

COVID-19 Monitor and Quarantine Mobile App

Based on Spring 2015 Smart Wearable Devices for Elderly People

Spring 2020 ECE 445 Project Proposal

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COVID-19 Monitor and Quarantine Mobile App	0
1 Introduction	2
1.1 Objective	2
1.2 Background	3
1.3 High-Level Requirements	5
2 Design	5
2.1 Control Unit	8
2.1.1 Microcontroller	8
2.1.2 SD Card	9
2.1.3 Input/Output: On/Off Button and LCD Screen	9
2.2 Power Unit	9
2.2.1 9V Battery	10
2.2.2 Voltage Regulators	10
2.3 Bluetooth Unit	10
2.4 Sensor Unit	11
2.4.1 Heart Rate Sensor	11
2.4.2 Temperature Sensor	11
2.4.3 Oximeter	12
2.5 Schematics	13
2.6 Software	15
2.7 Tolerance Analysis	16
3 Project Differences	17
3.1 Overview	17
3.2 Analysis	18
4 Costs	20
5 Schedule	21
6 Safety and Ethics	21
References	24

1 Introduction

1.1 Objective

Keeping track of elderly/sick patients in a family is always a matter of concern. Especially if they are not sick enough yet to be in a hospital and are at home recovering. This ties in with the current issue of COVID-19 where elderly people, especially with compromised immune systems, are being affected. There is a need for medical devices targeted for people who are at home recovering or sick so that their health/vitals/symptoms can be monitored by their loved ones. This can also be used in the current situation of COVID-19 to alert people around the person, via an app, showing symptoms of coronavirus so that they can quarantine.

We propose to create a device that records temperature, heart rate, respiration rate, and SPO2. The hardware device will include a LCD display that constantly shows all the data, so you can view it anytime. This data will also be sent to a cellular app through a bluetooth module. The app will record the data, and if any symptoms look abnormal, the patient is alerted and given the choice to alert others and/or alert medical professionals. The physical hardware allows you to get real-time data, even if you do not have your phone on you, and the cellular app enables extra features like alerting others or recording your own symptoms; the app can be used on its own without the hardware, but obviously will not have the ability to record vitals.

Furthermore, the app will give medical and isolation/quarantine advice to the patient to reduce spread. The app uses city or zip code information given upon sign-up so it can send an alert to anyone within that city or zip code area. Although the physical device is recommended for people who are at risk, such as older people or people with a weakened immune system, the app is free to anyone. If someone with the hardware device contacts emergency for the symptoms or is diagnosed with COVID-19, the application will alert anyone within a city or zip code area to quarantine themselves and take extra precautions to prevent the spread. Anyone with only the phone application can also send an alert to people within their city or zip code area or call emergency, if they feel they are at risk of having COVID-19.

The hardware device can be beneficial for elderly patients who cannot access the hospital (especially with the sudden lack of supplies and medical professionals) and are recovering in quarantine. While not designed to replace current methods of diagnosing worsening symptoms, the hardware device can be used to monitor their vitals and report to their loved ones which they can add through the app so that the app shares their vitals with them. This can hopefully lower the stress of said loved ones.

Although this device will not diagnose or cure COVID-19, it could be a cheap, mass-produced product to help control viral spread and to get vulnerable patients help immediately. The most important part of this project is for the app to relay quick alerts to people within a city or zip code area. As long as alerts are correctly made, we can keep the public alert and aware. By social distancing or being in quarantine,

people lower the risk of spreading COVID-19, which will greatly help the general public, but will also reduce traffic in hospitals.

1.2 Background

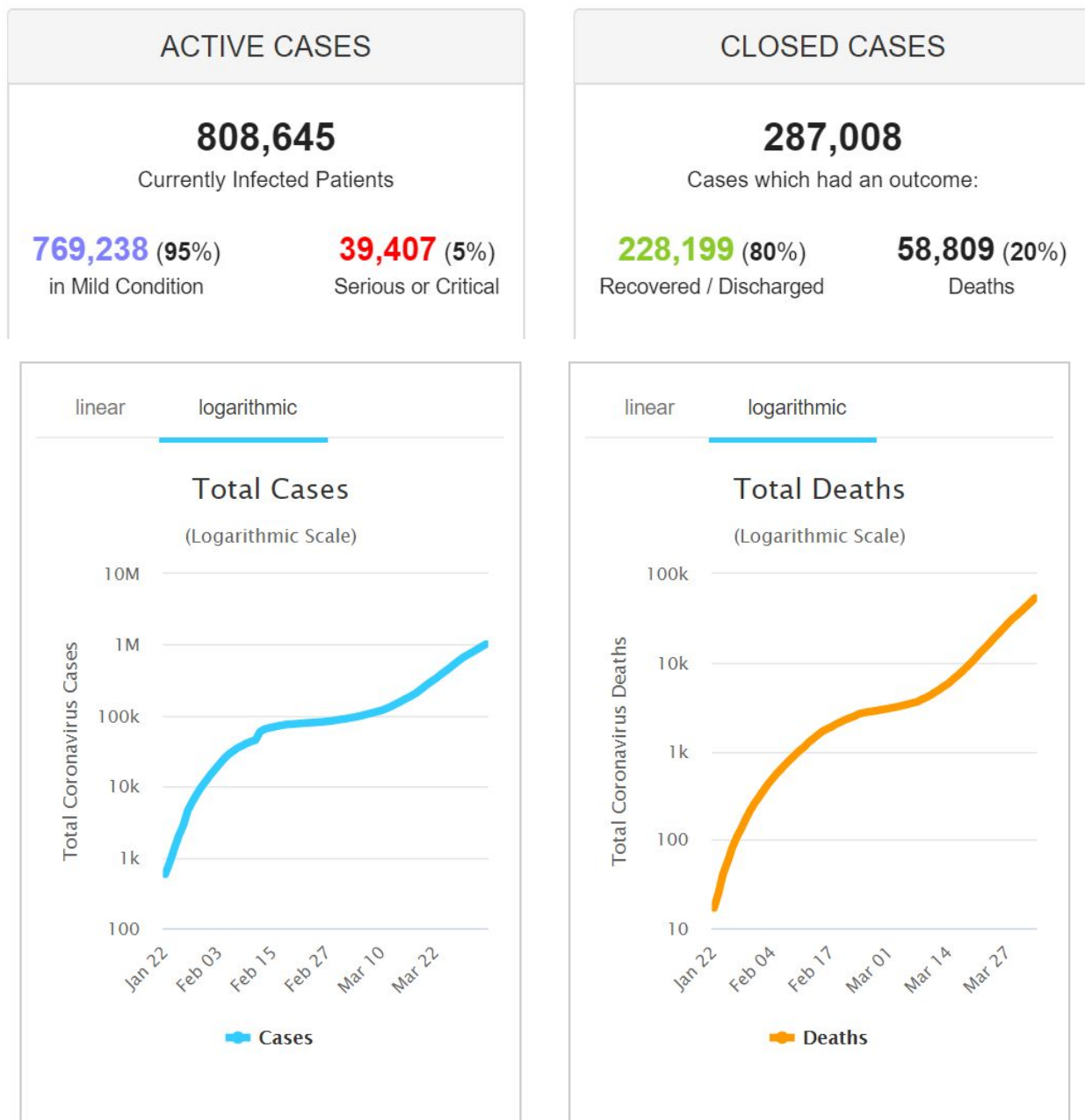


Figure 1. Breakdown of current cases statistics for SARS-CoV-2. These figures show the rate at which people are getting infected and also the fatality rate. So far, the fatality rate is approximately 3%. It is also proving to be very contagious.¹

¹ Fig 1 was updated on April 3rd, 2020. This data is only valid up until then. COVID-19 is a new illness and data is being analyzed and updated everyday. These figures will be constantly changing.

The Vital Importance of Social Distancing

How a reduction in social contact can reduce the spread of the coronavirus

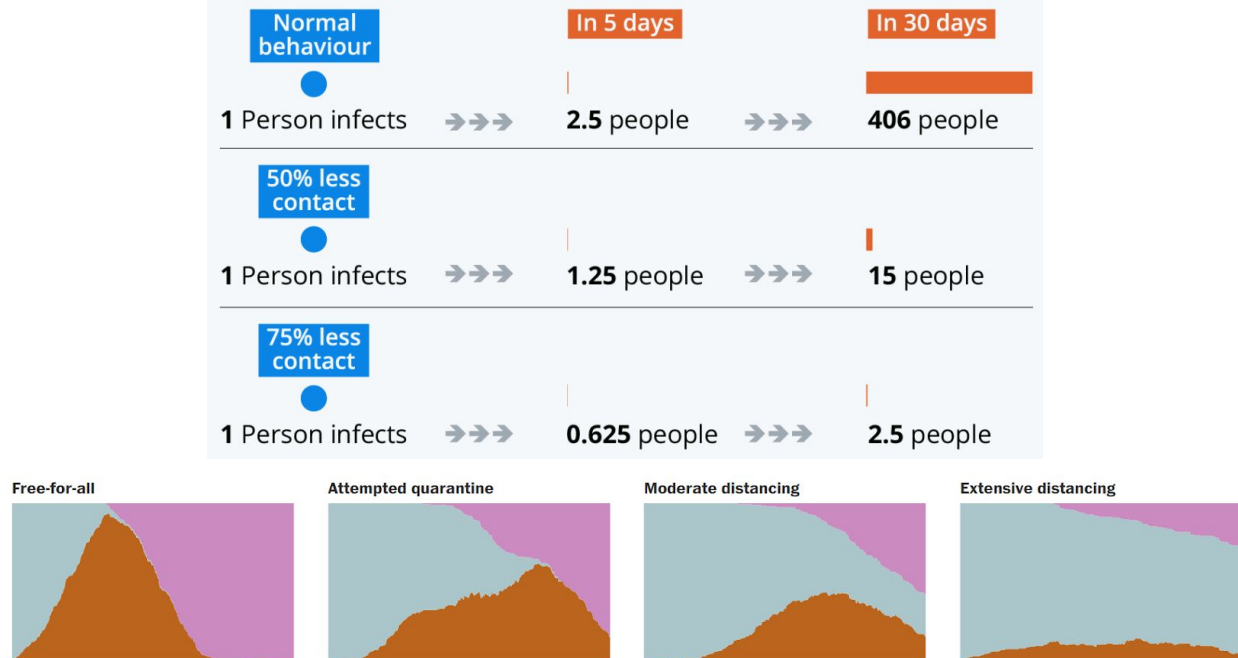


Figure 2. These figures show the importance of quarantining/social distancing. By limiting social interactions we can drastically reduce the spread of COVID-19. In the bottom sequence of images, the teal represents healthy people, brown represents infected/sick people, and pink represents people who recovered from the illness.

COVID-19 refers to the illness caused by the SARS-CoV-2. The world has become intimately familiar with it since late 2019 and early 2020. It has forced lockdown, severely damaged the economy, and killed over a hundred thousand since it first appeared.

People with lowered immune systems and older people are most susceptible to COVID-19. The symptoms, experienced within 2-14 days include fever, cough, or shortness of breath; immediate attention is needed if you have difficulty breathing, constant pain or pressure in the chest, confusion or have difficulty awakening, or bluish tint to skin.

The most important part of this project is for the app to relay quick alerts to people within a certain proximity. As long as alerts are correctly made, we can keep the public alert and aware. By social distancing or being in quarantine people lower the risk of spreading COVID-19 which will greatly help the general public, but will also reduce traffic in hospitals.

Our project is based upon Spring 2015's Smart Wearable Devices for Elderly People. That project was an attempt to provide a wearable that could replace the need for a nursing home or an in home caregiver. The primary difference in our device is that we targeted the current pandemic and we don't claim to totally replace any need, but rather provide a supplement as well as hopefully providing a way to decrease the stress of loved ones.

1.3 High-Level Requirements

1. Sensors can detect worsening lung function.
2. Family members can track changes in symptoms in the provided app.
3. Neighbors can obtain info on their neighborhood without comprising user privacy.
4. Must have the ability to be mass produced and sold inexpensively nationwide.

2 Design

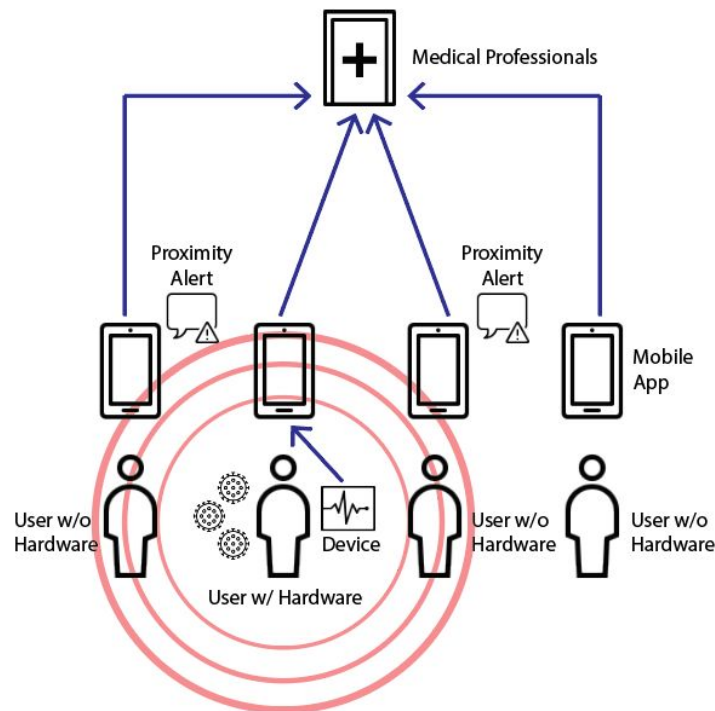


Figure 3. Figure shows the flow of information. It flows from user to neighbors as well as from user to relative. Any user, with or without the hardware, has the ability to alert people within the community about their symptoms/possible infection via the phone app. The phone app will give you the choice to either alert others or not and then allows you to call medical professionals (911) if so desired.

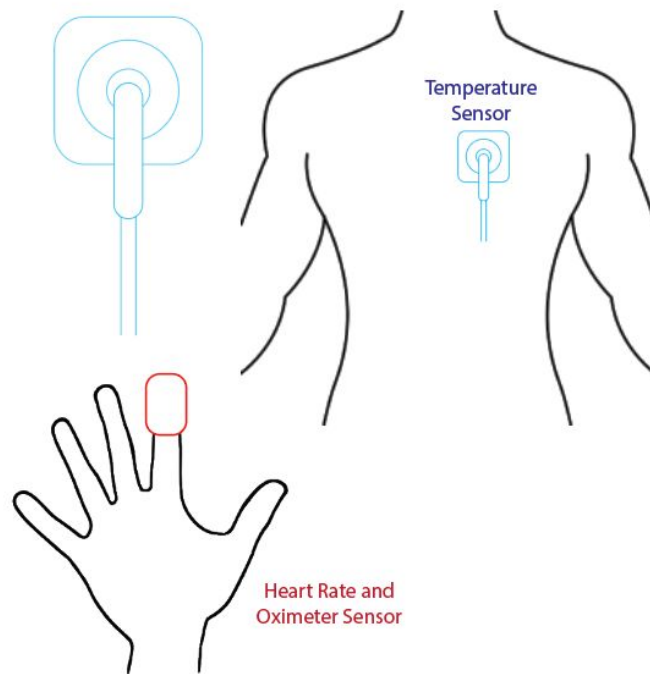


Figure 4. Hardware equipment layout. The sensors will be pasted on the torso (front) in this orientation with medical sticky patches. The hardware is an optional extra purchase for users. Users can simply self-record their symptoms on the app.

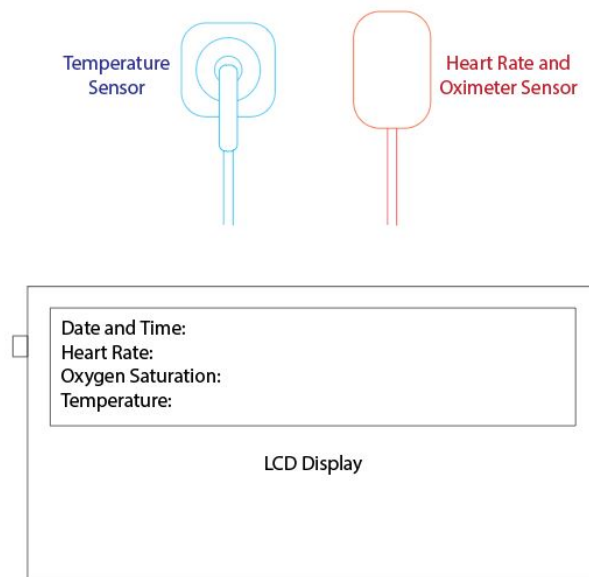


Figure 5. Sensors connect to small processing device that displays information. This allows hardware users to track their symptoms even if they do not have their phone on hand. This display box can be clipped on your pant waistband. It will contain the control unit, visual display, and bluetooth module.

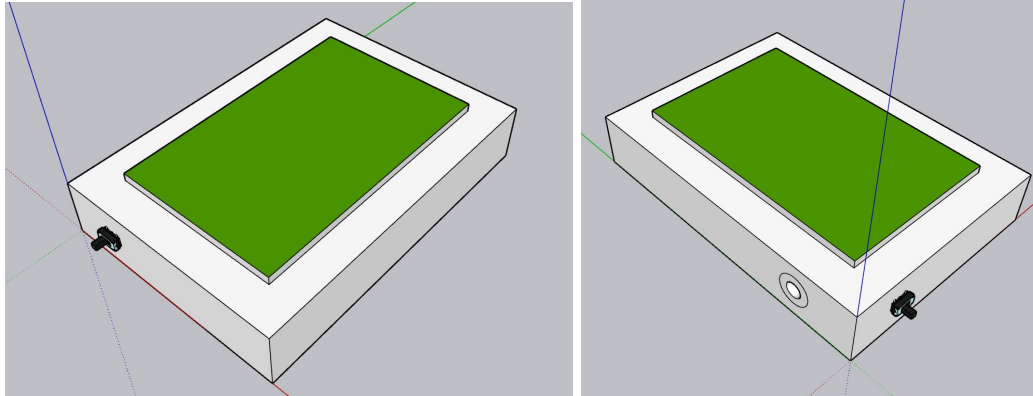


Figure 6. Imagining of how the control unit might look. The dimensions are 3.5"x5"x1" and it includes an on/off switch, LCD display, and a connection for the temperature sensor. The heart rate and oximeter readings will be sent via bluetooth. If the hardware is switched off, the readings will not be displayed on the LCD display nor on the phone app.

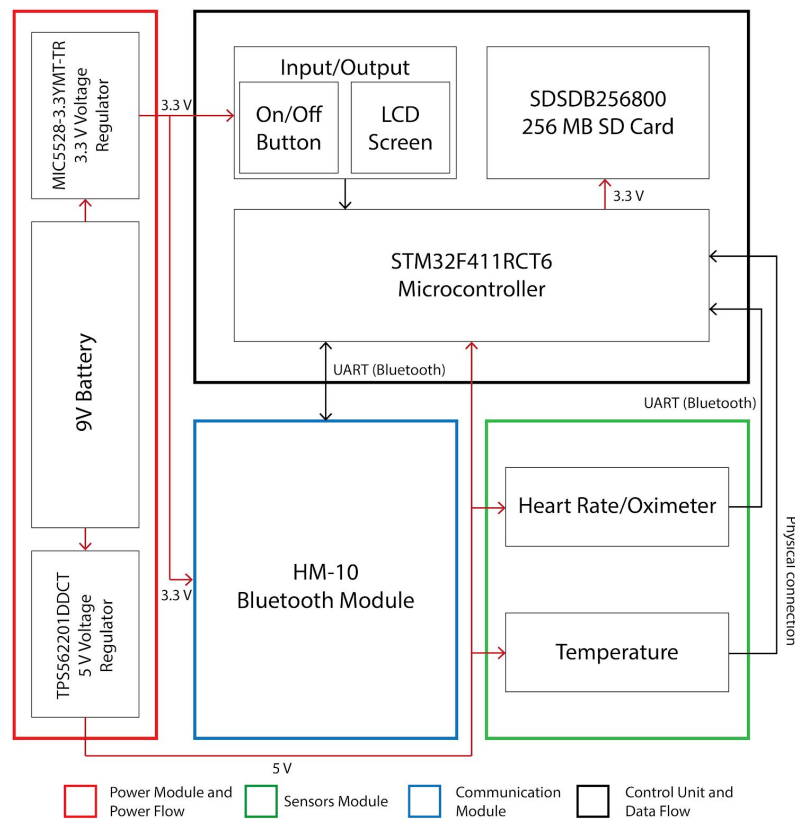


Figure 7. Block Diagram. Black box is the control unit and black arrows are data flow. Red box is the power unit and red arrows are power flow. Blue box is the Bluetooth unit. Green box is the sensor module.

2.1 Control Unit

The control unit will be responsible for coordinating the sensor module and the software app. The control unit has the microcontroller that will be responsible for analyzing the data and use the bluetooth module to send the data to the app. It has the data management block also: SD card. The control unit also has the input/output block which consists of the LCD and buttons. The buttons control whether the hardware device is on/off and also controls when the patient wants to record the respiration data.

2.1.1 Microcontroller

The microcontroller samples from the temperature sensor and works with the bluetooth module to communicate with the oximeter. The microcontroller should be able to collect data at a rate of at least 5-10 Hz in order to record proper heart/respiratory rate. Temperature can be sampled at a rate of 1 Hz or less. Microcontroller should be able to decipher abnormal vitals and send signals to phone and hardware device as an alert. Abnormal vitals in this case refers to a temperature, pulse rate, or SpO₂ measurement trending past a user chosen reference point or sustaining a worrying trend over time. Worrying trends include a change of 0.5°C vs. the previous day, a change of 2% SpO₂ over the previous day, or having a median heart rate 5bpm higher than the day previously over the course of 3 hours. The microcontroller will also work with the bluetooth module to send data to the app. If the sensors are removed, the microcontroller will obtain null values and not display any data to the LCD display nor the app. After 3 minutes it will shut-down.

Requirement	Verifications
<ol style="list-style-type: none">1. <i>Can receive data from the sensor module at 10 Hz. Should be able to transmit signals to phone and hardware device within 60 seconds.</i>2. <i>Must be able to run simple programs involving its ADC pins.</i>	<ol style="list-style-type: none">1.<ol style="list-style-type: none">A. <i>Compare heart rate readings from sensors and actual medical devices. Results should vary between 0-5%.</i>B. <i>Run alongside an Arduino to check that they produce similar sensor readings; error should be within 0-5%.</i>2. <i>Upload and run a known program and see if the results match the expected results.</i>

2.1.2 SD Card

The SD card is responsible for storing regular and irregular data and will include a timestamp.

Requirements	Verifications
<i>1. Should be able to store abnormal data for 2 - 14 days (amount of time for symptoms to show). Assuming 1Hz recording rate for 4 sensors that note a 2 byte value each time. We use about 1MB for each day to store all values. So, a greater than 20MB storage card should fulfill all of our possible needs.</i>	<i>1. Fill the SD Card with 20MB of known data then read it back and verify the read data matches original data</i>

2.1.3 Input/Output: On/Off Button and LCD Screen

On/off button should turn on and off the hardware device. A button will be located to start measuring the respiration rate sensor data. LCD display should visibly display current data including timestamp, heart/respiratory rate, and temperature.

Requirements	Verifications
<i>1. Must be easy to press. 2. The LCD screen should be easily readable and is backlit. 3. LCD can display both alphabets and numerical data.</i>	<i>1. Pushing the button doesn't cause strain. 2. Does not cause strain to read. 3. Use the microcontroller/arduino to write a simple program to display values and alphabets on the screen.</i>

2.2 Power Unit

The power block is responsible for providing power to the PCB containing the sensor module, control unit and the bluetooth module. The 9V battery pack will be connected to 2 voltage regulators: 5V and 3.3V to maintain the voltage for all the components. We need constant voltage for the sensors so that the baseline readings are not affected too much. Both the regulators used will be linear to minimize error.

2.2.1 9V Battery

The 9V battery is responsible for providing power to the whole circuit by stepping it down via the two voltage regulators 5V and 3.3V which will be fed into the control unit and the sensor module/bluetooth module respectively. The battery will need to have a long life and be reliable. It will be connected to a 9V battery holder that will connect to the PCB.

Requirements	Verification
<ol style="list-style-type: none">1. Stores and reliably provide 9V for at least an 8 hour period.2. Maintains thermal stability below 48°C in order to not physically harm patients [11].	<ol style="list-style-type: none">1. Discharge to make sure that it lasts at least 8 hours a day (ideally should last much longer).2. Monitor temperature for prolonged use (approximately 6 hours). Make sure that it does not cause any harm or damage.

2.2.2 Voltage Regulators

There will be two voltage regulators: 3.3V voltage regulator will feed the Input/Output and Arduino Bluetooth Module. A 5V voltage regulator will feed the microcontroller. The voltage regulators need to work efficiently and reliably since we have a sensor module.

Requirements	Verification
<ol style="list-style-type: none">1. Linear regulator provides 3.3V/5V from a 9V source.2. Maintains thermal stability below 48°C in order to not physically harm patients [11].	<ol style="list-style-type: none">1. Charge then discharge. Measure the output voltage using an oscilloscope, to ensure that the output voltage stays near 3.3V/5V.2. Monitor temperature for prolonged use (approximately 6 hours). Make sure that it does not cause any harm or damage.

2.3 Bluetooth Unit

This will function as the communication device between the microcontroller and the software mobile application. The microcontroller will collect all the vitals and constantly send real-time data to the phone application through the bluetooth module whenever the phone polls. It will communicate with the microcontroller using a UART connection. If the hardware is too far from the cellular device, the app will receive no data. The bluetooth is HM-10 which is BLE (low energy) and will run at 2.4GHz.

Requirements	Verification
<ol style="list-style-type: none">1. <i>Must be able to communicate with the microcontroller using UART.</i>2. <i>Must be able to receive data from the pulse oximeter.</i>	<ol style="list-style-type: none">1. <i>Transfer a piece of known data from the phone to the microcontroller. Then, transfer it back to the phone and check to make sure that no errors have occurred.</i>2. <i>After testing pulse oximeter and microcontroller attempt to pass data through the bluetooth and into</i>

2.4 Sensor Unit

This sensor unit is tasked with gathering the data which will try to identify a new or worsening case. The temperature sensor will be our primary source of early detection while the rest of the sensors function to detect worsening symptoms in someone previously diagnosed. These sensors will connect to the physical hardware device and continuously provide readings to the microcontroller.

2.4.1 Heart Rate Sensor

Median readings for resting heart rate are slightly elevated, but again within the normal range. Additionally, the difference between ICU patients and those for which the ICU was unnecessary only show a small difference. [8] Therefore, while useful, this should likely receive a small weight in any decision tree.

Requirements	Verification
<ol style="list-style-type: none">1. <i>The heart rate of an average individual is about 60 - 100 bpm [11]. This means the heart rate monitor has a little wiggle room, and should measure with an error of +/- 5 bpm at least.</i>2. <i>Be able to measure heart rate in the zone 60-150 bpm, as patients with some heart conditions generally have a resting heart rate of 100 bpm.</i>	<ol style="list-style-type: none">1. <i>We first hook up the sensor to one of us. Next, we have a second person count the beats via the wrist while sitting/walking and then compare the manual count to recorded count after one minute.</i>2. <i>Use another FDA approved heart rate monitor while inducing higher heart rate by exercising to see if the heart rate sensor works accurately in this range of 60-150 bpm.</i>

2.4.2 Temperature Sensor

In Wang *et al.* [8], 98.6 % of cases were associated with a fever. In Guan *et al.* [10], 88.7% were associated, however only 43.9% were associated with a fever above 37.5°C upon admission. Still, it was the most common symptom beyond perhaps coughing, so it will form the core of our attempt at detection. A higher temperature was also highly correlated with more severe cases in Wang *et al.* [8].

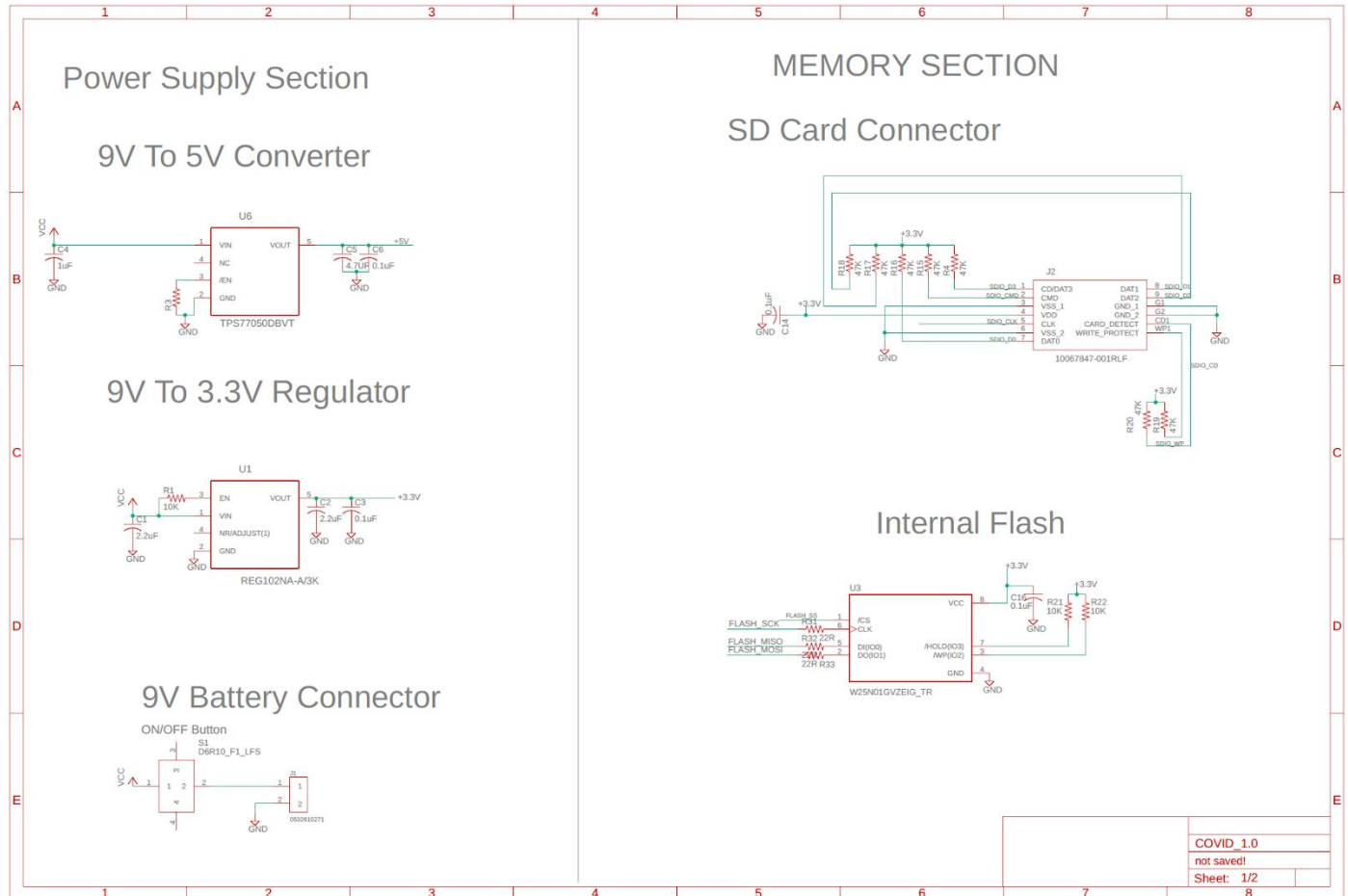
Requirements	Verification
<i>1. A fever is typically considered to be 1 °C above normal, which is 37 – 38 °C. So, this should have an inaccuracy of less than 0.5 °C when compared to core temperature. [6]</i>	<i>1. We will compare results of the sensor on ourselves to measurements obtained using a regular off-the-shelf FDA approved oral thermometer, such as the Vicks ComfortFlex Thermometer with Fever InSight [18]. The results should be within 1 °C of each other.</i>

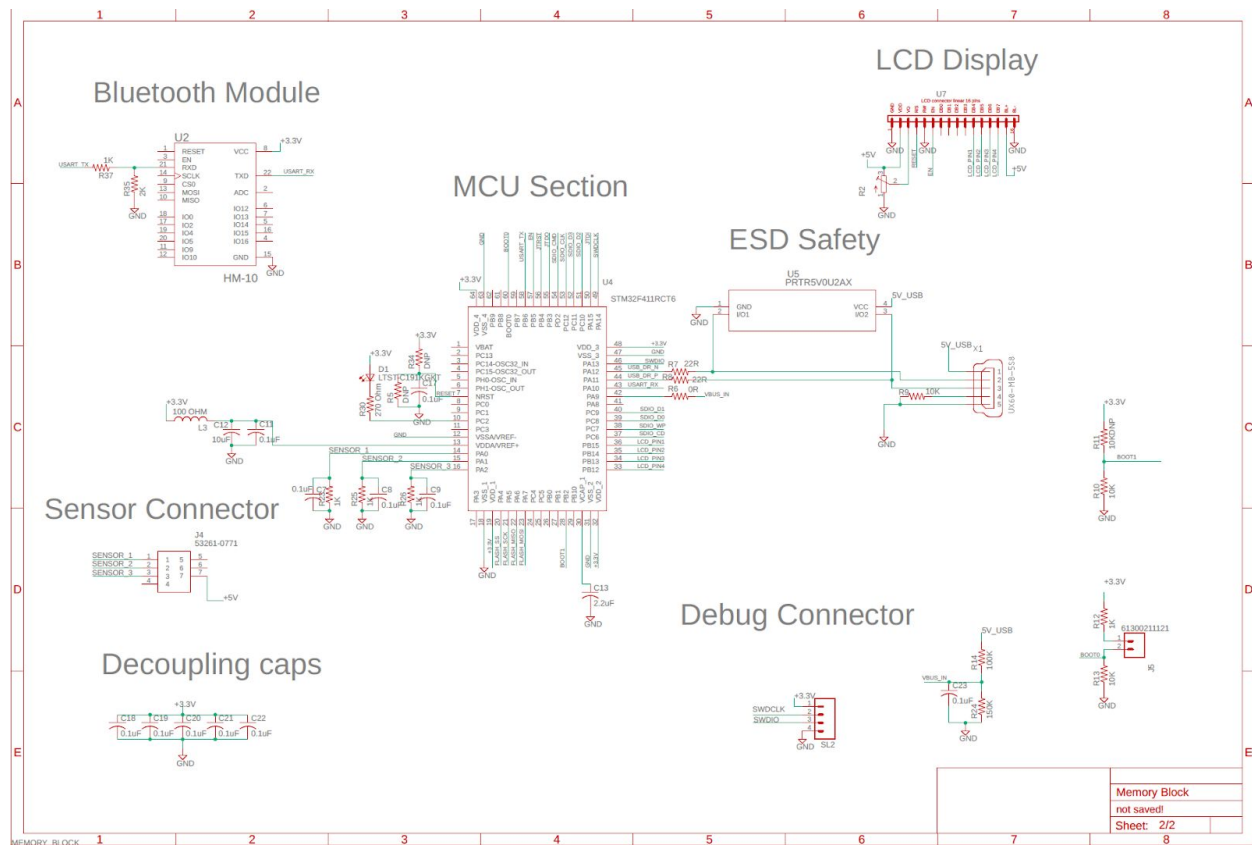
2.4.3 Oximeter

This sensor is very essential to determine whether the patient is deteriorating or not. The pulse oximeter will give information about a person's oxygen level in blood. There is a certain amount of oxygenated blood that is necessary, if not present it indicates that the lungs are not working properly. This is going to be the main way that we determine if symptoms are worsening. Covid-19 is a primarily respiratory disease and SpO₂ which is what an oximeter measures correlates well with lung function. [16]

Requirements	Verification
<i>1. It has been recorded that people with a severe version of COVID-19 have had a blood oxygen saturation of approximately 93% or below [8]. Hypoxemia, or low oxygen levels, which is dangerous for a person at <90% SpO₂ [12]. Since we want to alert someone in the worst case (90% or below) and not give false positives, we need an accuracy of +/- 2.5%, since the regular oxygen saturation varies between 95 - 100%. [8]</i>	<i>1. Compare results to measurements obtained using an alternative off-the-shelf FDA approved pulse oximeter, such as the AccuMed Oximeter Blood Oxygen Sensor [19]. The results should be within 2% of each other.</i>

2.5 Schematics





2.6 Software

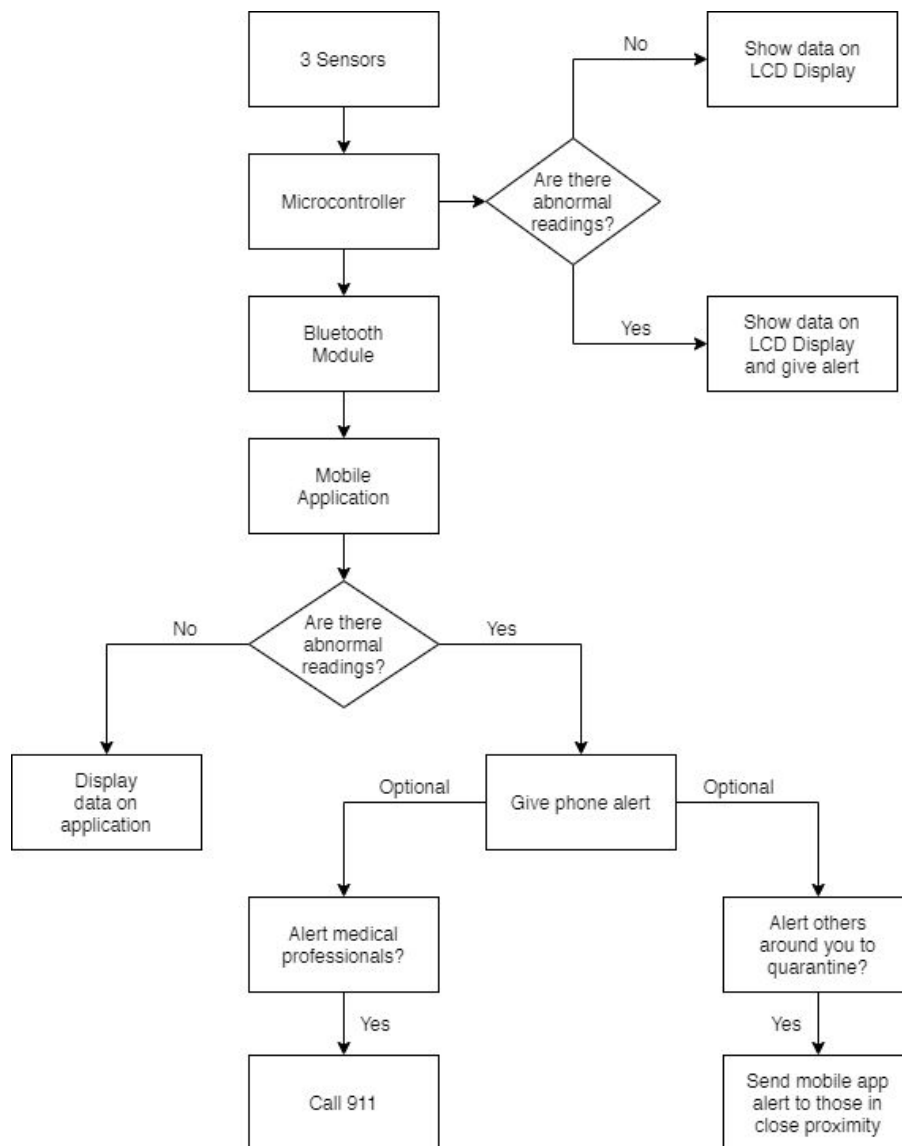


Figure 8. Flow chart for users with hardware device.

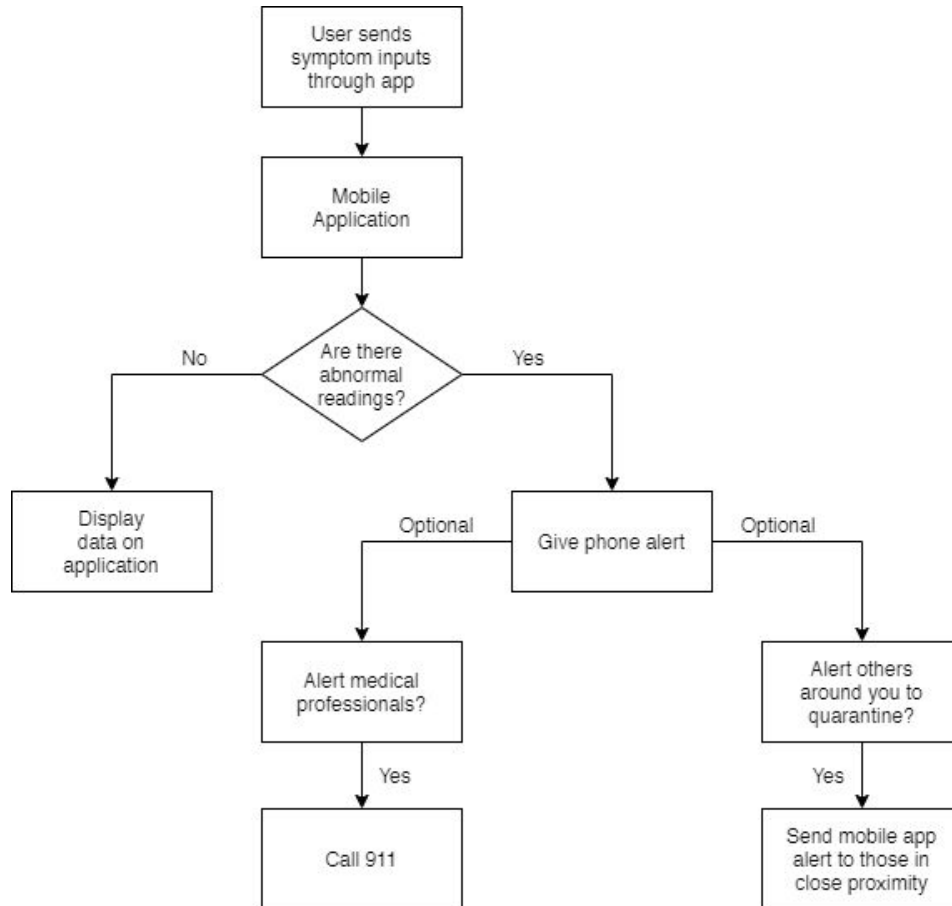


Figure 9. Flow chart for users without hardware device.

2.7 Tolerance Analysis

In order for our project to work it needs to be able to detect worsening symptoms. For this, we will mainly focus on the oximeter as how much oxygen is in the blood is probably the best non-invasive indicator of how well the lungs are working [16] and getting oxygen to the blood is one of the lung's main tasks. It's not perfect, that is why we include other sensors, but in general it does give a good approximation.

For this project, if it were to be implemented we would want to implement it quickly and for that reason we mainly focused on all ready FDA approved sensors. This would hopefully allow us to go to market much quicker as well as simplifying the design process. We were not confident in our ability to master the physical/biological interaction involved with creating our own oximeter in the time provided.

The FDA requires an error of less than 3% for an oximeter to be approved [14]. This is sufficient to differentiate between the lower range of what is considered normal (95%) and the level considered dangerous (89%) [15]. This is obviously non-ideal considering that mild divergences from normal will need to be considered serious.

One solution to this is that most sensors of this type have a resolution of 1% [17], so by using trend lines instead of concrete accuracy we can create meaningful warnings without undue alarm. I.e. if the reading starts trending 2% lower we generate a warning in the app.

3 Project Differences

3.1 Overview

The original project is a wearable device for the elderly, to track their vitals much like the smart watches/fitness bands available in the market today. The wearable device is able to monitor the user's heart rate, track the user's location, track step count/movement, and Fall detection. In terms of the sensors: the wearable device has an optical heart rate monitor, pedometer, and an inertial measurement unit(IMU). The IMU includes the pedometer, 3 axis gyroscope, accelerometer, and magnetometer. The features include displaying heart rate, step count, notifying loved ones about a fall/location.

The fundamental difference in our implementation of the project is that our solution is targeted at more sicker patients and is modified for the on-going COVID-19 situation. The previous project has no integration with a smartphone while ours has a bluetooth module to continuously send sensor collect data to smartphones. The previous implementation does show a bluetooth integrated with a computer but they do not give a detailed explanation of its exact function. They do mention that the project did not want to have a smartphone dependency. It looks like they send sensor data to a computer which loads it to a server. The data that is being collected in our solution is much more medically comprehensive of a patient's condition in the context of COVID-19. The sensors used in our implementation are heart rate monitor, temperature sensor, and pulse oximeter. The data collected from these sensors can be used to analyze the patient's condition and also detect COVID-19. The pulse oximeter helps determine the blood oxygen level which is an important tool to figure out if the lungs are operating properly. Our implementation also takes this vitals data collected and sends it to an app on the smartphone. The app truly differentiates us from the previous implementation which had no smartphone dependence. The app also can be used by other people to report their symptoms who do not have the hardware. The user's of the app can see the number of people experiencing symptoms in their county and the vitals of their loved ones if they have been granted access through the app. The previous implementation consists of a watch but since our implementation is aimed at sicker patients and uses more sensors our hardware consists of a box. Our solution consists of sticky patches that stick to the torso of the patient and a finger clip for the oximeter. In this ongoing issue of COVID-19, it has become harder to take care of elderly patients without the fear of infecting them because of their high vulnerability to this disease. Our implementation gives the user's of the app the ability to monitor their elderly relatives without the need for physical contact, whereas the previous implementation was more like a fitness band to satisfy very basic needs.

Improvements made in the design and engineering trade offs:

1. Added bluetooth module to send data from the microcontroller to the software app so that registered family members can monitor them via smartphones: decreases the overall battery life

and pivoted the project from a wearable wristband into a portable box. Also, complicates the previous simple circuit design and adds extra variables into making the project work.

2. Added extra sensors such as the pulse oximeter and temperature sensor to help check vital deterioration: the pulse oximeter we required needed to be FDA approved since this a medical product aimed at sick patients. In order to ensure that the pulse oximeter we chose is FDA approved, has a good resolution/accuracy and is not too costly we were left with only one option that is bluetooth instead of USB. So, we need to integrate the bluetooth oximeter with our bluetooth module since they communicate using the same protocol.
3. Took out the fall detection since this aimed at very sick patients: any smart watch available in the market today provides fall detection. This simplified the schematic design and integration since it took out the IMU unit which consisted of a gyroscope, magnetometer and an accelerometer.
4. Took out the GPS unit from the previous implementation. Since the previous implementation had no smartphone dependence they required a GPS unit in their circuit design which did not work well according to their final reports due to antenna issues. Since we use smartphones we do not have to deal with that issue.
5. Added the smartphone app to help share data with registered family members and update users about the number of people experiencing COVID-19 symptoms in their county: this solved a lot of GPS issues and added greater functionality but also requires designing a whole application and brings in the HIPAA policy and requires more hours needed to complete the project.

3.2 Analysis

Since we incorporated smartphones and an app in our design we added a bluetooth unit to send data from the microcontroller to a user's smartphone. One of the big issues is that the bluetooth has a certain range of distance till which it can successfully transmit data to the phone. The bluetooth module HM-10 will receive data through UART from the pulse oximeter (that has its own bluetooth) and the microcontroller(which collects data from the other sensors). HM-10 bluetooth version is 4.0 BLE it operates at a low energy, its current draw is 8.5mA in active state and 50-200uA in sleep state. So, in our implementation this low current draw is favorable. The microcontroller we use has USART so to make both compatible we will run it in asynchronous mode.

One of the major concerns is that elderly people need to keep their phone in the bluetooth range always when they want to measure their vitals to enable the app to update. So, we need to focus on the RSSI(Received Signal Strength Indicator).

$$RSSI = U_L - 10 * n * \log(d / d_0)$$

U_L : RSSI in dB at d_0 distance

n : path loss coefficient factor

d : distance between 2 wireless devices in m

According, to the data sheet the RF power is +6dBm. All the variables can be experimentally measured except n which needs to be assumed varies depending on surroundings. The formula for path loss estimation in dB is:

$$P_L(d)_{\text{FREE SPACE}} = 32.44 + 20 \log_{10}(fc) + 20 \log_{10}(d)$$

$$P_L = 2 \text{ for free space}$$

2.4 GHz Propagation Prediction Models for Indoor Wireless Communications Within Building

Description	Model A		Model B		Model C		Number of locations
	n	X_σ	n	X_σ	n	X_σ	
All Locations	4.9711	14.6238	4.2537	13.3488	3.6408	12.4124	480
Same floor (I)	4.1402	11.5931	3.4750	11.3904	2.9069	11.3591	73
One floor below	5.1917	16.1941	4.4971	14.5917	3.9038	13.2973	71
One floor above	5.0954	15.3905	4.4037	13.9776	3.8128	12.8396	69
Two floor above	4.9140	10.8938	4.2434	9.4804	3.6707	8.3884	66
Same floor (Ground)	5.3138	10.5795	4.5030	9.0443	3.8105	8.0948	93

Figure 10. Table showing path loss coefficient values for a building and X_σ is standard deviation [13]. The table shows how variable the path loss coefficient varies in different settings. So it is hard to know with performing experiments how much the distance d can be between the receiver and transmitter. The graph below kind of represents the Rx power v/s distance.

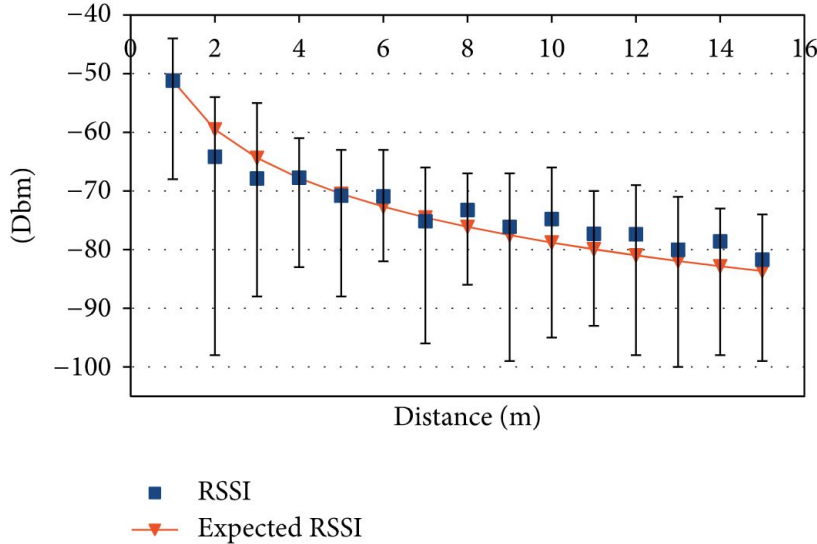


Figure 11. The graph above represents the Rx Dbm v/s distance(m)[20].

From the above figure we see that the greatest drop in the RSSI is in the first 8m. So, bluetooth generally works well in line of sight. After all this analysis we came to the conclusion that an average room size is 13 x14 ft. Even if the bluetooth gives a good signal strength only upto 8m that is 26 ft. So in a large space if the patient has their smartphones nearby it should work. The signal strength really does vary based on

the number of walls and other factors. Overall adding the bluetooth unit has given us a lot of functionality because it enables the smartphone app implementation. The app allows for vital sharing with relatives and COVID-19 tracking.

4 Costs

People	Hourly wage	Total Hours	Total
Tyler Schuldt	\$40/hour	200	\$8000
Isha Sharma	\$40/hour	200	\$8000
Umaiylal Sridas	\$40/hour	200	\$8000
Total x 2.5			\$60000

Part	Manufacturer	Part Number	Cost Per Unit	Total Cost
9V Battery	Duracell	4967493	\$3.61	\$3.61
5V Voltage Regulator	DigiKey	TPS562201DDCT	\$0.76	\$0.76
3.3V Voltage Regulator	DigiKey	MIC5528-3.3YMT-TR	\$0.19	\$0.19
Microcontroller	DigiKey	STM32F411RCT6	\$5.32	\$5.32
LCD Display	DigiKey	LCD-14074	\$25.00	\$25.00
On/Off Buttons	C&K	D6R10 F1 LFS	\$1.20	\$2.40
256 MB SD Card	OEMPCWorld	SDSDB256800	\$10.59	\$10.59
HM-10 Bluetooth Module	DSD Tech	HM-10	\$6.95	\$6.95
Temperature Sensor	SparkFun	TMP117	\$13.95	\$13.95
Heart Rate Sensor & Oximeter	Wellue	PC60F	\$45.00	\$45.00
Assorted Resistors, etc.	Various	Various	~\$10.00	~\$10.00
Total				\$123.77

5 Schedule

Week	Tyler Schuldt	Isha Sharma	Umaiya Sridas
1	PCB Schematic Design and Layout	PCB Schematic Design and Layout	Verify layout and schematic and buy sensors and test them
2	Submit PCB for audit get everything verified	Continue to test sensors with the arduino, collect data	Software and UI/UX
3	order finalized parts, work on interfacing with oximeter	Work on interfacing with oximeter	Software Debugging
4	Accuracy Testing, match up results from arduino testing	Accuracy Testing, durability testing, assemble control unit with LCD display	Accuracy Testing and Software Testing
5	Soldering and Physical Configuration	Soldering and Physical Configuration	Final Product Design
6	Environment Testing and Debugging	Environment Testing and Debugging	Environment Testing and Debugging
7	Mass Environment Testing	Mass Environment Testing	Mass Environment Testing
8	Prepare final presentation and final report.	Prepare final presentation and final report.	Prepare final presentation and final report.

6 Safety and Ethics

This project is a medical vital monitoring device so it has to satisfy all the required medical health regulations such as the: FDA requirements [9] and also the HIPAA policy [21]. Also, a huge part of this project is the app which can be used with/without the hardware and will be collecting sensitive health data. Since the app developed in this project does not necessarily require the hardware device, FDA may classify this as: “software as a medical device”. The application will ask the user to input their symptoms and alert everyone around them in their close proximity if they have the symptoms linked to COVID-19. It is important to make sure that the user symptoms and health data being collected by the hardware device is not shared with any outside source.

The app also has a feature which enables the hardware-device collected data to be shared with the authorized family members in the software application. This application should satisfy the regulations put forth by HIPAA [21]. This app will not ask for personal data such as name, but will ask for data like email, symptoms, and location. This data will not be used by any other entities such as healthcare providers or insurance. According to HIPAA compliance for medical software application, if the personal data is not being shared with healthcare providers/medical professionals then the software app does not have to comply with the HIPAA policies [21].

The app works like a medical device according to the FDA definitions: “In general, if a software function is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device...” [9]. Our device, however, does not exactly diagnose COVID-19 but actually just asks the user for the symptoms they are experiencing and if they satisfy the criteria set forth by the CDC, the app will then urge them to isolate/quarantine themselves, contact 911 and get tested.

“For purposes of this guidance, a “regulated medical device” is defined as a product that meets the definition of device in section 201(h) of the FD&C Act and that has been cleared or approved by the FDA review of a premarket submission ...”[9]. We will have to contact the FDA to understand exactly how strict the requirements will be for our app and if there are any regulations that we need to satisfy.

“As described in this guidance, FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient’s safety if the device were to not function as intended...”[9]. The FDA seems to regulate the software application only if the software application fails to perform and causes a health risk to the patient. Since, our application is more of an early diagnoses app to encourage quarantine by showing the number of people experiencing symptoms nearby and also notify the registered family members on the app -- our app doesn't exactly pose a threat to a patient's health. Of course, the sensors should provide accurate data to the registered family members and the patient otherwise it loses its usefulness.

The hardware device on the other hand contains the actual sensor unit: heart rate sensor, respiration rate sensor, pulse oximeter and temperature sensor. We will use sensors that are FDA approved and satisfy the required health regulations. We will just collect data using these existing regulation approved sensors and integrate them with the microcontroller to send these readings/vitals to the phone using bluetooth. So, we technically are just integrating existing technology to use it in a novel way for this current situation. We just need to make sure that whatever sensor we use is currently being used in the market and gives us accurate readings so that we can integrate them into our design. So, the hardware device will not be heavily regulated by any medical health regulations.

When it comes to COVID-19, testing is the only reliable source to confirm whether the patient actually has COVID-19 or the regular flu/cold. The symptoms are pretty similar to a regular flu except the COVID-19 in the worst cases attacks the respiratory system more strongly. Also, in the current condition, spring is almost coming to an end and warmer temperatures cause the regular flu to taper off so now if

someone is having pneumonia like symptoms there is a much greater probability that they have the COVID-19 considering how widespread it is currently with over 1 million cases worldwide.

Another factor when it comes to COVID-19 is that not everyone is symptomatic so the app might provide users with a false sense of security. This may also happen if there are not enough users actually recording their symptoms. The user might not take the correct quarantine precautions or other safety precautions like washing hands and maintaining 6ft difference. This app is to encourage social distancing but it may have the opposite effect.

Our beliefs align with the IEEE Code of Ethics, #3: “to be honest and realistic in stating claims or estimates based on available data” [2]. We wish to achieve our results reliably by using/safe-guarding data we collect and helping the patients. We will try to ensure that our device provides real time feedback reliably to the patient and their loved ones while encouraging social distancing practices in these rough times.

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