ECG SHIRT

ECE 445 DESIGN DOCUMENT CHECK

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1. Introduction

1.1 Problem

Cardiovascular disease is currently the leading cause of death in the world, with myocardial infarctions being one of the most common types of this disease. Myocardial infarctions are often treatable when diagnosed quickly; however, symptoms of a myocardial infarction are not always detectable and thus, treatment may be delayed. Around 17.9 million people around the world die from heart attacks each year and over 1/3 of those who experience a heart attack do not experience the most common warning signs. [6] The first test done to diagnose any past or present myocardial infarctions is an Electrocardiogram, or ECG. The ECG can often detect a heart attack earlier than blood tests for heart damage, which can take 4+ hours to indicate damage to the heart. The increased accessibility of ECGs to the public can increase the detection of heart attacks and decrease the fatality of these events. [3]

1.2 Solution

Our proposed solution to increase public accessibility to ECGs is to design a low-cost portable ECG that contains 3 leads (4 electrodes) in the ECG and transmits data to a health-app which can warn the user of an abnormal cardiovascular behavior that might result in a myocardial infarction. This portable ECG can be worn at any time and will be developed in such a way that it can be attached to t-shirts and will be particularly useful to populations at risk for myocardial infarction. Other ECG wearables, such as the Apple Watch, only measure 1 lead and are therefore unable to reliably detect heart attacks. [2] An additional challenge that long-term ECG wearables continue to face is motion artifacts. We hope to design a low cost 3 lead ECG portable device which can be attached onto a variety of t-shirts or other wearables and is, thus, accessible to everyone and can be used in everyday activities.

1.3 Visual Aid and Physical Design

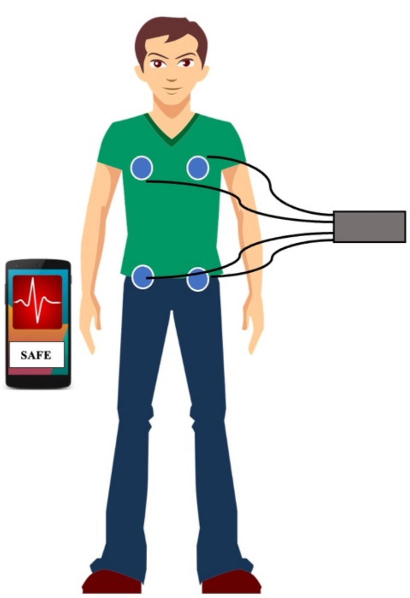

Figure 1

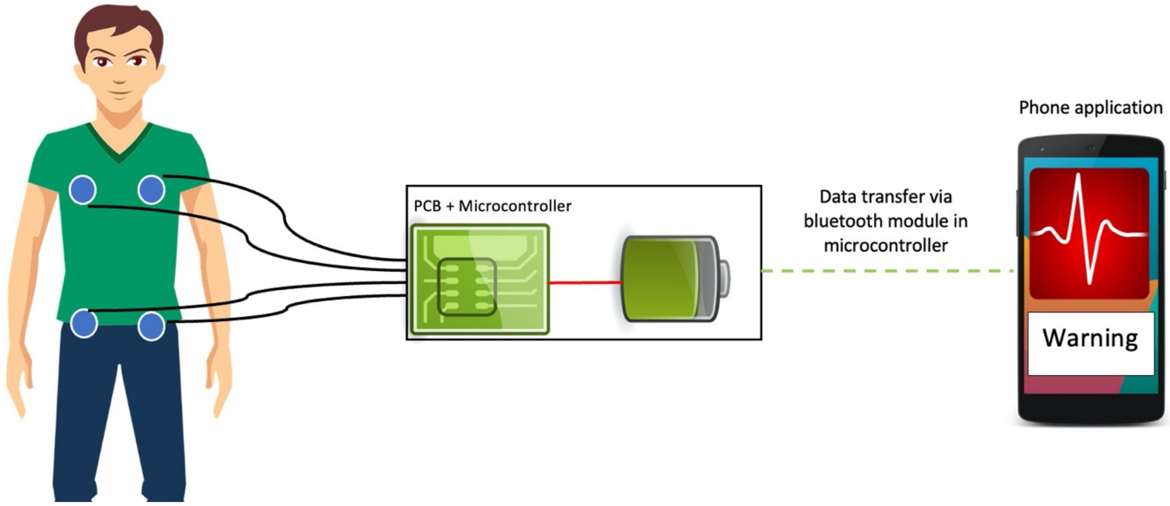

Figure 2

1.4 High Level Requirements

- *Take Measurements:* The microcontroller should be able to read the user's heart rhythm by filtering noise using the cutoff frequencies of 0.5 Hz and 40 Hz such that the P, QRS, and T points of the heartbeat are sampled at a rate of at least 100 Hz.
- *Transmit Measurements:* The Bluetooth module of the microcontroller can relay recorded data to our phone application within 30 seconds.
- *Analyze Measurements:* When passed pre-recorded data of an ECG human heartbeat dataset the algorithm can distinguish between the heartbeat of a safe person and one at risk of a heart attack.

2. Design

2.1 Block Diagram

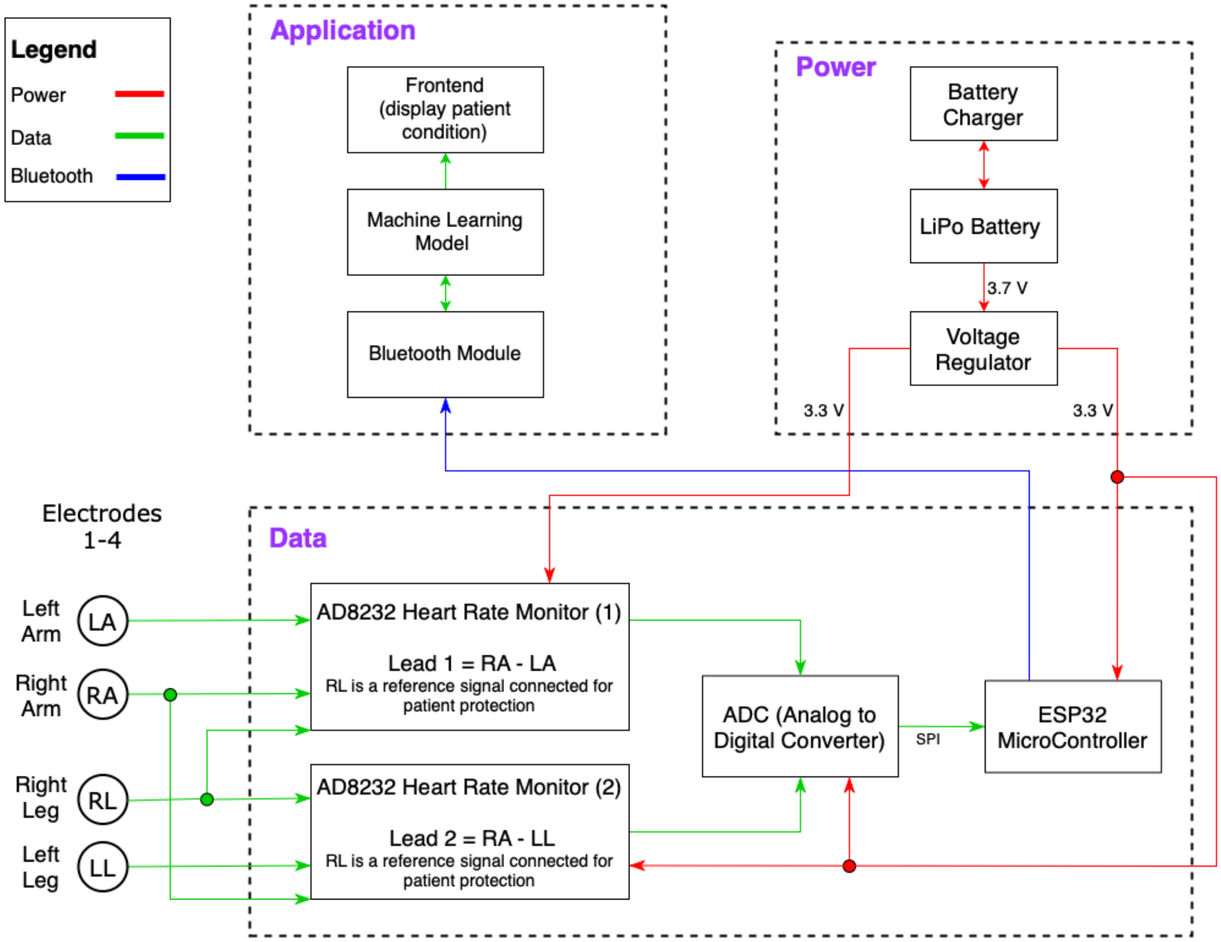

Figure 3

2.2 Block Descriptions

2.2.1 Power

This is the subsystem that will supply power for our data subsystem, which will be our on-board circuit. It is composed of a lithium polymer battery which will be charged by a battery charger to 3.7V. The voltage from our battery will go through a DC linear voltage regulator, specifically a low-dropout regulator to supply the microcontroller and the ADC in the data subsystem with a constant supply of 3.3 V and maintain at least 1400mAh for the subsystem to operate. The power subsystem is important to our design since our data acquisition process through the ECG leads is dependent upon constant and correct power supply to the circuit.

Table 1 RV Table for Power Subsystem

Requirements	Verification
The battery charger will charge up the LiPo to 3.70V±50mV when supplied with an input voltage of 3.75-6V.	a) Discharge and recharge the battery using an input voltage of 6V without limiting current. b) Once the battery is fully charged check that it is between 4.2-4.5V.
Rechargeable battery with a battery capacity of at least 72 hours.	a) Discharge the battery completely to 2.75V±50mV and then charge it completely to 4.2-4.5V±50mV. Check that the battery voltage is 3.7V±50mV. b) Charge the battery completely to 4.2-4.5V±50mV. Let the battery discharge for 72 hours and check to make sure the voltage remains at 4.2-4.5V±50mV.
Provides 3.3V±50mV from a 3.7-4.5V±50mV source. Operate at currents between 0-500 mA	a) Measure the output voltage using an oscilloscope and ensure that it is within 50mV of 3.3V. b) 1) Connect the output of the voltage regulator to Vdd. 2) Deliver 500±50mA and check using a multimeter. 3)Finally, check the output voltage using an oscilloscope and ensure that it is within 50mV of 3.3V.
When charging the battery at the maximum input voltage and current the temperature of the IC is kept under 27ºC.	Use an IR thermometer throughout the discharge/recharge process to ensure the temperature does not exceed 27ºC.

2.2.2 Data

The data subsystem acts as our electrode reading acquisition subsystem. It is composed of 3 leads, 4 electrodes which will read heartbeat rhythms from the user's right arm, left arm, right leg and left leg. Those heartbeat rhythms will be passed through two analog heart rate monitor frontends to extract, amplify, and filter the small biopotential signals and output amplified, noise reduced analog signals. The right arm, left arm, and right leg electrode data will act as the inputs for the first heart rate monitor, and the right arm, left leg, and right leg electrode data will act as the inputs for the second heart rate monitor, where the right leg electrode will act as the reference electrode for patient protection. The outputs of heart rate monitors will be passed through the ADC to convert the analog signals into digital signals that can be read by the microcontroller. These digital signals will be sent to the microcontroller using SPI. The microcontroller will wirelessly transmit this data to the phone application. It will do so using the Bluetooth module in the microcontroller and the Bluetooth module in the mobile phone. The data subsystem is important since this is where we will take the heartbeat measurements, filter it from noise, and convert the analogue signals into digital signals, this allows for the data to be analyzed by the machine learning model that can tell whether someone is at a risk of a heart attack.

Table 2 RV Table for Data Subsystem

Requirements	Verification
The input signals are filtered with the cutoff frequency of 0.5 Hz and 40 Hz.	Check the output signal and check to see if it is clearer (we can tell it is clearer by noticing the PQRST points): 1) Connect the heart rate monitor to an Arduino, pick up ECG signal by placing electrodes on one of the team members. 2) Use Arduino Serial Plotter to display the ECG Signal 3) Check the passband levels by checking the point where output to input ratio is 0.707 and ensure that those align with our cutoff frequencies.
Microcontroller receives data over SPI at a frequency of at least 100 Hz.	a) Send a sample ECG signal (of known size) from the ADC to the microcontroller. b) The microcontroller supports fast SPI connections with an external SD card. We will use the SPI flash lines of the microcontroller to store the sample ECG signal on the external SD Card. c) Plug the SD card into a computer and verify that all the sample data was received by the microcontroller. d) Use the timestamps of the data arrival to check the frequency of data transmission. Ensure it is at least 100 Hz.

Microcontroller can transmit data through Bluetooth at a speed of at least 100 Mbps.	a) Send a sample ECG signal data of known size through Bluetooth module of microcontroller b) Once the data arrives on the mobile application check the timestamp of arrival to ensure the speed is at least 100 Mbps.
Communicate digitally with the microcontroller over SPI.	a) Send sample ECG signal to the microcontrollers SD Card and ensure that the microcontroller receives it. b) Plug the SD card into a computer and verify that all the sample data was received by the microcontroller.

2.2.3 Application

The application subsystem is the subsystem that our users will be able to interact with. It is composed of the phone's Bluetooth module, an on-board storage, the machine learning model, and the frontend application. It stores the ECG signals coming in via Bluetooth from the data subsystem transmitted to the phone's Bluetooth module on the on-board storage. That data will then be read by the machine learning algorithm, which will look for an ST elevation in the signal and accordingly classify it as "safe" if it's a normal heartbeat or "warning" if the person is experiencing an ST elevation > 1mm (sign of heart attack). This machine learning model will be implemented using python. Lastly, the UI frontend will be the display for our design. Whenever a "warning" signal is indicated by the ML model, the frontend will display a warning sign indicating to the user that their body is at risk of a heart attack. The frontend will be developed using React Native. The application subsystem is important to our design since this will be the main form of interaction that our product will have with the user, and it will display the results of our subsystems working together.

Table 3 RV Table for App Subsystem

Requirements	Verification
Machine learning model analysis time is within 180 seconds.	a) Run the machine learning algorithm on a 3-lead sample set. b) Each lead should capture data for at least 10 seconds. c) Measure to check that the algorithm analysis is below 180 seconds.
Data is received by the phone's Bluetooth module via the microcontroller's Bluetooth module at a rate of at least 100 Hz.	Send a sample set of data via Bluetooth and measure the rate at which it's received by the phone.

Frontend interface updates with the output of the machine learning model in at most 30 seconds.	Send randomized output to the frontend server and ensure it updates in at least 30 seconds.

2.3 Schematic

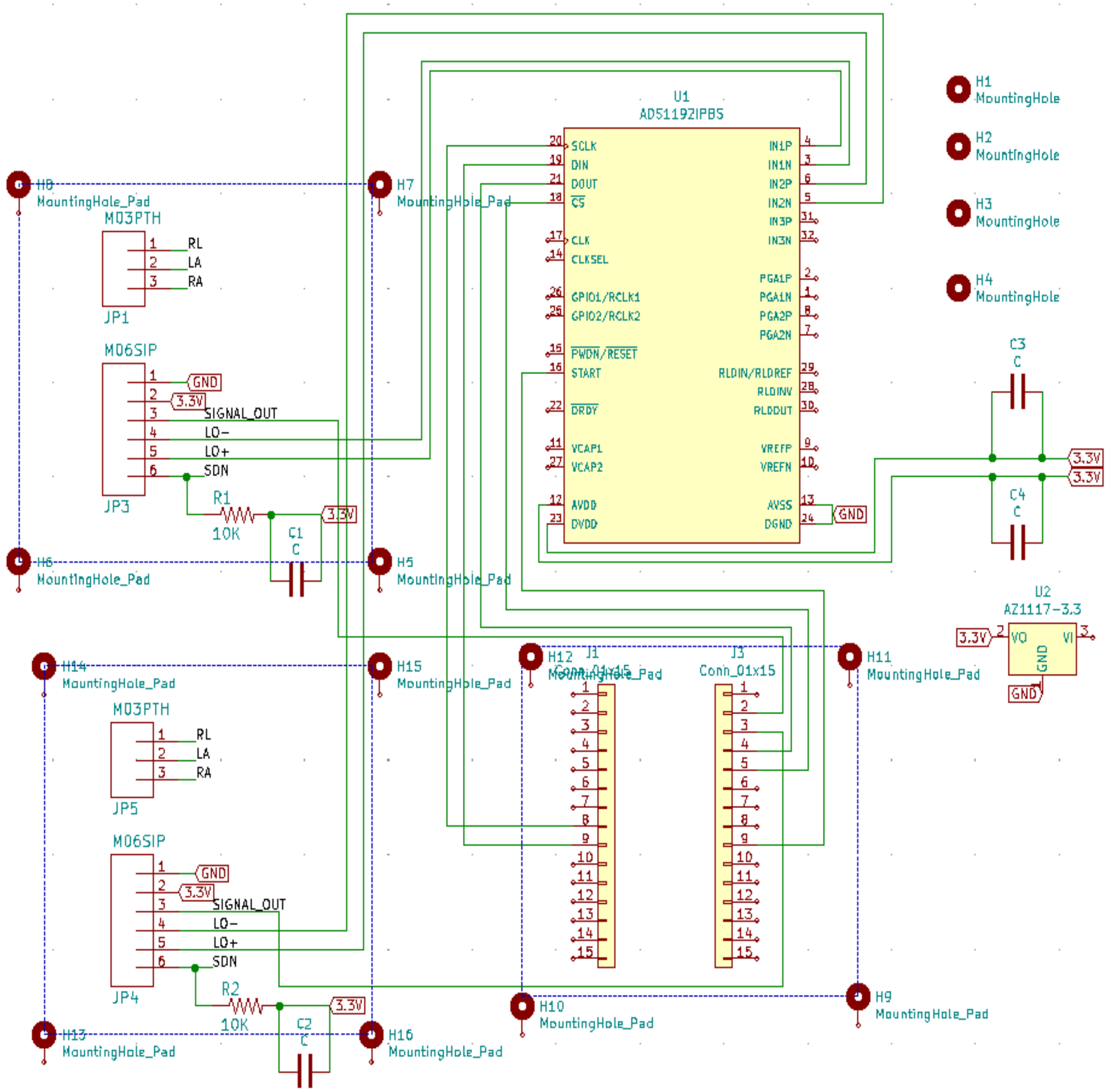

Figure 4 PCB Schematic

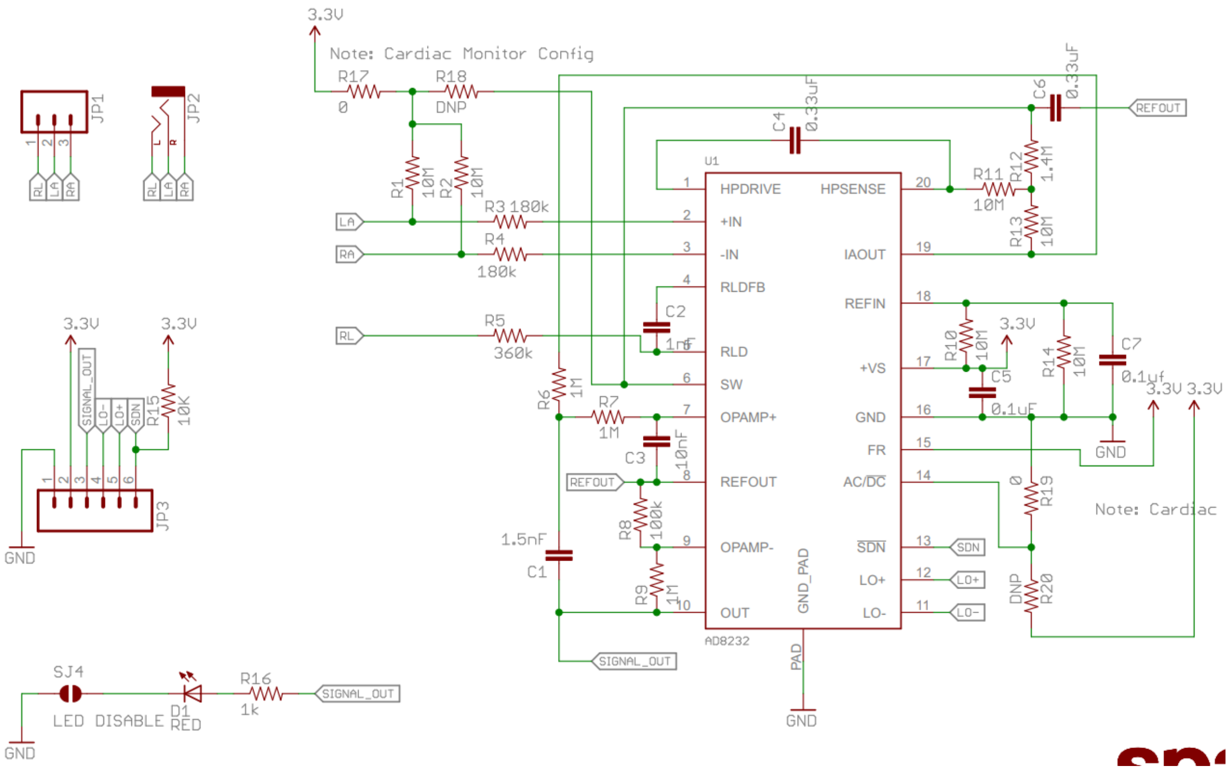

Figure 5 Heart Rate Monitor Schematic

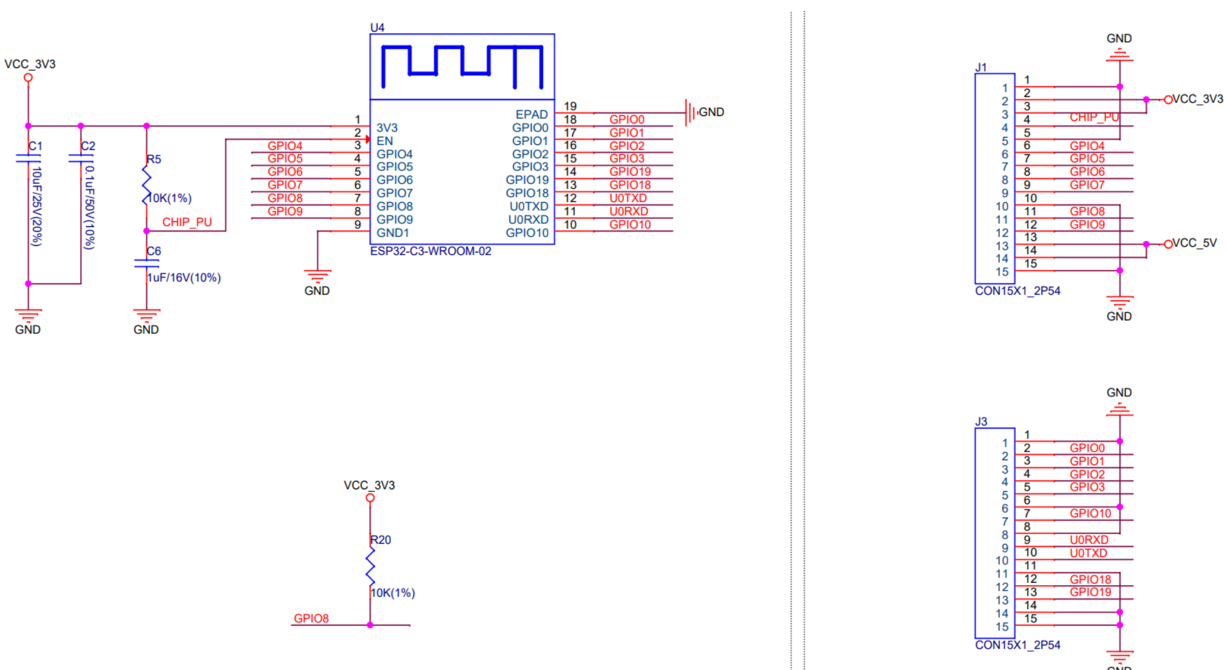

Figure 6 Microcontroller Schematic

2.4 Tolerance and Semantics Analysis

Our biggest concern in this project is that a 3-lead ECG will not be sufficient to always recognize the risk of a heart attack. To overcome this, we will be performing extra calculations in our machine learning model. The mathematical analysis below highlights how we will overcome this issue, so our project is accurate as possible in detecting heart attacks.

The tolerance analysis is based upon an ECG signal data set provided to us by Dr. Erickson. The data set is a 12-lead ECG reading of a man experiencing a heart attack on the back of the heart. Since we are only using 3 leads (Leads I, II, III) and they are all measuring towards the front of the heart, a heart attack that occurs at the back of the heart is our worst-case scenario.

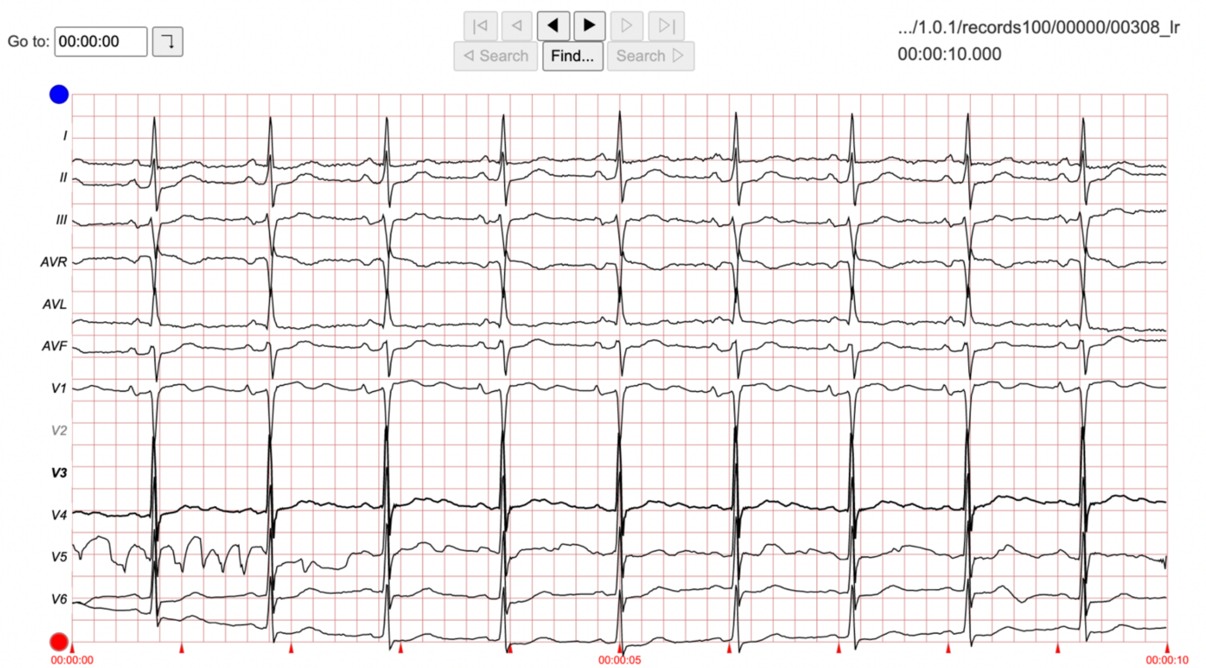

Figure 7

The diagram above is a screenshot of data provided to us by Dr. Erickson on PhysioNet. The symbols on the left (I, II, III …. V6) represent all 12 leads. This is real life ECG data performed on a patient experiencing a heart attack.

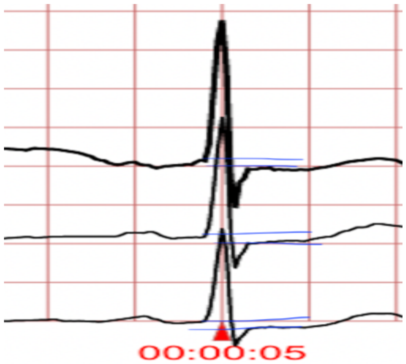

Figure 8

The heart attack is occurring at the back of the heart, this means leads V4, V5, and V6 are at the closest proximity and should be able to detect the ST segment depression accurately. The ST depression in these leads is highlighted in blue below.

This ST depression is NOT visible in any other of the 9 leads. Our 3 lead ECG comprises leads I, II, and III which show no sign of an ST depression. If this person were to use our ECG it would show that he is perfectly healthy even though he is experiencing a heart attack.

When looking at an ECG signal, we have the P, Q, R, S, and T points of use to us. An ST elevation/depression greater than 1mm qualified as a heart attack, however our machine learning model plans to do more calculations than just that. The measurements in the table below from Kalyan and Sharma shows all the calculations that our ML model will take into consideration.[5]

Table 4 ECG Waves and Acceptable Measurements

ECG	Description	Measurements
1)QRS Complex	Indicates the atrial systole, atrial diastole, and ventricular excitation respectively	0.08 -1.2 sec
2)R-R interval	Indicates the heart rate in beats per minute	1 second
3)P-R interval	Indicates the electrical signal generated by the sinus node is normal and travelling in a normal fashion in the heart.	0.08-0.20 sec
4)Q-T interval	Indicates the flow of electrical impulse and blood from the atrial chambers to ventricles	0.36-044 sec
5)R-wave amplitude	Indicates the atrial diastole	1 millivolt
6)P-wave duration	Indicates the rate of atrial excitation	0.06-011 <0.25 sec
7)T-wave duration	Indicates ventricular systole	0.16 <0.5 sec

Looking at the PR interval, an interval of *0.08-0.20 seconds* indicates a normal, healthy heart.

Mathematical Analysis

Measuring PR Interval for Leads V4, V,5, V6 (ST depression shows in these leads, heart attack is occurring in these leads):

- Time (PR, V4) = 0.713 - 0.458 =0.255 seconds (>0.20)
- Time (PR, V5) =0.693 - 0.409 = 0.284 seconds (>0.20)
- Time (PR, V6) = 0.703 - 0.409 = 0.294 seconds (>0.20)

Measuring PR Interval for Leads I, II, III (ST depression is NOT shown in these leads, but these are the leads we are using in our project):

- Time (PR, I) = 0.683 - 0.489 =0.194 seconds (<0.20)
- Time (PR, II) =0.692 - 0.448 = 0.244 seconds (>0.20)
- Time (PR, III) = 0.693 - 0.478 = 0.215 seconds (>0.20)

Looking at the PR intervals from leads V4, V5, and V6 the interval is not within the range of a healthy person, this makes sense since the ST depression indicates a heart attack.

Looking at the PR intervals from leads I, II, and III we observe that lead I is within the range of a healthy person but leads II and III are not. In this case, two contiguous leads (Leads II and III) convey that the person being checked does NOT have a completely healthy heart. Therefore, our ML model will return an output of "warning" to the frontend. The user can see the "warning" sign and get further information by going in for a checkup.

Our tolerance analysis shows that even though in the worst-case scenario of our ECG not picking up a ST depression there are other forms of analysis and calculations that we will consider in order to ensure our ML Model recognizes that the heart is not healthy.

3. Cost and Schedule

3.1 Cost Analysis

Labor
Cost per hour = $42 (average hourly pay for a software engineer)
Hours per week = 8 hours
Weeks remaining = 10 weeks

Cost per person = 42 ($/hour) * 2.5 * 8 (hours/week) * 10 (weeks) = $8,400
For all team members (3 people) = $25,200
Total cost (including the overhead cost) = $25,200 * 2.5 = $63,000

Materials

Table 5 Material Cost

Part	Unit Cost	Quantity
LiPo Battery, 3.7V, 2300 mAh (LP655262)	$12.50	1
Battery Charger (Adafruit, MCP73831)	$6.95	1
Voltage Regulator (LP2989)	$2.68	1
Heart Rate Monitor (Sparkfun, AD8232)	$19.95	2
Microcontroller (Espressif, ESP32)	$9.00	1
ADC 16-bit (ADS1192)	$6.655	1
2.75" Round Textile Electrode (Axelgaard 672 0062)	$14.59	1 (4 pack)
Total	$92.23	8

3.2 Schedule

Table 6 Schedule for Project

Week	Pakhi	Pooja	Ruthvik
10/4	Design Review	Design Review	PCB Design/Ordering Parts
10/11	Solder PCB	Solder PCB	Solder PCB
10/18	Test data subsystem	Test data subsystem	Machine learning model development/
10/25	Test data subsystem	Test data subsystem	Machine learning model development
11/01	Test application subsystem and test transmitting data via Bluetooth	Test application subsystem and test transmitting data via Bluetooth	Build frontend for mobile application and connect it to output of ML model
11/08	Whole System Test	Whole System Test	Whole System Test
11/15	Prepare for demo	Prepare for demo	Prepare for demo

11/22	**BREAK**		
11/29	Final presentation	Final presentation	Final presentation
12/06	Final paper	Final paper	Final paper

4. Ethics and Safety

We think that the technology that could come to creation from further iterations of what we are attempting to build could change the lives of people suffering from heart diseases and many other diseases whose symptoms are reflected on the ECG. (ACM 1.1) [7]

Medical data obtained for testing and validation was obtained in a legal manner from Dr. Hanna Erickson, who initially pitched the concept. Any medical data used or obtained will be kept private and will strictly be used for research proposals. (ACM 1.6, ACM 1.7) [7]

Our team of computer engineers is working with Dr. Hanna Erickson and her team of researchers, and we are making sure that we have a deep understanding of the physiological aspect as we move ahead in the project. Our goal would be to create a prototype which can be further iterated to a market ready product which can be made available to the public through a healthcare program. (ACM 2.1, ACM 2.6, ACM 3.5) [7]

To claim that our tech can detect any diseases, we would require an FDA approval. Until then we will be in a testing/validation phase and this tech cannot be used to monitor actual heart patients in need to ensure the safety of our users. (ACM 1.3, ACM 3.2) [7]

We are trying to change the approach taken to wearable ECG monitors by using textile electrodes for ECG leads. Health-tech is filled with innovation and there are a lot of other ECG monitors which are mobile; ours has an end goal of being portable or being incorporated into a T-shirt and we believe the approach is innovative. (ACM 1.5) [7]

5. References

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