COVID-19 Monitor and Quarantine Mobile App

Spring 2020 ECE 445 Project Proposal

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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 with compromised immune systems are being affected the most. 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 respiration rate. This will connect to a cellular app that records the data and can be used to contact medical professionals if certain symptoms seem to point towards COVID-19.

Furthermore, the app will give medical and isolation/quarantine advice to the patient to reduce spread. 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 can be used by 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 certain radius to quarantine themselves and take extra precautions to prevent the spread.

This 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. The hardware device can be used to monitor their vitals and can be reported to their loved ones which they can add through the app so that they can share them.

Anyone with the app could contact emergency without the medical device as well. 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 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.

1.2 Background

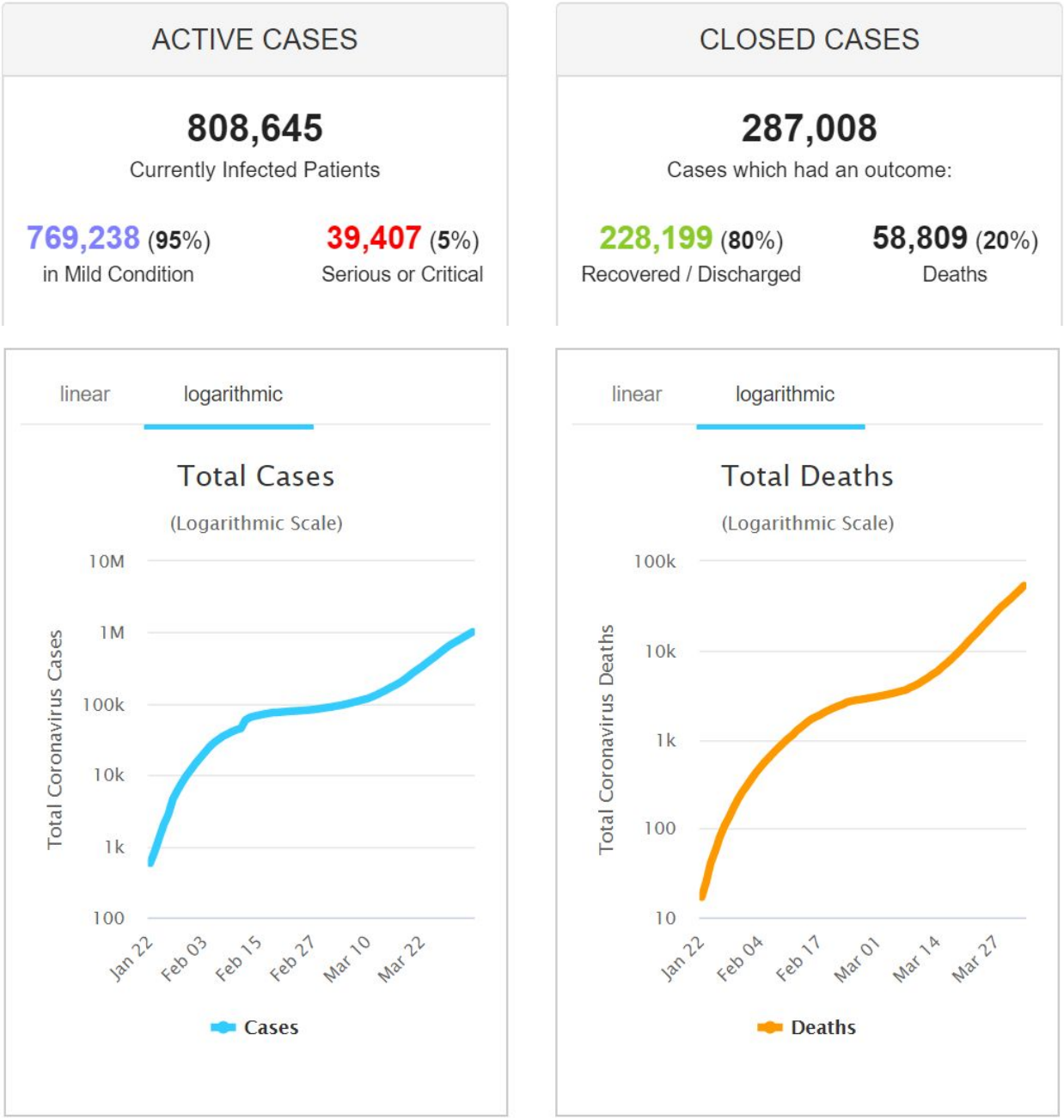
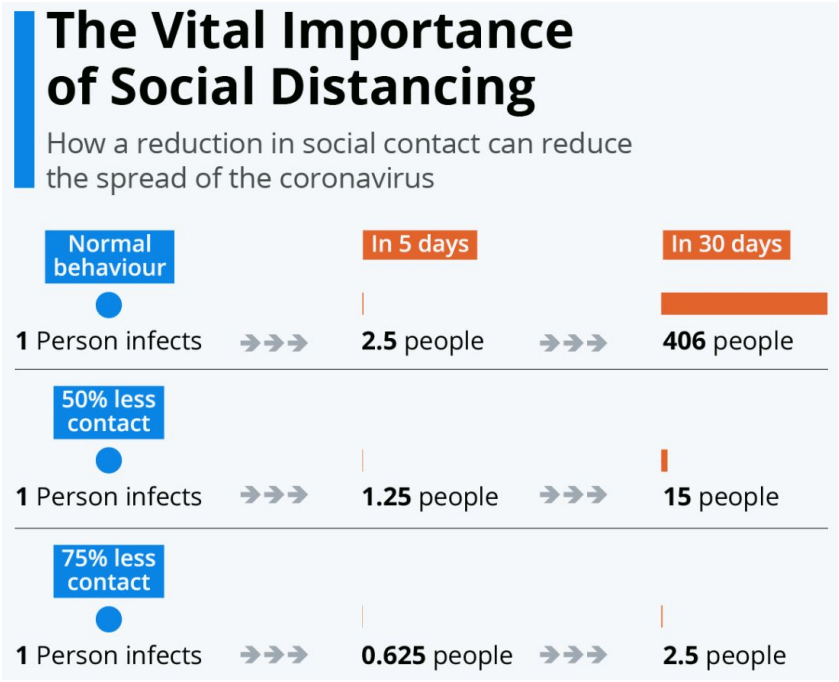


Figure 1.[1]These figures show the rate at which people are getting infected and also the fatality rate. So far, the fatality rate is approximately 3%, but it is very contagious [1].

[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.



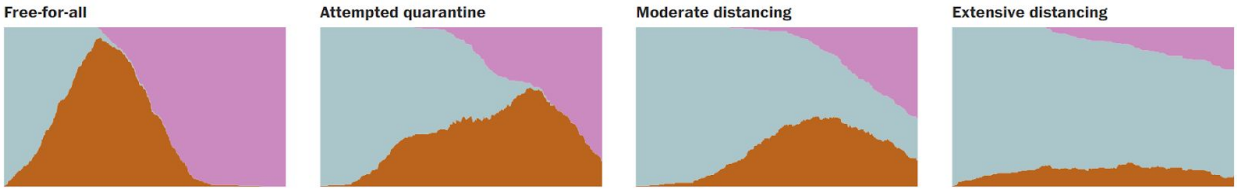


Figure 2. These figures show the importance of quarantining/social distancing [4]. By limiting social interactions we can drastically reduce the spread of COVID-19 and flatten the curve [5].

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 [3].

1.3 High-Level Requirements

1. Must alert patients of possible symptoms and allow patients to quickly contact nearby medical professionals.
2. Must be able to quickly inform citizens within close proximity of the danger and inform them of quarantine tips, while not disclosing any private or medical information of the patient.

3. Must be a portable, wearable device that can consistently track accurate data and record it on the application or in the cloud.
4. Must have the ability to be mass produced and sold inexpensively nationwide.

2 Design

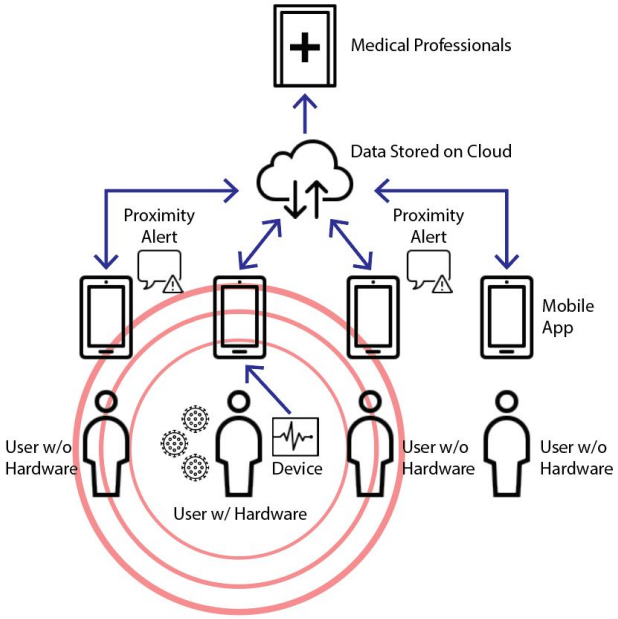


Figure 3. High level design and information flow diagram.

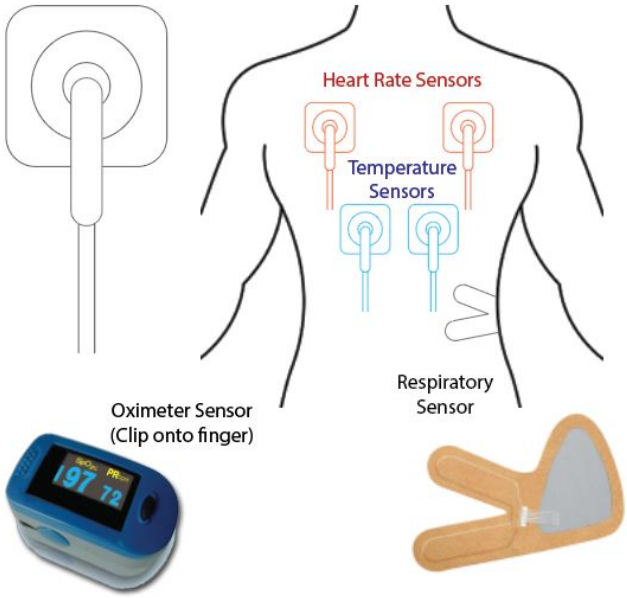


Figure 4. Hardware equipment layout. The sensors will be pasted on the torso (front) in this orientation with medical sticky patches. The hardware is an optional extra purchase for users. Users can simply self-record their symptoms on the app.

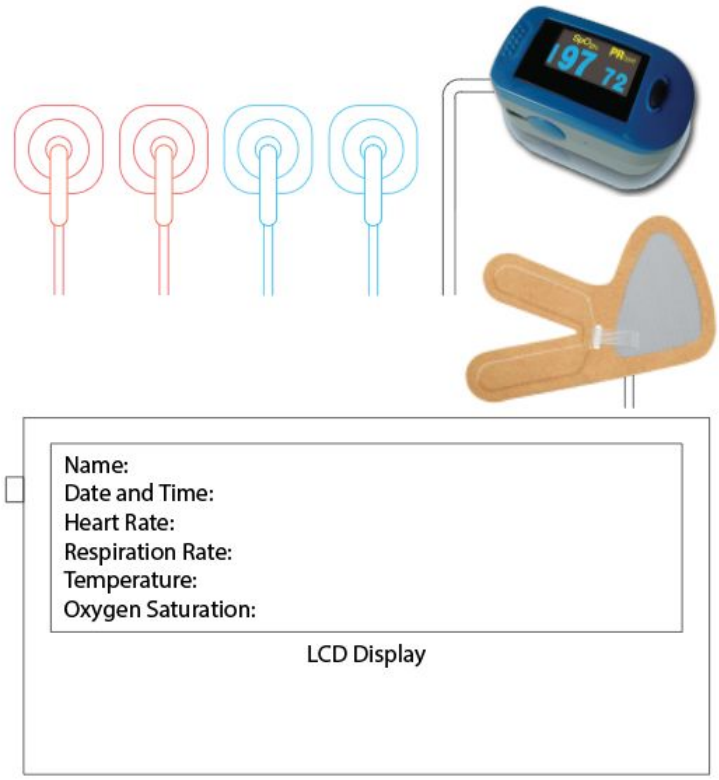


Figure 5. Sensors connect to small processing device that displays information.

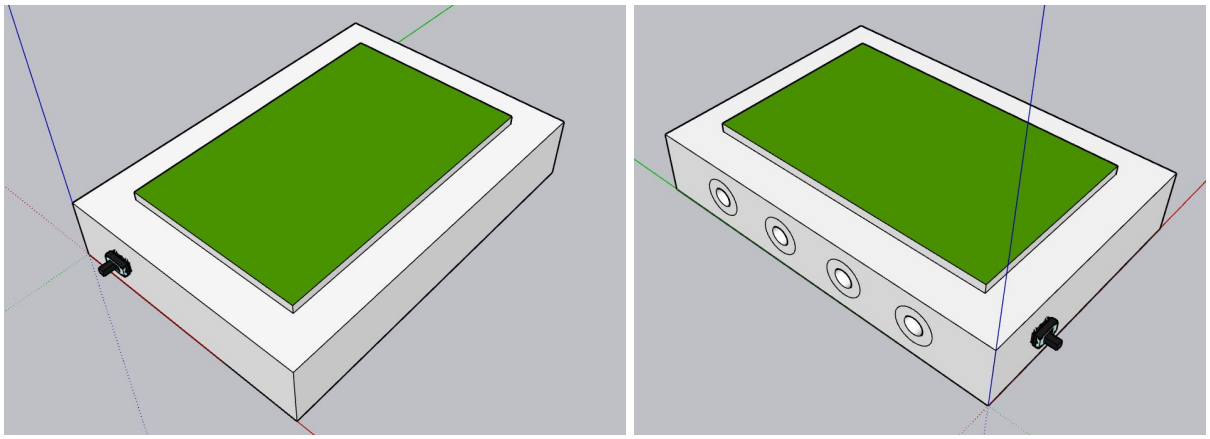


Figure 6. 3.5”x5”x1” Includes on/off switch, LCD display, and connectors for the two heart rate sensors, the two temperature sensors, an oximeter, and a respiratory sensor.

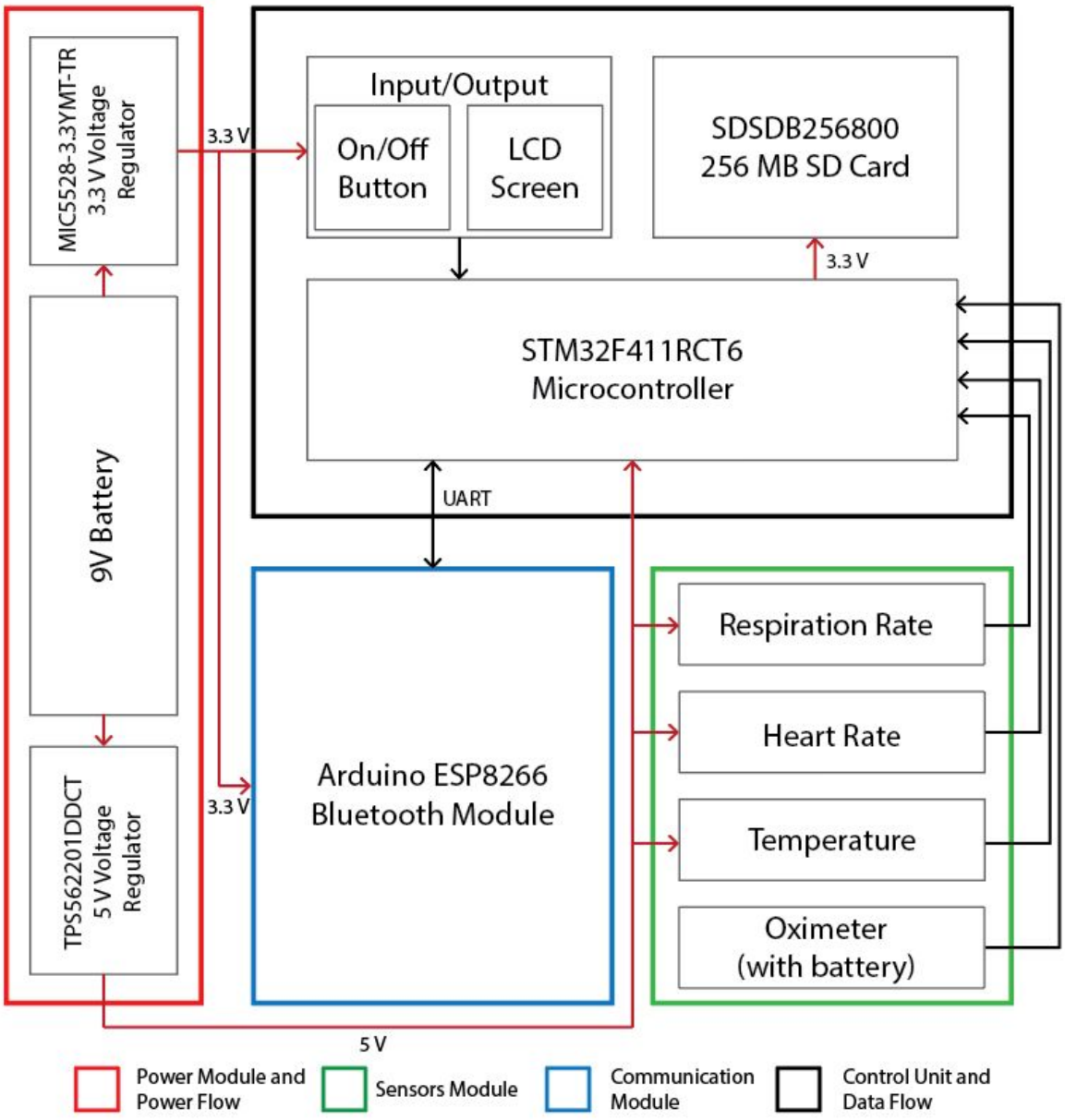


Figure 7. Block Diagram. Black box is the control unit and black arrows are data flow. Red box is the power unit and red arrows are power flow. Blue box is the Bluetooth unit. Green box is the sensor module.

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

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. The microcontroller will also work with the bluetooth module to send data to the app.

Requirements:

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.*
2. *Must be able to run simple programs involving its ADC pins.*

2.1.2 SD Card

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

Requirement:

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.*

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:

1. *Must be easy to press.*
2. *The LCD screen should be easily readable and is backlit*

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:

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].*

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:

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].*

2.3 Bluetooth Unit

This will function as the go between for the microcontroller and the software mobile application. It will communicate with the microcontroller using a UART connection. It will send data collected from the sensor module through the microcontroller at a fixed frequency.

Requirement:

1. *Must be able to communicate with the microcontroller using UART.*

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 Respiration Rate Sensor

This sensor will operate only when the user is not moving. We plan to require the user to push a button to signify that they are ready to have us collect data. We will likely need the person to remain very still during collection.

This sensor is not necessarily useful in early detection with the median respiration rate at time of admission being elevated, but with-in the normal range [8]. However, it can be useful in at home monitoring, as increasing respiration rate is associated with worsening condition with a respiration rate of 30 bpm being considered one of the signs of severe illness [7].

Requirement:

1. *20 bpm is considered the upper end of the normal range with 25 bpm being considered to be worrying [7] [8]. So, we choose a requirement of +/- 2.5 bpm accuracy when resting, so that we might be able to at least distinguish between the two.*

2.4.2 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 shows a small difference [8]. Therefore, while useful, this should likely receive a small weight in any decision tree.

Requirement:

1. *The difference in median between ICU patients and non-ICU patients was 3bpm [8]. So, we choose +/- 1.5 bpm to be our max tolerance.*

2.4.3 Temperature Sensor

In [8], 98.6 % of cases were associated with a fever. In [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 a more severe case in [8].

Requirement:

1. *A fever is typically considered to be 1℃ above normal, which is 36.5 – 37.5 °C. So, this should have an inaccuracy of less than 0.5℃ when compared to core temperature [6].*

2.4.4 Pulse 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. When this drops it is a pretty sure sign that the illness is becoming severe [8].

Requirement:

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. We must need an accuracy of +/- 1%, since the regular oxygen saturation varies between 95 - 100% [8].*

2.5 Risk Analysis

In this project, it is very essential for the sensors to work properly and collect accurate data. The other important aspect is to send this data to the software application reliably to update the registered family members. These two modules: sensor module and the bluetooth module together are the riskiest part of this project.

This project basically has two main purposes: the hardware part of the project for the elderly/sick patients ensures that their vitals are being collected and updated on the software app for their loved ones to see. We need to ensure that these sensors are collecting data accurately enough so that there is no unnecessary panic created if the readings have a very high standard deviation or are faulty. The sensor module contains three sensors out of which the respiration sensor is the most difficult to deal with because it measures the movement of the chest walls to calculate the respiration rate. Also, it is an important sensor because the respiration rate is used to determine if a patient is deteriorating. So, our current plan involves maybe adding a button to the hardware device so that the user can press that button and remain still to ensure accurate data collection.

The hardware device also involves successfully transmitting data to the software app every certain interval via bluetooth. We need to ensure that the bluetooth module works properly and is able to successfully transmit data to ensure that the hardware device is worth buying to monitor their loved ones. Integrating all these sensors and managing data might be hard to do. So, we need to ensure that data is updated using bluetooth every certain time period and outliers in the data are ignored which may be introduced due to movement. The sensor readings will be affected by the patient's movement so we will make clear in our policy that to get the most accurate reading the patient needs to be still.

While doing the risk analysis in more detail we might look at how big the standard deviation is from the nominal data when the patient is moving around versus lying still to see if we can get sensors that reduce this effect of movement as much as possible. We might also consider how frequent the data update should be from the hardware device to the app. We might consider displaying average values over a period of time rather than just doing real time feedback (we might think about processing data to remove outliers).

3 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 and also the HIPAA policy. 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. 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.

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”[12]. We wish to achieve our results reliably by using/safe-gaurding 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.

4 References

[1] “Coronavirus Cases:” Worldometer. [Online]. Available: https://www.worldometers.info/coronavirus/. [Accessed: 24-Mar-2020].

[2] “Symptoms,” Centers for Disease Control and Prevention, 20-Mar-2020. [Online]. Available: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. [Accessed: 24-Mar-2020].

[3] A. Park, “The Tech That Could Be Our Best Hope for Fighting COVID-19,” Time, 19-Mar-2020. [Online]. Available: https://time.com/5805622/coronavirus-pandemic-technology/. [Accessed: 24-Mar-2020].

[4] M. Armstrong and F. Richter, “Infographic: The Vital Importance of Social Distancing,” Statista Infographics, 23-Mar-2020. [Online]. Available: https://www.statista.com/chart/21198/effect-of-social-distancing-signer-lab/. [Accessed: 24-Mar-2020].

[5] “These simulations show how to flatten the coronavirus growth curve,” The Washington Post, 14-Mar-2020. [Online]. Available: https://www.washingtonpost.com/graphics/2020/world/corona-simulator/. [Accessed: 24-Mar-2020].

[6] D. I. Sessler, “Temperature monitoring and perioperative thermoregulation,” *Anesthesiology*, Aug-2008. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2614355/. [Accessed: 02-Apr-2020].

[7] S. B. Park, “Tachypnea,” *StatPearls [Internet]*., 31-Dec-2019. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK541062/. [Accessed: 03-Apr-2020].

[8] D. Wang, “Clinical Characteristics of Patients With 2019 Novel Coronavirus (2019-nCoV)–Infected Pneumonia in Wuhan, China,” *JAMA*, 17-Mar-2020. [Online]. Available: https://jamanetwork.com/journals/jama/fullarticle/2761044. [Accessed: 03-Apr-2020].

[9] 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].

[10] W.-jie Guan, N. van Doremalen, A. S. Fauci, M. L. Holshue, and China Medical Treatment Expert Group, “Clinical Characteristics of Coronavirus Disease 2019 in China: NEJM,” *New England Journal of Medicine*, 27-Mar-2020. [Online]. Available: https://www.nejm.org/doi/full/10.1056/NEJMoa2002032. [Accessed: 03-Apr-2020].

[11] Divakar, “Surface Temperatures of Electronics Products: Appliances vs. Wearables,” Electronics Cooling, 01-Aug-2019. [Online]. Available: https://www.electronics-cooling.com/2016/09/surface-temperatures-of-electronics-products-appliances-vs-wearables/. [Accessed: 27-Feb-2020].

[12]Ieee.org, "IEEE IEEE Code of Ethics", 2016. [Online]. Available: http://www.ieee.org/about/corporate/governance/p7-8.html. [Accessed: 3- April- 2020].