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Inexpensive, Portable, Smartphone-Based 12-Lead Electrocardiogram

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Approved:

Professor Reinhold Ludwig, Advisor

Professor John McNeill, Co-Advisor

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Abstract

The electronics industry is constantly focusing on creating cheaper, more portable electronics that integrate with smartphone technology and the increasing demand for affordable and effective medical instrumentation. Furthermore, the healthcare industry is beginning to follow suit, with many medical devices moving to mobile-based platforms and hardware. This Major Qualifying Project aims to complete preliminary development of an inexpensive, accurate, portable, Bluetooth 12-lead electrocardiogram (ECG) that interfaces with any Android smartphone. The current market lacks in mobile ECGs for portable devices to use clinically and other portable ECGs are extremely expensive. This project aims to use a compact analog front-end board, an embedded processor with Bluetooth adapter, and generic Android smartphone to revolutionize the way the healthcare industry envisions portable 12-lead ECGs.

Chapter 1 – Introduction

We live at an exciting time in the technology industry. Despite the fact that modern technological devices such as phones, computers, and various peripherals are getting cheaper and smaller, they continue to become more powerful, more accurate, and more portable. Combining these observations with the fact that science is continually discovering new methods for acquiring and processing data, we find that individuals are using today's smartphone technology to create innovative solutions to issues that would not have been solvable otherwise.

One of the most prominent issues in medical technology today is the cost of medical devices and, more specifically, how much individuals are able to spend on average to purchase life-saving diagnostic equipment. According to the World Health Organization (WHO), developed countries such as the United States spend $290 per capita on medical equipment, whereas developing countries such as India only spend a miniscule $6 per capita on medical equipment.[1] Devices such as electrocardiograms (ECG/EKG) are used to measure the electrical activity of the heart and diagnose life-threatening conditions such as myocardial infarctions (MI), or heart attacks. The cost of such devices currently range from about $2,000 and $8,000 for simple units to over $13,000 for portable units that contain defibrillators.[2] [3] Given these huge costs, it is apparent that there needs to be more affordable alternatives created for the healthcare markets in countries that simply cannot spend that much on medical devices.

Given the current environment of both consumer electronics and medical devices, it was inevitable that an increasing number of corporations and startups would work toward developing low-cost, smartphone-based medical devices. From Bluetooth blood pressure cuffs[4] to watches that measure your blood-oxygen saturation[5] to glucometers that report your blood glucose to your phone[6], there are new

[1] (Nimunkar, David Van Sickle, Van Sickle, & Webster, 2009)

[2] (Johnson, 2011)

[3] (DXE Medical, 2015)

[4] (Withings, 2015)
[5] (Withings, 2015)
[6] (iHealth, 2015)

devices practically every day that try to blend the realm of consumer electronics and medicine to improve modern healthcare both in and out of the clinical setting.

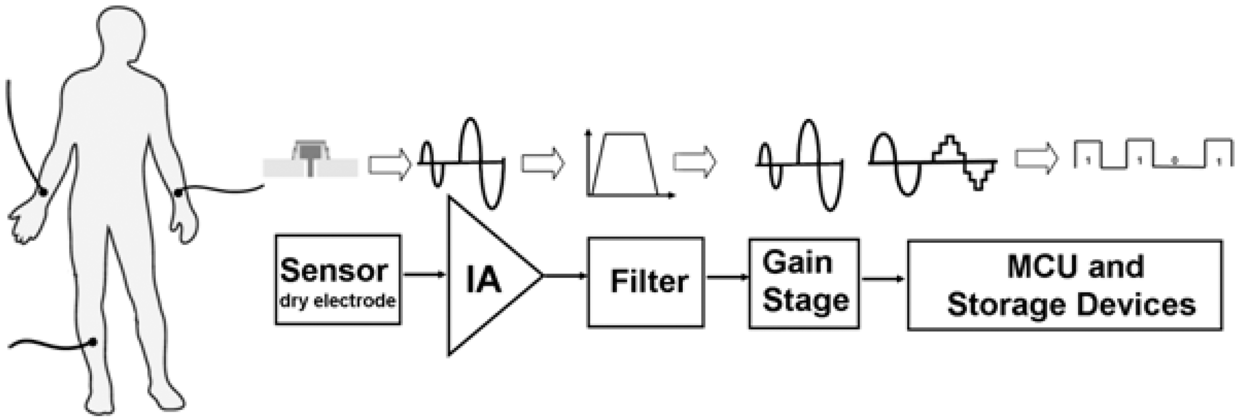

FIGURE 1 - ECG BLOCK DIAGRAM[7]

In this project, we aimed to combine our skills in electrical engineering and software engineering with our clinical knowledge of the human cardiovascular system to develop a low-cost, smartphone-based ECG. Figure 1 outlines the basic block diagram of an ECG. The ECG is capable of pairing to any Android smartphone using Bluetooth to allow physicians and other healthcare providers in practically any setting at practically any socio-economic position to gather extremely important clinical information and transmit it anywhere in the world over the internet. This will allow healthcare providers tools to better diagnose the chief complaints of patients and achieve an improved differential diagnosis using essential data that they most likely would not have had access to previously.

Chapter 2 – Background

2.1 – Definition and History of the 12 ECG Leads

The ECG is hardly a new piece of technology. Augustus Désiré Waller, a British physiologist from the late 19th century, experimented with bio-electromagnetism, which lead him to develop the first electrocardiogram in 1887. Unlike modern ECGs, which use the right arm, left arm, and left leg to get signals, Waller used these three positions, as well as the right leg and mouth, to get ECG signals. An ECG ultimately displays what are referred to as leads. Leads are differential signals, which compare the difference in potential (voltage) between different points on the body. Waller's system ultimately created 10 leads between each of his 10 body positions.[8]

It was not until 1908 when Willem Einthoven, a Dutch doctor and physiologist, published a paper describing the electrode positions that we use today to acquire data for the limb leads on an ECG. These

[7] (Chen, et al., 2013)

[8] (Malmivuo & Plonsey, 1995)

three leads are appropriately named the *Einthoven Lead System*. The graphic below outlines Waller's lead system (A) as well as the modern Einthoven (B).[9]

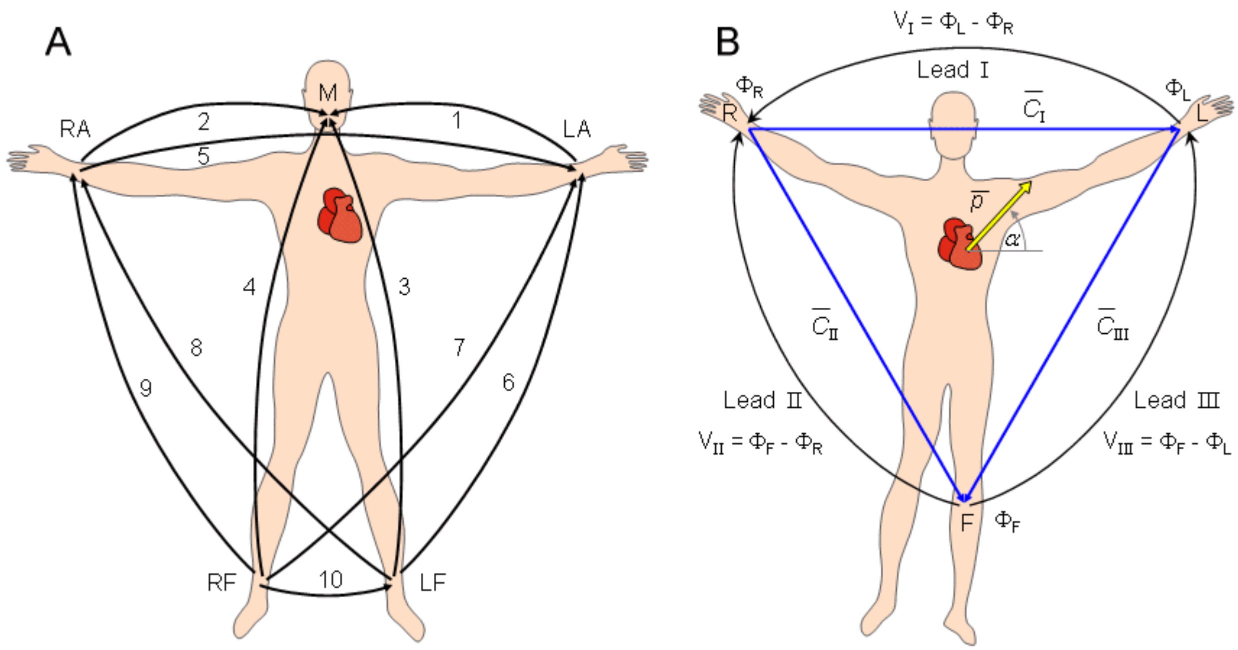

FIGURE 2 – 10-LEADS OF WALLER (A) AND EINTHOVEN LIMB LEADS (B)[10]

As can be seen in the above graphic, Einthoven's electrode placement defines the first three of our twelve-lead ECG system. Those first three leads, referred to as the limb leads, are Lead I, Lead II, and Lead III. The limb leads are defined as follows[11]:

$$\text{Lead I:} \qquad V_I = \Phi_L - \Phi_R \qquad (1)$$

$$\text{Lead II:} \qquad V_{II} = \Phi_F - \Phi_R \qquad (2)$$

$$\text{Lead III:} \qquad V_{III} = \Phi_F - \Phi_L \qquad (3)$$

In these equations, V_n, where n is the number of each respective lead, represents the differential voltage of lead *n* and ϕ_n represents the potential (voltage) at the electrode location on the skin. We can therefore deduce that, according to Kirchhoff's Voltage Law, V_I+V_{III} = V_{II}. Therefore, this means that only two of the three leads are independent. To form the remaining nine leads of the twelve-lead ECG, we have to use the average of the three limb electrodes to create the *Wilson Central Terminal (CT).*

Frank Norman Wilson, a professor of internal medicine at the University of Michigan, investigated how to define unipolar potentials on the ECG, since the limb leads are all bipolar. Although his work did not

[9] ibid

[10] ibid

[11] ibid

allow him to gather any information from any purely unipolar potentials, he ultimately developed the *Wilson Central Terminal* as a way to create pseudo-unipolar leads. In order to do this, three equal-size resistors are placed between each of the three limb electrodes and the central junction. As is shown in Figure 3, this terminal averages to a potential that, when considering the body as a plane, creates a triangulated point over the heart. This resistor network is outlined in Figure 3a where arbitrary resistor values shown.

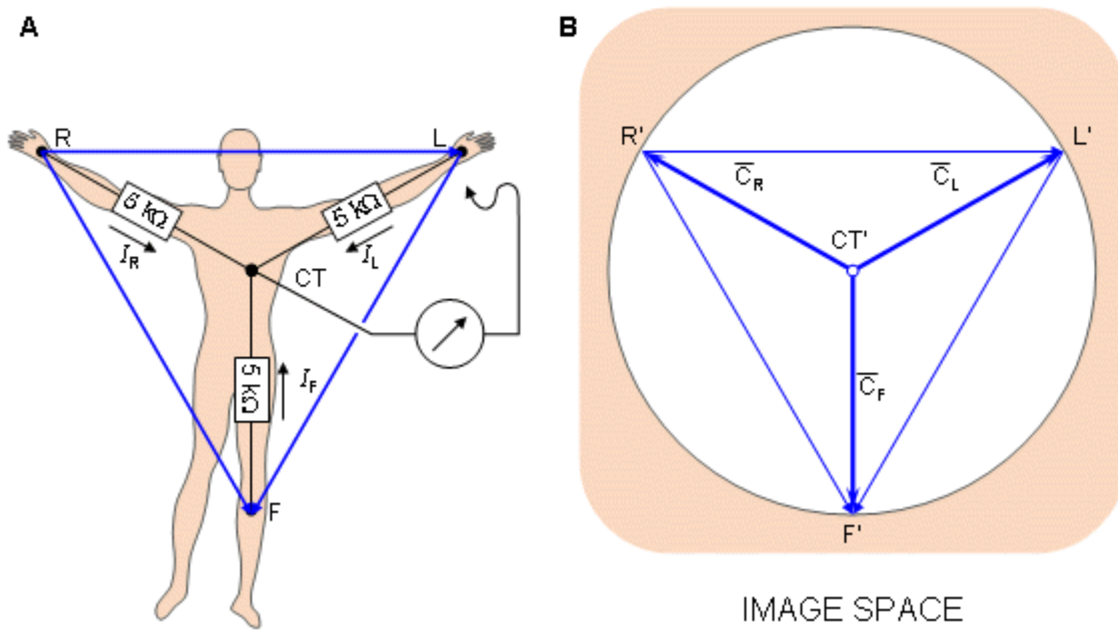

FIGURE 3 - WILSON CENTRAL TERMINAL[12]

Using this central point of potential, we are able to acquire both the three so-called *Goldberger Augmented Leads* and the six *Precordial Leads*. With these remaining nine leads, we have all twelve of the leads for our ECG. The Goldberger Augmented Leads are named in honor of Dr. Emanuel Goldberger, a Manhattan cardiologist and researcher, who discovered in 1942 that, by omitting one of the three resistors in the *Wilson Central Terminal*, one can create three additional leads which, due to the nature of their orientation, are considered unipolar augmented leads.[13] These additional three leads use the existing three limb leads to gain three additional perspectives on the heart's electrical activity, as noted in the first image below. In addition to creating the *Wilson Central Terminal,* Wilson added the six *Precordial Leads* in 1944, which added the final six perspectives provided by the modern twelve-lead ECG. These leads, named V_1, V_2, V_3, V_4, V_5, and V_6, are simply defined as the voltage differential between the *Wilson Central Terminal* and the respective *Precordial Lead*. These six leads, which are placed in order starting at both sides of the sternum and continuing to a position just between the mid-clavicular

[12] ibid

[13] (Emanuel Goldberger, Cardiologist, Dies at 81, 1993)

and mid-axillary lines, allow the ECG to see the electrical activity on the anterior and left-inferior sides of the heart.

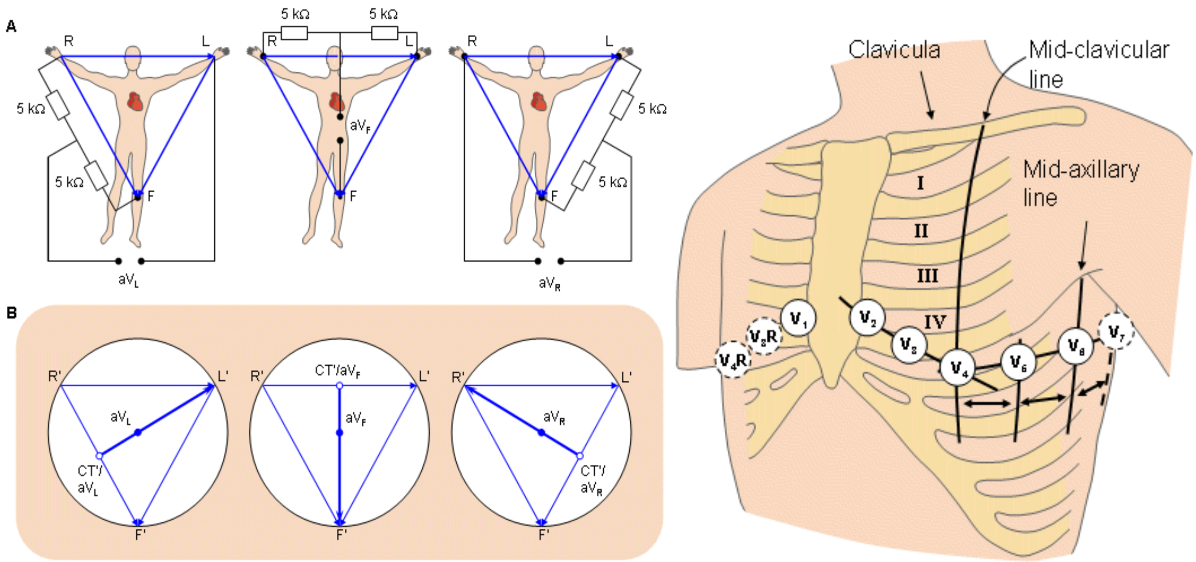

FIGURE 4 - GOLDBERGER AUGMENTED LEADS (A), THEIR LOCATION (B), AND PRECORDIAL LEAD PLACEMENT[14]

The twelve leads of the ECG ultimately grant the user the ability to obtain a three-dimensional electrostatic representation of the heart, which is illustrated in Figure 5. The following graphic helps to describe the perspective offered by all twelve leads. If we were to imagine a plane that was created along the vector of each lead and then were to follow an electrical impulse from the heart's Sinoatrial Node to the Atrioventricular Node through the Bundle of His to the Purkinje Fibers, the ECG would create a trace following this electrical impulse along that plane.

[14] (Malmivuo & Plonsey, 1995)

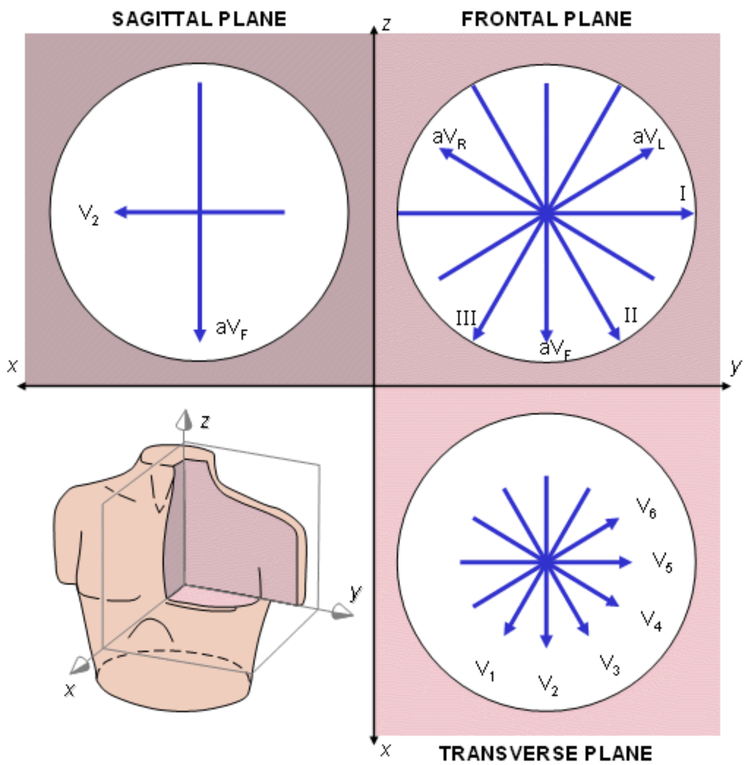

FIGURE 5 - PROJECTION SO THE 12 LEAD VECTORS[15]

2.2 – ECG Physiology

As was described at the end of the previous section, the ECG follows the electrical activity in the heart. Figure 6 outlines what we observe on an ECG for a normal sinus rhythm, the normal electrical activity in a properly functioning heart. The normal sinus rhythm is broken up into a number of waves, the most prominent are the P, Q, R, S, and T waves. U waves are typically not seen on the ECG. P waves signify atrial depolarization, the QRS complex signifies ventricular depolarization, and the T waves signify ventricular repolarization. Atrial depolarization is hidden behind the QRS complex. As can be seen in the graphic below, in order to get all of the necessary detail for an ECG, the analog system has to be able to detect voltage changes as small as approximately 0.1mV in the Q wave. Each wave on the ECG corresponds to a crucial phase of a heartbeat.

[15] ibid

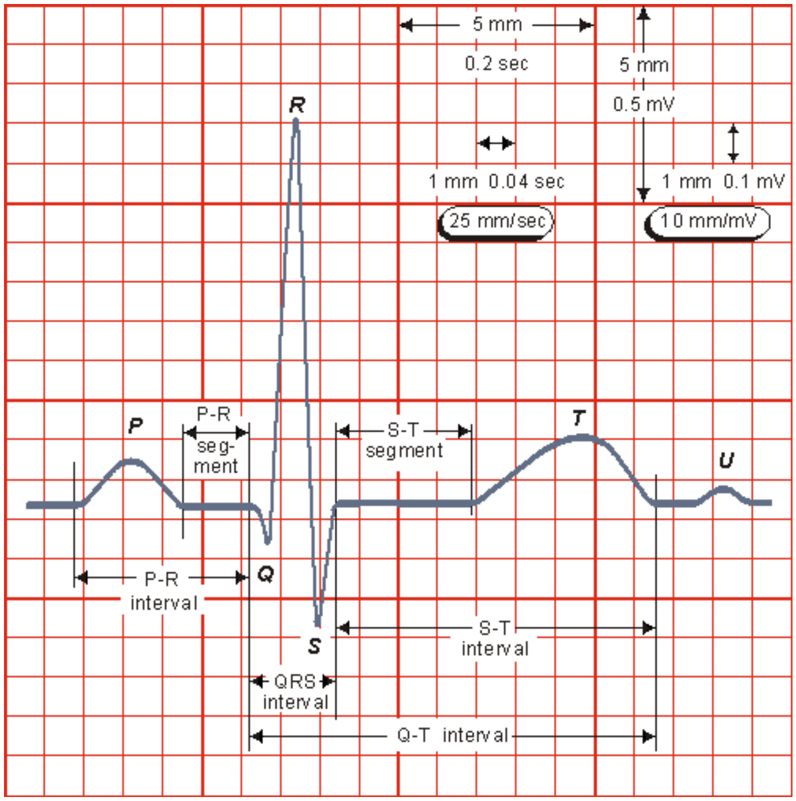

FIGURE 6 - NORMAL SINUS RHYTHM ON AN ECG[16]

When a heart beats, it is broken into a number of specific actions and phases. The action of the myocardium (cardiac muscle) contraction, and subsequently pumping blood out of the contracting chamber, is referred to as depolarization. The P wave is the result of the depolarization of the heart's atria. The Q, R, and S waves together are referred to as the QRS complex. The QRS complex signifies the depolarization of the heart's ventricles. The repolarization (or return to rest) of the heart's atria is hidden behind the electrical activity from the QRS complex. The T wave is the repolarization of the ventricles. As can be seen in the image above, there are a number of different time segments, which can be used by medical professionals to diagnose different conditions of the heart.

In order to generate these potentials through the heart, which lead to the heart's depolarization and subsequent repolarization, the heart has an electrical system that is shown in detail in Figure 7. The pacemaker of the heart, the Sinoatrial Node (SA node), creates the first electrical stimulus of the heart. This impulse travels through the atria, causing atrial depolarization, ultimately gathering again at the Atrioventricular Node (AV node). From here, the impulse gets sent down the Bundle of His and down the left and right bundle branches. At the bottom of the branches, the impulse is sent to the left and right ventricles. As the impulse passes through the conductive pathways, it causes the depolarization of the ventricles. Meanwhile, as the ventricles are contracting, the atria are repolarizing. After the ventricles contract, they slowly repolarize back to the state of rest.

[16] ibid

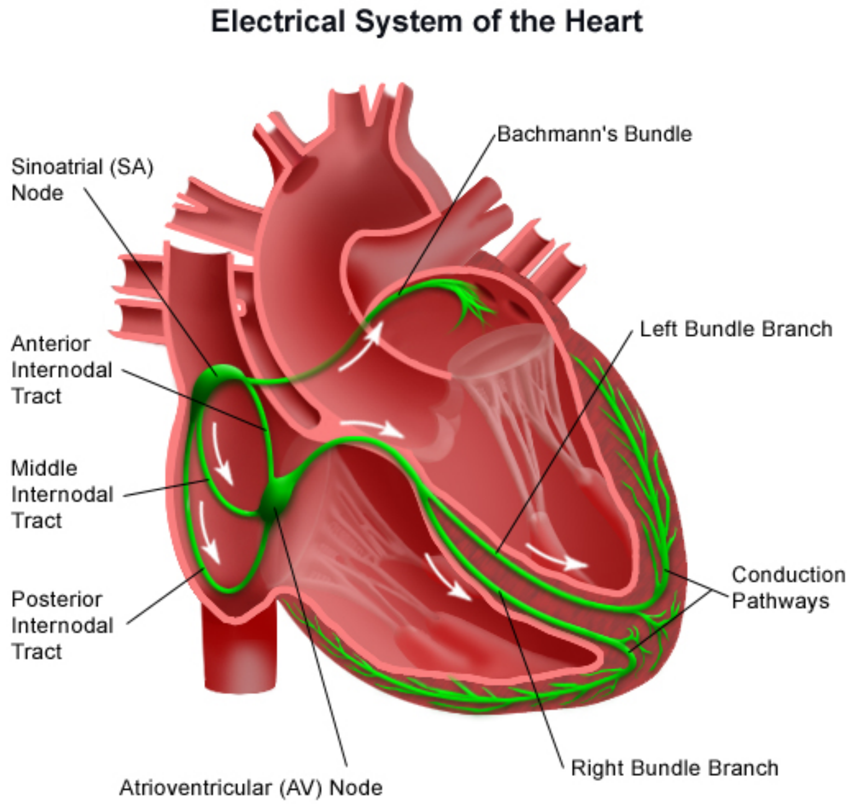

FIGURE 7 - ELECTRICAL CONDUCTION SYSTEM OF THE HEART[17]

Although the actions of the myocardium tissue described above are what we see in an ECG, there is a significantly greater amount of action occurring at the cellular level that leads to the ECG output. As the electrical impulse from the SA node travels through the heart, it is stimulating the myocardial cells. What actually happens during this stimulation is the activation of a sodium-potassium pump in the cells. As the myocardial cells conduct and then pass the signal along to adjacent cells, electrically stimulated sodium channels are being opened up. These fast sodium channels take in positive sodium ions (Na^+), which surround the cells at rest. Eventually, this rapid influx of positive sodium ions causes the depolarization of the cell to reach a threshold, causing the cellular action and contraction. The cell achieves depolarization because the potassium channels, which expel positive potassium ions (K^+) from the cell, are much slower than the sodium channels. This causes the depolarization to be drastically positive until the potassium ions are expelled. This rapid and large change in cellular charge is what creates the change in electrical potential on the ECG output.

[17] (University of Rochester Medical Center, 2015)

2.3 – Current ECG Technology

ECG technology, although all designed to accomplish the same objective, varies greatly between the hospital environment, the pre-hospital environment, and the home environment. In the hospital environment, there are large, expensive, powerful devices that can be used to get resting measurements and others that are designed for actives measurements, such as those done during a stress test. One example of these modern resting ECG machines is the Philips PageWriter TC70 16-lead ECG. This is a relatively expensive device with an MSRP of $9990, which incorporates a large cart and battery for hospital use. These ECGs allow for additional precordial leads for hospital use so as to diagnose right-side myocardial infarction involvement. Furthermore, they contain very powerful processors for advanced DSP that simply is not practical for use in the smaller, less expensive devices. However, these devices allow for database integration over Wi-Fi so that clinicians can easily access old ECGs. Although typically only 12-lead ECG, the active ECGs for stress tests typically cost more than the resting ECGs.[18]

In the pre-hospital environment, devices tend to get significantly more expensive. Although these devices tend to incorporate a number of additional features such as blood-oxygen saturation, carbon-dioxide concentration, automatic blood pressure monitors, biphasic defibrillators, and pacers, they typically lack the resolution of the hospital-grade equipment. These portable units are built extremely robust to take falls and physical damage in the pre-hospital environment. Despite their lack of accuracy compared to the hospital equipment, they are still accurate enough to provide life-saving differential diagnoses on patients in the field. These portable units typically cost between $10000 and $50000.[19]

In the wireless ECG environment, there are very few options that are available at the moment. There are a number of products currently available that are able to acquire a single-lead ECG and wireless transmit to a device to view, but there are few to none that are able to interface with a smartphone over Bluetooth. The only current example of a company trying to achieve a smartphone-based 12-lead ECG is Nimbleheart Inc. in California. However, none of their proposed products are currently market-ready. No pricing is presently available to serve as a reference. Despite being in this early state, the company is pursuing a FDA Class II certification for its device. The cost of this certification is expected to be extremely high and will likely exclude the medical device markets in developing countries due to exorbitant cost like most other devices currently available.[20]

Chapter 3 - Project Objectives

High-Level Architecture

In this project, we aim to create a novel architecture for an Android-based 12-lead ECG that is capable of streaming live ECG data to a smartphone with an accuracy that is comparable to that of a modern

[18] (Philips, 2015)

[19] (Physio-Control Inc., 2015)

[20] (Nimbleheart, 2015)

hospital-grade ECG. In order to do this, there are three major components to the overall architecture which are outlined in (INSERT) with their respective interfaces. The first and arguably most important is the ECG analog front end (AFE). This AFE will be responsible for acquiring all ECG signals in the analog realm in real time with tremendous accuracy. The second major part of the architecture is the embedded processor board. This board will be able to read in the 12 analog outputs from the AFE via analog-to-digital conversion at a rate that best preserves the resolution of the acquired lead signals. This board will then have to interface with a smartphone over Classic Bluetooth at a rate fast enough to keep the acquired signals real-time. Finally, a smartphone running the Android operating system will read in the data received through Bluetooth and display this data in real time on the phone's display.

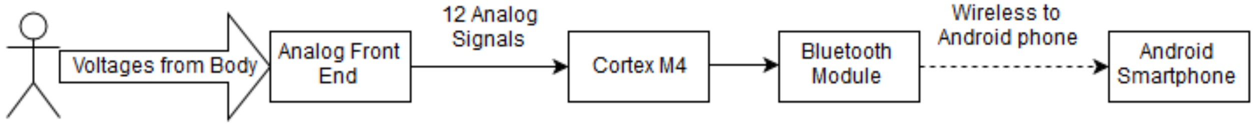

FIGURE 8 - HIGH LEVEL ARCHITECTURE

ECG Analog Front End Board

The analog front end of the device is the most crucial part of the system as this is responsible for the initial signal acquisition for the leads. As was discussed in a prior section, the signals that have to be acquired range from approximately 0.1mV to approximately 1mV. These are extremely small values so we will need to use medical-grade components. Typically speaking, most ECG systems use a total system gain of 1kV/V for each of the output leads. In order to achieve high accuracy, high gain, and high resolution, we will need to have to use the most accurate resistors for gain while using operational amplifiers with an input offset voltage on the order of picovolts. Texas Instruments makes a number of components that are specifically designed for this type of signal acquisition. Finally, another important aspect of the AFE board is the right-leg drive circuit. A RL-drive circuit is a feature commonly used in electrical medical instruments such as EEGs and ECGs to reduce noise and to set the common-mode ratio voltage of the body. This is a feedback loop that takes the average voltage from the acquired signals, offsets them to the median voltage of any ADC's voltage (2.5V in this case), and amplifies them at -38 to reduce the body's noise. We aim to keep the cost of this under $300 for a single board, not taking economies of scale into account. We will simply use an off-the-shelf set of electrodes to plug into the board.

Embedded Board and Bluetooth Connectivity

For our embedded board, we aim to read the 12 analog inputs through 12 unique analog-to-digital converters on a Cortex M4 processor into buffers with a resolution of at least 12-bit accuracy at a speed of at least 1MS/s. in order to give us the greatest level of flexibility since the AHA only requires us to sample at 500S/s for an ECG. These buffered inputs are transmitted into time-divided blocks over Classic Bluetooth using a Bluetooth capable expansion board to an Android smartphone. The smartphone will be running a bespoke application that is designed to read our data stream. This board, along with the AFE board, will run off a 5V lithium-ion rechargeable battery pack that can be charged over USB. This entire unit will be housed in a 3D printed enclosure. If money and time permit, we would like to create an all-inclusive printed circuit board (PCB) that contains the ARM processor, AFE for lead acquisition, and any wireless hardware.

Android Application

The Android smartphone application, as previously stated, will be the end-point for data acquisition. The app will be designed to take in a Bluetooth serial data stream, determine which lead it belongs to, and append it to the current display of real-time ECG data. The app will also be responsible for taking standard ECG time measurements such as ventricular rate, PR interval time, QRS duration, among others. The app will also be capable of "printing" out the ECG acquisition. It will look similar to the standard ECG output shown in Figure 9. This image will have the ability to be emailed to other physicians. There may have to be some research done in how to make this output HIPAA compliant. Given extra time, we may add in rhythm detection to detect rhythms such as atrial fibrillation, ST-Elevation Myocardial Infarctions (STEMIs), heart blocks, and more.

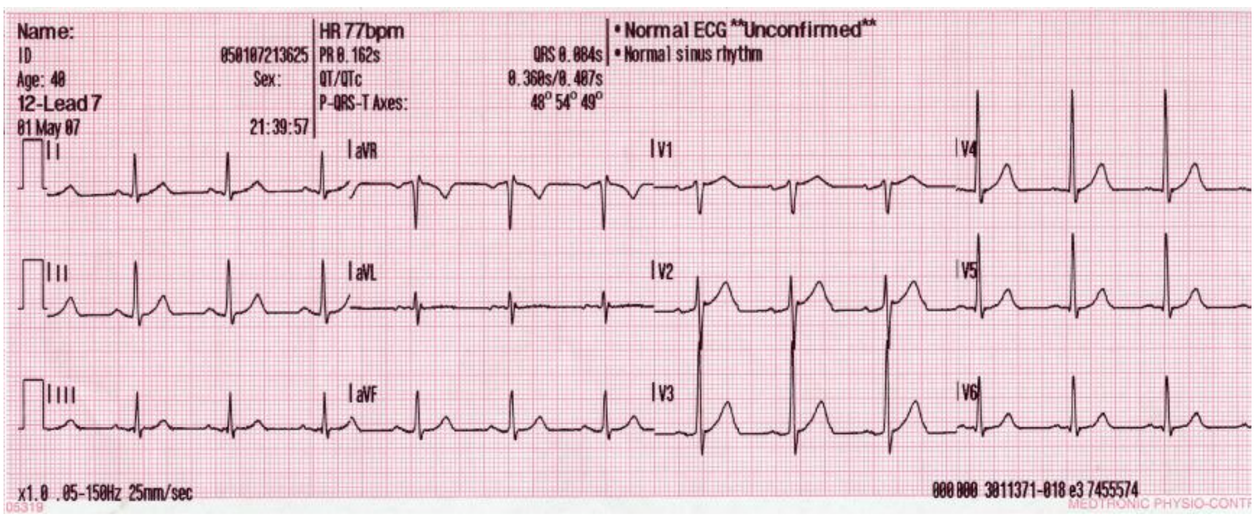

FIGURE 9 - TYPICAL OUTPUT OF A 12-LEAD ECG[21]

Chapter 4 - Approach

Step 1 – Background Electronics Research

Our design approach is straightforward. When creating our ECG circuit, we are relying on existing circuitry. Specifically, the circuit to acquire 12 ECG leads is widely published and a number of different component manufactures either make application specific IC's that output SPI for this purpose or make instrumentation amplifiers and operational amplifiers that are intended for use in ECG applications. As a design challenge, we are going to make the entire analog front end. As an initial reference, we based

[21] (Larson, 2014)

our 12-lead design on a single-lead, single-supply, very low power ECG circuit from the OPA333 data sheet, shown in Figure 10.[22]

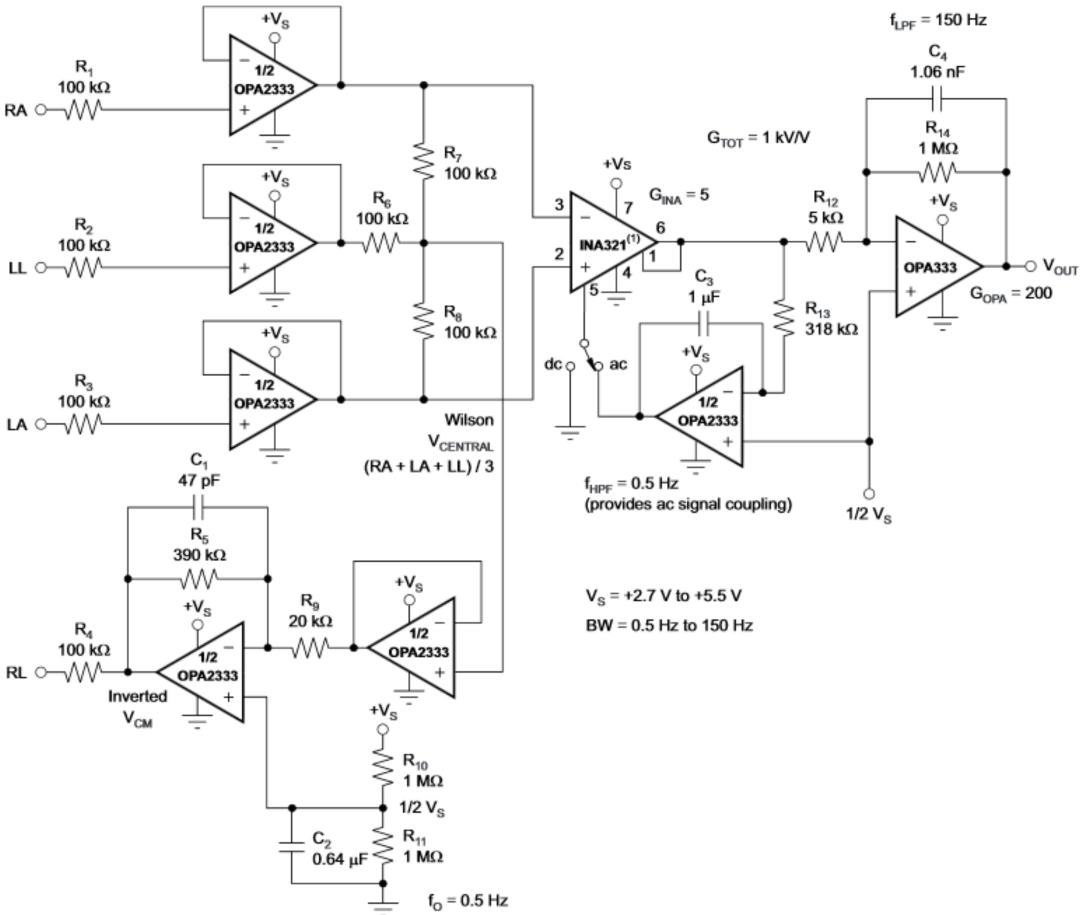

FIGURE 10 - SINGLE-SUPPLY, VERY LOW POWER, ECG CIRCUIT[23]

Step 2 – Expansion and Verification of the Analog Front End (AFE)

As can be seen in Figure 10, TI has generated a circuit for a single-lead ECG acquisition like those found in hospital bedside monitors. A single-lead ECG uses three sensing leads (RA, LA, LL) and compared two to create its single output lead. It also uses a right-leg drive circuit (RL) to set the common-mode voltage and reduce noise in the body. Using the knowledge we gained in pre-project research that can be found in our background section, we were able to appropriately expand this circuit to include all 12 ECG signals. The output stage is the same for each of the 12 output leads as this allows each output lead to have the same frequency response and. The difference lies mainly in the use of the correct input for the INA321 instrumentation amplifier. To verify this circuit, we use the analog analysis software Multisim to

[22] (Texas Instruments, 2013)

[23] (Texas Instruments, 2013)

confirm that the output of the circuit functions as anticipated and within the correct frequency response required for an accurate ECG (frequencies below 150Hz), as defined by the AHA.[24]

In order to achieve expected functionality from the analog front-end board outlined in Figure 10 - SINGLE-SUPPLY, VERY LOW POWER, ECG CIRCUIT through Figure 15, there needed to be some relatively simple hand analysis. The input buffers simply function such that $V_{in} = V_{out}$. The Wilson Central Terminal is a voltage averaging circuit of the limb-lead signals. V_{out} is defined as follows:

$$V_{out} = \frac{\frac{RA}{R1}+\frac{LL}{R2}+\frac{RA}{R3}}{\frac{1}{R1}+\frac{1}{R2}+\frac{1}{R3}} \tag{4}$$

The resistor values used in the averaging circuit are arbitrary. However, evenly averaging all three signals against one another requires that all three resistors be equal. For the ECG, we are using resistors of 100kΩ. As was defined above, the AHA recommends approximate frequency bandwidth of <150Hz to achieve correct ECG functionality. We achieve this using an active low-pass filter on the output amplifier stage of the ECG, which is shown in Figure 13. This is simply an RC circuit for which the analysis is shown as follows:

$$f_c = \frac{1}{2\pi RC} = \frac{1}{2\pi(1M\Omega)(1nF)} = 159Hz \tag{5}$$

As is shown here, the active low-pass filter used on the output will provide a cut-off frequency of 159Hz when using the resistor value of 1MΩ and the capacitor value of 1nF. This allows the device to meet the AHA guideline on frequency bandwidth. Most right-leg drive circuits also contain an active low-pass filter so that unnecessarily high frequencies are not driven back to the body when attempting to reduce noise. Our right-leg drive circuit's filter is defined as follows:

$$f_c = \frac{1}{2\pi RC} = \frac{1}{2\pi(390k\Omega)(47pF)} = 8.682kHz \tag{6}$$

This cutoff frequency allows reasonable noise reduction with filtering for abnormally high frequencies that do not need to be driven to the body. The final analysis determined what resistors to use to get the desired output gain of the output stage shown in Figure 13. It is important to note that the INA2321 has a default gain of 5, which means that the output gain that is set is multiplied by 5. In order to get desired ECG output, we needed a gain of 1000, or 1kV/V. The simulated output stage showing the simulated gain of 1000 is shown in Figure 14. This is shown as follows:

$$A_V = \frac{V_{out}}{V_{in}} = 5 * \frac{R2}{R1} = 5 * \frac{1M\Omega}{5k\Omega} = 1000V/V \tag{7}$$

Figure 15 shows that we have the expected active low-pass filter response with the knee positioned at 150Hz. Figure 11, Figure 13, and Figure 16 show our solution to generating inputs, creating the Wilson Central Terminal, generating outputs, and using the Right-Leg Drive circuit to reduce system noise and set the Common-Mode Ratio Voltage of the body to 0.5*Vcc. The input stage in Figure 9 involves using buffers to separate the High-Z impedance of the human body from the rest of the circuit. It also shows how the limb leads are combined, as previously defined, to create the Wilson Central Terminal. The output and amplification stage in Figure 10 shows us using an INA321 instrumentation amplifier and two OPA333 operational amplifiers to get our output signal, do active filtering on the output to meet our

[24] (Rijnbeek, Kors, & Witsenburg, 2001)

frequency response requirement, amplify the output with a gain of 1kV/V, and set the reference voltage to that of the body (currently 0.5*Vcc due to the RLD circuit). Finally, we can see how our right-leg drive circuit in Figure 11 uses two OPA333 operational amplifiers to buffer the output, invert the signal from the WCT, filter the signal to reduce noise, and set the common-mode ratio voltage of the body. This circuit was fabricated into a PCB for testing. As large-scale production (a run of 1000 or more), the cost of the analog front end hardware would only cost approximately $100 for a full turn-key system. This means that this analog front end is an extremely cost-effective method for ECG signal acquisition.

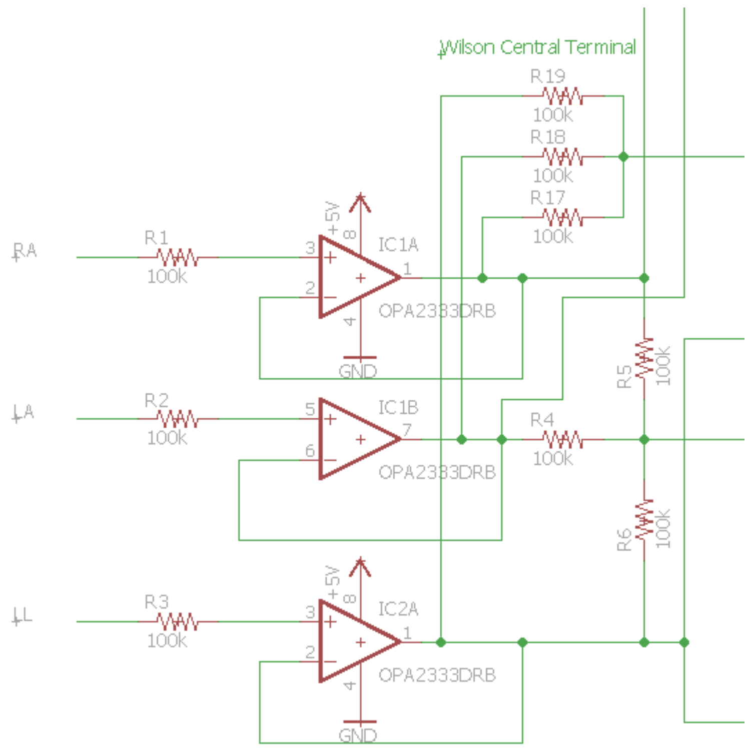

FIGURE 11 – INPUT BUFFERS AND WILSON CENTRAL TERMINAL

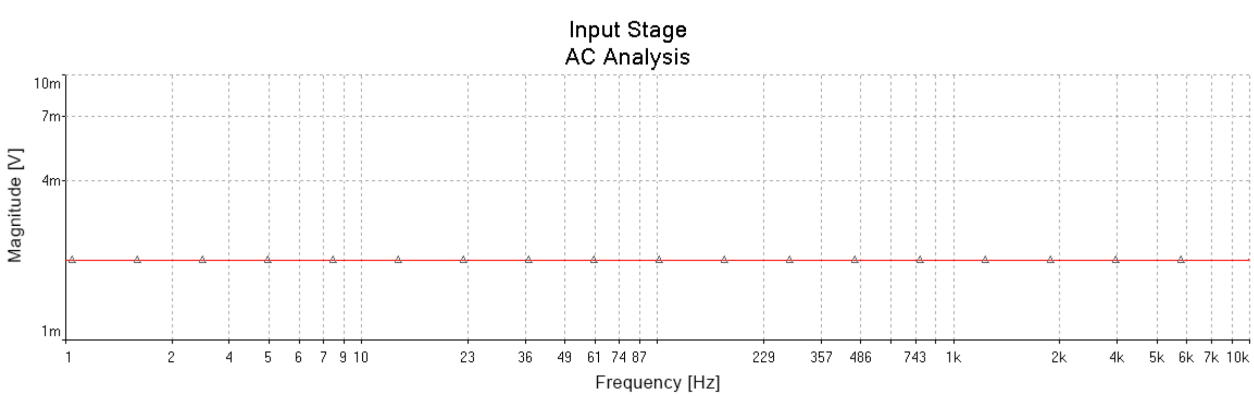

FIGURE 12 - INPUT BUFFER FREQUENCY RESPONSE

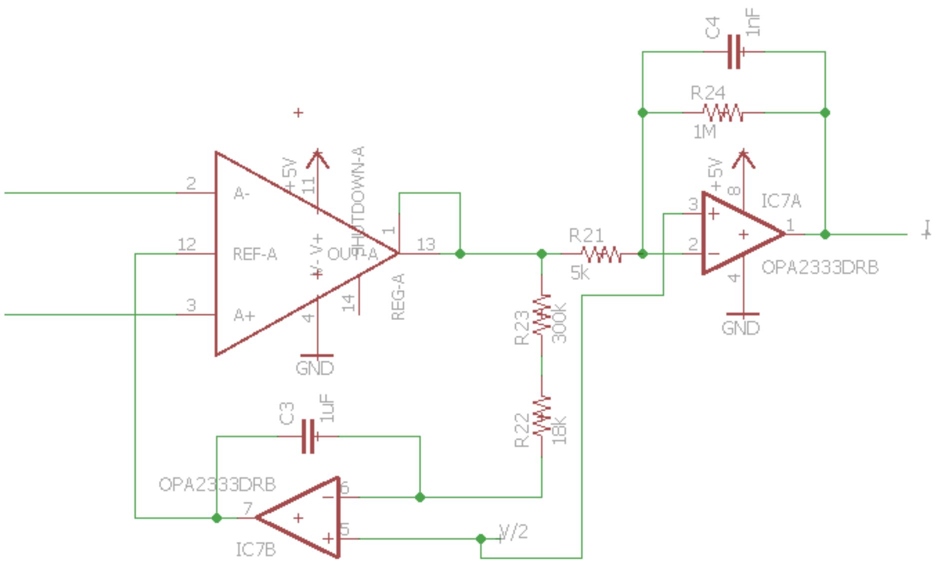

FIGURE 13 – OUTPUT STAGE WITH ACTIVE FILTERING

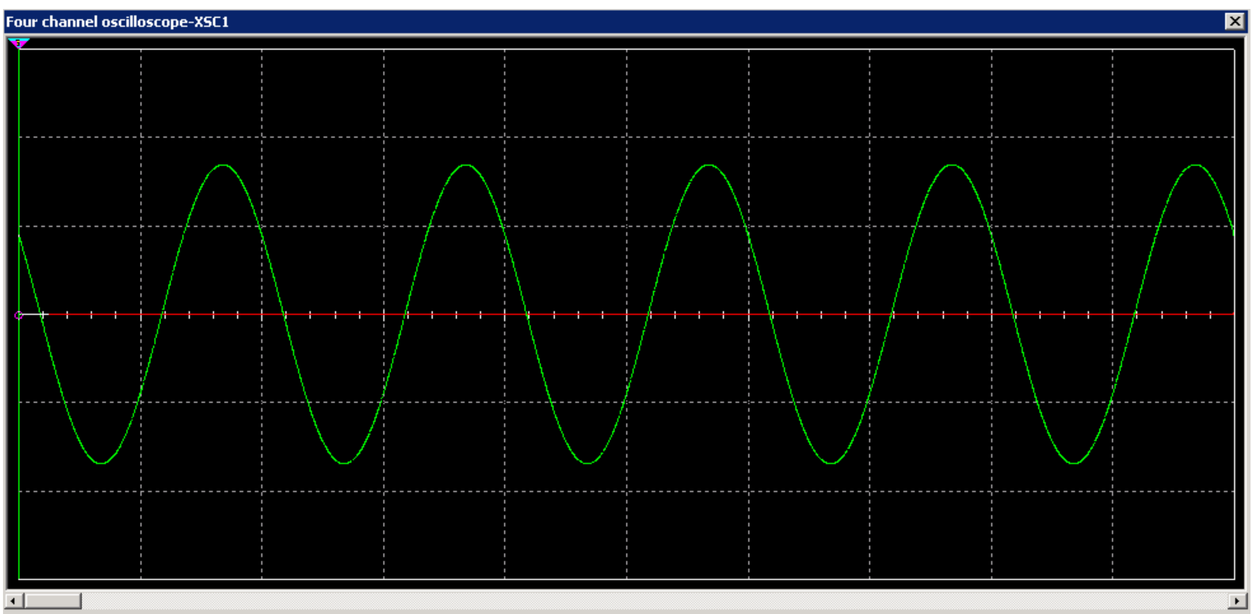

FIGURE 14 - SIMULATED OUTPUT FROM 1MV SINEWAVE @100HZ (500MV/DIV, 50MS/DIV)

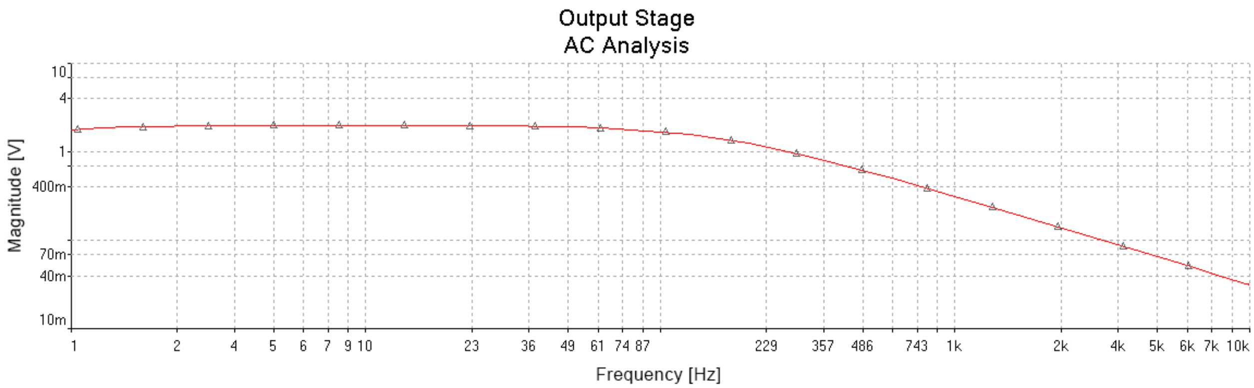

FIGURE 15 - OUTPUT STAGE FREQUENCY RESPONSE

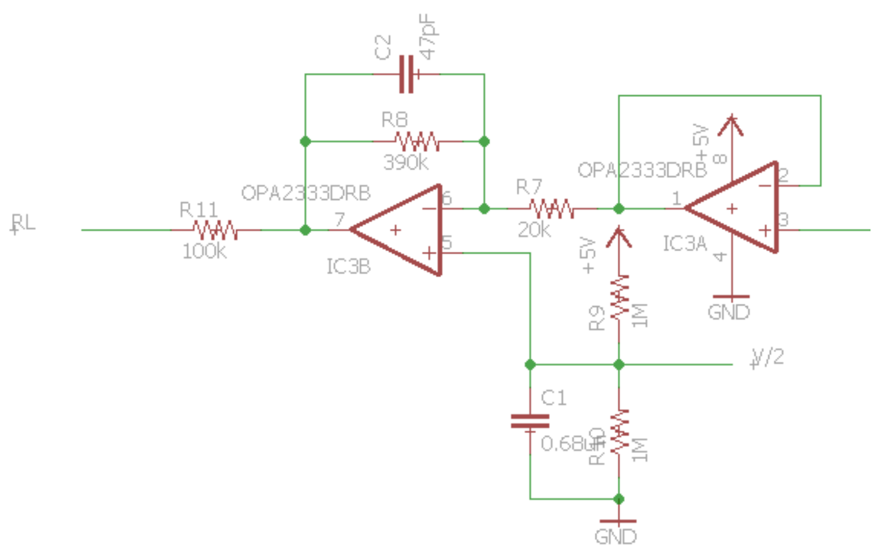

FIGURE 16 – RIGHT-LEG DRIVE CIRCUIT (RLD)

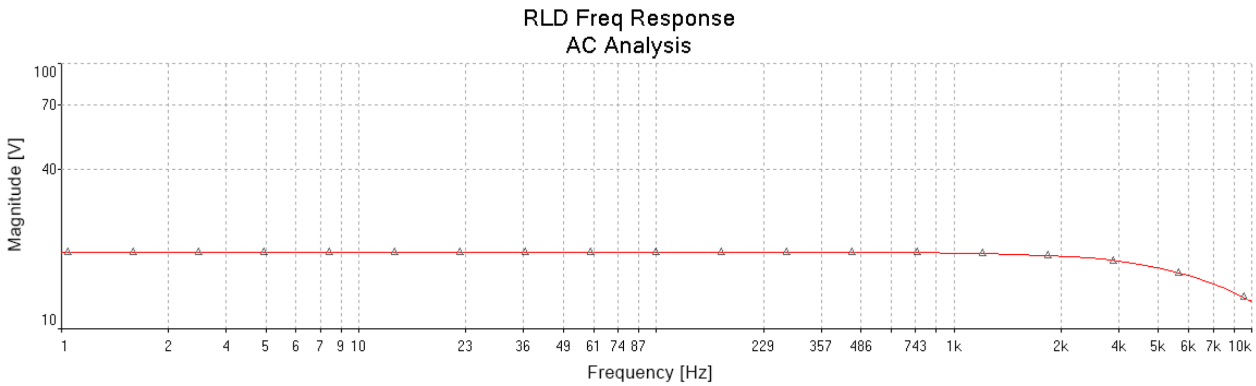

FIGURE 17 - RIGHT LEG DRIVE FREQUENCY RESPONSE

Step 4 – Embedded Software

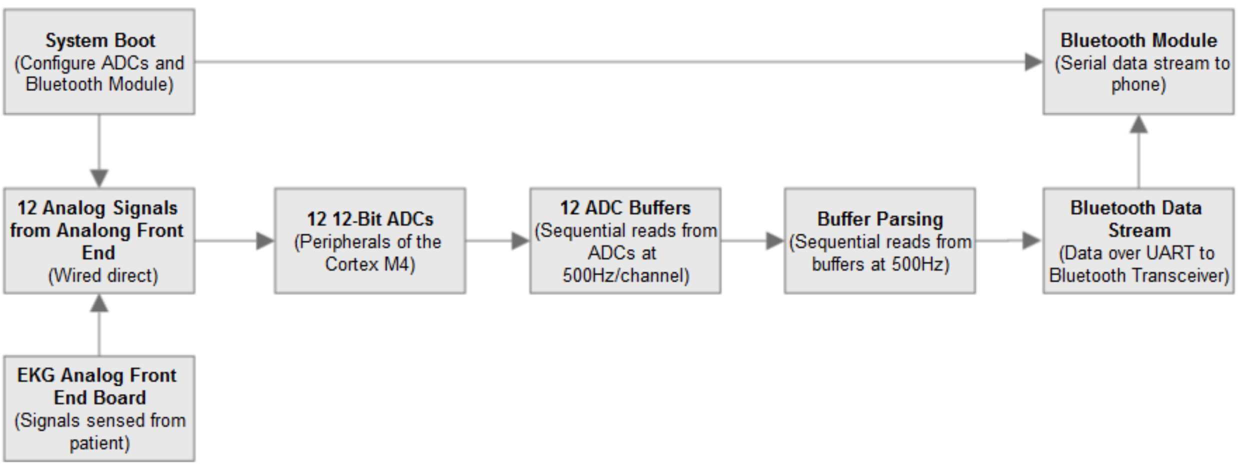

FIGURE 18 - EMBEDDED SOFTWARE DIAGRAM

For the embedded board, we will simply be using an ARM Cortex M4 evaluation board from Texas Instruments that has a sufficient number of analog input and processing power to acquire all 12 analog signals. The TM4C123G from Texas Instruments provides this functionality as well as a dedicated UART connection that is used to interface with out SparkFun Bluetooth module. Using these two boards together provides sufficient data acquisition, processing speed, and wireless output to achieve our desired results. Using the Bluetooth module, we use Bluetooth Serial (SPP), essentially a wireless serial connection, to an Android Phone for the data acquisition. Figure 18 shows a basic block diagram of the embedded software architecture. To comply with AHA recommendations, this system will need to transfer samples at 500Hz per lead.[25] This means a sampling rate of 6kS/s. Assuming that each sample is 12-bits in size, this means that the overall data rate would have to be 72kbps over Bluetooth to achieve the correct data stream on the smartphone.

[25] ibid

Step 5 – Android Development

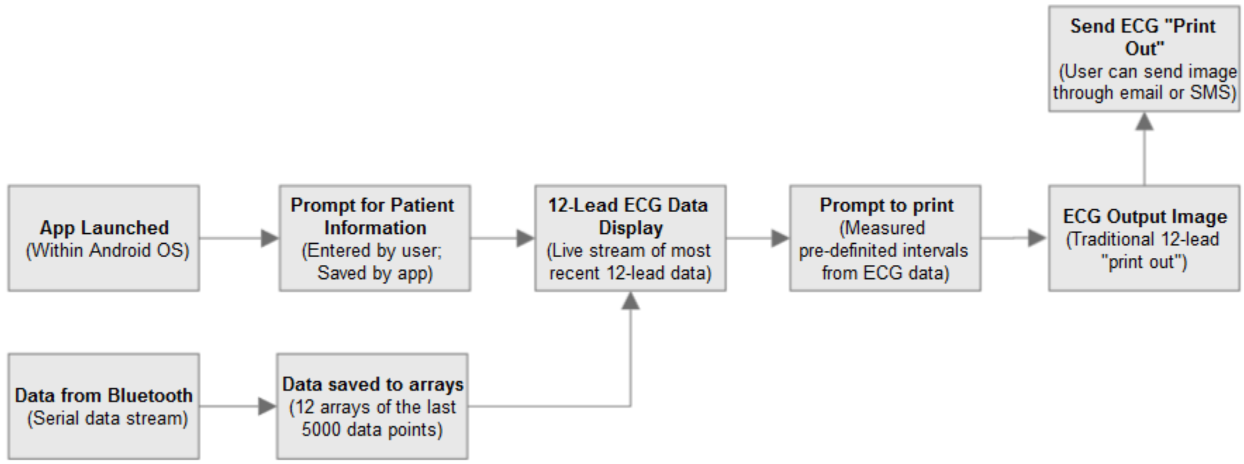

FIGURE 19 - ANDROID SOFTWARE FLOWCHART

For our application, we will be programming for Android using the Java programming language. Although we were initially going to use Bluetooth LE to communicate with an Apple iPhone, we quickly realized that Apple places a number of licensing restrictions for Bluetooth peripherals through their "Made for iPhone" program. We would have had to apply through the program and spend a large sum of money to get the appropriate licensing so, instead, we had to make the move to Android smartphones. Another factor was that Android has a very large market share of the smartphone market, especially in developing countries, so the switch from iPhone to Android had additional benefits and reasons along with the Bluetooth restrictions.

In order to meet all of the baseline requirements of a 12-lead ECG, a number of complex features were developed to meet the project goals. The first major challenge was developing software to give a live-display (cardiac monitor) of all 12 signals being acquired in real-time. In order to do this, data was received on the smartphone sequentially. Data that was stored in a 12-element array on the embedded software was sent to the phone over SPP Bluetooth sequentially as the phone requested samples. In order to comply with AHA regulations for data acquisition for ECGs, the smartphone requests a set of samples 500 times per second. When the data stream ends, the phone has received the entirely of the last sample, and can parse the data to the screen accordingly. Furthermore, the last 10 seconds of data for all 12 leads are stored in a buffer for the ECG "print out." In order to activate the printout, the user simply touches an on-screen button.

The most crucial element for functionality was to display the acquired ECG. Using Figure 9 as a guideline, the application displays the acquired ECG following the aforementioned convention. Additionally, the user is able to select which of the 12 leads should be shown across the bottom of the image (the 10-second-long rhythm strip). The last and most important part of the application's software was to add functionality to calculate the RR interval (heart rate), PR interval, QT interval, QTc interval, QRS duration, and axis. In modern digital 12-lead ECGs, the software combines the full 10-seconds of data for all 12 leads into a single “mega-lead” for rhythm analysis.[26] This allows the software to determine the average electrical activity from the entire acquisition. The next step was to determine the heart rate. A peak detection algorithm was developed which was able to distinguish R waves from any other data or noise in the signal. The internals were then used to determine heart rate. Using the R waves as reference, the algorithm then searches in both directions until the previous and next R waves to find any other ways in that space. Using more peak detection, the remainder of the intervals are acquired and their times converted to milliseconds. In order to determine axis, the algorithm deviates from the “mega-lead” and simply compares the magnitude of the peaks for Lead I and Lead aVF. The appropriate data is displayed in a conventional format on the ECG printout. All calculated values were compared with a conventional 12-lead ECG in order to determine clinical significance. Figure 20 shows an example 12-lead ECG printout from the Android application. Note that the electrode on V1 was coming off due to a poor application of adhesive on the off-the-shelf electrode. This does not effect the rest of the output.

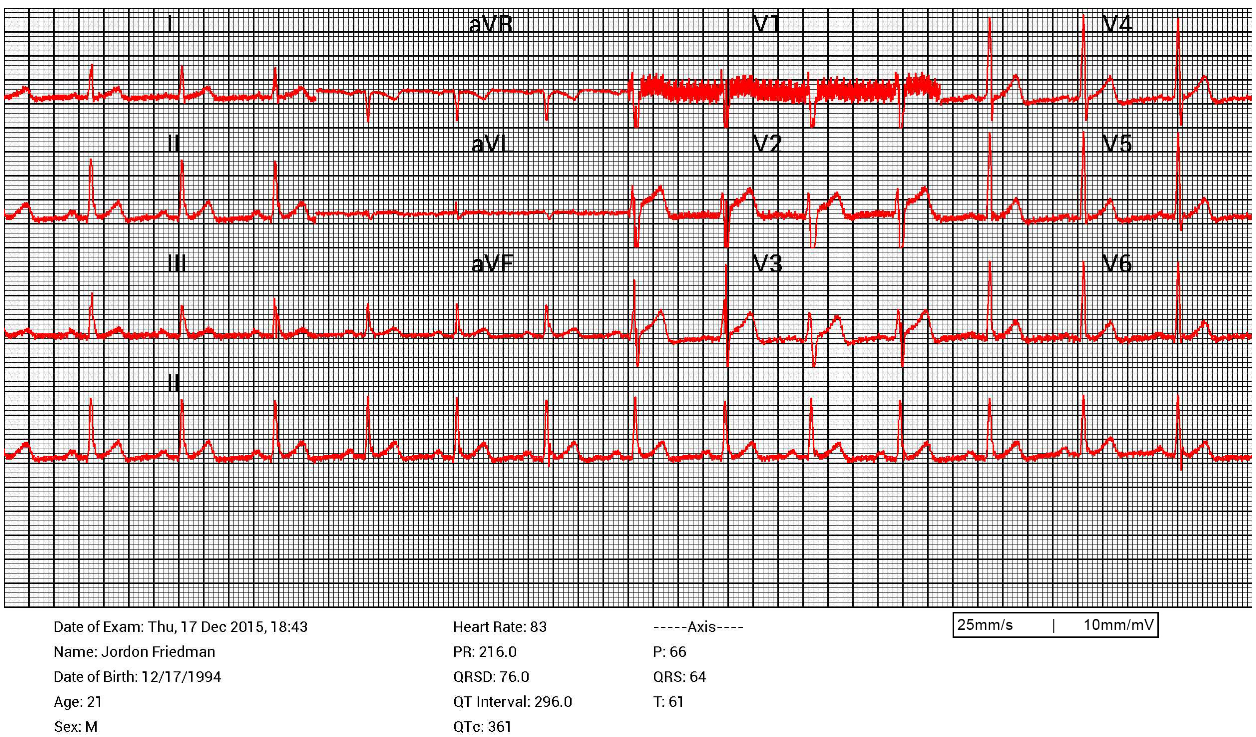

FIGURE 20 - SAMPLE 12-LEAD ECG OUTPUT

Step 6 – Functionality Test

In order to verify that the 12-lead ECG functions correctly in a clinical environment, we will have to create a functionality and testing plan. The group currently holds relationships with a number of cardiologists in the region who are interested in assisting in the testing process. Furthermore, the group currently possesses a professional 12-lead ECG to use to test equivalency. Before pursuing FDA approval for the device, we simply have to prove equivalency with pre-existing technology. Our possession of an ECG will make the verification significantly easier however the process takes a substantial amount of

[26] (Clifford, 2006)

time that will extend past the scope of this project. In order to test functionality, we plan to have professionals use the device to determine that it is providing them with all of the information that they need in order to do their job.

To verify functionality in lab, we will be able to take the ECG cable that would be attached to one of the group members, acquire an ECG from one device, plug it in to another, and acquire a second. Our acquisition should be equal in quality, if not better than the professional device. All calculated values for intervals should be equivalent as well. Printouts should look nearly identical. In order to finalize verification after the end of the project period, we will likely move on to in-depth clinical trials in order to test functionality on individuals presenting rhythms which are not simply healthy normal sinus.

Chapter 5 - Project Deliverables

Project deliverables are as follows:

- A working ECG analog front end board that successfully captures all 12 ECG leads with correct relative magnitude
- An embedded board with software to convert the analog signals to digital signals and transmit them wirelessly to an Android smartphone over Bluetooth
- A smartphone application designed to acquire the ECG lead signals over Bluetooth and display them in real time, as well as generate a "print-out" image.

Future development of this project includes creating a fully custom embedded board that matches the size constraints of the analog front end board for convenient placement into an enclosure. A prototype board has already been developed by the team, however there is significant debugging to be done until this can be considered a fully functional replacement for the solution that has already been implemented. Furthermore, the group intends to pursue a patent application and, after substantial development and clinical testing, FDA approval.

Chapter 7 - Conclusion

This project has shown to be an extremely viable proof-of-concept that a 12-lead ECG that is accurate, portable, and low-cost. Considering that retail costs can be as much as 10 times that of hardware costs, this would mean that our analog solution would cost $1000 or less. Considering that other products on the market cost well over $8000 do not meet the same level of functionality or convenience that our mobile-based product provides, we can confidently say that we have developed a cost-effective and accessible solution for a portable 12-lead ECG. With Bluetooth battery charging and the ability to use any Android-based smartphone with the device, this project has the ability to appeal to a great number of audiences in various markets (particularly those where cost of the device is a significant factor).

Although our requirements for proof-of-concept have been met, there are still a number of objectives to complete as we move forward outside of the scope of the MQP timeline. The group will continue developing and polishing the software functionality, as well as further iterating over the two PCB designs that are being used for the project. Furthermore, the device will be continually tested in order to verify functionality on a number of individuals to further solidify equivalency for potential FDA approval. Finally, with help of various resources, the group will be compiling a patent application to be submitted to the US Patenting office in order to protect and all intellectual property that has been tested and developed during the completion of the MQP.

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