Bubz, a 12-lead Wire-free EKG

By

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Design Document for ECE 445, Senior Design, Fall 2021
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26 September 2021
Project Number 13

Section 1: Introduction

1.1 Overview

The heart is an organ that operates on a series of electrical impulses, creating a repeating rhythm of PQRST waves (further explained below) that many medical professionals analyze to assess cardiac function and health. An electrocardiogram (ECG/EKG) is a graph measuring these impulses in the form of a voltage versus time chart. A sample of what this output looks like is shown in Figure 1. This data is collected by strategically placing electrodes across the chest to determine the horizontal and vertical changes in electric potential. The electrodes essentially perform as an electric dipole; the resulting field vector is measured at the surface of the skin (called skin potential) through medical adhesive or suction.

The patterns that these impulses create gives doctors and other medical staff necessary insight on the functioning of a patient's heart. Deviations from the standard EKG pattern can mean a variety of cardiac issues, ranging from cardiac arrhythmias (abnormalities in heart rhythm) to compromised blood flow in the coronary artery to electrolyte disturbances. This can be determined by assessing the speed of the heart beat, the steadiness of its rhythm, and the strength of the impulses being sent within the heart itself. It is important to note that no electricity is sent into the body.

The basic EKG measures the electrical signals sent through the four chambers (left atrium, right atrium, left ventricle, right ventricle) of the heart to detect any medical anomalies and monitor the cardiovascular health of the patient. Essentially, the heart receives a series of electrical signals that are seen in the PQRST wave seen in Figure 1. The first P wave is the signal sent to the atria to contract, pushing oxygenated blood into the ventricles. This is called the Atrial Depolarization. The ensuing QRS complex, as it is called, is the electrical signal for the ventricles to constrict, sending the blood throughout the body, referred to as Ventricular Depolarization. The atrial repolarization also takes place at this time but is generally not seen due to the high electrical activity of the ventricle depolarization. Finally, the T wave contains the Ventricular Repolarization, where the ventricles reset and are ready to constrict once again.

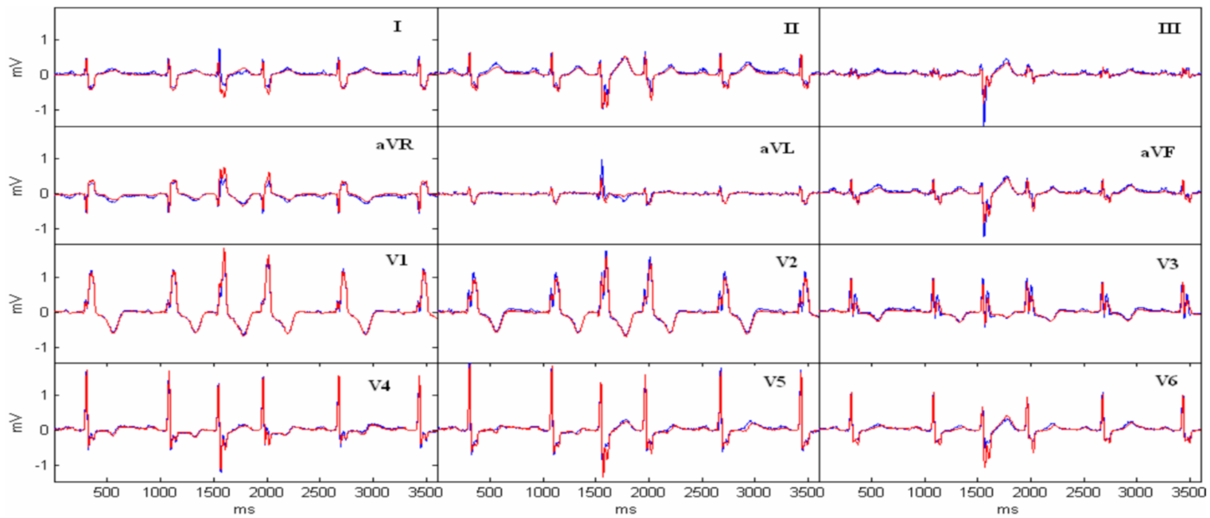


Figure 1. Sample of EKG results.

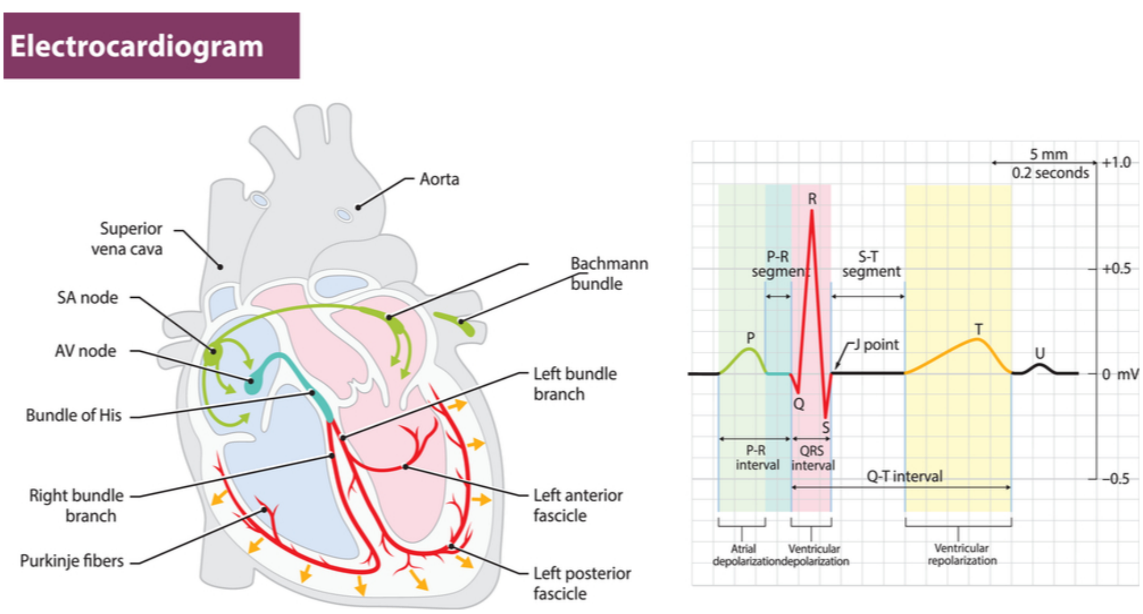


Figure 2. Diagram of electrical signals in the heart and how they translate to PQRST waves.

1.2 Problem

In a traditional 12-lead EKG, ten electrodes are placed on the chest and limbs of a patient as shown in Figure 2. As seen in the image, there are a lot of long, confusing wires along with heavy, bulky equipment. These wires frequently get tangled, and make it difficult for doctors to do their jobs quickly. According to Mayo Clinic, setting up an EKG can take between 10-20 minutes. While this may not seem like much of an issue on a relaxed day, in emergency cases, even a minute could be the matter of life or death. In addition to this, EKG equipment is generally bulky and hard to transport to underserved communities. This can mean decreased access to this test, which could mean compromised patient care in such regions.

Current attempts to address this problem include solutions like a product from KardiaMobile (shown in Figure 3). However, while this solution is incredibly user-friendly, it only provides a single lead capability, meaning that there is no way to see any of the data from the horizontal plane. In addition, other 12-lead solutions like AMD's still include wires to connect all of the electrodes together, and focus on transmitting data wirelessly over a long range for telemedicine applications.

Figure 3. Patient receives a traditional 12-lead EKG

Figure 4. KardiaMobile, single-lead wireless solution

1.3 Solution

Our goal is to build a 12-lead wire-free EKG that does not require any wires to transmit data from nodes to a computer. We want to prioritize ease of use, reusability, and keeping the maintenance requirement low. In our solution we want to create small suction bulbs to conveniently assess a patient's heart health. Our choice for a suction device is a design choice made to ensure reusability of the device in the larger goal of reaching underserved communities. Each of these bulbs will contain a circuit board with wireless connectivity and a power supply (potentially rechargeable if time permits) to transmit a PQRST wave quickly to the data display. In addition, each bulb will require a method of measurement and a filtration process to ensure the data that is displayed is insightful and actionable. Using Body Surface Potential Mapping, we can measure the electrical potential gradient at various points of the body to create a vector mapping including these 12 views from 2 different planes (vertical and horizontal). We hope that this solution would make the process of getting an EKG faster, easier, and more efficient.

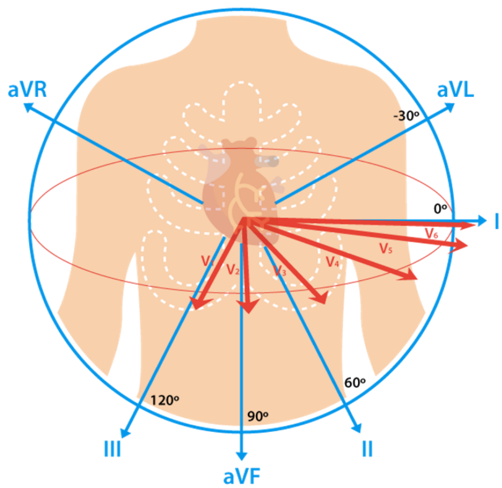


Figure 5. Vectors that show node placement in a 12-lead EKG

1.4 Visual Aid

While a whole 12-lead EKG would require a minimum of 9 bulbs, for the scope of our project, we want to focus on the creation of a single bulb that can accomplish the task of measuring the data and transmitting it wirelessly to create some data visualization with an associated timestamp. We hope that this project will be scaled up easily after the design of the bulb device itself.

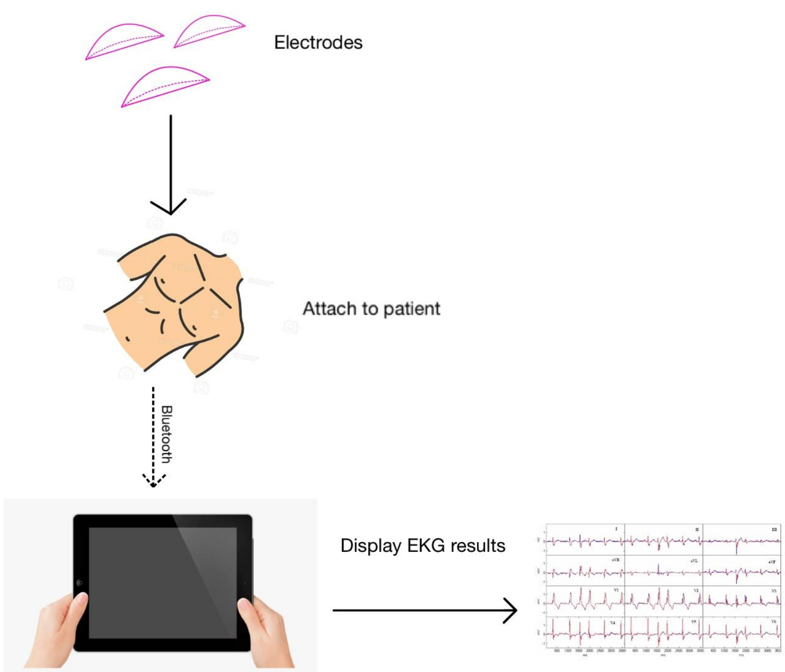


Figure 6. High-level visual representation of solution pipeline

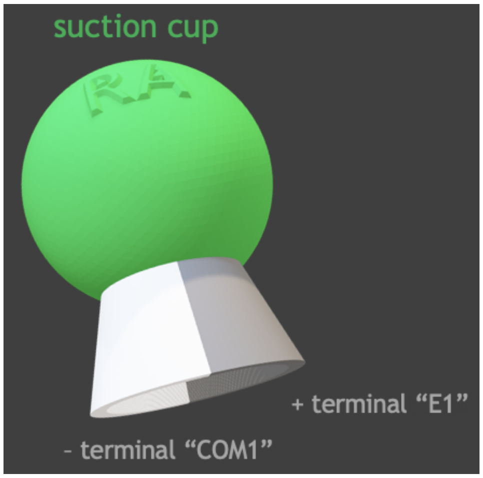


Figure 7. Potential design structure for individual bulb

1.5 High-Level Requirements

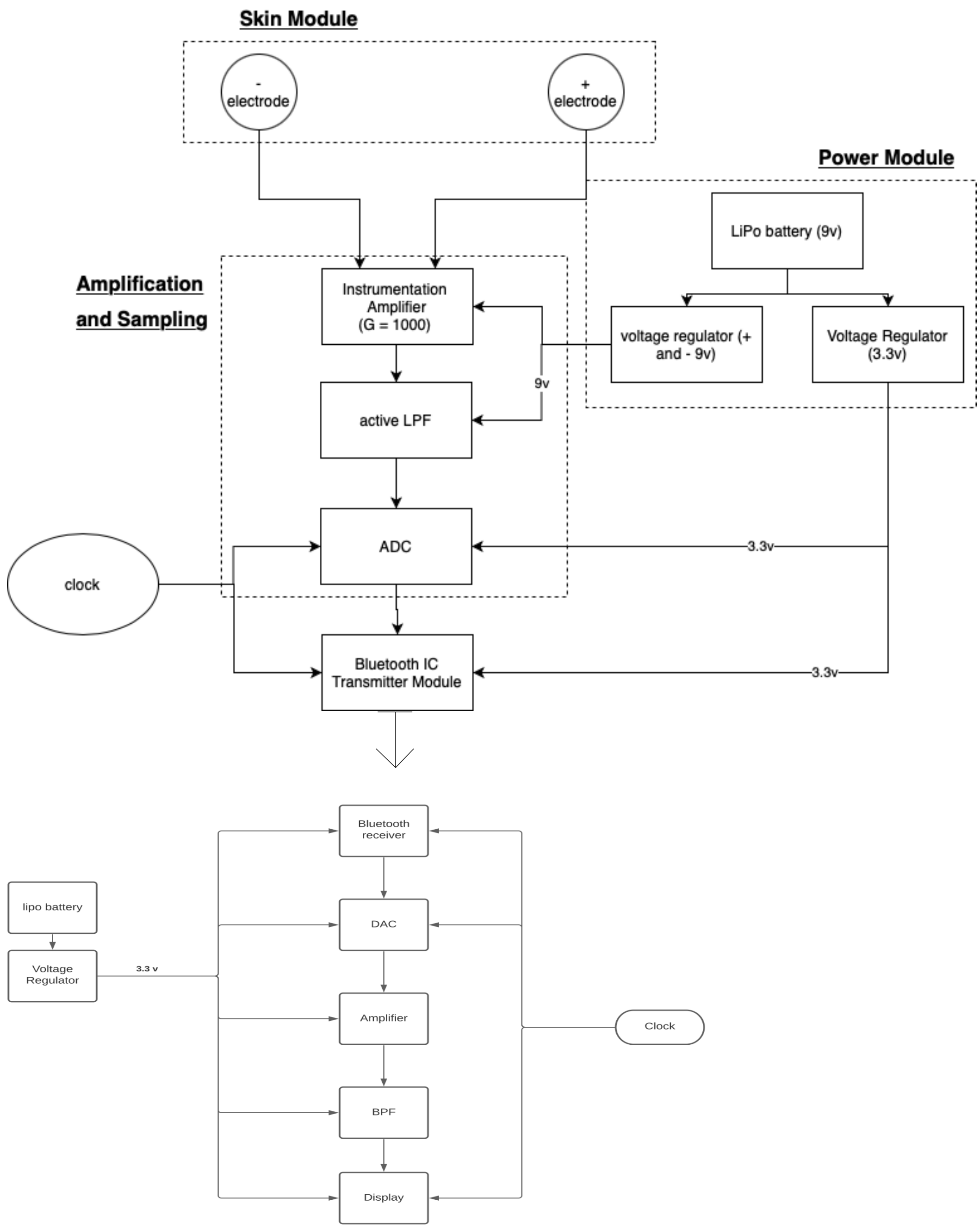
1. **The device should display PQRST waves within accuracy of 0.1 mV for at least 15 seconds with timing delay of 1-2 ms.** We will determine the accuracy through extrapolating what standard theoretical values are for EKG readings in each segment of the PQRST wave. Although it would be far more ideal to compare with real EKG results, we unfortunately do not have access to a traditional EKG machine to be able to directly compare results so we feel this method would be the most accessible way to determine accuracy. The reason we are looking for at least 15 seconds of transmission is because we need to see multiple PQRST cycles to be able to determine trends or rhythms. For an individual whose heart rate is 50 bpm, we should still see 12 beats within 15 seconds, which would be the minimum to be able to assess trends. Finally, we understand that data transmission via Bluetooth cannot occur in real-time, but due to the urgency of data accessibility in emergent medical cases, we hope to keep the timing delay as low as possible. As such, research into applications that use the NRF24L01 chip report seeing timing delays at around 1-2 ms, so we hope to stay within this range as well. Since we are creating a single bulb for the scope of this project, we will not include both horizontal and vertical views of the heart.
2. **Device should transmit potential difference and associated timestamps with zero wires for a radius of 5 feet, while the whole device should fit within a 13 X 9 X 6" box. The device should also be reusable and have a battery life of at least 1 hour.** According to an esteemed medical device wholesaler, the average length of EKG wires is

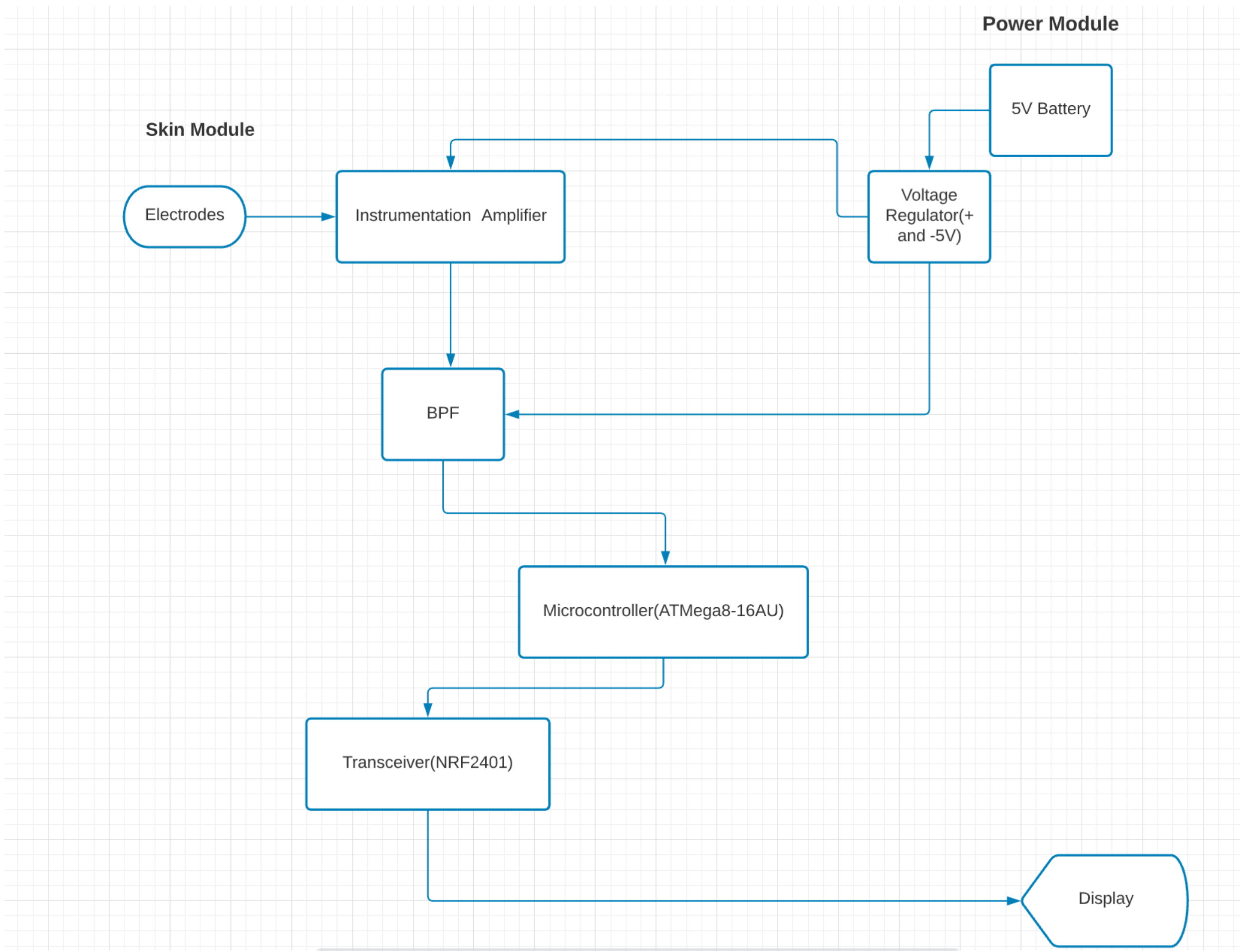
about 3 feet. This leads us to believe that it is reasonable to expect that EKG data would be collected within this range. We propose a radius of 5 feet to allow some leeway during device setup and data collection as well. Since our primary goal is to cater to potentially underserved communities and emergent situations, it is a priority to make sure that the device is portable and low-maintenance. We set the size constraint to the size of a standard Emergency Response Trauma Bag, which is of the dimensions listed above, so that the device would be able to be transported quickly and fit within already existing storage locations. In addition, we added the requirement of reusability and battery life to ensure that the device would not require significant upkeep during or between uses.

3. **Data (potential difference and associated timestamps) should be sampled at a frequency of 500 Hz and be transmitted at a minimum of 2 Mbps.** Kenny Leung, this project's sponsor, mentioned that a standard EKG device (along with current market solutions) include a minimum of 20 samples per EKG grid box. Each square on the standard EKG graph paper (1mm length) represents 0.04 seconds.

Section 2: Design

2.1 Block Diagram




Power Module
5V Battery
Skin Module
Electrodes
Instrumentation Amplifier
Voltage Regulator(+ and -5V)
BPF
Microcontroller(ATMega8-16AU)
Transceiver(NRF2401)
Display

2.2 Subsystem Overview/ Requirements

2.2.1 Control Unit:

For our Microcontroller, we have chosen to use the ATMega8-16AU to handle our core functions. One of the advantages of the ATMega8-16AU is that it has high performance with low power consumption which is ideal for our bulb. This specific chip was chosen due to the on-board ADC which eliminated the need for a separate ADC module which would grow to be exceedingly complicated since this would also need to be controlled by the ATMega. In this design, the core will take our filtered and amplified analog signal from the electrodes and sample this data at a sufficient rate above the Nyquist frequency (further explained in Risk Analysis). It will then send our filtered signal to the bluetooth module using an SPI protocol.

Requirement	Verification
1. Microcontroller must get input signal from BPF 2. Microcontroller gets input VCC and GND from power supply 3. Microcontroller sends signal to Bluetooth Module within 5m range	1. Connect an oscilloscope to PIN 19 on Microcontroller and GND. Check to make sure that data signals have been received 2. Connect voltmeter to VCC and GND of Microcontroller to make sure +5V is available 3. Connect a pair of wires to Pin assigned for Bluetooth Module and GND to the transceiver. Using SPI protocol check for outgoing signal from microcontroller.

2.2.2: Instrumentation Amplifiers & Filtering:

An Instrumentation Amplifier will take the electrical signals measured from the electrodes and amplify this signal by a factor of 100. From here the signals will be sent through the band-pass filter to filter out the noise and clean up the signal. Most of our signal will be in the range of 10 Hz - 200 Hz. Anything out of this range is essentially noise unproductive to our data visualization and measurement. Next, our signal will be sent from the passive filter to the analog to digital converter in the ATMega. This will convert our analog signal to digital so that we can view the PQRST wave on our display. One of the most important parts of this analog to digital converter is the speed at which it converts the signal.

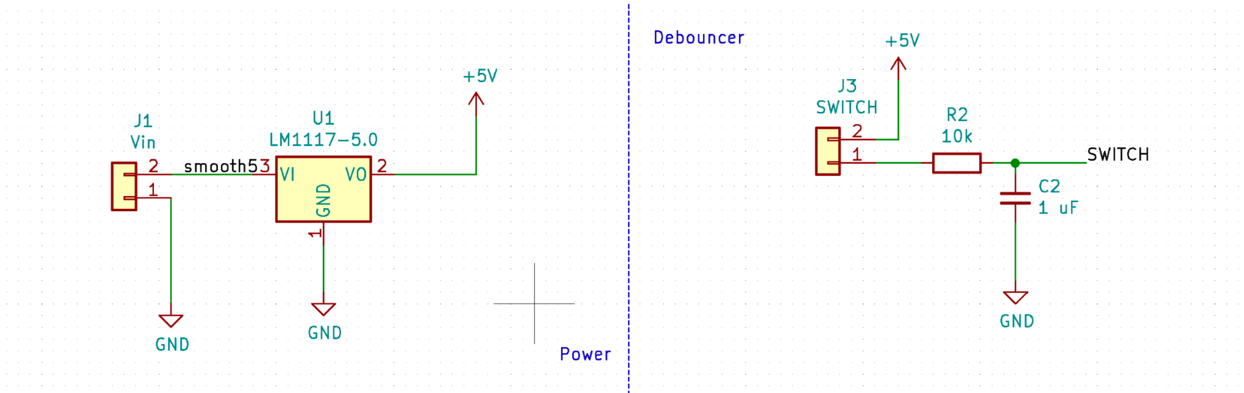
We will be using an Instrumentation Amplifier which will take the electrical potential difference measured from the electrodes. In typical EKG, the electrical voltage is between 1mV and 5mV(). The signal that we gather will need to be amplified so we will use Instrumentation Amplifiers to do that. An Instrumentation Amplifier is a type of differential amplifier that is used for measurement because it contains input buffer amplifiers which eliminates the need for input impedance matching(). For our project, we will use the AD620 by Analog Devices in order to accomplish this. The AD620 has quite a few characteristics that make it perfect to use for our bulb. The AD620 has low noise, low power, and low input bias current which makes it ideal for use with medical applications. In addition, the AD620 has a low offset and offset drift which is perfect for data acquisition. The AD620 also allows for a low power supply which is ideal for our bulb since we are using a coin-cell battery to power our system. For the AD620 we have chosen to use a resistance of ___ because ____. Insert formula for calculating gain and figure of AD620 circuitry with Resistor values and capacitance values. We expect that we need to amplify our signal by ____.

After passing the signal from the electrodes to the Instrumentation Amplifiers, it will be sent to our low-pass filter. Filters are used to attenuate frequencies of signals. We will be using a low-pass filter to attenuate high frequency noise. Insert RC CIRCUIT for low-pass filter here with calculations for R and C.

Requirement	Verification
1. Instrumentation Amplifier must amplify the signal by a factor of 15 2. Signal will be sampled at a Nyquist frequency of 500Hz	1. Use oscilloscope to view signal generated by electrodes. Attach wires to PIN __ and GND on instrumentation amplifier and measure the amplitude difference to see if signal has been amplified. 2. Use oscilloscope to view channel settings of the signal and calculate Nyquist frequency to make sure its at 500Hz as we expected.

2.2.3 Power Supply:

The power supply module is essential to supplying power to the microcontroller in order to send the signal to our display. We expect our power supply to provide 5V of power in order to provide the sufficient power necessary for our control unit. The power supply we have designed uses a battery voltage around 5 volts attached to our Vin which is then regulated with the LM117-5.0 voltage regulating chip. This is then exported to our +5V node which is then easily run to many other parts of the circuit. We continue our power module with a debounced on-off switch that uses a capacitor to ensure smooth operation of switching power to our IC's.



Requirement: Power Subsystem must be able to supply 5V to the rest of the system continuously during operation with low noise to ensure proper operation of the ADC in the ATMega Microcontroller.

Requirement	Verification
1. Stable +5V supply at up to 0.2A is supplied	1. Connect a voltmeter to PIN 2 and GND to make sure that voltage of +5V is being supplied

2.2.5 Skin Module:

Our bulb will attach to the skin of the user. Through the use of suction, a vacuum will be created, holding the device to the skin tightly and ensuring a proper electrical connection between the metal contact pads and the skin with no air in between. These electrodes will gather the potential difference of the skin across the two electrodes and send this signal to our control unit.

In order to measure the biopotential created by the heart, we need to attach our bulb to the skin of the user. Through the use of suction, a vacuum will be created which will hold the device to the skin tightly, This will ensure that a proper electrical connection has been established between the metal contact pads and the skin. We will be using reference electrodes made of Silver-Silver Chloride half-cells for a few reasons. These electrodes use the breakdown of AgCl in the reaction below to carry charge between the skin and the metal of the electrode wires.

$$\mathrm{AgCl(s)} \rightleftharpoons \mathrm{Ag}^{+} + \mathrm{Cl}^{-}$$

In this reaction, the silver and chloride ions are actually the charge carriers across the boundary instead of electrons. This is needed because typical metal electrodes would build a potential barrier or half-cell potential derived from the Nernst equation:

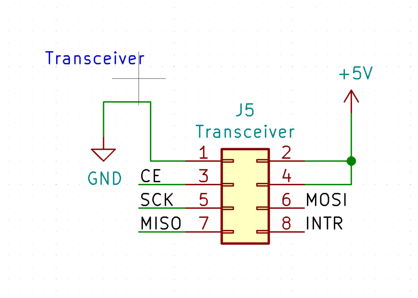
$$E = E^{0} - \frac{RT}{F} \ln a_{\mathrm{Cl}^{-}}$$

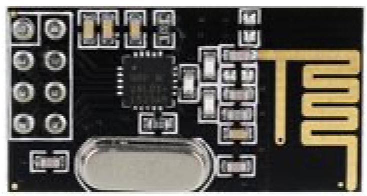
Surface Ag/AgCl electrodes are the most common and favored electrodes in clinical measurements for recording all biological signals such as EKG, EMG and EEG. One of the main advantages of using Ag/AgCl electrodes is the low noise level it generates during biological signals recording. Additionally, the potentials of these electrodes do not change over time or with temperature which offers long-term stability. Lastly, these electrodes also importantly have non-toxic components which is instrumental for our project since our product will be used on humans.

Requirement	Verification
1. Skin attachments should stay within 20-37 degrees C 2. Bulb must constantly adhere to skin, specifically metal contacts that have strong electrical connection over the entire time interval of use(~30s-1min)	1. Use a thermometer to measure the temperature of the attachment 2. Place bulb on human chest and if it does not detach from skin after 1min, successful attachment!

2.2.5 Bluetooth Transceiver Module:

From the Microcontroller, the signal will be sent to our bluetooth transceiver, the NRF24L01 chip. After a lot of research we chose this chip for a plethora of reasons. The NRF24L01 allows us to send up to 2Mbps of data which is our ideal speed. While this chip consumes low power, it has a communication range of up to 800m. This is well beyond the range that we are looking for which is around 5ft. In addition to that, this chip communicates with the microcontroller via SPI communication.





Requirement	Verification
1. Ensures that data from microcontroller is being sent to transceiver 2. Data is sent at 2Mbps 3. Ensure that data range is within at least 5m	1. Connect wires from PIN 15 of microcontroller to PIN 7 of transceiver. Connect computer to SPI pins on microcontroller and test to see that data is being sent 2. Send a bitstream of data from microcontroller to transceiver and calculate time it takes 3. Stand 5m away from transceiver and send data to make sure it is sent and received 4.

2.2.6 Data Visualization Module:

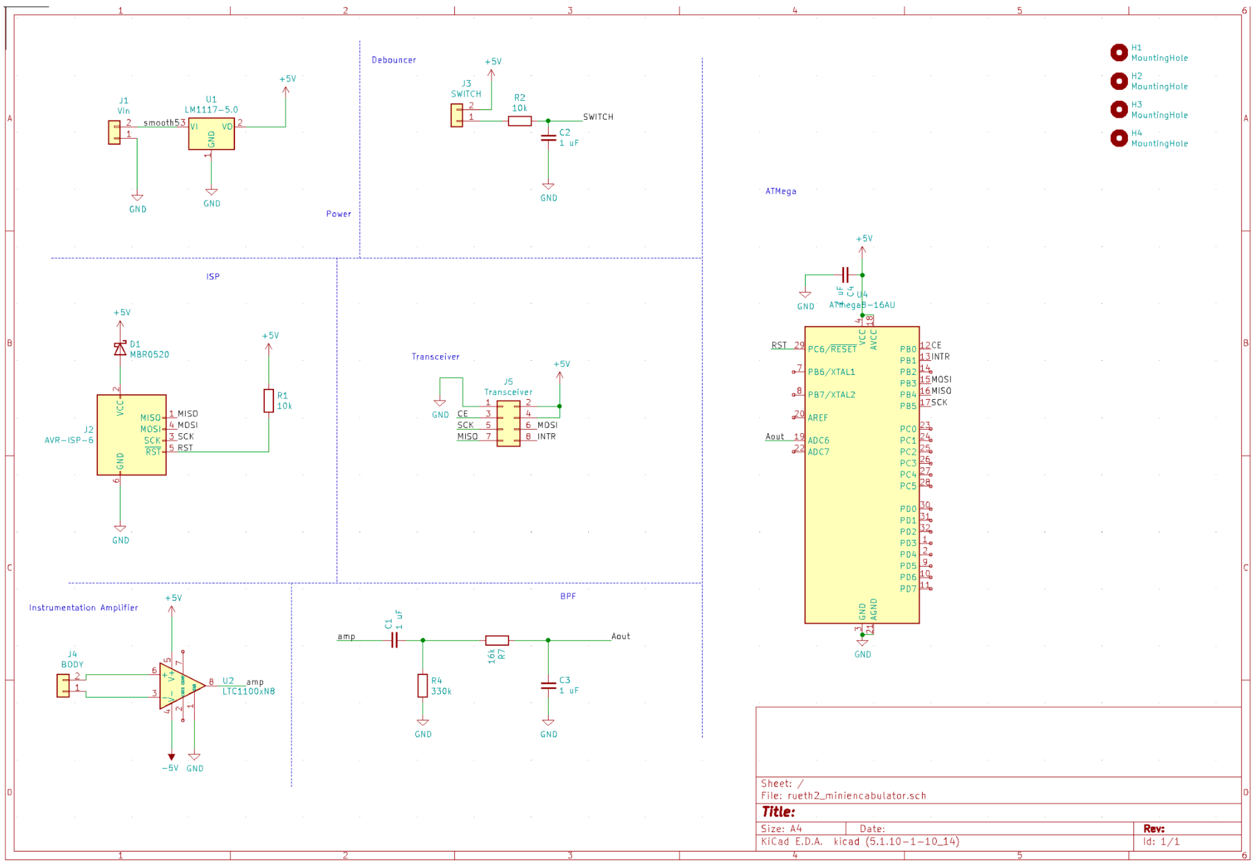
Our display interface will have a graphical display of our signal in a PQRST wave form. An image of this wave is shown below. As the signal comes in from the receiver it will be put through an algorithm that will display the wave and the timestamp.

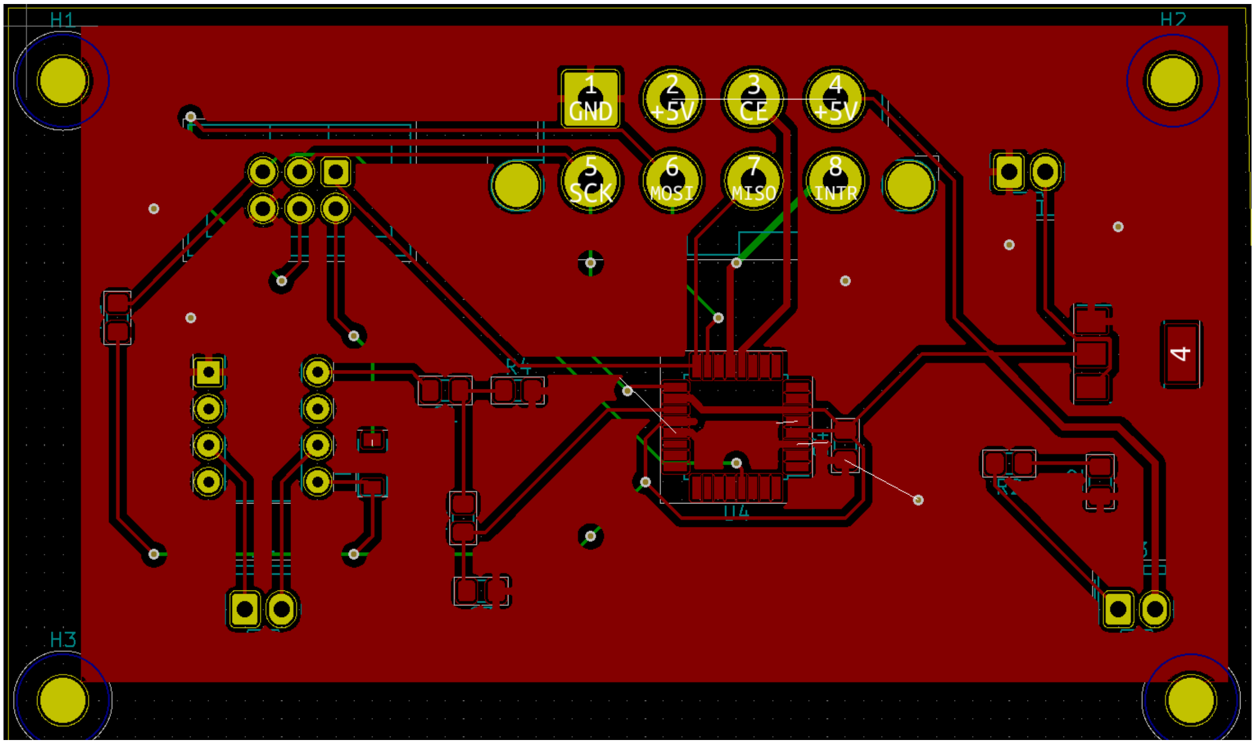
From our Transceiver, we send the data to our display(laptop). In order to display our data as a PQRST wave form we will put our data through an FIR filter. This FIR filter will enable us to calculate the QRS complexes.

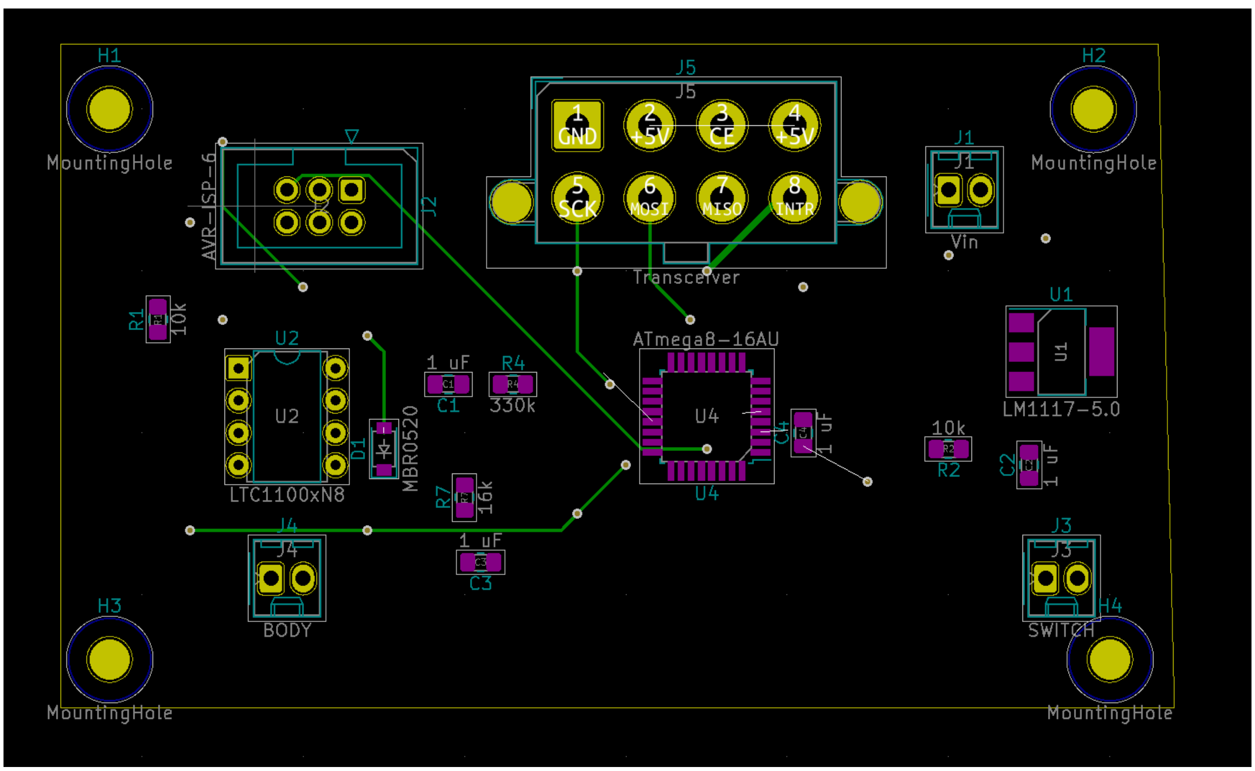
Requirement: PQRST wave will have 20 samples per EKG box

Requirement	Verification

2.3: **Schematics and PCB Design:**




H1
H2
H3
1 GND
2 +5V
3 CE
4 +5V
5 SCK
6 MOSI
7 MISO
8 INTR
R4
U4
4


H1
MountingHole
J5
J5
1 GND
2 +5V
3 CE
4 +5V
5 SCK
6 MOSI
7 MISO
8 INTR
Transceiver
J1
J1
Vin
H2
MountingHole
AVR-ISP-6
J2
R1
10k
U2
U2
LTC1100xN8
1 uF
C1
R4
330k
D1
MBR0520
R7
16k
ATmega8-16AU
U4
U4
C4
1 uF
U1
U1
LM1117-5.0
10k
R2
C2
1 uF
J4
J4
BODY
1 uF
C3
J3
J3
SWITCH
H3
MountingHole
H4
MountingHole

2.4 Software Design

Microcontroller:

Transceiver Module:

Example Code Outline for Transceiver Module:

```
//Include Libraries

#include <SPI.h>
#include <nRF24L01.h>
#include <RF24.h>

//create an RF24 object
RF24 radio(9, 8);  // CE, CSN

//address through which two modules communicate.
const byte address[6] = "00001";

void setup()
{
  radio.begin();

  //set the address
  radio.openWritingPipe(address);

  //Set module as transmitter
  radio.stopListening();
}
void loop()
{
  //Send message to receiver
  const char text[] = "Hello World";
  radio.write(&text, sizeof(text));

  delay(1000);
}
```

Data Display:

2.4 Risk Analysis

The biggest risk to the completion of this project will be the bluetooth/RF module and receiver. These units are responsible for sending and receiving the signal from the electrodes and to our display. While we think the general range of 1-2 Mbps will be sufficient for the needs of our project, we are concerned that the data transmission may not occur at a satisfactory level. On top of this, we have a very tight size constraint as the general size of an EKG bulb is a few centimeters wide. Since we are choosing to measure the electric potential across a slightly larger area to be able to reuse the bulbs, we don't have to follow the constraint of a few centimeters as strictly, but portability is a defining factor of our project and we have to be mindful of this success criteria while making design decisions. In addition, a big challenge for creating wireless EKGs is that there is no clock signal shared between all 9 or 10 electrodes, which makes time synchronization difficult across multiple electrodes. We hope to address this challenge by rearranging data as it appears to our data visualization subsystem, so that data associated with a certain timestamp will be reordered to appear before later time stamps.

Going off of our requirement to have a minimum of 20 data points per EKG grid box. Each square on the standard EKG graph paper (1mm length) represents 0.04 seconds. This would mean:

20 data points * 1/0.04 seconds= 500 Hz

Therefore, we get the minimum sampling frequency to be 500 Hz.

2.5 Physical Design:

Table 8: Suction bulb (not to scale)

Section 3: Cost and Schedule

3.1 Cost Analysis

To consider the fixed costs of labor for this project, we look at an hourly rate of $40/hour for 3 individuals at approximately 20 hours per week. We consider the development lifespan to be 12 weeks since the last four weeks of the semester are dedicated to final demos, presentations, etc. In this fixed cost estimation, we ignore the additional time spent from our sponsors and ECE lab resources. As such, our estimate is the following:

$3 * \$40/hr \ * \ 20\, hr/week \ * \ 12\, weeks \ * \ 2.5 \ = \$72,000$

In addition to our labor costs, we must also consider our costs for parts. We break down this analysis into prototype costs and also mass production estimates in the case of scaling this product for commercial use.

Part	Prototyping Costs	Commercial Costs
Double Handle Locking Suction Cup	$9.63	$2.26
Multi-Purpose ECG Monitoring Electrodes	$0.18	$0.06
NRF24L01- Single chip radio transceiver	$1.30	$0.39
AD6204		

It is important to note that these estimates are made from the production of one bulb. Once fully scaled, the final product would have 9 of these bulbs so the total cost would be INSERT TOTAL COST HERE.

3.2 Schedule

Week	**Jack**	**Madhavan**	**Samhita**
9/26	Finalize PCB Design, revise block diagram from proposal feedback	Define subsystem verification, perform risk analysis	Research bluetooth options, cost analysis, convert to final format
10/3	Revise Round 1 PCB Design,	Prepare for Design Review based on feedback from Doc Check	
10/10			
10/17			
10/24			
10/31			
11/7			
11/14			
11/21			
11/28			
12/5			

Section 4: Ethics and Safety

When building our project, there are certain ethical issues and safety precautions that we have to consider. Since we are creating a product that will be used on the human body, we need to ensure the safety of all patients. Especially when handling electricity, we must make sure the voltage of our battery maintains safe levels of exposure to the human body so that it does not harm our user when they are getting an EKG. Specifically, we need to make sure that we follow Section 1.2 of ACM Code of Ethics: Avoid harm. We deeply understand the ramifications of injuring a patient, even unintentionally. We hope to exercise extra caution to ensure the safety of our users and follow all relevant regulatory standards. Since our product is being used on humans, it is imperative that we follow this code. In terms of ethics we must abide by 7.8 of the IEEE Code of Ethics. Thus we must uphold the highest standards of integrity, responsible behavior, and ethical conduct in professional activities. As we are working in a group it is critical that we treat all persons fairly and with respect, avoid injuring others, and to not engage in harassment or discrimination. Finally it is vital that we all support our co-workers.

Sources:
https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983
https://amdtelemedicine.com/product/12-lead-digital-wireless-ecg/
https://store.kardia.com/products/
https://www.ieee.org/about/corporate/governance/p7-8.html
https://www.acm.org/code-of-ethics
https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/electrocardiogram
https://ecgwaves.com/topic/ekg-ecg-leads-electrodes-systems-limb-chest-precordial/
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https://www.medcablesource.com/din-ecg-compatible-leadwire-3-leads-snap/