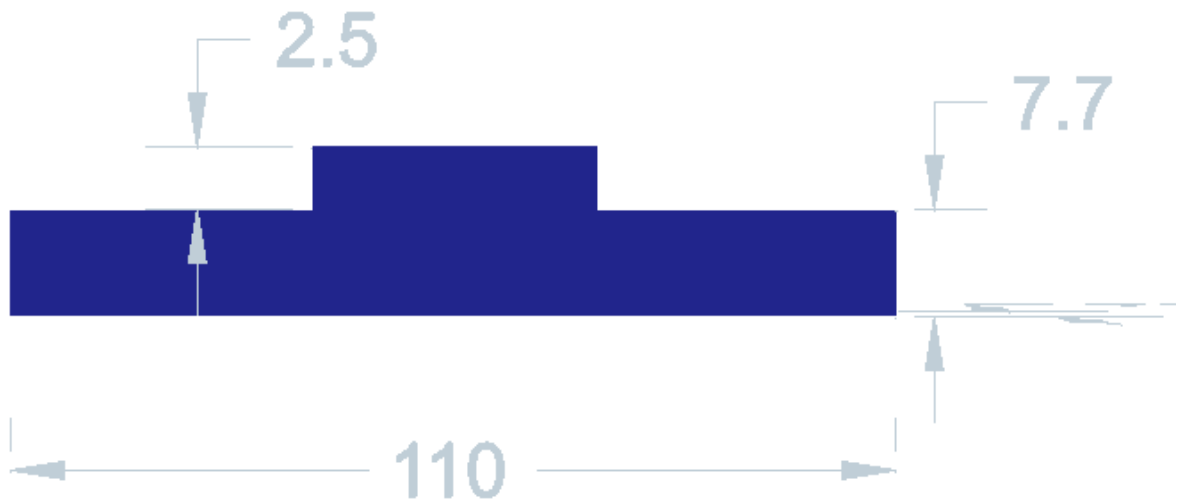


Figure 27: Front View of the Module

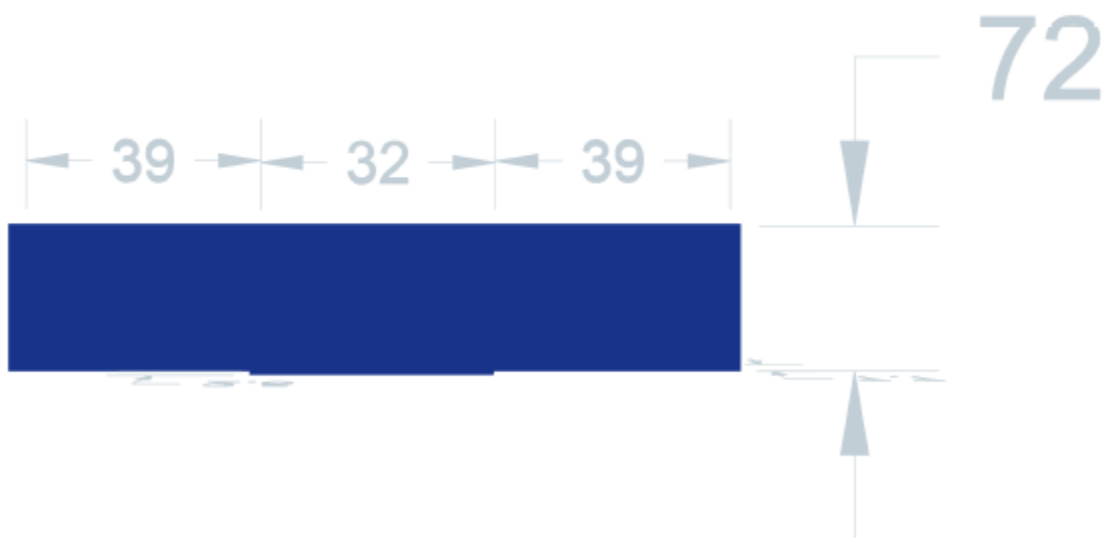


Figure 28: Top View of the Module

B.3 User Analysis

The target audience of Chiron Solutions’ product is usually people with hypertension or specific diseases, which requires constant observations of the Blood Pressure. The abilities of this product became more realistic because of the smartphone’s application that will read and store

Harp Blood Pressure Monitor - Design Specifications

the data from the module. The module will be placed on the patient's chest with the help of a comfortable strap, and the measurements will be transmitted to the smartphone.

To collect and observe the data from the module, the patient is required to install the Android app. The app will store the information of the Blood Pressure, Heart Rate, and Pulse Oximetry with access to any time from the past. According to our team's plan, after successful data transmission to the Android app, then we will start working on supporting iOS devices. In this case, we represent the processed data by plotting the graph and number with color. This product does not require users to have related knowledge about ECG, SCG and PPG.

B.4 Technical Analysis

In his "The Design of Everyday Things" book, Don Norman states that there are seven major criteria for everyday designs: Discoverability, Feedback, Conceptual Models, Affordance, Signifiers, Mapping, and Constraints. This part will analyze and discuss each of these criteria, and how they can be applied to our device.

B.4.1 Discoverability

The point of discoverability is to make an intuitively understandable design. Our app will display two measurements: Blood Pressure(BP), Pulse Rate(PR), and Pulse Oximetry(%SpO2) in real-time on the home screen as shown in Figure 24. At the bottom of the screen, there is a navigation toolbar, which consists of the home screen, statistics, and settings. The app will start from the home screen by default, and if the user clicks on the statistics button, it can show three graphs with detailed data for the last 5 hours at 1 minutes intervals, as shown in Figure 25. The "Settings" page, which is demonstrated in Figure 26, will show four buttons: Personal Information, About, Privacy & Security, Help & Support.

B.4.2 Feedback

Feedback is needed to inform the user that there are any changes or issues with the system that required his intervention. So, if there is no Bluetooth Connection or the device is not connected to the chest properly, the mobile application will pop up the windows as shown in Figure 23. The Blood Pressure Data is changing colour by analyzing the measured data, and how it will work is shown in the Signifiers Section. Feedback for the last 5 hours with 1 minutes intervals is shown in the Statistics screen for Blood Pressure, Pulse Rate, and Pulse Oximetry.

B.4.3 Conceptual Models

Conceptual models are needed so that the user has experienced the same experience with other products. In our case, using the product will be similar to other Bluetooth paired health monitoring devices such as a smart watch. The user will need to pair the device, and wear it at the appropriate location, and will be able to visualize/read statistics about their health on the mobile application.

B.4.4 Affordance

Affordance makes clear how the device should be used. We have implemented that in our app by displaying only the required information for the user. Moreover, the BP measurement module will have only one Turn On/Turn Off button.

B.4.5 Signifiers

The signifiers of our device are not used in the module itself. The reason is that the patient will not be able to see it constantly because it will be under his clothes, but the required signifiers are used in the app. First, if the Bluetooth connection is lost or the device is not working correctly, then the app will notify the user immediately. Second, the results of the BP analysis will give immediate feedback to the user, such as:

- If the colour of the BP display is green, then everything is fine.
- If the colour of the BP display is yellow/orange, then try to measure the device without any external noises (running, physical activities, etc.)
- If the colour of the BP display is red, then contact the doctor immediately.

B.4.6 Mapping

Mapping is allowing the user to intuitively control the device. For that purpose, the “Turn On/Turn Off” button will be labeled within our device, and the user will know when the device is on or off.

B.4.7 Constraints

Constraints are the limitation that may restrict a user’s interaction with Chiron Solutions BP Measurement Device. A patient must have a smartphone to access their data because the module, that will be placed on the chest, does not display any information. The hardware constraint will be using rechargeable lithium batteries, and the user needs to charge it from time to time. For this moment, only Android users will be able to access the app. The patients must have the minimum experience with a smartphone so that they know how to access the statistics and settings of the app, which are located at the bottom of the screen.

B.5 Engineering Standards

The user interface is an important design aspect of the product. Therefore the product will follow several different engineering standards to ensure that proper standards involving user interface design are followed. Table 18 below lists the engineering standards code and a short description of each.

Harp Blood Pressure Monitor - Design Specifications

ISO/IEC TR 11580:2007	Information technology — Framework for describing user interface objects, actions, and attributes [1]
ISO/IEC 24755:2007	Information technology — Screen icons and symbols for personal mobile communication devices [2]
ISO/IEC 11581-10:2010	Information technology — User interface icons — Part 10: Framework and general guidance [3]
ISO 9241-112:2017	Ergonomics of human-system interaction — Part 112: Principles for the presentation of information [4]
ISO 9241-161:2016	Ergonomics of human-system interaction — Part 161: Guidance on visual user-interface elements [5]
ISO 9241-210:2019	Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems [6]
IEEE 1621-2004	IEEE Standard for User Interface Elements in Power Control of Electronic Devices Employed in Office/Consumer [7]
ISO/IEC 24786:2009	Information technology — User interfaces — Accessible user interface for accessibility settings [8]
ISO/IEC 27033-6:2016	Information technology — Security techniques — Network security — Part 6: Securing wireless IP network access [9]
Safety Code 6:	Safety Code 6: Health Canada's radiofrequency exposure guidelines [10]

Table 18: List of Engineering Standards

B.6 Usability Testing

B.6.1 Analytical Usability Testing

Analytical usability testing will be done by the development team on the product to ensure that the user interface of the device functions as expected. The tests will focus on finding if any tasks are difficult or if there is any confusing language, and in general test the overall flow of the product's user interface. This type of test will not require users and is expected to be easier and faster than empirical usability testing. For the proof-of-concept, there will be minimal UI testing as the main focus will be on data collection from the hardware device.

B.6.1.1 Harp Blood Pressure Monitor

1. There is a physical on/off switch that powers on and off the device
2. A green LED will be lit to indicate that the product is on and is functioning regularly
3. The green LED will be off when the device is off
4. A yellow LED will be lit when the device is low on power
5. The yellow LED will off when the device is off or the device is not low on power

B.6.1.2 Mobile Application

1. When the device is turned on, it should automatically be available for pairing to the mobile application.
2. When the mobile application is first started, the user should be given the option to pair to the device.
3. The application should clearly display the navigation options
4. The application should display diastolic blood pressure data graphically and numerically
5. The application should have a settings page that displays user preferences, personal information, privacy & security, and a help section
6. The user is able to navigate between the different pages
7. The application should notify the user when the device stops functioning

B.6.2 Empirical Usability Testing

The empirical usability testing will be done by our team members on potential customers that have been previously identified with no prior knowledge of the device. The testing will involve a minimum of 5 user participants [11]. The empirical usability tests will involve several different methods such as questionnaires, testing user's knowledge before and after using the device, and observations of the user. Empirical testing is important to ensure that the product is safe, efficient, and high quality. The tests will also ensure that the user interface portion of the product remains error-free by having participants operate the product normally.

To test the device during normal operating conditions, the users will turn on the harp blood pressure monitor, and then open the accompanying mobile application on a phone. Next, the user will follow the on-screen instructions on the mobile application to pair the device through bluetooth. Continuing to follow the on-screen instructions, they will then place the harp blood pressure monitor on their chest as indicated. The user will then view and explore the mobile application to see the different data views as well as visit the about/settings/help pages. Finally, testing will finish with the user answering a set of questionnaires. Some sample questionnaires designed to test if the design goals are met or need to be improved are listed below.

B.6.2.1 Harp Blood Pressure Monitor

1. How would you rate the comfortability of the device when strapped on?
2. Did you experience any difficulties with connecting the device to the mobile application?

Harp Blood Pressure Monitor - Design Specifications

3. Did you experience any difficulties strapping the device to the correct location?
4. Have you tested your blood pressure before?
 - a. If yes, how does the device compare? _____
5. Do you have any concerns or problems regarding the device? _____

B.6.2.2 Mobile Application

1. Did you like the layout of the mobile application?
 - a. If no, then what improvements would you suggest? _____
2. Is the mobile application intuitive to use?
3. Is there any other data you would like to see? _____
4. Do you feel that the application is easy to use?
5. Is the mobile application user-friendly and meets accessibility requirements?
6. Have you looked at the settings page?
 - a. Is there any additional information you would like to see?

B.7 Conclusion

This appendix outlines the user interface design and guidelines to be followed. A summary of the topics includes engineering standards, usability testing, and the seven stages of design (discoverability, feedback, conceptual models, affordance, signifiers, mapping, and constraints). The goal is to improve the design of the user interface through the use of engineering standards, testing, and analysis of the product. Additionally, some sample UI mockups for the mobile application are provided and guidelines on how to implement and test them are discussed. Work still needs to be done in regards to finalizing the UI for the mobile application and may depend on further testing and design. The proof-of-concept stage will only consist of the hardware portion of UI, where the functionality of the sensors is the main showcase. This

document will be continuously updated as the development progresses and details may be subject to change.

B.8 References

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Appendix C - Design Choice Justification

C.1 Software Design

Requirement Specification	Design Specification	Justification of choice
Req7.2.1-b	D.2.1.1-B	We considered supporting iOS or Android. We chose to support the Android platform because our team members have more

Harp Blood Pressure Monitor - Design Specifications

		experience developing Android apps than iOS apps. Furthermore Android users represent 79.63% of mobile phone users [1]
Req7.1.2.2-b	D.2.2.1-B	We considered using either bluetooth(BT) or bluetooth low energy (BLE) as our transmission protocol. We decided to use BLE mainly due to its low power consumption compared to BT [2]
Req7.1.2.1-a	D.2.3.1	We chose the Sparkfun sensors because they readily interface with the arduino and have libraries that can facilitate the data-collection process

Table 19: Software design choices justification

C.2 Hardware Design

Requirement Specification	Design Specification	Justification of choice
Req7.1.1.2-b	D.3.1.2-A	We considered various ECG sensors such as the "MAX30003WING", "MAXREFDES117", and "AD8232". We chose the AD8232 due its smaller size, affordable price and compatibility with our chosen microcontroller
Req7.1.1.2-b	D.3.1.3-A	We considered different Accelerometers such as "MMA8452Q", "EVAL-ADXL327, and the "LSM6DSM". WE chose the MMA8452Q due to its availability, short shipping time, affordable price, and low power consumption.
Req7.1.1.2-b	D.3.1.4-A	We researched different PPG sensors such as "MAX300101WING", "MAXREFDES117", and "SEN-15219". We decided to use the SEN-15219 sensor due to its lower price, smaller size, lower power consumption and compatibility with our chosen microcontroller.
[Req7.1.2.1-a]	D.4.1.1-A	For the microcontroller, we had three main choices; "MAX32630FTHR", "Arduino", and "Raspberry Pi". We decided to use the Arduino Pro as our microcontroller because our developers are more familiar with it compared to the "MAX32630FTHR" and the sensors that we bought have comprehensive guides detailing how they interface with the arduino board.
[Req7.1.2.2-b]	D.4.1.9-B	For the bluetooth low energy modules, we considered multiple options such as "BLE Link Bee", "JY-MCU", "BLE Mini", and "ESP32". We decided to use the ESP32 because it has a lower

Harp Blood Pressure Monitor - Design Specifications

		power consumption, supports both Wifi and BLE, compatible with IoT application development platforms such as Blynk [3] and the abundance of tutorials online describing how to interface it with an arduino..
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Table 20: Hardware design choices justification

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