Bubz, a 12-lead Wire-free EKG

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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 [7]. 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 [8]. 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 2. 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 [6].

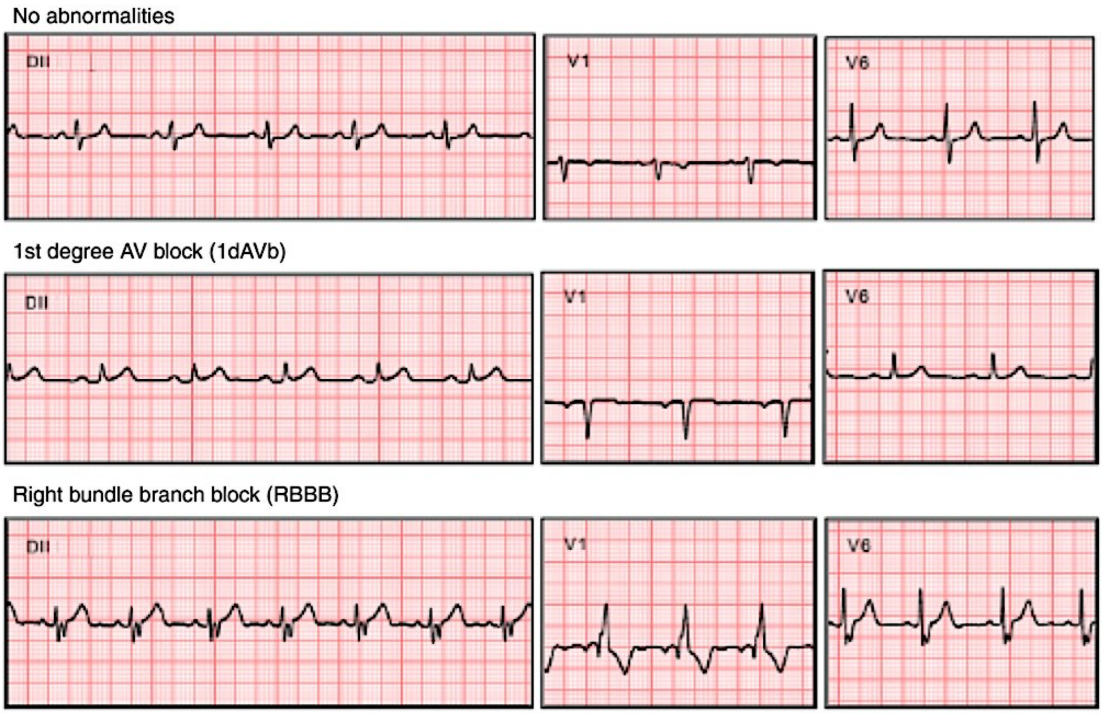

Figure 1. Sample of EKG results.[12]

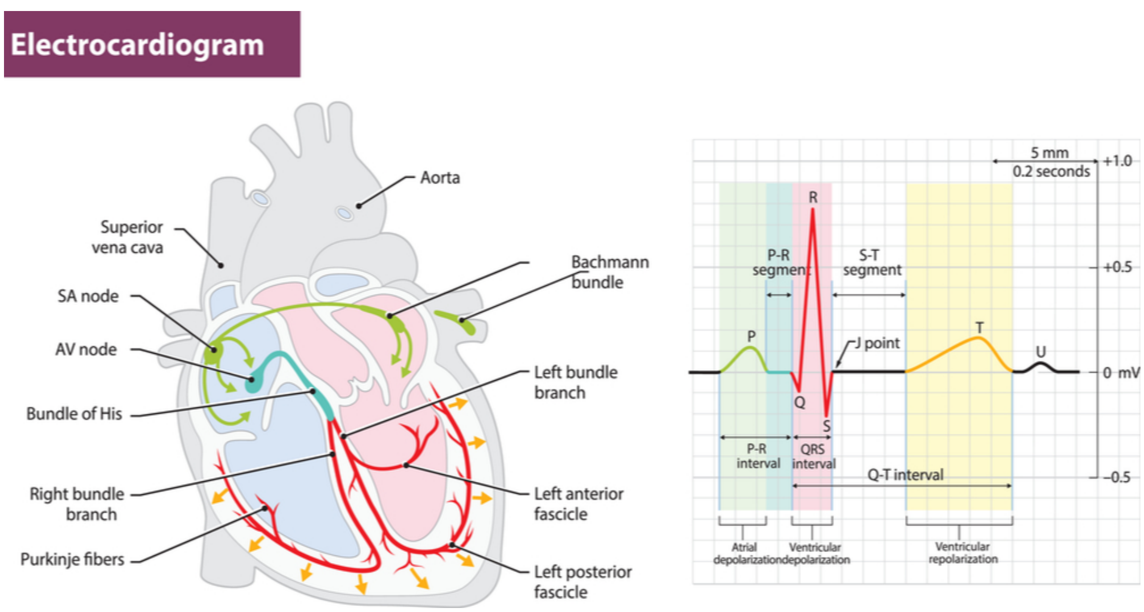

Figure 2. Diagram of electrical signals in the heart and how they translate to PQRST waves.[8]

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 3. 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 [7]. 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 4). 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 (shown in Figure 5) .

Figure 3. Patient receives a traditional 12-lead EKG [7]

Figure 4. KardiaMobile, single-lead wireless solution [10]

Figure 5. AMD, 12-lead semi-wireless solution [1]

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.

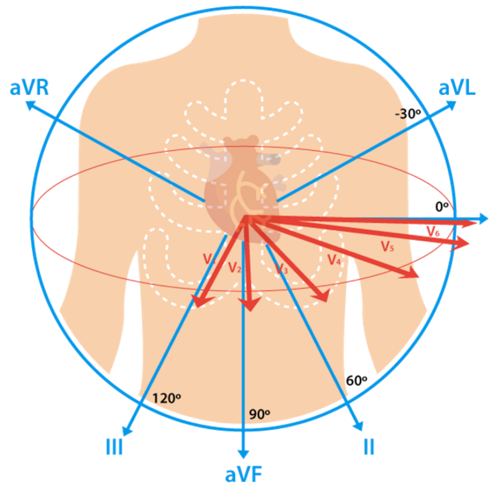

Figure 6. Vectors that show node placement in a 12-lead EKG [6]

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.

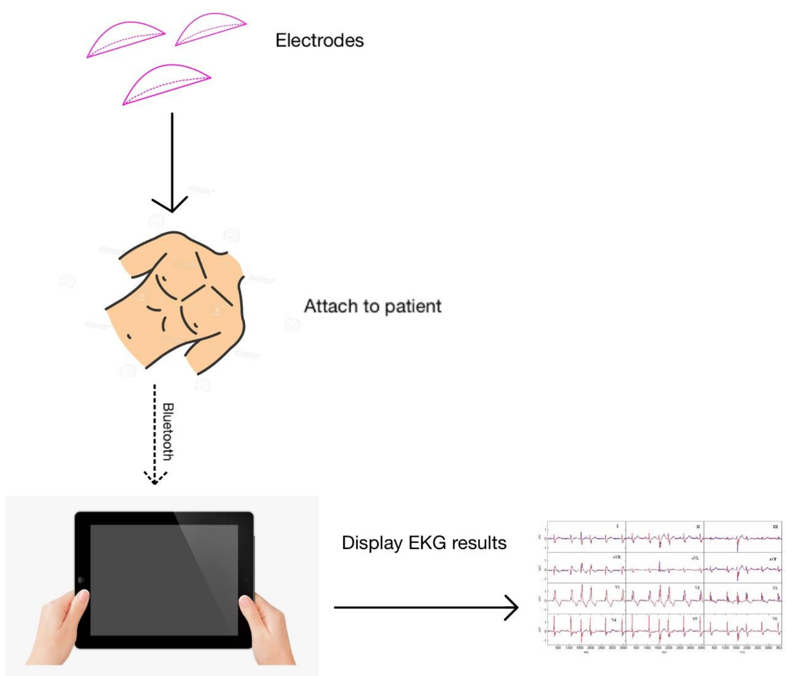

Figure 7. High-level visual representation of solution pipeline

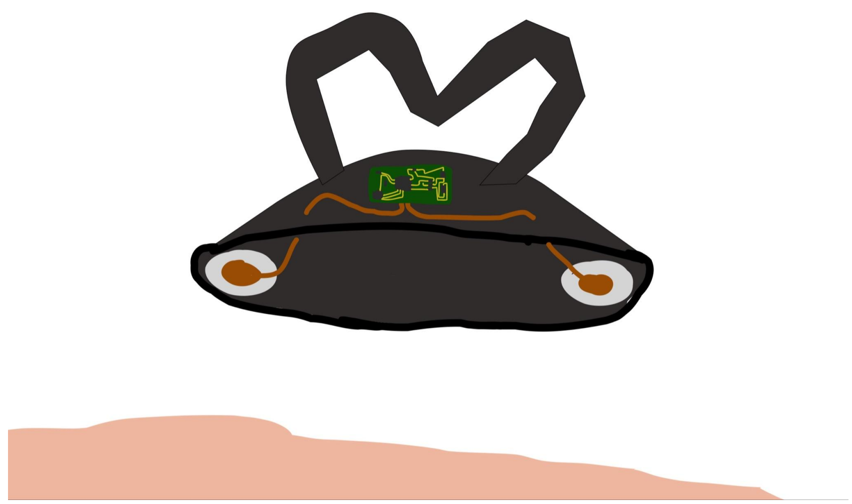

Figure 8. Physical design of suction cup system with handle and visible attached PCB above the skin

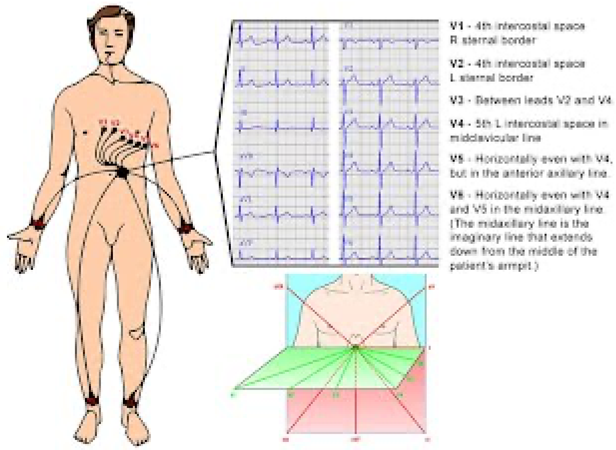

Figure 9. Shows placement of the bulbs in a fully scaled product[11]

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.**
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.**
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.**

1.5.1 Expansion on High-Level Requirements

1. 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 ESP32 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. According to an esteemed medical device wholesaler, the average length of EKG wires is about 3 feet [1]. 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. Kenny Leung, this project's sponsor, stated that a standard EKG device (along with current market solutions) includes a minimum of 20 samples per EKG grid box. Each square on the standard EKG graph paper (1mm length) represents 0.04 seconds.

2. Design

2.1 Block Diagram

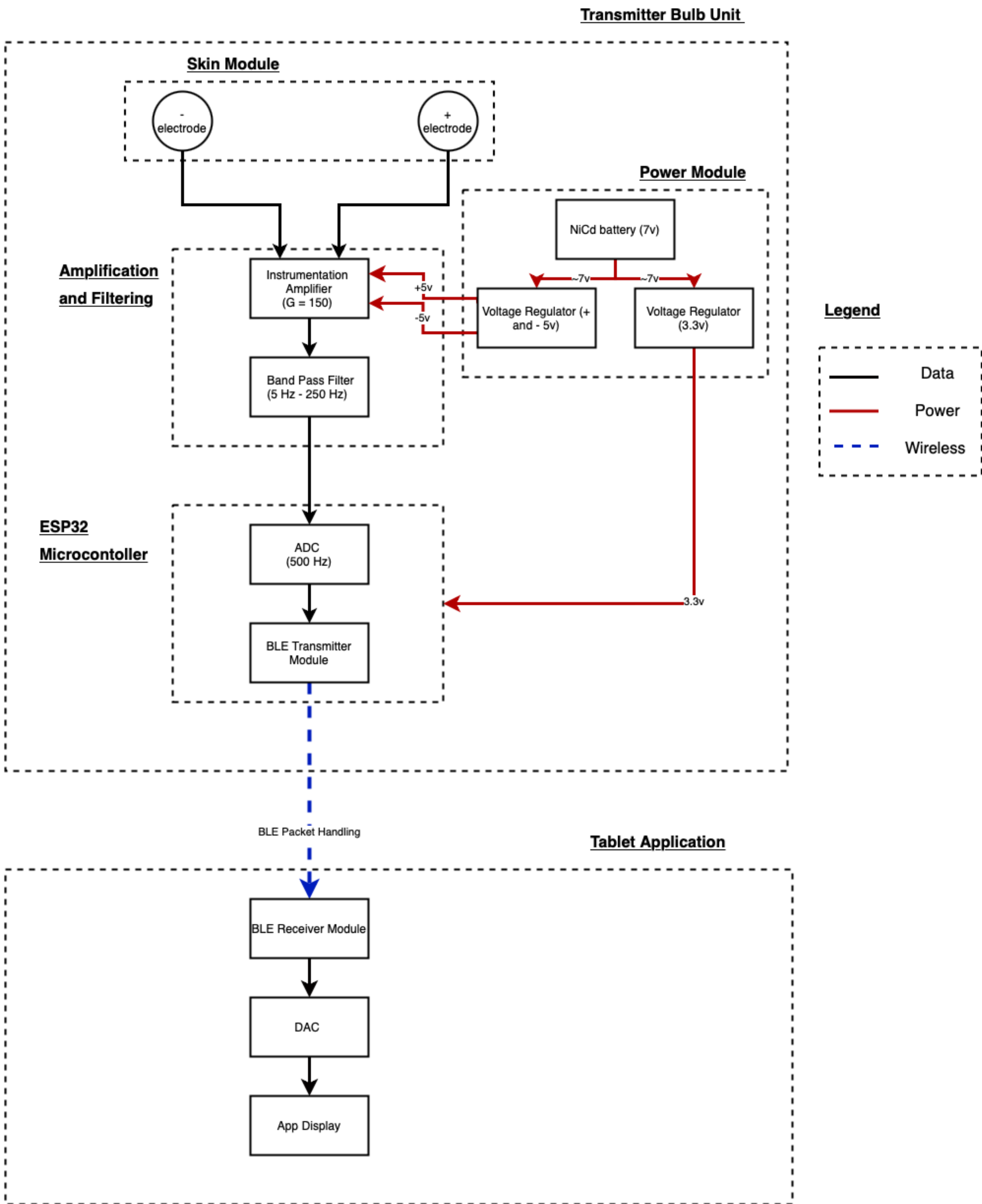

Table 1. Block Diagram detailing subsystems of proposed wireless EKG design

2.2 Subsystem Overview/ Requirements

2.2.1 Control Unit:

Our control unit subsystem consists of handling wireless communication and signal processing of our biopotential signal. For wireless communication we chose to use BLE for a few reasons. BLE has low power consumption which is ideal for our project that overall consumes low power. Since BLE has low power consumption there is not as high of a range for communication. This fits into our project as the furthest we expect the communication from the bulb to the display be is 5 meters.

For our Microcontroller, we have chosen to use the ESP32-WROOM-32 to handle our core functions. One of the advantages of the ESP32-WROOM-32 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 Bluetooth system that allows the user to conveniently connect to a phone through a mobile application or broadcast low energy beacons for its detection. The sleep current of the ESP32 chip is less than 5 µA, making it suitable for battery powered and wearable electronics applications. The module supports a data rate of up to 150 Mbps, and 20 dBm output power at the antenna to ensure the widest physical range.

In this design, the ESP32 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 can both receive and transmit over SPI at 2Mbps 2. Microcontroller gets input VCC and GND from power supply 3. Microcontroller sends signal to Bluetooth Module within range of ±5m	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 +3.3V is available 3. Send a bitstream of 4kB data from microcontroller to display that is within ±5m and check that data has been sent

Table 2. Requirement and Verification table for control unit subsystem

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 150. Next, our signal will be sent from the passive filter to the analog to digital converter in the ESP32 microcontroller. 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 an Instrumentation Amplifier 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[8]. 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 low power batteries in our design. We expect that we need to amplify our signal by 100.

After passing the signal from the electrodes to the Instrumentation Amplifiers, it will be sent to our band-pass filter. Filters are used to attenuate frequencies of signals. We will be using a low-pass filter to attenuate high frequency noise, and the high-pass filter should remove any unwanted DC bias. Most of our signal will be in the range of 10 Hz - 200 Hz. Anything out of this range is essentially noise that is unproductive to our data visualization and measurement.

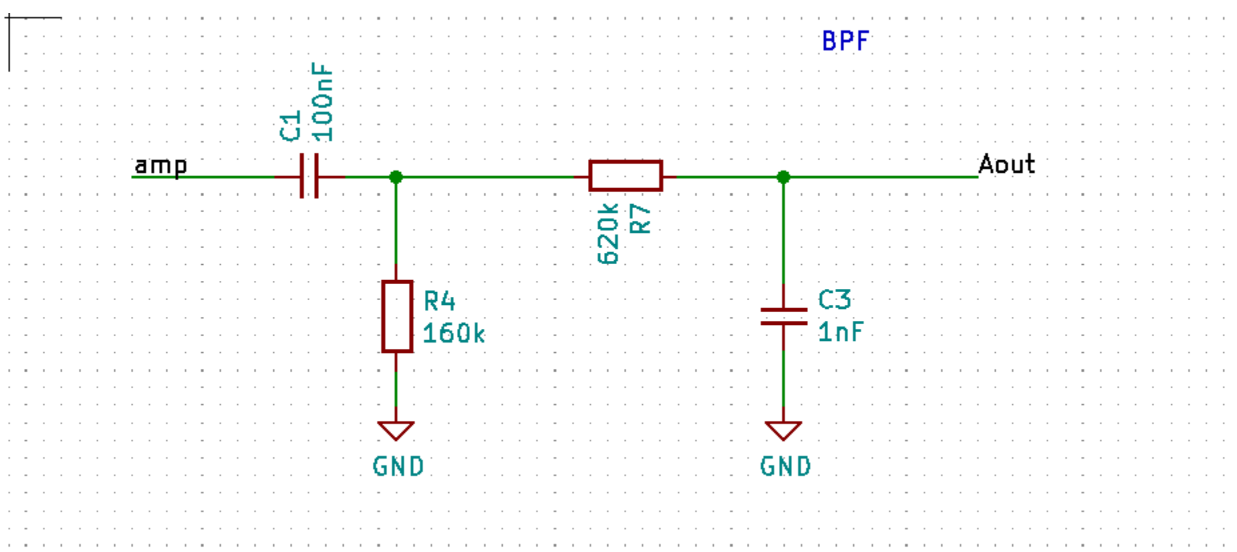

Figure 10. Circuit schematic for band pass filter

Requirement	Verification
1. Instrumentation Amplifier must amplify the signal by a factor of 150 with low noise 2. Signal will be sampled at a Nyquist frequency of 500Hz	1. Use oscilloscope to measure 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 perform FFT on amplified data as well as original data to ensure first three major harmonics are retained with proper magnitude. 3. Use oscilloscope to measure channel settings of the signal and calculate Nyquist frequency to make sure its at 500Hz as we expected.

Table 3. Requirement and Verification table for Instrumentation Amplifier & Filtering subsystem

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 and to our instrumentation amplifier to filter the signal. We expect our power supply to provide 3.3V 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 3.3V attached to our Vin which is then regulated with the LM117-5.0 voltage regulating chip. This is then exported to our +3.3V 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	Verification
1. Stable +3.3V ±0.3V supply at up to 0.2A is supplied to control unit and instrumentation amplifier	1. Connect a voltmeter to VCC and GND of ESP32 and Instrumentation Amplifier to make sure that voltage of +3.3V ±0.3V is being supplied

Table 4. Requirement and Verification table for power supply subsystem

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[11].

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

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[11]:

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

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[6].

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 Mercury thermometer to measure the temperature of the attachment 2. Place bulb on human chest and make sure it stays attached for at least 1 minute

Table 5. Requirement and Verification table for skin module

2.2.5 Bluetooth Transceiver Module:

After the analog data is sampled by our ADC, the ESP32 will then use its onboard Bluetooth transmitter to broadcast the data using Bluetooth Low Energy (BLE). This was one of our main reasons for using the ESP32 microprocessor, as it simplifies the transmission process greatly. The ESP32 allows us to send up to 2Mbps of data which is our ideal speed. While this chip consumes low power, it has a theoretical communication range of up to 100m. This is well beyond the range that we are looking for which is around 5ft, so there is little doubt the chip will be able to satisfy this requirement. Typically BLE cannot transmit large amounts of data quickly, so BLE would not be a great choice for an application such as high fidelity audio, but our data is relatively light and can be handled easily by BLE. This will give us a distinct advantage by helping prolong the battery life of the transmitter devices.

Requirement	Verification
1. Ensures that data from microcontroller is being sent to Bluetooth transmitter 2. Data is sent at 2Mbps ±5% 3. Ensure that data range is within at least ±5m	1. Connect wires from data pins of microcontroller to Bluetooth transmitter pins on microcontroller. Connect Computer to SPI pins on the microcontroller and test to see that a bitstream of 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

Table 6. Requirement and Verification table for bluetooth subsystem

2.2.6 Data Visualization Module:

The data visualization subsystem is critical to confirming that all our subsystems work together seamlessly. As with a normal EKG, the end result is to visualize a PQRST wave of the patient. It is of the utmost importance that the data being visualized is not only correct but accurate. Physicians use this data to recognize and diagnose serious heart conditions, so an incorrect display of data is In order to accomplish this we will have 3 parts: BLE receiver, digital to analog converter, and an app for visual display. The EKG signal from the BLE transmitter will be sent to the BLE receiver. From the receiver, the signal will be put through an on-board digital-to-analog converter. This is accomplished digitally through software. The signal will be then put through our Python program and mobile application which will ultimately display our EKG signal as a PQRST wave.

Requirement	Verification
1. The PQRST waveform will have 20 samples ±5 per EKG box 2. Data is received from microcontroller to app display at a speed of 2Mbps ±5% 3. App interface has a start/stop button to decide when to display data	1. Count the number of samples per EKG box on the PQRST waveform 2. Send a bitstream of data from microcontroller to app display and calculate speed 3. Send randomized data to app interface and press start/stop randomly to ensure button works

Table 7. Requirement and Verification table for data visualization subsystem

2.3 Risk Analysis

The biggest risk to the completion of this project will be the amplification of the signal detected across the electrodes. This signal has a potential within the range of 1mV-5mV. With an incredibly small signal voltage, amplifying this signal and ensuring that noise is reduced is critical to the success of this project. Typical noise for a circuit can be 1-2mV. By calculating Signal-to-Noise Ratio(SNR) we can show that the level of noise will be significantly reduced. Taking the fact that typical EKG values are 5mV and under, our typical signal voltage should be expected to be around 2.5mV. However, typical noise such as ripples generated from power supplies or MOSFET switching can easily be in excess of 2 mV. This result, after being put through our Instrumentation Amplifier and its gain of 150, shows similar results with a poor signal to noise ratio with even normal, expected values of noise.

$$2.5mv = (2.5/1000) * 150 = 0.375v$$

$$2mv = (2/1000) * 150 = 0.3v$$

$$SNR = (0.375/0.3) = 1.25$$

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
ESP32 - Single chip radio transceiver	$5.59	$1.07
Instrumentation Amplifier (AD6204)	$2.98	$0.04
3.3 Voltage Regulator (LM117)	$0.71	$0.26
NiCd Battery, 6V	$13.75	$1.60
PCB Order	Free	$1
Total:	$32.84	$6.29

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 parts cost would be

$32.84 * 9 = $295.56 for prototyping and about $56.61 if commercially produced. This would make the total production cost $72,295.56.

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	Order initial round of parts, start testing electrodes and suction bulbs	Prepare for Design Review based on feedback from Doc Check	Start building app framework for wireless communication between microcontroller and phone
10/10	Solder Round 1 PCB, Continue design and testing of electrodes	Solder Round 1 PCB, Continue design and testing of electrodes	Continue app framework and infrastructure design
10/17	Revise Round 1 PCB Design	Revise Round 1 PCB Design	Develop front end of app
10/24	Refine filtering and amplification methods	Refining skin module and physical design	Finalize end to end app development
10/31	Move from wired to wireless model	Move from wired to wireless model	Move from wired to wireless model
11/7	System Integration, Testing	System Integration, Testing	System Integration, Testing
11/14	Testing/Debugging and Demo Prep	Testing/Debugging and Demo Prep	Testing/Debugging and Demo Prep
11/21	Break	Break	Break
11/28	Presentation Prep, begin working on final report	Presentation Prep, begin working on final report	Presentation Prep, begin working on final report
12/5	Final Report refinement	Final Report refinement	Final Report refinement

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 an electricity-powered product that will be used on the human body, we need to ensure the safety of all patients. We are aware of the risk of electrocution, and will mitigate this risk by using instrumentation amplifiers, which will cutoff the backflow of current from device to patient. In addition, we will conduct testing on our device to ensure that the current that the user is exposed to stays under 6μA, which is significantly under the safety limit of 10μA that is set by the American Heart Association [13]. Finally, we will limit over flow of voltage with a voltage regulator.

Another safety concern is the use of the NiCd battery since the potassium hydroxide in these batteries is highly corrosive to the skin [14]. If the battery is damaged or mishandled, this fluid could leak and since the bulb is in contact with the skin, this could be potentially dangerous to the patient. For this reason, we must regulate the temperature the device will be operating under. Although this is already restricted due to the human tolerance for heat, we have added ventilation between the bulb and outside of the bulb to our design to ensure that heat cannot be trapped inside the bulb.

A final safety concern is the use of RF communication using the ESP32 BLE enabled microcontroller in our design. According to the FCC, we must stay from operating between the frequencies of 9kHz and 3000 GHz as they are unsafe for humans to be exposed to for prolonged periods of time due to radiation [15]. Since we are using the ESP32 microcontroller, the communication frequency is already limited to be within these safe limits.

When considering the ethical implications of this project, we need to make sure that we follow Section 1.2 of ACM Code of Ethics: Avoid harm [2]. We deeply understand the ramifications of injuring a patient, even unintentionally. We hope to exercise extra caution to ensure the safety of our users as mentioned above and follow all relevant regulatory standards we have previously mentioned during this safety analysis. In addition, 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 [9]. 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.

We also consider 1.7 of the ACM Code of Ethics to maintain user confidentiality [2]. We do not collect any data that can link a patient's medical records to their EKG results. We take user privacy at the utmost importance, and we hold ourselves accountable for what happens with the use of this product.

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