# 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**

# 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 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, 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 is 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. An important part of this project is for the app to relay quick alerts to people within a county. 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

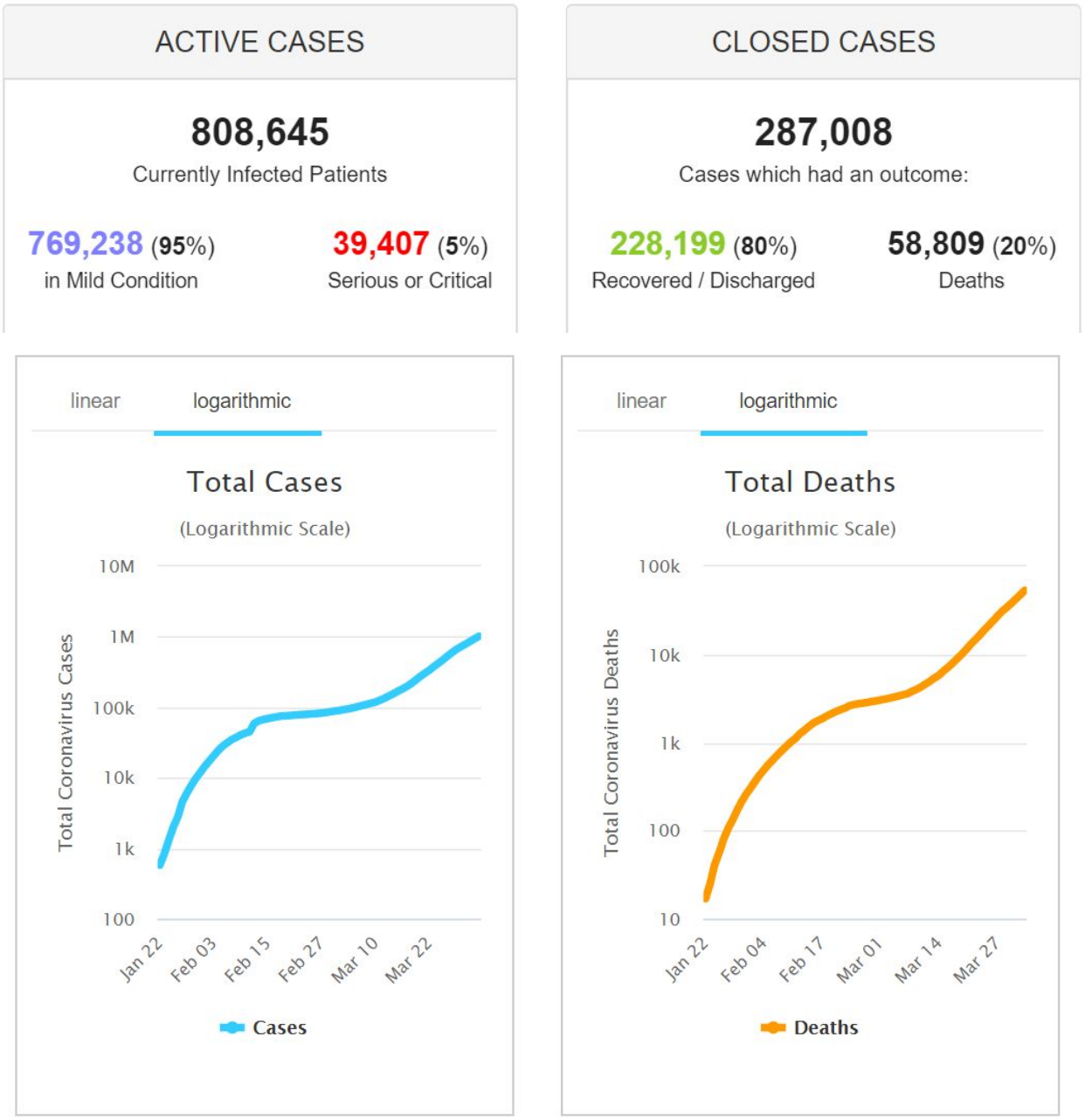
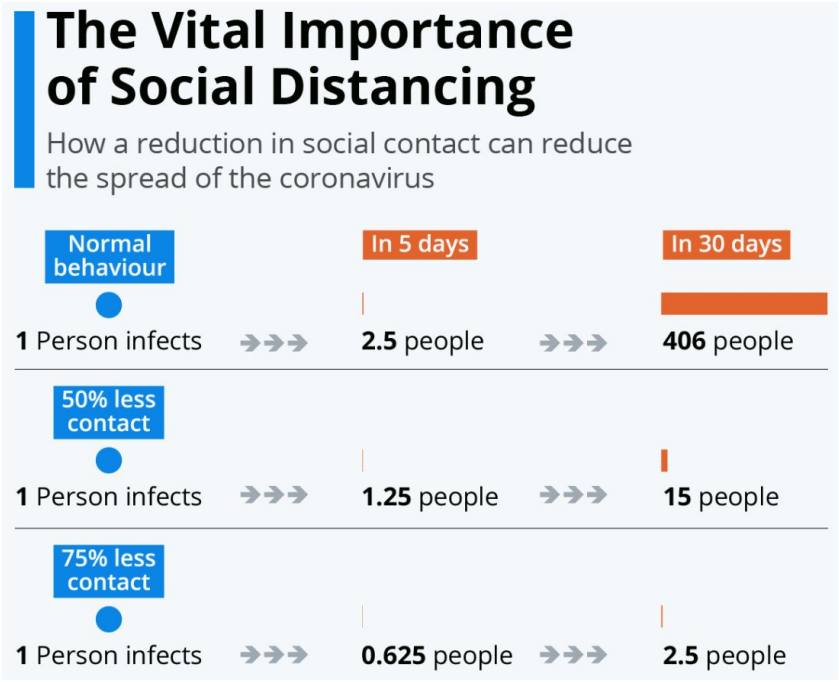



Figure 1. Breakdown of current cases statistics for SARS-CoV-2. These figures show the rate at which people are getting infected and also the fatality rate. So far, the fatality rate is approximately 3%. It is also proving to be very contagious.[1]

[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.



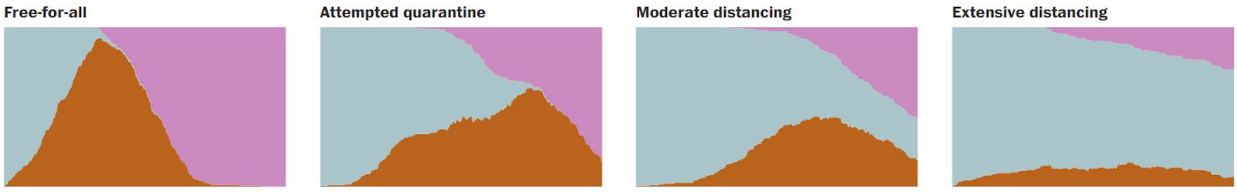




Figure 2. These figures show the importance of quarantining/social distancing. By limiting social interactions we can drastically reduce the spread of COVID-19. In the bottom sequence of images, the teal represents healthy people, brown represents infected/sick people, and pink represents people who 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 should provide accurate readings to help detect deteriorating symptoms.
2. Registered family members should be able to track changes in symptoms.
3. Must be able to quickly inform citizens within a county of the number of people experiencing COVID-19 symptoms while not compromising user privacy.
4. The hardware device should be portable, be able to seamlessly collect data from the sensors, analyze it, and send it to the smartphone app.
5. The hardware device must have the ability to be mass produced and sold inexpensively nationwide.

# 2 Design

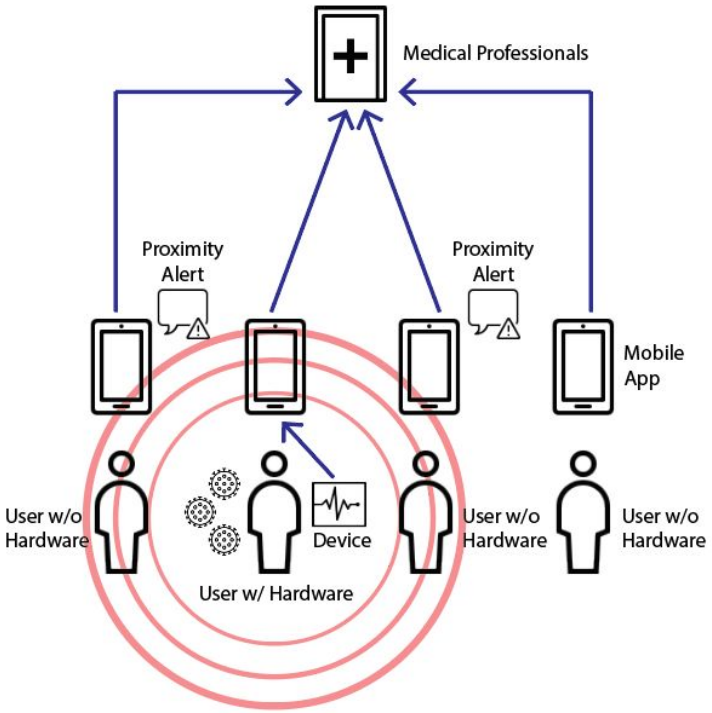



Figure 3. Figure shows the flow of information. It flows from user to neighbors as well as from user to relative. Any user, with or without the hardware, has the ability to alert people within the community about their symptoms/possible infection via the phone app.  The phone app will give you the choice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

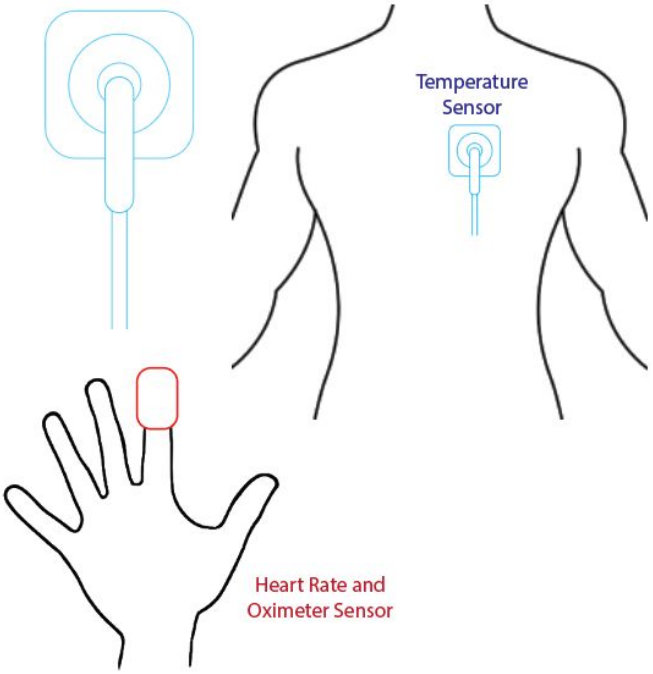



Figure 4. Hardware equipment layout. The sensors will be pasted on the torso (front) in this orientation with medical sticky patches. The hardware is an optional extra purchase for users. Users can simply self-record their symptoms on the app.

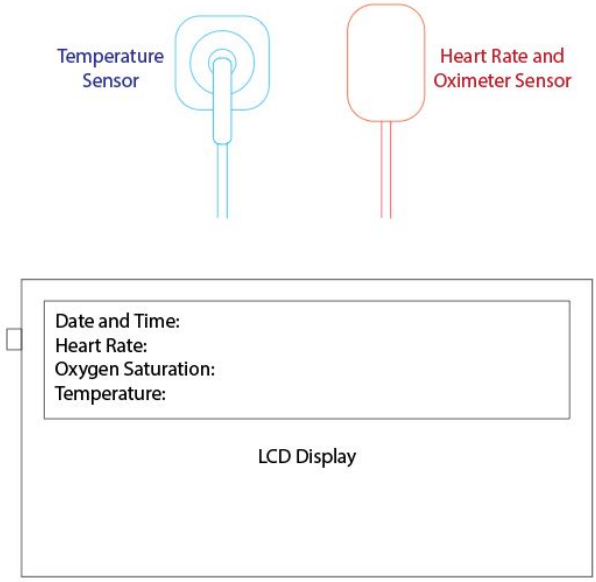



Figure 5. Sensors connect to small processing device that displays information. This allows hardware users to track their symptoms even if they do not have their phone on hand. This display box can be clipped on your pant waistband. It will contain the control unit, visual display, and bluetooth module.

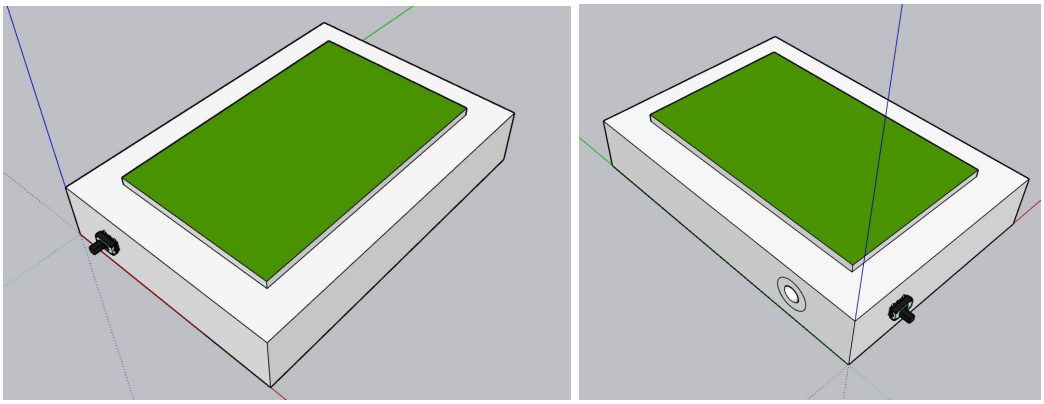


Figure 6. Imagining of how the control unit might look. The dimensions are 3.5”x5”x1” and it includes an on/off switch, LCD display, and a connection for the temperature sensor. The heart rate and oximeter readings will be sent via bluetooth. If the hardware is switched off, the readings will not be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

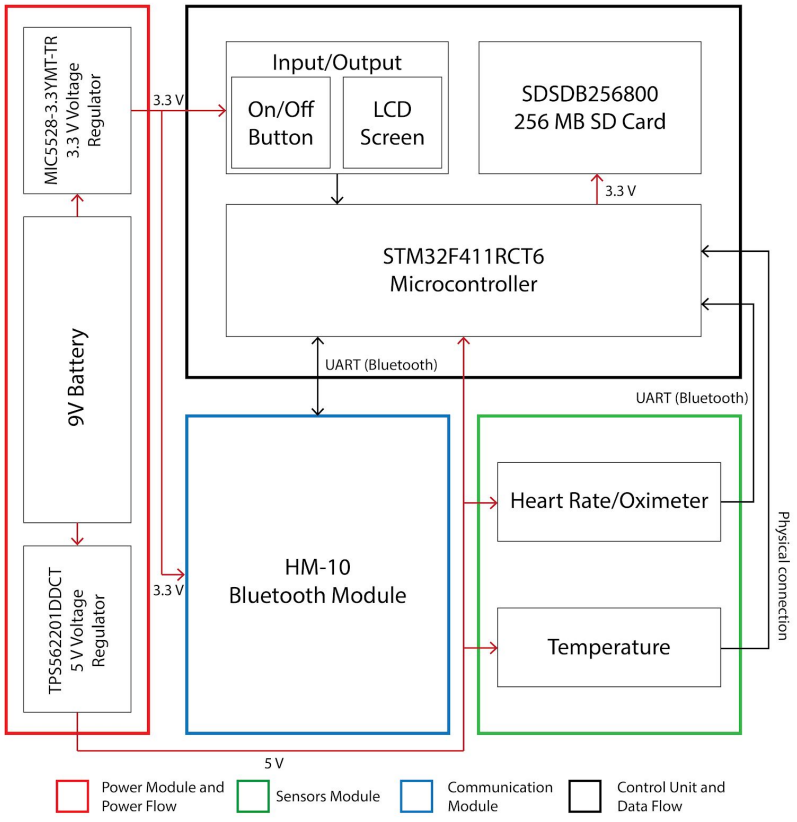



Figure 7. Block Diagram. Black box is the control unit and black arrows are data flow. Red box is the power unit and red arrows are power flow. Blue box is the Bluetooth unit. Green box is the sensor module.

## 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, the bluetooth module which will send the data to the app, and the SD-card which will store the past values that we want to keep track of. The control unit also has the input/output block which consists of the LCD and a button. The button controls whether the hardware device is on/off.

### 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 rate. Temperature can be sampled at a rate of 1 Hz or less. The 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 $SpO_2$ measurement trending past a user chosen reference point or sustaining a worrying value over time. We generate warnings based on 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** |
|---|---|
| 1. *Can receive data from the sensor module at 10 Hz. Should be able to transmit signals to phone and hardware device within 60 seconds.*<br>2. *Must be able to run simple programs involving its ADC pins.*<br>3. *Must be able to access values from the SD-card.* | 1. *Run alongside an arduino. They should both read and broadcast the same values.*<br>2. *Upload and run a known program and see if the results match the expected results.*<br>3. *Transfer 20MB of known data and then read it back verifying that it is the same.* |

### 2.1.2 SD Card

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

| **Requirements** | **Verifications** |
|---|---|
| 1. *Should be able to store 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.* | 1. *Fill the SD Card with 20MB of known data then read it back and verify the read data matches original data* |

### 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 sensor data. LCD display should visibly display current data including timestamp, heart/respiratory rate, and temperature.

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

## 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.

### 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** |
|---|---|
| 1. *Stores and reliably provide 9V for at least an 8 hour period.*<br>2. *Maintains thermal stability below 48°C in order to not physically harm patients [11].* | 1. *Discharge to make sure that it lasts at least 8 hours a day (ideally should last much longer).*<br>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** |
|---|---|
| 1. *Linear regulator provides 3.3V/5V from a 9V source.*<br>2. *Maintains thermal stability below 48°C in order to not physically harm patients [11].* | 1. *Charge then discharge. Measure the output voltage using an oscilloscope, to ensure that the output voltage stays near 3.3V/5V.*<br>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** |
|---|---|
| 1. *Must be able to communicate with the microcontroller using UART.*<br>2. *Must be able to receive data from the pulse oximeter as well as send data to the phone.* | 1. *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.*<br>2. *After testing pulse oximeter and microcontroller attempt to pass data through the bluetooth and into microcontroller.* |

## 2.4 Sensor Unit

The sensor unit is tasked with gathering the data which will be used to try to identify a worsening case. These sensors will connect to the control unit either through bluetooth or via wires and continuously provide readings to the microcontroller.

### 2.4.1 Heart Rate Sensor

For patients with COVID-19 median readings for resting heart rate are slightly elevated, but are within the normal range. Additionally, the difference between ICU patients and those for which the ICU was unnecessary only shows a small difference [8]. Therefore, while useful and readily available through the pulse oximeter, this should receive a small weight in any decision tree.

| **Requirements** | **Verification** |
|---|---|
| 1. *The heart rate of an average individual is about 60 - 100 bpm [11]. This means the heart rate monitor has a little wiggle room. We choose a max error of +/- 5 bpm at most.*<br>2. *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.* | 1. *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. The recorded count should have an error of at most 5 bpm.*<br>2. *Use another FDA approved heart rate monitor while inducing higher heart rate by exercising to see if the heart rate sensor works accurately in the range: 60-150 bpm.* |

### 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 is the most common symptom beyond perhaps coughing, so it has formed the core of most attempts at detection. A higher temperature was highly correlated with more severe cases in Wang *et al.* [8].

| **Requirements** | **Verification** |
|---|---|
| 1. *Normal range for temperature is 36.1℃ to 37.2℃. A high-grade fever is considered 39.4℃ [6]. So, we need an error of less than 1.1℃.* | 1. *We will compare our results 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 after adjustment to different body measurement sites should be within 2.2℃ of each other.*<br>2. *Repeat during normal movement.* |

### 2.4.3 Oximeter

This sensor is essential to determining 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 then cells will start being damaged. This is going to be the main way that we determine if symptoms are worsening. Covid-19 is a primarily respiratory disease and $SpO_2$, which is what an oximeter measures, correlates well with lung function [16].

| **Requirements** | **Verification** |
|---|---|
| 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% $SpO_2$ [12]. Since at the very least, 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]* | 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 5% of each other.* |

## 2.5 Schematics

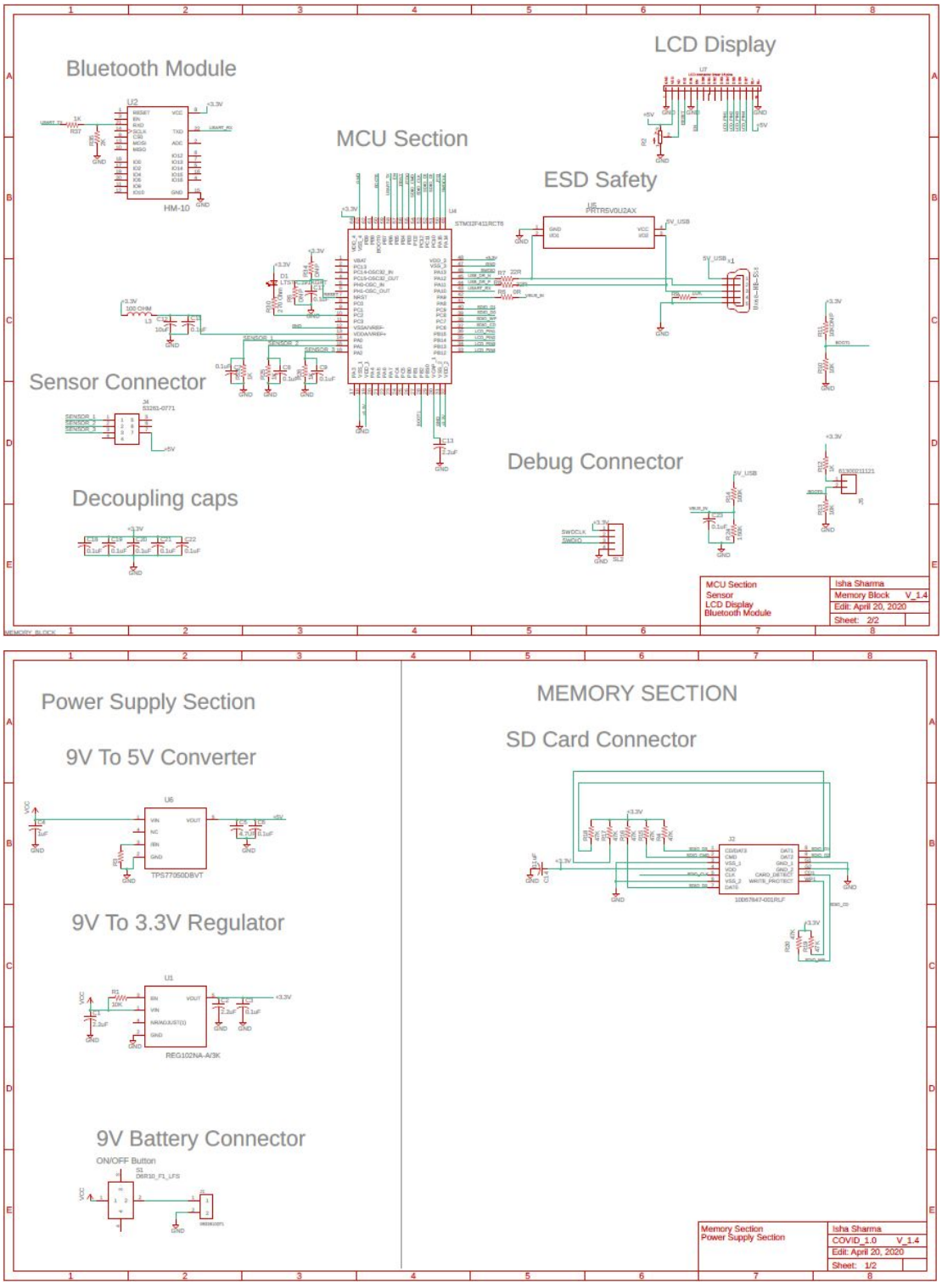



Figure 8A.(Top) Schematic for the MCU section, bluetooth, LCD display.
Figure 8B.(Bottom) Schematic for the power supply section and the SD card connector.

Figures 8A and 8B represent the PCB schematic designed for the Hardware device using Eagle software. Figure 8B contains the 9-5V and 9-3.3V regulators. We based our design using that data sheet to find typical applications. The 9V battery will be in a battery holder that will physically connect to the PCB board which is connected to a on/off button. The SD card connects to the MCU as shown in the schematic. Figure 8A shows the rest of the connections unit wise. The MCU connects to the Bluetooth module via the Tx and Rx. The LCD display also directly connects to general I/O of the MCU. Decoupling Caps are required according to the data sheet and are shown. We included an additional USB for future use if we decide to change/add new sensors (added an ESD safety to go with that).

## 2.6 Software

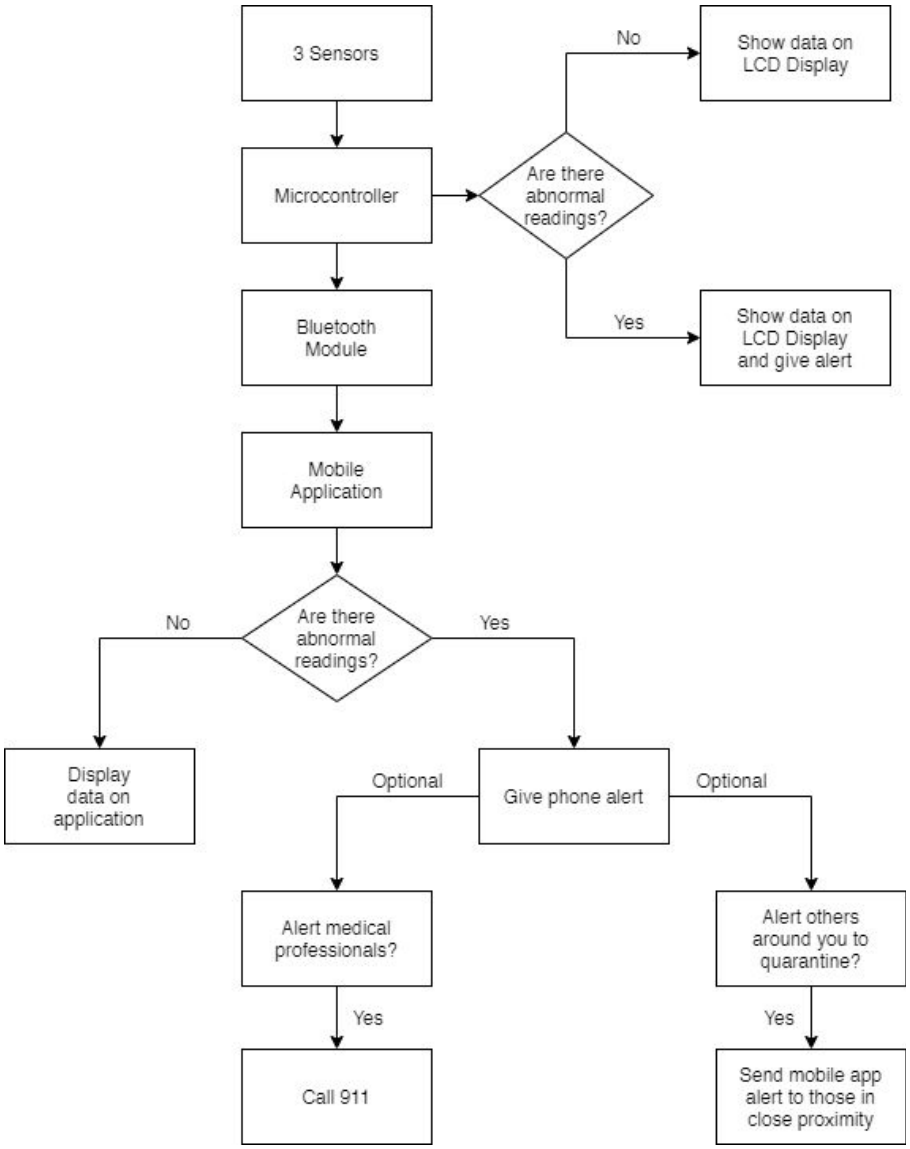



Figure 9. Flow chart for users with hardware device.

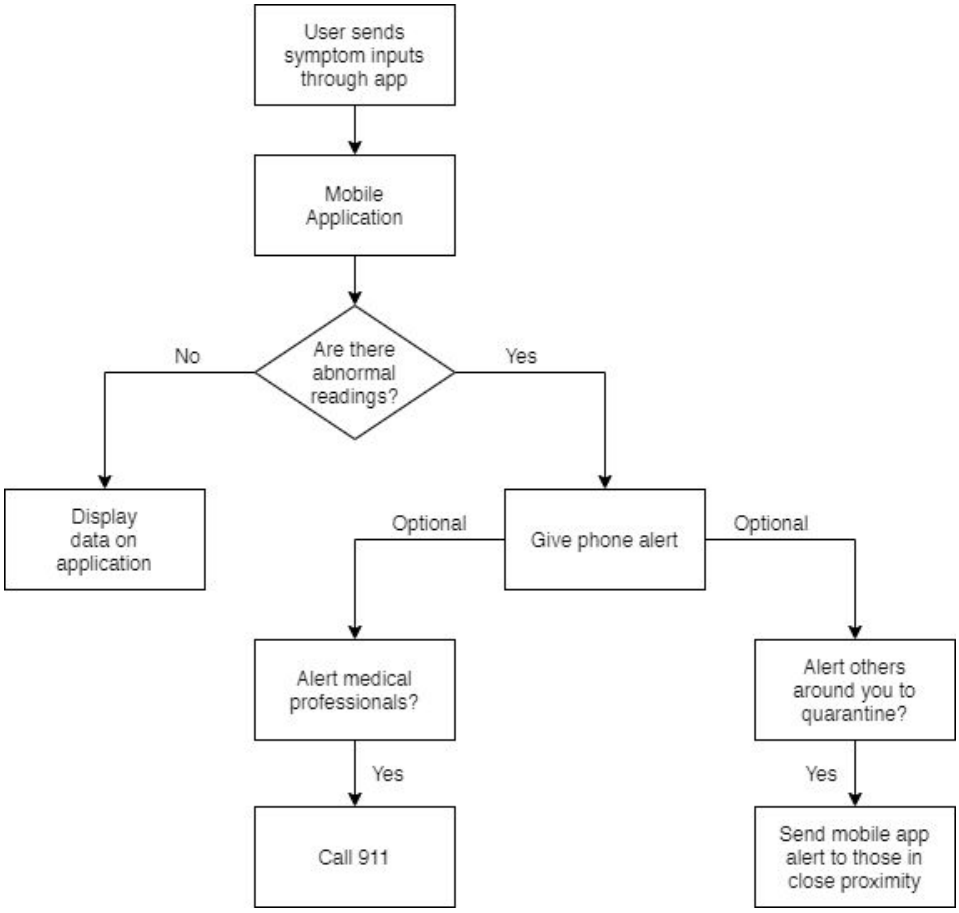



Figure 10. Flow chart for users without hardware device.

## 2.7 Tolerance Analysis

In order for our project to work it needs to be able to detect worsening symptoms. We attempt to do this via two sensors: A pulse oximeter which measures a user's pulse rate and $SpO_2$ values and a temperature sensor that attempts to measure core body temperature.

We choose to use a pre FDA approved  oximeter. Our specified oximeter guarantees an accuracy of +/-2% for $SpO_2$ [22]. For pulse rate, the same device guarantees an accuracy +/- 2 bpm for 30-99 bpm and 2% in the range 100-250bpm [22] which translates to a max error of 5bpm.

For our temperature sensor things are a little more complex since we can not just go off of device accuracy, we also must account for biological and environmental components as well. Device accuracy is +/-0.1℃ with a resolution error of 0.0078°C. We consider the resolution error to be negligible and do not consider it further.  Skin temperatures are not sufficient as core temperature is what is considered medically relevant. Core temperature is only available at certain sites on the body. Axillary (armpit area) measurements of skin temperature are sufficient to approximate core body temperature when adjusted upwards by 1℃ [27] [28]. In Vliet, *et al.* [26], continuous measurements of axillary temperature were found to differ from more controlled measurements by -0.9℃ to  0.5℃. Giving ourselves a bit of a buffer

as well as accounting for device error, we choose to specify our temperature sensor as having an accuracy of +/- 1 ℃ when compared to core temperature.

Covid-19 is a new phenomenon as such there is a lot that is not known. For example, we seem to be lacking good data on early warning scores which are used to detect and quantify deterioration of patients. For this reason, we are going to look at 2 different methods of determining severity of cases and look at how our measurements stack up against each.

Before we begin, it is prudent to reiterate that we do not plan to replace a hospital's evaluation or an in-home caregiver. All that we try to give is some quantitative values and, hopefully, piece of mind to what otherwise might be a very subjective experience. As such, we accept that we are not going to catch everything and our requirements are going to necessarily be somewhat lax to keep cost, complexity, and invasiveness down to a reasonable level. A necessary requirement of this is that our product would not be for people with high risk, such as people over age 65 with comorbidities such as heart disease or COPD, as they might very well deteriorate rapidly. Users should also not be smokers as smoking can interfere with the pulse oximeter.

In Verity *et al.* [23], patients with tachypnoea (rapid breathing: ≥ 30 breaths per minute) or oxygen saturation of ≤ 93% at rest are considered severe. This methodology is good for us as we can easily measure both of these things. Oxygen saturation is provided via the pulse oximeter and the respiration rate can be provided easily by the user.

We did originally plan to provide a sensor to try to measure respiration rate. Unfortunately, we decided against providing it after looking at available options and realizing that they all either required wearing a mask, had accuracy issues especially during movement, or had cost issues [24]. Additionally, respiration rate is easily measured by the user via counting during a 30 second interval much like how a pulse is sometimes taken. So, the amount of value added by such a sensor is questionable.

One challenge for us in the classification by Verity *et al.* [23] is that our Pulse oximeter has an error of +/- 2%. In order to catch all cases of ≤ 93% we will need to generate warnings when it dips below 95%, but since 95 - 100% represents the normal range, error on the lower end could generate false positives. Additionally, more accurate sensors are cost-prohibitive. One possible way to improve results would be to take the median value over a long period of time, however actual improvements via this method aren't specified in any documentation. The time distribution of readings relative to a reference value is not specified either.

NEWS (see figure 11 below) is a scoring system for use in hospitals. It is based on predicting mortality in the next 24 hours [25] as such we focus on finding the two intermediate values instead of the worst value as the person likely needs to be in the hospital by the time the worst value is reached.

Respiration rate can be determined by the user as previously mentioned. If we assume an error of +/- 2 which corresponds to 1 error in the 30 second testing interval, then we should still be able to differentiate the worst case on both sides.

For the first $SpO_2$, we have an error of 2% which isn't sufficient to localize it to a specific score, but it is sufficient to localize dangerous values. For example, if the true value is 93% the sensor should always report a non-normal number. The second $SpO_2$ is similar.

We choose not to implement a blood pressure sensor, because it didn't seem to be a good fit for our product which is based on continuous monitoring. If the user is concerned then there are off-the-shelf products for them to look into.

Oxygen can be determined by the user. Consciousness will need to be checked by an in-home care provider.

The error on our pulse sensor is about 2-4bpm which is more than sufficient to notice dangerous levels.

Lastly, the error on our temperature sensor is 1℃ which is just barely sufficient to notice dangerous levels.

| Physiological parameter | Score 3 | 2 | 1 | 0 | 1 | 2 | 3 |
|---|---|---|---|---|---|---|---|
| Respiration rate (per minute) | ≤8 | | 9–11 | 12–20 | | 21–24 | ≥25 |
| $SpO_2$ Scale 1 (%) | ≤91 | 92–93 | 94–95 | ≥96 | | | |
| $SpO_2$ Scale 2 (%) | ≤83 | 84–85 | 86–87 | 88–92 ≥93 on air | 93–94 on oxygen | 95–96 on oxygen | ≥97 on oxygen |
| Air or oxygen? | | Oxygen | | Air | | | |
| Systolic blood pressure (mmHg) | ≤90 | 91–100 | 101–110 | 111–219 | | | ≥220 |
| Pulse (per minute) | ≤40 | | 41–50 | 51–90 | 91–110 | 111–130 | ≥131 |
| Consciousness | | | | Alert | | | CVPU |
| Temperature (°C) | ≤35.0 | | 35.1–36.0 | 36.1–38.0 | 38.1–39.0 | ≥39.1 | |

Figure 11. The above chart is for calculating adapted NEWS score. NEWS (National Early Warning Score) is based on a model that predicts in-hospital patient mortality within 24 hours of recording of symptoms [25].

# 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 perform fall detection. The wearable device has the following sensors: an optical heart rate monitor, pedometer, and an inertial measurement unit(IMU). The IMU includes the pedometer, 3 axis gyroscope, accelerometer, and magnetometer. The targeted features included displaying heart rate, step count, and notifying loved ones about a fall and the location of that fall.

The fundamental difference in our implementation of the project is that our solution is targeted at sick 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. 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 the 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 users 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 uses sensors distributed across the body 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 everyday 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 younger 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).

$$RSSI = U_L - 10 * n * \log( d / d0 )$$

UL: RSSI in dB at d0 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:

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

$P_L = 2$ 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 | $X_\sigma$ | n | $X_\sigma$ | n | $X_\sigma$ | |
| 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 12. 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.

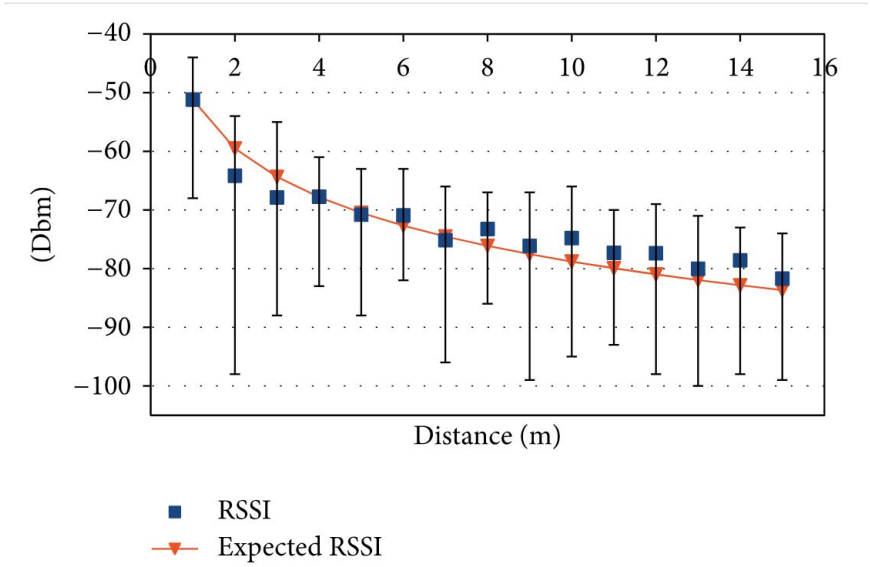



Figure 13. The graph above represents the Rx Dbm v/s distance(m)[20].

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 |
| Umaiyal 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 | iHealth | PO3M | $70.00 | $70.00 |
| Assorted Resistors, etc. | Various | Various | ~$10.00 | ~$10.00 |
| Total | | | | $143.77 |

# 5 Schedule

| Week | Tyler Schuldt | Isha Sharma | Umaiyal 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 software application is more of a supplement 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, 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/safeguarding 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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