

# COVID-19 Monitor

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## Abstract

Elderly citizens want or, today in the case of COVID-19, need to be able to navigate life on their own without the assistance of other people. The Spring 2015 Smart Wearable Devices for Elderly People uses fall detection through an inertial measurement unit (IMU), a pedometer, and heart rate to keep the daily vitals of an elderly person; although software was mentioned in their final report, we do not believe the software was implemented. Our wearable device is also made for elderly people, but catered directly towards monitoring symptoms of COVID-19, as elderly people are more susceptible to the illness. Our device includes a heart rate monitor, an oximeter, and a thermometer to keep careful, continuous watch of respiratory symptoms and uses a Bluetooth module to feed the data to a mobile app. The mobile app will allow authorized loved ones to see vital updates, but will also alert citizens within the proximity to quarantine to prevent the spread of COVID-19. The hardware is an optional purchase and the mobile app can work with or without the hardware. If the hardware is not purchased, users can input their own symptoms via the app.

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## 1. Second Project Motivation

### 1.1 Updated Problem Statement

COVID-19 refers to the respiratory illness caused by the SARS-CoV-2 virus. 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. People with lowered immune systems and older people are most susceptible to COVID-19.

A sick relative is always a concern and source of stress. However, with COVID-19, this problem is magnified. We are trying desperately to limit the spread of the disease, so while some patients are at home recovering, you may not be able to see them, due to CDC social distancing guidelines. This can be especially stressful, because infected patients who are recovering at home need to be in isolation; this means no one is around to attend to their needs and the patient could possibly deteriorate without anyone noticing.

Our device should put loved ones at ease as it continuously monitors respiratory symptoms, while still encouraging social distancing. Currently, the best action the general public can take to fight the spread of COVID-19 is quarantining; our device will allow a patient and loved ones to be aware of their symptoms while social distancing and reducing the burden on medical professionals who are dealing with a mass number of cases.

### 1.2 Updated Solution

Our solution to this problem is centered around trying to detect/monitor symptoms of COVID-19. We aim to provide alerts to the family members about their loved ones that will hopefully decrease their worry by monitoring metrics found in the modified NEWS2 score, including heart rate, temperature, and SpO<sub>2</sub> levels<sup>1</sup>.

The original project analyzed basic vitals of an elderly person, including fall detection, step count, and heart rate, like a fitness band. We are specifically aiming our efforts towards respiratory vitals in order to gauge the symptoms of COVID-19 through temperature, heart rate, and SpO<sub>2</sub> levels which are all good indicators of lung function. Both projects were focused on tracking potential problems/symptoms in older patients to update their loved ones. While we focused on providing significant information in the context of COVID-19, previous implementation focused more on the general case of health in the elderly. In short, our project is an improvement in its usability in the context of COVID-19 because we added sensors that are more medically comprehensive to differentiate us from a fitness band.

While the readings we are offering are not necessarily unique, the sensors on the market can be expensive and all come separately. We aim to integrate a heart rate sensor, an oximeter, and a thermometer all together with software in order to provide the user with accessible and

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<sup>1</sup> SpO<sub>2</sub> or oxygen saturation is the percent of hemoglobin carrying oxygen.

comprehensible readings in a clean, sleek format. This product is a vital monitoring device, but only a test can confirm if a person has COVID-19.

### 1.3 Updated High-Level Requirements

1. Sensors can differentiate between severe and mild symptoms.
2. Registered family members can 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. Hardware devices can be mass produced and sold inexpensively nationwide.

### 1.4 Updated Visual Aid

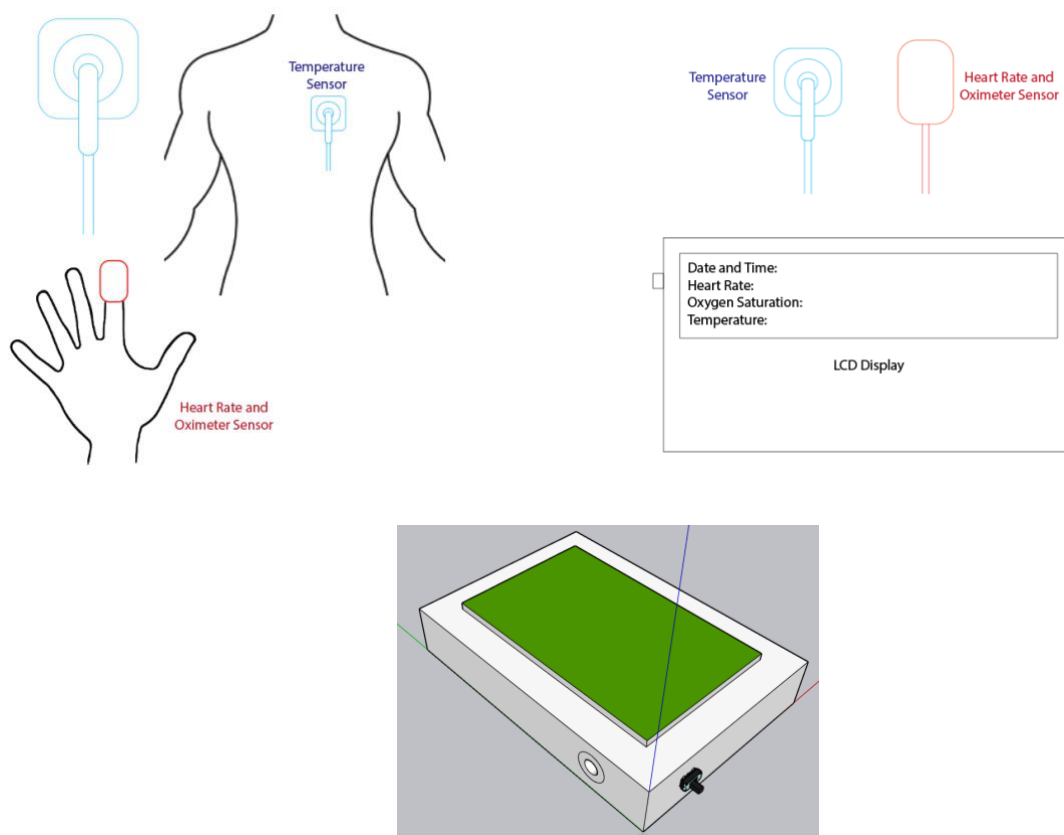


Figure 1A. (Left) Hardware equipment layout. The sensors will be pasted on the torso in this orientation with medical sticky patches. The oximeter and the heart rate sensor are combined into one finger clip sensor. Figure 1B. (Right) Sensors connect to small processing device that displays information. This allows hardware users to track their symptoms if they do not have their phone on hand. This can be clipped on your waistband. It contains the control unit, visual display, and Bluetooth module. Figure 1C. (Bottom) Control unit drawing. This 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.

## 1.5 Updated Block Diagrams

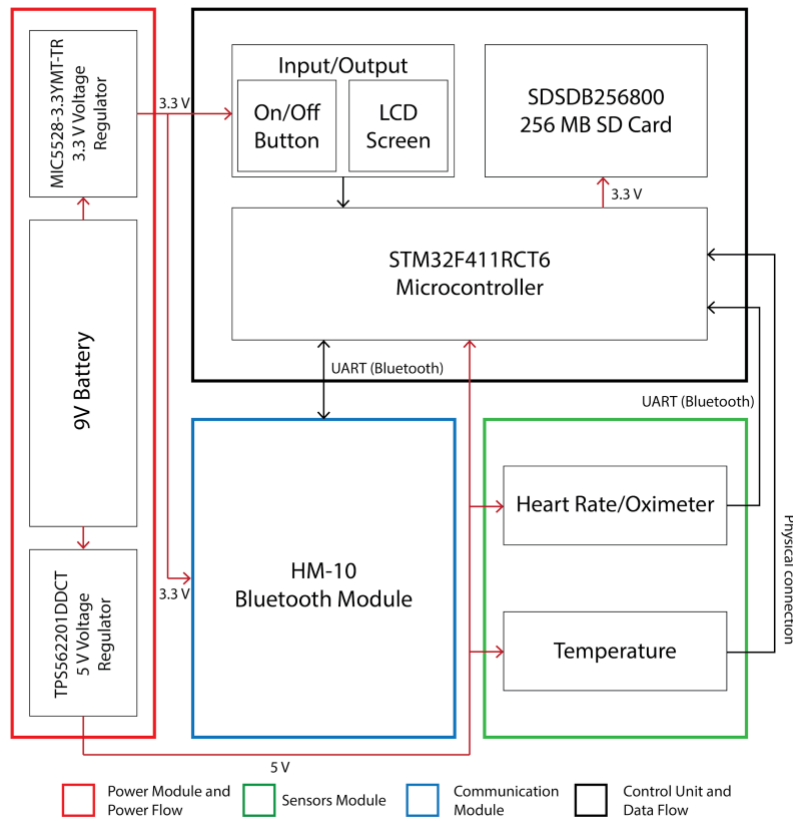


Figure 2. Block Diagram: Black box is the control unit and black arrows are data flow. Red box is the power unit and red arrows are power flow. Blue box is the Bluetooth unit. Green box is the sensor module.

## 2 Second Project Implementation

### 2.1 Implementation Details and Analysis

The hardware design and software implementations were done remotely for this project. Keeping in mind the high-level requirements, we implemented all the hardware design and the software application. Since we do not have the Bluetooth module, PCB, and the physical sensors we perform mathematical analysis for those parts in the sections below.

#### 2.1.1 Schematic, Board Layout and BOM

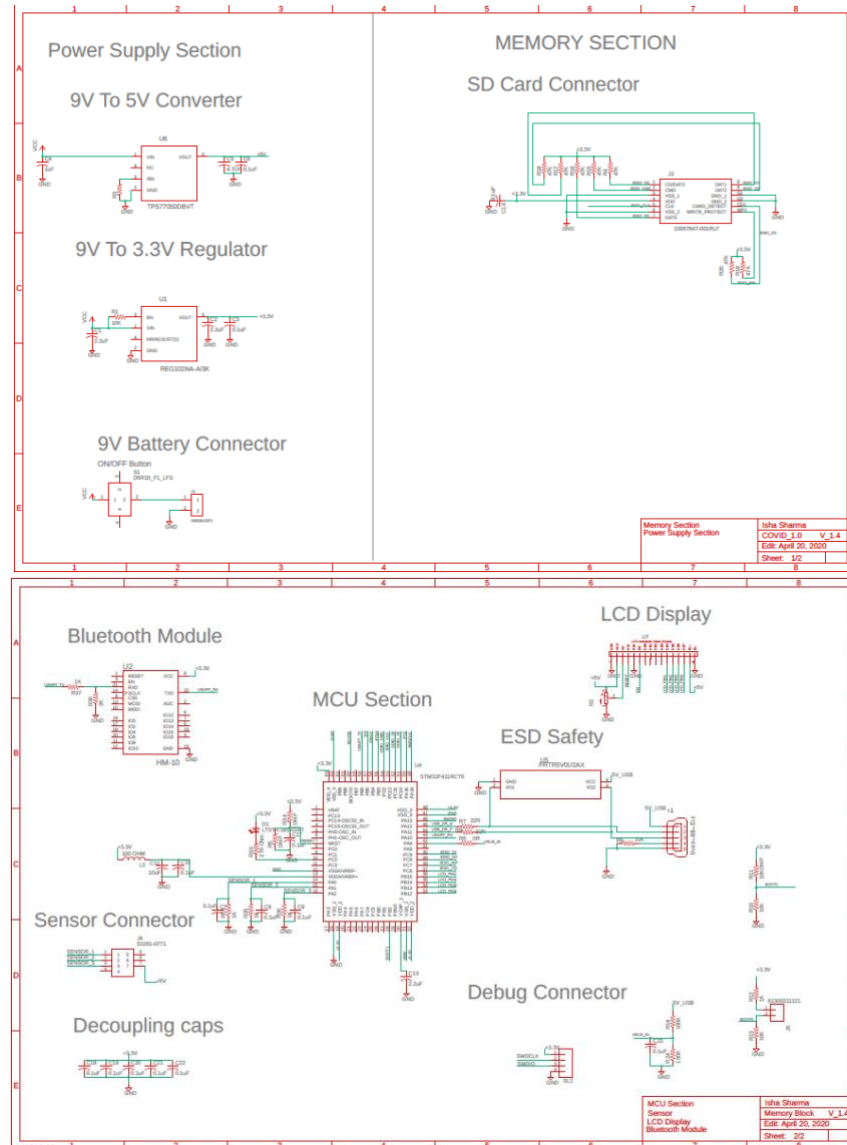


Figure 3A. (Top) Schematic for the power supply section and the SD card connector.

Figure 3B. (Bottom) Schematic for the MCU section, Bluetooth, LCD display.

Figures 3A and 3B represent the PCB schematic designed for the Hardware device using Eagle software. Figure 3A contains the 9-5V and 9-3.3V regulators. We used data sheets to find typical applications for each component. The 9V battery will be in a battery holder that will physically connect to the PCB board and to an on/off button. The SD card holder connects to the MCU as shown in the schematic. Figure 3B 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 for the MCU according to the data sheet and are shown. We included an additional USB for future use if we decide to change/add new sensors (analyzed further in the project improvements section).

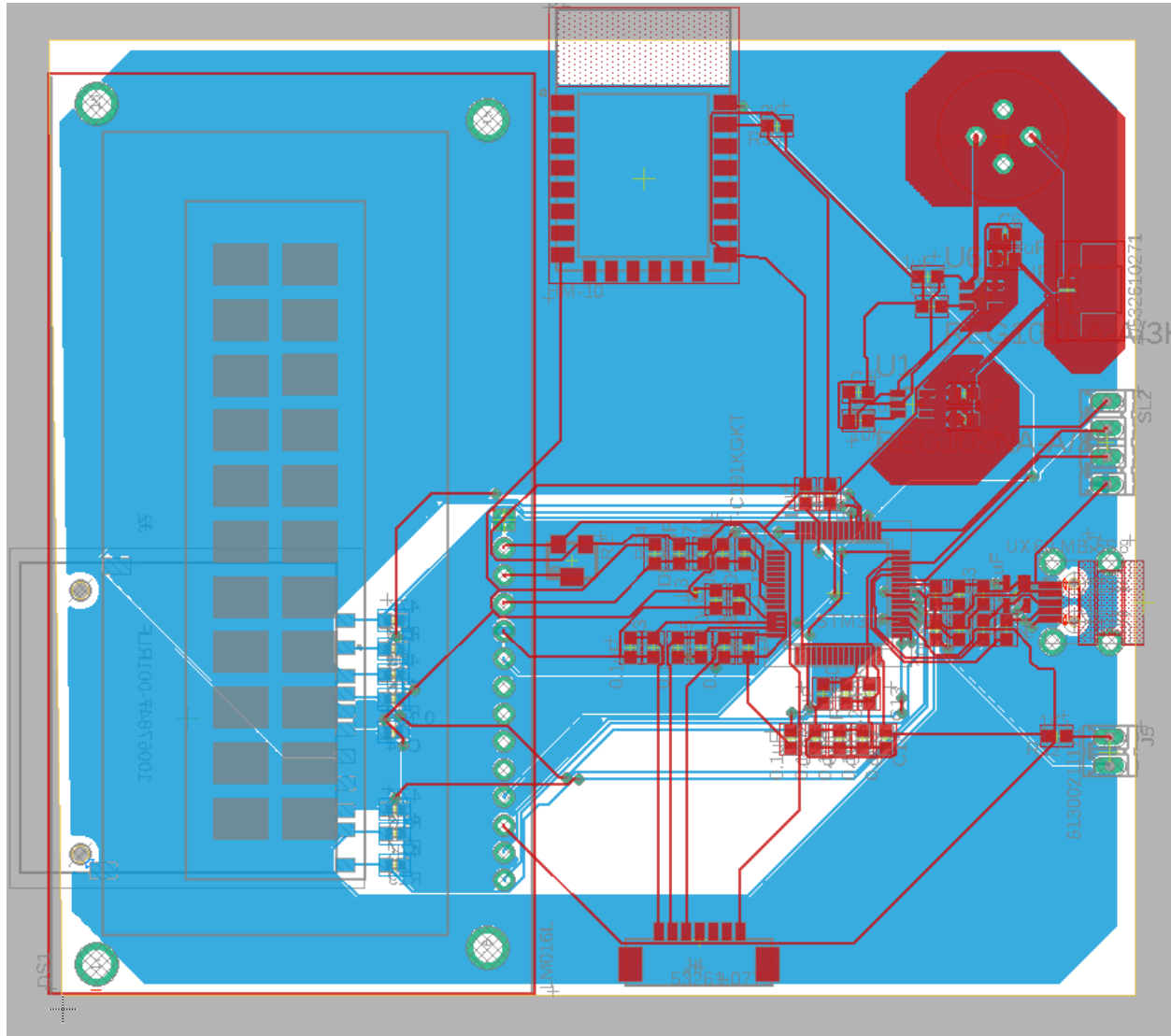


Figure 4. PCB design for the hardware box based on the schematics shown in Figure 3. This 2 layered PCB will be in a box (shown in figure 1C.) and will have only the LCD portion visible to the user. Three different types of shielding are done since there are three voltage levels: 9, 5 and 3.3V. The overall ground shielding has been done on the back side. The on/off button is on the top right side. The SD card holder has a portion coming out of the PCB so that a SD card can be inserted inside.



Below is a table detailing the BOM for only the PCB portion.

Part	Qty	Manufacturer	Part Number
9V Battery Connector (right angle)	1	Molex	532610271
9V connector (female part)	1	Molex	510210200
5V Voltage Regulator	1	DigiKey	TPS562201DDCT
3.3V Voltage Regulator	1	DigiKey	MIC5528-3.3YMT-TR
Microcontroller IC	1	STMicroelectronics	STM32F411RCT6
Sensor connector (7positions)	1	Molex	532610771
LCD Display	1	DigiKey	LCD-14074
On/Off Button	1	C&K	D6R10 F1 LFS
256 MB SD Card	1	OEMPCWorld	SDSDB256800
USB Connectors 5P MICRO USB (TYPE B RCPT W/ REAR PEGS)	1	Amphenol FCI	10118194-0001LF
HM-10 Bluetooth Module	1	DSD Tech	HM-10
SD card holder	1	Amphenol FCI	10067847-001RLF
9V battery wire connector	1	Keystone Electronics	232
Assorted Resistors, etc.	Various	Various	Various

This section of the implementation helps satisfy high level requirement #4, so that the hardware device can be mass produced and sold inexpensively nationwide.

## 2.1.2 Analysis for Bluetooth BLE 4.0 RSSI

This section helps satisfy high level requirement #2, so that the Bluetooth data can be sent to the smartphone app to help loved ones keep track of their vitals. The main unit in this project implementation is the Bluetooth. Bluetooth interfaces the hardware device with the smartphone app by transmitting data from the microcontroller to a user's smartphone. The hardware device is for the elderly, who might not always have their smartphones close to them. It is important to analyze if the range of the Bluetooth we are using is practical. The Bluetooth module being used is HM-10 which is a 4.0 BLE (Bluetooth low energy). It has a current draw of 8.5mA in active state and 50-200uA in sleep state. Due to these favorable characteristics 4.0 BLE is usually used for medical device applications. This analysis is done to ensure that the Bluetooth will practically work with a good enough range and update the smartphone app.

We focus on the RSSI (Received Signal Strength Indicator):

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

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 for HM-10 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:

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

$P_L = 2$  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 5. Table showing path loss coefficient values (n) for a building and  $X_\sigma$  is standard deviation [1].

The table shows how variable the path loss coefficient is for different settings based on obstructions such as walls. Bluetooth generally works best in line of sight. So, we analyze the RSSI for two devices that are in line of sight and are separated by some distance (m).

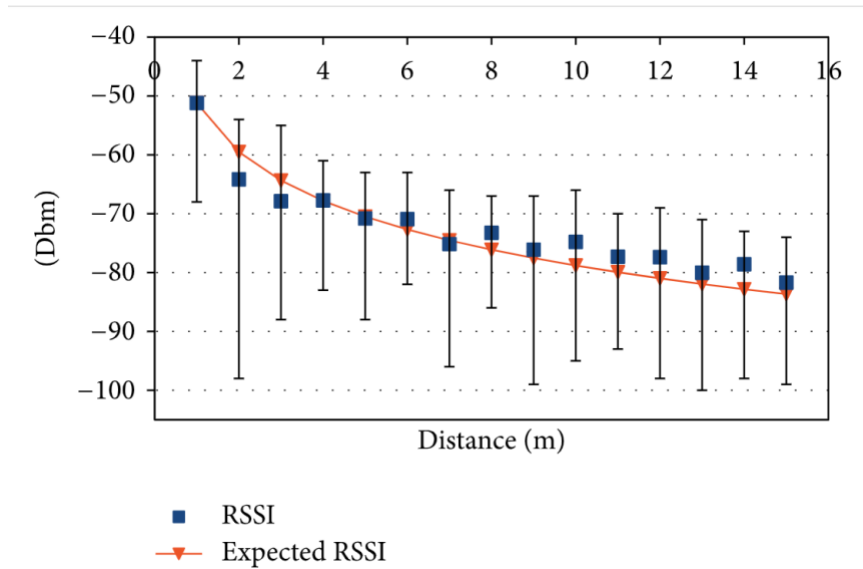


Figure 6. The graph above represents the Rx (Dbm) v/s distance (m)[2].

The graph shows how as the distance between two devices increases the Rx (Dbm) decreases. From Figure 6 we see that the greatest drop in the RSSI happens in the first 8m. So, Bluetooth generally works well in line of sight. After this analysis, we concluded that an average room size is 13 x14 ft. Even if the Bluetooth gives a good signal strength only up to 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. From this analysis we conclude that the Bluetooth device HM-10 has a practical range for the hardware product.

## 2.1.3 Software Implementation

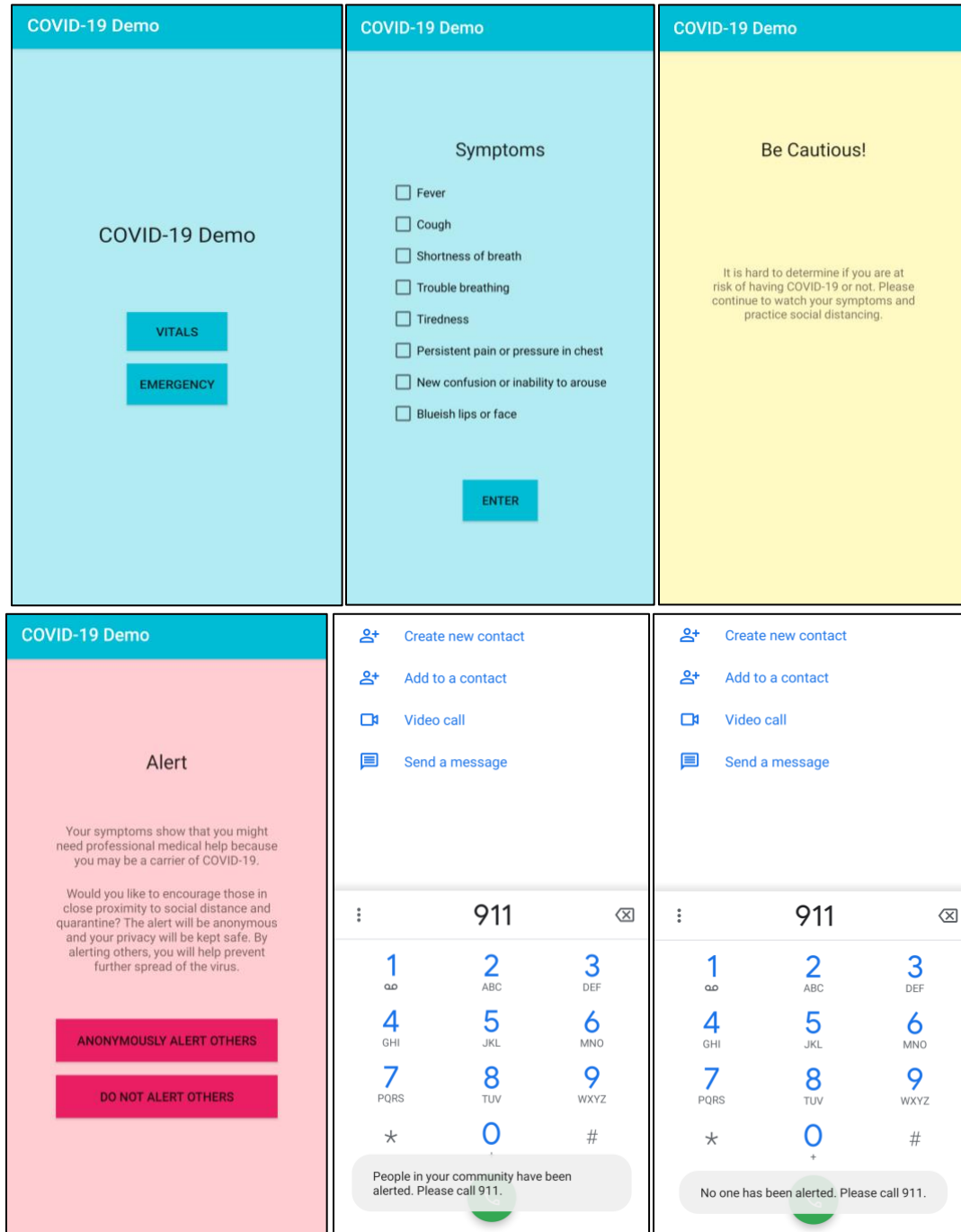


Figure 7. These are screens of the Android application created in Java. Without hardware, it allows a user to input their symptoms and receive a notification to watch for further symptoms or gives a recommendation to call 911 while alerting other users to quarantine/social distance. The code can be accessed through GitHub: <https://github.com/usridas/covid-19-app>.

This section implementation helps satisfy high level requirement #3, by quickly sending alerts to social distance. As shown in Figure 7, this app allows users to interact with a simple, sleek interface in order to encourage social distancing, which has been continuously recommended by the CDC. This app was created with Java for Android devices. Through the Vitals/Symptoms window, users can check off symptoms that they have been experiencing. The symptoms listed are reported by the CDC to be the most common indicators of COVID-19, but obviously symptoms can vary case to case; we decided to follow CDC guidelines and common symptoms, rather than trying to opt for more specific cases in order to cater to the general population. If two or less symptoms are recorded, a caution warning is generated, recommending the user to follow social distancing guidelines and to continue watching their symptoms. If more than two symptoms are recorded, an alert pops up saying they may be at a higher risk of having COVID-19. The window will ask if the user wants to alert others in the vicinity of his or her symptoms; by alerting others, the user will encourage social distancing to reduce the spread of COVID-19. The user's information will all be kept private as an anonymous notification is sent out to other app users with the same zip code. While the notification is sent out, the user is redirected to the dial pad where they can simply press dial to call 911. The user can also choose not to notify other users and will be immediately directed to the dial pad to call 911. If the user is fairly certain they are contaminated or want to directly call medical professionals, they can access the Emergency window directly from the home page where they can choose to alert others or not. This application is in no way a replacement for COVID-19 Testing Kits; it is simply a way for people to gauge symptoms and quickly access 911 if necessary. By making a mobile application to follow these symptoms, users can be more aware of their condition and encourage social distancing among the community. As said before, social distancing is the best way for citizens to prevent further spread of COVID-19.

#### 2.1.4 Sensor Modeling

A main goal of our product is to help make things easier on COVID-19 patients and relatives. One of the primary ways to do that is by offering some meaningful numbers for what otherwise might be a very subjective experience. We do that by collecting data on 4 vital signs: SpO<sub>2</sub>, heart rate, respiration rate, and core body temperature and ranking the values based on NEWS (see figure 8 below). We hope in this way to differentiate between severe and mild symptoms, satisfying high level requirement #1.

The plan was to collect the values with a pulse oximeter placed on the finger and a temperature sensor placed in the axillary region (armpit area). The pulse oximeter we were planning on using was FDA approved and would collect data on SpO<sub>2</sub> and heart rate. While the temperature sensor collected data on core body temperature, and the user provided the respiratory rate via a method similar to checking your pulse. We would generate warnings when a sustained increase in NEWS score occurred. In this case, sustained means the median score over the course of the last hour was above the score of the previous hour.

However, given the time-constraints and a lack of hardware, we are making do with software modeling based on given specification rather than a more rigorous implementation and evaluation. A small problem with this is that we do not have great data on the general distribution of various measures and we have no data on any distributions over time. As such, we assume that distributions are independent and gaussian. We also only consider instantaneous values. Considering only instantaneous values is very

much a worst case for us, since longer time horizons is the primary way we were seeking to mitigate false positives and negatives. We could consider each sensor reading as independent, but that is likely too optimistic. This would give our sensors only negligible error rates and there would likely be some persistent errors.

Physiological parameter	3	2	1	Score 0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO <sub>2</sub> Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO <sub>2</sub> 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 8. 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 [12].

For the modeling, our basic approach was to first generate an approximate distribution of physical levels in people. We used the equation

$$f(x) = \frac{1}{\sigma b\sqrt{2}\pi} e^{-\frac{(x-\mu)^2}{2\sigma^2}} \quad (2.1)$$

where  $\sigma$  is the standard deviation,  $b$  was a scalar to account for the number of bins we wanted,  $x$  represented the placement of the current bin, and  $\mu$  represented the value about which the distribution was centered. We then propagated the derived distribution through a sensor. We did this by iterating through each bin in the original distribution, generating a new distribution centered on that bins value with the sensor's estimated standard deviation. We would then scale each bin in the new distribution by the value found in the original bin and, lastly, add these new scaled bins to the final distribution.

We considered two groups: healthy people and those hospitalized COVID-19. If data was available by age, we choose to focus on ages 65-80. The healthy group is a stand-in for people with mild cases of COVID-19. There is a distinct lack of data on symptoms in mild non-hospitalized cases.

For SpO<sub>2</sub>, our sensor had root mean squared error (RMSE) of 2% [6]. Assuming a gaussian distribution, the standard deviation equals RMSE, so we use 2%. For healthy people, Bhogal and Mani [8] found a mean of 97% and a standard deviation of 0.707. For hospitalized people with COVID-19, Richardson, *et*

*al.* [7] found an interquartile range (IQR) of 91% - 97%. Assuming a gaussian distribution, we get a mean of 94% with a standard deviation of 4.45%.

For heart rate, our sensor had a RMSE of 2 beats per minute (bpm) under 100 bpm and 2% the actual value over 100 bpm [6]. For healthy people, Ostchega *et al.* [9] specified the 5th percentile to be 54 bpm and the 95th percentile to be 91bpm for 40 – 79 year old people. Assuming gaussian distribution, we get a mean of 72 bpm and a standard deviation of 9.25 bpm. For hospitalized people with COVID-19, Richardson, *et al.* [7] found an IQR of 85 bpm - 110 bpm. Assuming a gaussian distribution, we get a mean of 97.5 bpm with a standard deviation of 18.53 bpm.

For respiration rate, we assume an RMSE of 1 breath per minute (bpm). For healthy people, Rodriguez *et al.* [10] found a mean of 19.2 bpm with a standard deviation of 4.1 bpm in patients. For hospitalized people with COVID-19, Richardson, *et al.* [7] found 17.3% of patients as having more than 24 breaths per minute. Assuming a distribution the same as the one above but shifted over, we get a mean of 20.57 breaths per minute.

For core temperature, our device has an error of  $\pm 0.1$  °C. In healthy people, Geneva, *et al.* [11] noted that axillary temperature varies from 35.01 - 36.93 °C where the range is defined by mean  $\pm 2$  standard deviations. This yields a mean of 35.97 °C and standard deviation of 0.48 °C. For hospitalized people with COVID-19, Richardson, *et al.* [7] found an IQR of 36.9 °C - 38.3 °C. Assuming a gaussian distribution and subtracting 1 °C since we are measuring in the axillary region, we get a mean of 36.6 °C with a standard deviation of 1.04 °C.

The following figures illustrate the results of these derived values.

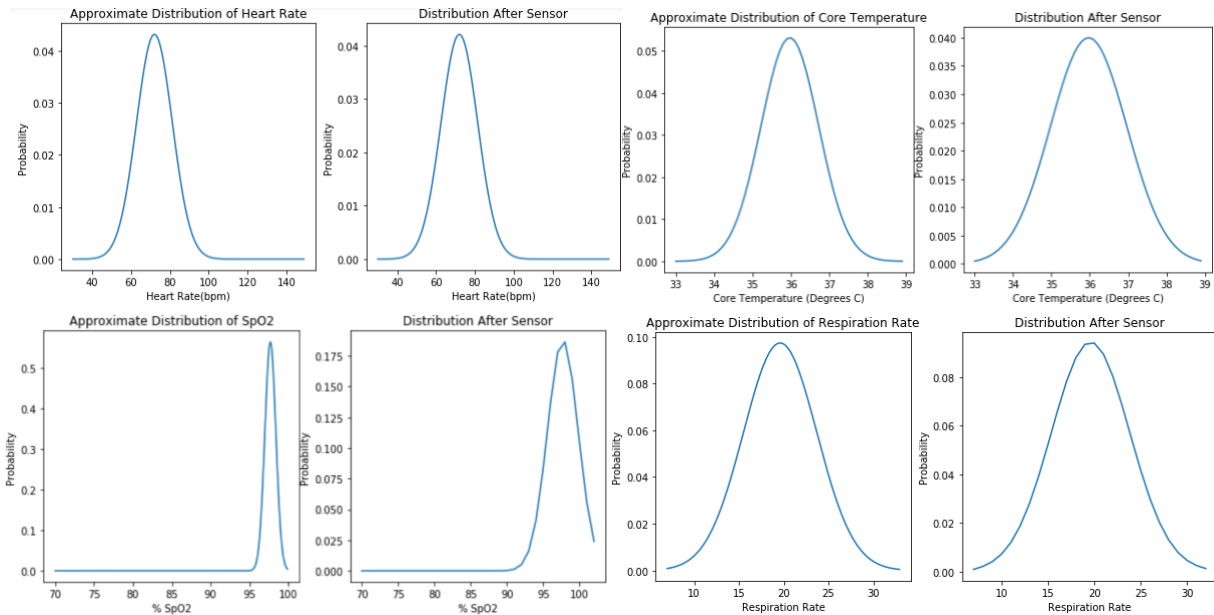


Figure 9. Figures made using the method described above with the values derived above. This data is for healthy adults only. In each corner the figure on the left represents the original distribution while the one on the right represents the distribution after it goes through the sensor. (Top Left) Approximate distribution of heart rate in healthy adults aged 40 - 79. (Top Right) Approximate distribution of Core Body Temperature in adults. (Bottom Left) Approximate distribution of SpO<sub>2</sub> for the entire population. (Bottom Right) Approximate distribution of Respiration Rate for ages greater than 65.

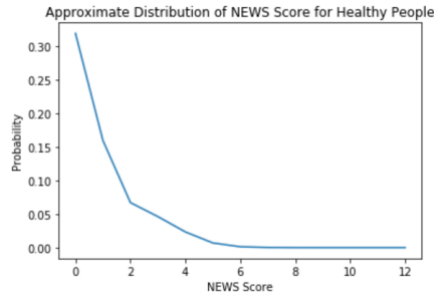


Figure 10. Approximate adapted NEWS score for healthy adults. Derived from data in figure 9. Zero is most likely and the probability quickly decays from there. However, the probability is still non-negligible until 4 or 5.

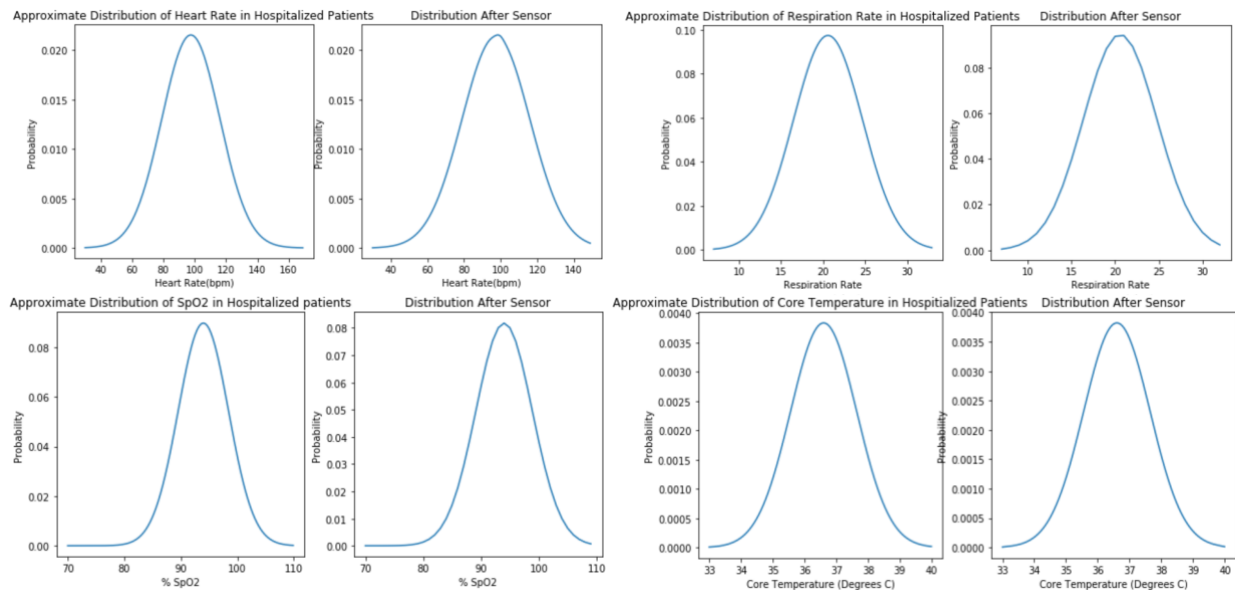


Figure 11. Figures made using the method described above with the values derived above. This data is for hospitalized COVID-19 patients only. In each corner the figure on the left represents the original distribution while the one on the right represents the distribution after it goes through the sensor. (Top Left) Approximate distribution of heart rate in hospitalized COVID-19 patients. (Top Right) Approximate distribution of Core Body Temperature in hospitalized COVID-19 patients. (Bottom Left) Approximate distribution of SpO<sub>2</sub> in hospitalized COVID-19 patients. (Bottom Right) Approximate distribution of Respiration Rate for ages greater than 65 in hospitalized COVID-19 patients.



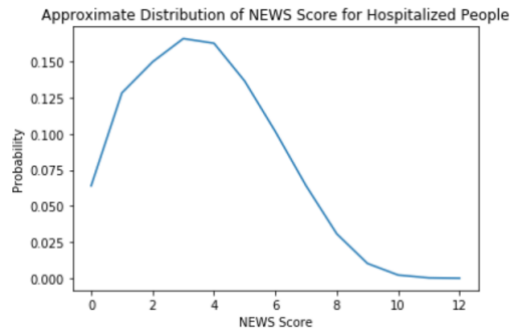


Figure 12. Approximate adapted NEWS score for Hospitalized COVID-19. Derived from data in figure 9. Three is most likely, but the probability of a lower score is 30%+. However, the distribution is still significantly different from Figure 10, which shows the healthy distribution.

If we compare Figure 10 and Figure 12, we notice a few things. First, there is a significant difference, so we can say that our measurements are meaningful. However, the chance for 0 scores among hospitalized patients and the change for 3-4 scores among healthy patients is too high for this product to fully replace existing evaluation methods.

### 3. Second Project Conclusions

#### 3.1 Implementation Summary

With the limited time and resources, we tried to implement as much as could remotely. We did not have access to the lab, required sensors, and the physical PCB. So, we were unable to do the firmware for the PCB, any physical PCB testing and collection/transmission of sensor data through Bluetooth. Without the sensors and the physical PCB, we decided to divide the implementation section into four parts: hardware design, software application, analysis of the Bluetooth module, and mathematical modelling.

In chapter 2, we implemented parts of the project and left out the parts that required the physical PCB and lab access. We divided up the tasks as shown below:

1. Isha Sharma: Used Eagle to design schematics, PCB layout and BOM for the hardware device. Performed analysis of Bluetooth module HM-10 4.0 BLE to ensure practical Bluetooth range (Sections 2.1.1 and 2.1.2).
2. Umaiyal Sridas: Used Java to implement the Android smartphone application that allows a user to input symptoms common to COVID-19; users will either receive a notification to watch for further symptoms or will receive a recommendation to call 911 while alerting other users within the same zip code to social distance or quarantine (Sections 2.1.3).
3. Tyler Schuldt: Used mathematical modelling to further analyze tolerances by examining distributions using Python (Section 2.1.4).

### 3.2 Unknowns, Uncertainties, Testing Needed

We have a few unknowns remaining. The first is interfacing with the pulse oximeter. We decided to use a pre-existing one that was pre-approved by the FDA. While this simplified some things, its method of interfacing with external components is via Bluetooth. Since both the Bluetooth module and oximeter work using UART protocol we need to spend some time to ensure the communication between them is seamless.

Another set of big unknowns concerns the modeling in section 2.1.4. In general, we lack data and that made us make a lot of assumptions some of which are likely wrong. We assumed that the distributions would be gaussian, but that likely isn't true for everything. The SpO<sub>2</sub> readings are especially known to be problematic since we actually went over the physical limit of 100% and not by a small margin. There does not seem to be good data on the actual distribution, and we do not want to make the distribution something arbitrary.<sup>2</sup> Similarly, we lacked data on the time distribution of sensor readings and lack of data in mild non-hospitalized cases. To account for the lack of time distribution data, we only considered instantaneous readings (see 2.1.4 for more details) and to account for the lack of data in mild cases we choose to use stand-in readings from healthy people. Hopefully, these two decisions somewhat offset each other. We expect instantaneous readings to result in much higher error margins for our sensors which lowers the difference in NEWS score between our two considered population. On the other hand, we expect patients with mild cases to have a higher NEWS score than those that are healthy. The decision to use healthy people as a stand in for patients with mild cases likely raises the difference in the found NEWS score.

### 3.3 Ethics and Safety

This project is a medical vital monitoring device, it must satisfy all the required medical health regulations such as the: FDA requirements [3] and also the HIPAA policy [4]. Since the smartphone application can be used with/without the hardware device FDA will classify it 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 symptoms linked to COVID-19. It is important to make sure that the user symptoms, exact location and sensitive health data being collected by the hardware device is not shared with any outside source. The health data will only be shared with authorized family members through the app. 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 [4].

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..." [3]. Our device, however, does not exactly diagnose COVID-19 but actually just asks the user for the symptoms

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<sup>2</sup> This would likely benefit us as it would lead to higher scores among hospitalized patients.

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 ...”[3]. 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...”[3]. 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 it doesn't 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 contains sensor units such as heart rate, oximeter and temperature sensor. We will use sensors that are FDA approved and satisfy the required health regulations. We will just collect data using the existing regulation approved sensors and integrate them with the microcontroller to send these readings/vitals to the phone using Bluetooth. Thus, the hardware device will not be heavily regulated by the FDA/health regulations. The hardware device does not detect COVID-19. Testing is the only reliable source to confirm that a person has COVID-19. The hardware is a vital monitoring device with the added functionality of an app to share data with loved ones and encourage quarantine. Since not everyone is symptomatic, the app might provide users with a false sense of security if there are not enough users to record their symptoms. The app is to encourage social distancing, but it might 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” [5]. 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. We will also keep in mind that faulty data might create anxiety for the users and their loved ones and will take steps such as averaging data over time to mitigate this. We wish to also encourage social distancing practices in this unique time.

### 3.4 Project Improvements

Hardware implementation would be the first priority on our future agenda, considering we had no supplies and no equipment to do adequate testing; this would have been especially critical for our project considering it is a medical device which measures heart rate, temperature, and oxygen saturation accurately to check for symptoms of COVID-19. Developing the hardware further would have allowed for smooth software integration. Our current software does not require any hardware at all, but if we were to build hardware, it would need to be adjusted appropriately to communicate and receive valid data from the hardware.

After properly developing the basic hardware, using the components listed above (Section 2.1.1) and the sensors listed in our design document, we wanted to make the product accessible and affordable by the general public. The best component for us to reevaluate would be the oximeter, since it is the component with the highest price value. If we can recreate our own oximeter and get it FDA approved, this will greatly reduce manufacturing costs, allowing us to reduce the price for the overall product.

If we were to further expand our project, our best addition to the hardware would be a respiratory sensor; this will give the user's respiratory rate (breathing rate), which is greatly considered for COVID-19, as it is a respiratory disease. When ideating for our original design, we hoped to find a respiratory sensor that was FDA-approved, non-invasive, and able to be integrated with our project. Frankly, there aren't many respiratory sensors available on the market. Finding one and integrating it with the rest of the hardware and the software would provide invaluable data to the user and aid greatly in detecting symptoms of COVID-19. Obviously, our first step would be to research respiratory sensors that are currently available on the market before committing to make our own FDA-approved sensor; creating a new respiratory sensor would probably be its own project.

## 4. Progress made on First Project: Foot Pressure Sensor Insole

After our first design review, we focused on having all our hardware design ready before the early PCB deadline. We were also doing sensor tests and data collection to come up with a feedback algorithm.

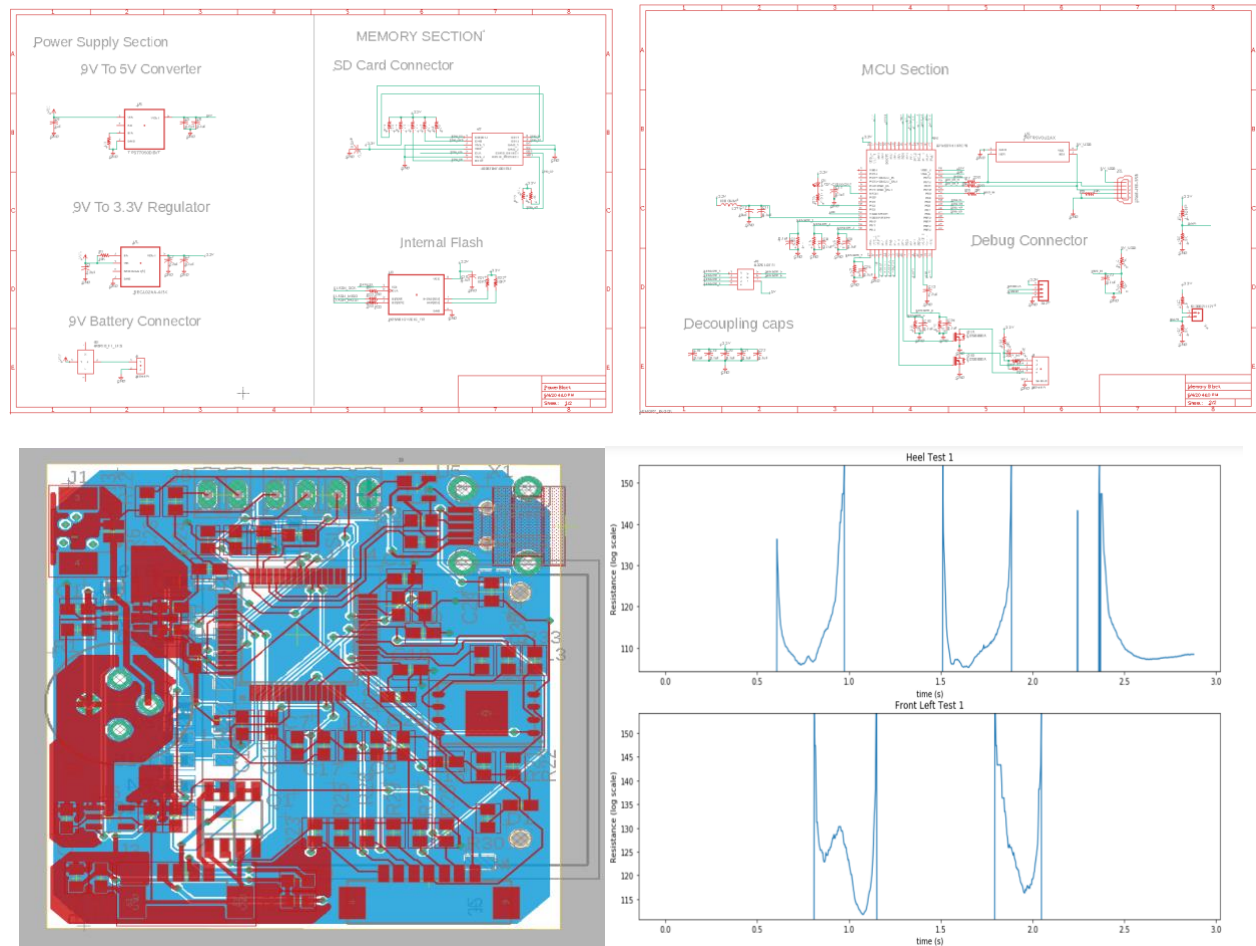


Figure 13A. (Top left) Schematic for power supply and SD card holder. Figure 13B. (Top right) Schematic for MCU section along with sensor, USB, and vibrational motor connectors. Figure 13C. (Bottom left) Eagle PCB layout for the ankle band box. Figure 13D. (Bottom right) Graphs made in python using the data collected by walking with a pressure sensor insole connected to an ADC pin on an Arduino. This graph shows two steps completely. Graphs show voltage varying, 0V denotes overload: no pressure on sensor.

Itemized implementations/testing done:

1. Hardware PCB design was fully implemented as shown in Figure 13C.
2. Data analysis was being done. We were trying to have the project work on an Arduino by hooking up the pressure insoles with its ADC pin. We were working on figuring out the type of data averaging we need to do over time to trigger the vibrational motors on the ankle band.
3. Sensors were being analyzed by performing walking tests every day to see if there was degradation in the resistance values over time with use.

## References

- [1] "2.4 GHz Propagation Prediction Models for Indoor Wireless Communications Within Building", Jul. 2012.[Accessed: 16-Apr-2020].
- [2] "An Analysis of Multiple Criteria and Setups for Bluetooth Smartphone-Based Indoor Localization Mechanism",23-Oct-2017. [Online]. Available: <https://www.hindawi.com/journals/js/2017/1928578/#references>. [Accessed: 17-Apr-2020].
- [3] FDA, "Policy for device software functions and mobile medical applications," Sep. 2019. [Online].Available: <https://www.fda.gov/media/80958/download>. [Accessed: 03-Apr-2020].
- [4] HHS Office of the Secretary,Office for Civil Rights and Ocr, "The access right, health apps, & APIs," HHS.gov, 31-Jan-2020. [Online]. Available: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access-right-health-apps-apis/index.html>. [Accessed: 17-Apr-2020].
- [5] Ieee.org, "IEEE IEEE Code of Ethics", 2016. [Online]. Available:<http://www.ieee.org/about/corporate/governance/p7-8.html>. [Accessed: 03- Apr-2020]
- [6] "510(k) Summary." [Online]. Available: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/K131111.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131111.pdf). [Accessed: 21-Apr-2020].
- [7] S. Richardson, J. S. Hirsch, M. Narasimhan, J. M. Crawford, T. McGinn, K. W. Davidson, D. P. Barnaby, L. B. Becker, J. D. Chelico, S. L. Cohen, J. Cookingham, K. Coppa, M. A. Diefenbach, A. J. Dominello, J. Duer-Hefele, L. Falzon, J. Gitlin, N. Hajizadeh, T. G. Harvin, D. A. Hirschwerk, E. J. Kim, Z. M. Kozel, L. M. Marrast, J. N. Mogavero, G. A. Osorio, M. Qiu, and T. P. Zanos, "Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area," *Jama*, Apr. 2020.
- [8] A. S. Bhogal and A. R. Mani, "Pattern Analysis of Oxygen Saturation Variability in Healthy Individuals: Entropy of Pulse Oximetry Signals Carries Information about Mean Oxygen Saturation," *Frontiers in Physiology*, vol. 8, Aug. 2017.
- [9] Y. Ostchega, K. S. Porter, J. Hughes, C. F. Dillion, and T. Nwankwo, "Resting Pulse Rate Reference Data for CHildren Adolescents, and Adults: United States, 1999-2008," *National Health Statistics Reports*, Aug. 2011.

- [10] A. Rodríguez-Molinero, L. Narvaiza, J. Ruiz, and C. Gálvez-Barrón, "Normal Respiratory Rate and Peripheral Blood Oxygen Saturation in the Elderly Population," *Journal of the American Geriatrics Society*, vol. 61, no. 12, pp. 2238–2240, Dec. 2013.
- [11] I. Geneva, T. Fazili, W. Javaid, and B. Cuzzo, "Normal Body Temperature: A Systematic Review," *Open Forum Infectious Diseases*, 2019.]
- [12] "NEWS (or NEWS2) score when assessing possible COVID-19 patients in primary care?," *CEBM*. [Online]. Available: <https://www.cebm.net/covid-19/should-we-use-the-news-or-news2-score-when-assessing-patients-with-possible-covid-19-in-primary-care/>. [Accessed: 21-Apr-2020].