Project µtu

California State University Sacramento
Department of Engineering & Computer Science

CPE190/EEE193A
Spring 2021
Senior Design
Professor Russ Tatro

Team 4

Thuong Nguyen
Manish Mishra
Ryan Smith
Brandon Steinlein
Travis Anderson

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EXECUTIVE SUMMARY

Elevator Pitch

Our project is to increase the accuracy, availability, and accessibility of data produced by electrocardiogram devices in a portable form.

Executive Summary

Our societies greatest death toll is due to cardiovascular diseases [1], and it keeps rising. This is due to the time it takes to diagnose using technologies that are unchanged relics. By utilizing modern technologies, we attempted to create a device to reduce the time to diagnose and save lives. This report details the rationale and development process to how this team created the device. Encapsulating the initial brainstorming process and suggested features with how we planned to address the problems, along with development and testing phases of the device. Within this report we include final features, budget, bill of materials, work breakdown structure, the project milestones, risk assessments, and our design philosophy as part of a comprehensive work.

The design idea of this project focused on several aspects of technical research into the various possible implementations of our device. In the beginning, we first looked at what key features we wanted to incorporate into the design. A major deciding factor was the one-year time constraint the team had to work with. Therefore, we narrowed the features down to a select few such as baseline-wandering elimination in real time, wireless connection to precordial leads from primary device, dry graphene-based electrodes, and portability. Each team member had been assigned a specific feature to conduct viability research and report on its implementation, prior to the selection of features. This was so as each member of the team investigated the feature assigned to them, they got the understanding of what is available to them in terms of hardware and software. An indirect result of this research was being able to see the limitations on what we had hoped to achieve initially in addressing the issues in existing electrocardiograms. This created clarity about what products to use to make our design functionable and narrowed down what each of us needed to research further before a physical design was created. We had felt that the features listed along with cloud connection and connection error handling could be achieved within the time constraint and managed to get quite a few of these features showing promising results.

In order to stay on track with the implementation of our selected features we established a method to structure the tasks surrounding the features in a work breakdown structure. Our project structure is simply divided into physical and software components. Within the work

breakdown structure this is further divided into manageable work packages that define the distinct features of our ECG device. The physical peripheral components can be rudimentarily defined as signal acquisition, filtering, and output. Brandon, Manish, and Ryan designed a torso-centric compression strap prototype with dry electrodes, analog signal filters, and algorithms for digital signal noise reduction. The software components, like the data processing software, user interface (GUI), and data storage were programmed by Travis and Thuong. The primary features of our project are defined to be Signal input, Movement Noise Filtering, Display data, Connectivity, Storage and Cloud connection. All of which are further defined in the work breakdown structure section of this report.

In order to balance the demand of the various work packages and tasks for the development of project µ-tu the team developed a project timeline. The project timeline shows the dates at which a task needed to be completed by, as well as predicted and actual times to completion that tasks within the work packages were completed by. This helped keep the team on track with the end goals of the project by providing flexible, internal deadlines. The flexibility of theses deadlines was crucial to the continued forward momentum of the project if something should delay the completion of a task.

It is for that reason that we have categorized the risks associated with our project into 4 subcategories and are classified by how detrimental to the project timeline each risk is. The lowest level of risk is classified as one which would delay the project by a couple of days. This could include a team member stuck in a task, for which a few extra days or more hands to help are required. Whereas the most severe of risks are classified as one that could place the project on hold due to unforeseen circumstances such as contracting Co-Vid 19 or trying to survive extreme societal turmoil.

The end product is to be evaluated for the current leakage testing. This test is to ensure that the device is not leaking any harmful amount of current to the patient. The testing protocols that we followed was the International Electrotechnical Commission 60601-1, which is the medical device safety standard.

ABSTRACT

Cardiovascular health conditions affect around 600,000 to 800,000 people in the United States each year. The primary diagnostic tool for cardiovascular conditions is the electrocardiogram (electrocardiogram or EKG). Electrocardiograms have been around since 1895 when Willem Einthoven invented the first device. However, these devices do have some issues that could be improved upon leading to better and faster diagnosis with better patient outcomes.

When designing a product there is a large phase of initial research that takes place. It is intended to identify the problem and find as many possible solutions as can be found or deduced. The solutions to the problems we have identified make up the array of features we wish to implement in the device, this is known as the feature set. The feature set selected was one of many, that included decisions such as whether to include machine learning techniques for atrial fibrillation detection or baseline wandering elimination. Therefore, based on criteria dictated by the powers that be and group decision making we centered our focus on signal input, movement noise filtering, data display, connectivity, and cloud-based storage connection as our feature set. The product is to be designed to take the electrocardiograph of the user for said user to view on a portable device, and to record continuous and real-time ECG signal data from the wearer. This data is then transferred to a cloud-based platform for storage and for further analysis by a physician or another qualified medical expert. The feature set was made with considerations to the unique skill sets present throughout the team. Therefore, the organization of tasks was arranged into a work breakdown structure to make use of the unique talents our team members have and facilitate a learning experience for any team member who was interested in learning about an aspect of the project.

The work breakdown structure was intended to give us a road map to the development phases of the project as we moved forward. Giving us the opportunity to estimate time to completion by dividing the necessary work into manageable work packs. Each work pack has a set of tasks assigned to one or more members of the team. These work packs reflect the feature set, so they include signal input, movement noise filtering, data displaying, connectivity, storage solutions, cloud integration, physical device implementation and prototyping, and course assignments. Each of these have subtasks that have a predicted total estimated time to completion of 430 hours (about 2 and a half weeks), as calculated in the Fall semester with eight remaining weeks left.

This was grossly underestimated as our total hours spent on project µ-tu was 639 hours (about 4 weeks) with 500 hours (about 3 weeks) towards only project tasks and the rest of the time spent on course assignments just in the sprint. In the spring semester this was added to, almost matching the hours worked on features from the fall at 664 hours (about 4 weeks). In addition to hours spent on course assignments this project totaled more than 2000 hours (about 2 and a half months). All of which were tracked and verified by use of a well-organized project timeline seen in the appendices.

The timeline is an integral part of organizing the progress of the project. It shows when the team expects tasks of the project to be started and completed by. This helps to ensure that tasks are not missed when accounting for the remaining time and that the team does not fall behind. The timeline also reinforces the Work Breakdown Structure by showing who will be working on what when. If deadlines are not met, then additional time or manpower can be applied to complete the project task on time. When deadlines are not met it can be due to any number of reasons. Because these setbacks occur, it is best to be proactive about planning for the unexpected delays. It was through a comprehensive risk assessment that we strategized out team's reactions to these setbacks. Risk Assessment is the forethought and analysis of potential issues that could arise while working on the project. These can include various levels of severity and are categorized as such. We address low, medium, high, and severe impact risks in this section for this. In addition to the severity of any potential risks, it is important to quantify the approximate probability of the risks occurring. It is likely that there will be scheduling conflicts amongst personal/school life and the project, while societal collapse and nuclear fallout are significantly less likely. In addition, the Risk Assessment includes potential plans of action to accommodate and work around whatever may interfere with the completion of the project.

Testing of the device was done for the current leakages testing following the International Electrotechnical Commission device testing standard for the medical devices 60601-1. The Current leakage test is to ensure the safety of the device as current above 2mA can be fatal to human beings.

***Keyword Index* – Cardiovascular Health, Electrocardiograms, wearable electrocardiogram, Internet of Things**

I. INTRODUCTION

Cardiovascular health conditions affect hundreds of thousands of people each year. About half of all people in the United States (47%) have at least 1 of 3 key risk factors for heart disease: high blood pressure, high cholesterol, and smoking [1]. Globally, cardiovascular disease is the leading cause of death among low to middle economically developed countries. Almost 25% of total deaths are caused by cardiovascular disease and by the year 2030 is projected to be the leading cause of death worldwide [2]. According to [3] Evidence shows that many of the Cardiovascular health conditions affecting people could be better diagnosed, managed, and prevented through continuous or more frequent monitoring of an individual's electrocardiograms.

Furthermore, [3] establishes issues related to current electrocardiogram technologies such as usability, data size, signal quality, durability, electrode/sensor type, data visualization and system integration. We believe that with modern technologies many of these challenges can be solved in an affordable way that can cater to low and middle economically developed countries by making it more affordable, and thus improving patient outcomes and quality of life worldwide.

The design idea of project μ-tu is an electrocardiogram that improves the user experience by incorporation of modern technologies to enable better signal quality, have the ability to store and view data in a centralized system of the device, as well as store historical data in cloud storage for the user or medical expert to view at later times. These modern technologies included in our designs are cloud-based storage, a six-input system-on-a-chip ECG, and graphene-based electrodes.

The graphene-based electrodes, in particular, provided much of the improvement to the signal input from the user. This is due to the low impedance characteristics of graphene, designs implemented in the compression strap and electrode padding. All together the combination creates enough delicate inward force and other benefits to reduce unwanted high impedance at the sensors and reduce skin irritation that is typically characteristic of standard dry electrodes. This makes the signal going through the system-on-a-chip more accurate which thus increases the quality of the signal output on the device. Furthermore, from the signal sent to the device from the electrode, the movement noise filtering methods allows for the elimination of baseline wandering giving a final improvement to the ECG signal even in the most stressful of diagnostic tests.

The electrocardiograph from the electrodes displays to the centralized handheld device for the user to view their data on. This data is also sent to cloud-based storage, via a wireless connection, to be viewed by the user or medical expert. Within this aspect of the system there is a backup protocol to store data locally in the event that wireless connection to the cloud storage is lost. This consideration was an essential addition to the storage of the user's historical ECG data.

Other considerations that lie just below the surface of our feature set include ease-of-use and portability. This is made to be intuitive and easy to use as it was created to facilitate usability in remote home monitoring for the chronically ill, suddenly ill, and health conscience users. With portability comes the issue of power and wireless connectivity. Both of which are needed to enable free range of movement without the hassle of wires and loss of data and were considered in the designs project µ-tu. For user interfacing, the device boasts touch screen controls that allow it to be turned on and off, change settings and display the user's real-time electrocardiograph.

In order to ensure these features of the design were addressed, the project was broken down into several milestones that reflect each feature in our feature set. In reaching one milestone after another we were able to track our trajectory and progress of the project. Each milestone consists of work packages that encapsulate multiple tasks that were projected to take a week to complete per.

Nonchronologically, the first milestone is signal input. It is arguably the most critical piece of our project because it is the primary function of an electrocardiogram to produce signals of the heart. The project is entirely based on the accuracy of input signals from the electrodes representing both the electrode input and the physical circuitry for filtering electromagnetic interference and noise. Therefore, its work package consists of electrode development and circuit design tasks. Where the circuit design tasks consisted of two iterations of higher order physical filtering circuits before reaching the deployable prototype stage of the project in Spring 2021. Electrode development tasks within the work package included researching and designing an improved dry electrode that incorporated graphene film.

Next milestone that we address, as part of the filtering process, is the movement-based artifact filtering milestone. This milestone is one of the primary improvements we attempted in this project and the feature involves an initial task to set up an accelerometer sensor that is used to detect body movement. Body movement is known to cause a type of artifacting known as baseline wandering. The task that follows uses the foundation of the prior task as a trigger to initiate a programmed algorithm to actively correct the artifacting ECG for the output to display and store. All together the tasks surrounding the development of this system included accelerometer setup, baseline wandering elimination algorithm, and system integration with the microcontroller.

To complete the third milestone, data display, the objective is to display the signal input from the electrodes onto a primary device. The objective is to develop an intuitive user experience through a well-designed graphical user interface as part of the device's communication to the user. Initial tasks were to display the heart rate and develop a device control interface. After these two initial development tasks we built an electrocardiogram wave display for the user to see.

The connectivity feature milestone gives the µ-tu device the ability to pass the data to a more powerful machine to do further analytics. This set of tasks are grouped by networking stack and cloud storage connection. The network stack work package tasks consist of tasks focused on how the systems of the project are configured to communicate with one another. In order to prepare for the possibility of connection loss, where the connectivity to the cloud storage fails, the first task in the work package incorporated a failsafe that uses onboard storage feature to store a finite amount of data until μ-tu has a valid connection to resume transmission of the user's data.

In conjunction, the cloud system milestone has work packages centered around the development of a cloud-based server that receives data from the device and stores it. This allows us to use an interface to display the data as well as gives other processes access to the data to do secondary analysis. It consists of database tasks such as database table formatting and device data transmission program development.

Lastly, the device milestone contains only one work package that focuses on the overall progress of the integration of our various systems that make up the physical device. Tasks such as power solutions, peripheral implementations, and testing are all addressed here.

All of these features are part of the whole device, which have had multiple iterations well before μ-tu's final release in Spring 2021. The first iteration's circuitry design was vastly different from the working prototype that was expected in December 2020. The work breakdown just described was parsed out to the team as follows. Signal input was handled by Ryan Smith, Thuong Nguyen, and Manish Mishra with Brandon Steinlein supporting development. Signal input work package time to complete is estimated at 75 hours (about 3 days). Movement noise filtering will be addressed by Brandon and Thuong with Travis Anderson supporting. Time to complete for this was estimated at 60 hours (about 2 and a half days). Another 60 hours (about 2 and a half days) to complete was estimated for the displaying of data (GUI) to be completed by Travis and Thuong with Brandon supporting. Travis assigned to the connectivity work package was given a tentative time to complete of 90 hours (about 4 days). Thuong and Travis address the onboard storage with a projected total time to complete of 75 hours (about 3 days). 45 hours (about 2 days) was allocated to Thuong for the cloud system feature. Brandon and Ryan, with Manish supporting, were estimated to accomplish the prototype device circuitry with a 25-hour allotment. Miscellaneous work was addressed as time permitted.

The work breakdown was written so that we had an overview of the project and its requirements. With the end of the fall semester approaching rapidly, time was a crucial resource. To keep the team organized we used the outlined milestones represented by the feature set referred to in the work breakdown structure to create a project timeline. The project timeline would be later updated to include possible delays and effects of those delays with contingency plans for the variety. These are further outlined in a risk assessment.

One of the most important aspects of designing a product is to assess the risks involved in the development and operation of the product. It is important to have contingency plans for a wide range of issues that may arise in the pursuit of bringing the product to market. Doing this allows the development team to keep moving the project forward in the event that one of these issues arises. When these issues arise, development teams must have mitigation plans and techniques in place to overcome them. To do this they must analyze the reliability of each feature the product promises through risk assessment.

Given the current circumstances with COVID-19, the need for our team's own risk assessment was dire. Due to the shelter in place orders and risk of infection, the school is almost entirely closed down with no way of accessing any of the laboratory equipment that would have made testing the developing product much easier. The risks outlined in this document are loosely based on this circumstance. To better comprehend the impacts of each risk they were divided into severity of impact to the project with LOW, MEDIUM, HIGH, and SEVERE severity on a 1 to 4 scale. Then subdivided into likelihood including Improbable, Possible, Probable, Likely, and Common on a 1 to 5 scale. If a risk is given a LOW impact rating, 1, with an improbable likelihood rating, 1, the effect of the risk is then 1 x 1 = 1. If a risk has a HIGH impact, 3, on the project and is Probable, 3, then the quantitative effect on the project is a 9. The most qualitative effect on the project is rated at 20 with the lowest being a 1. This rating system is outlined for visual pleasure in Tables IV and V. Along with each risk outlined in the tables we discuss mitigation strategies to keep the project moving forward with in this section.

In this section we discuss the low impact risks such as team member scheduling conflicts and testing software or hardware malfunctioning. Medium impact risks including build materials becoming unobtainable, sensor or component breakage, and when parts we ordered are delayed. We then discuss the higher impact risks such as hardware incompatibility and the event of complete loss of code. Which compared to the severe impact risks seem trivial. Some of the severe risks discussed in this section include the team or team members contracting COVID-19 and coffee shortages. All of these risks were prominent enough for us to discuss so the μ-tu team had the ability to prepare mitigation techniques to keep the project moving forward.

This project was embarked with the philosophy that cardiovascular diseases are one of the leading causes of death across the world, and the sole purpose of this project is to increase the reliability, accuracy and accessibility of the electrocardiogram data.

One of the most important aspect of an engineering project is to test the device. This to ensure the quality of the product, the safety of the device and to know and estimate the lifespan of the product. Since our device is a medical standard device, we followed the IEC 60601-1 testing protocol. The primary testing of the device was for the current leakage test. Current leakage is the primary reason for power loss in the devices as well a major safety concern. The testing of the device is to be done with the current leakage testing equipment that is loaned to us by Professor Smith at the Sac State. Since the lab access was impossible because of the bureaucratic paperwork, the testing is to be done at home of one of the teammates.

II. SOCIETAL PROBLEM

The costs of cardiovascular diseases.

Cardiovascular health has affected over 20 million people worldwide over the course of 20 years as seen in the figure below by the WHO.

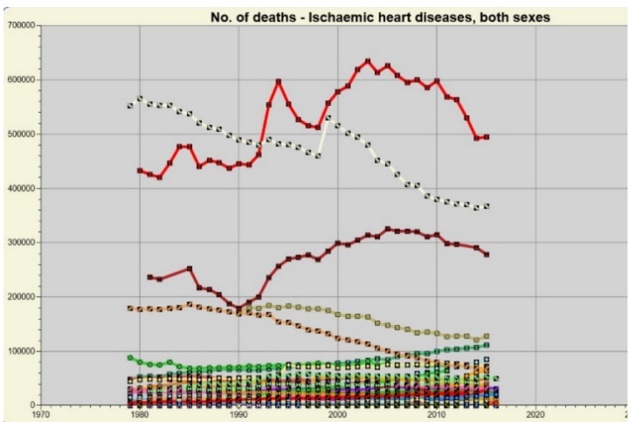

FIGURE 1: NUMBER OF DEATHS FROM ISCHEMIC HEART DISEASES BY COUNTRY PER YEAR [14]

From medical professionals in the intensive care unit to your everyday consumer, people everywhere are victims of cardiovascular disease. Some of these diseases are hard to diagnose, impossible to detect and even more difficult to treat. We looked at a cost analysis by [6] that shows how the cost of having a heart disease or stroke in 2015 directly and indirectly cost $351.3 billion nationwide and its only expected to grow to over $700 billion by 2035. Much of this is due to a plethora of issues with existing technologies centered around the electrocardiogram. Where we see the need for better quality and more affordable diagnostic equipment that will lead to better outcomes, reduce time from diagnosis to treatment, and increase accuracy of diagnosis all over the world.

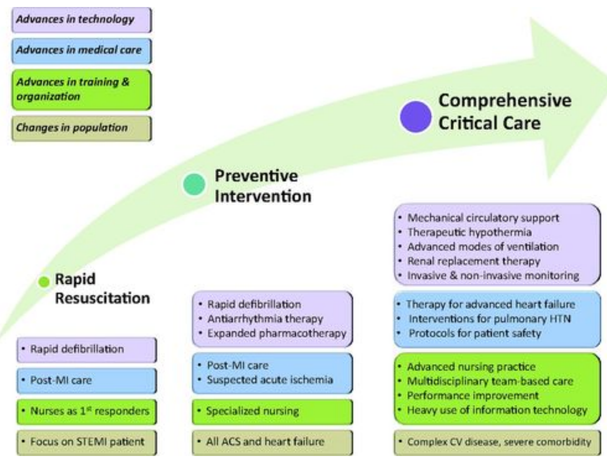

FIGURE 2: ADVANCEMENTS IN CARDIAC CARE ACROSS STAGES [9]

In this figure [9] show Advances in technology, medical care, critical care unit organization of a patient's critical level needed which led to increase in demand of medical demographics of general and cardiac critical care have evolved toward a patient population conditions who require more prolonged and more technology invasive support. As population of critical level patients increases more advances in technology are needed. An improved and more affordable diagnostic tool with increased accuracy of diagnosis can mitigate patients reaching the critical care stages.

One group affected by heart disease are athletes. One of the best ways to measure how well or poorly a workout is affecting your body is by knowing your heartbeat in real time. The idea behind this is to try and reach your target heart rate during a workout to maximize your workouts effectiveness. To do this one must perform a little arithmetic to calculate a rough estimate of your max heart rate by subtracting your age from 220. From there you get to guess because your target heartrate is between 50% to 80% of that max. Such a broad range can lead to a lot of error. A study to find the best way to find one's target heart rate was done by [8]. The research describes an exhaustive algorithm that cannot be implemented at home with much ease. However, given advancements in electrocardiogram technology it is possible to implement this algorithm in a compact device for athletes to use. The use of a device such as this can lead to less wasted workouts and even save a life. A study by [7] showed that the leading cause of deaths in athletes are cardiovascular diseases which always occur during exercise. Where the only initial symptoms of these deaths are possible unexplained fainting and a family history of sudden cardiac death. In order to be proactive against such tragedies an athlete or the athlete's primary care physician must be aware of their or their patient's natural heart rhythm. Knowing this natural rhythm is key to early detection. By being able to identify the norms in a person's unique electrocardiogram readout makes it significantly easier for the attending physician to identify the specific cardiovascular disease the athlete is experiencing in the event of a life-threatening emergency. However due to short falls in currently implemented machines there are issues with how well electrodes stick to a sweating moving person.

This leads to a more critical issue outlined by [4] is the problem of computer misinterpretation of the electrocardiogram due to inconsistent signals across a 12-signal electrocardiogram which led to a misdiagnosis of atrial fibrillation and many other cardiovascular diseases. However [4] did not specify what type of electrocardiogram device was used. But an in-person interview with a bay area emergency medical technician, Michael Roark, did elaborate on his everyday hands-on experience with a LIFEPAK 15 electrocardiogram, A 12-lead monitor/defibrillator. Roark describes during the interview that in several instances where while he was assessing a patient for a heart attack (also known as a STEMI) using the LIFEPAK 15, he did see the machine struggle to read the signals coming from the heart. He states that it seems not to know what heart rhythm to display when a patient is experiencing a cardiac abnormality. This is due to signal loss from the signal being received from the heart during these anomalies. This makes the electrocardiogram must pause and wait for an attempted regular rhythm to display. He says just seeing this only tells them as EMTs that something is wrong. Not what specifically is the issue. An improved electrocardiogram system can greatly reduce this issue because there are numerous cardiovascular heart diseases to look out for. Many of which can be mistaken for another during electrocardiogram analysis and can hinder the analyzing medical professional from making a treatment solution quickly.

The rate of change of premature deaths has been decreasing in recent years.

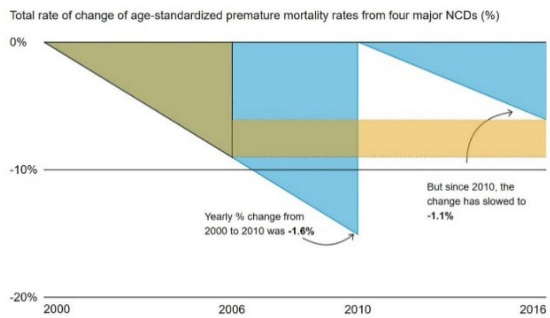

FIGURE 3: THE RATE OF CHANGE OF AGE-STANDARDIZED PREMATURE MORTALITY FROM FOUR MAJOR NON-COMMUNICABLE DISEASES [16]

Roark then goes on to say that if there were a way to get a person's electrocardiogram history it would greatly benefit the medical personnel trying to treat that patient because not everyone's heart beats to the same frequency, but this is not the only difference. Slight changes in electrical conductivity of the heart also make the ECG important for in diagnosis. What might be abnormal to one could be completely normal to another.

Another issue given by [5], the issue of real time data transfer to a care center by EMTs responding to an emergency cardiac event. The study found that a failure to transfer data lead to the delay of treatment because the patient was not exhibiting the same symptoms upon arrival to the care center.

This could be due to the EMTs forgetting to submit the data, or the data simply being incorrect from the patient moving or sweating enough for the electrodes to weaken contact with the body. This being a great shortfall of the most commonly used electrocardiogram machine.

The issue with the traditional electrocardiogram machine is that it only shows real time data while ignoring historical data. Historical data would be particularly useful for the elderly who are the primary victims of cardiovascular events as seen in the following figure.

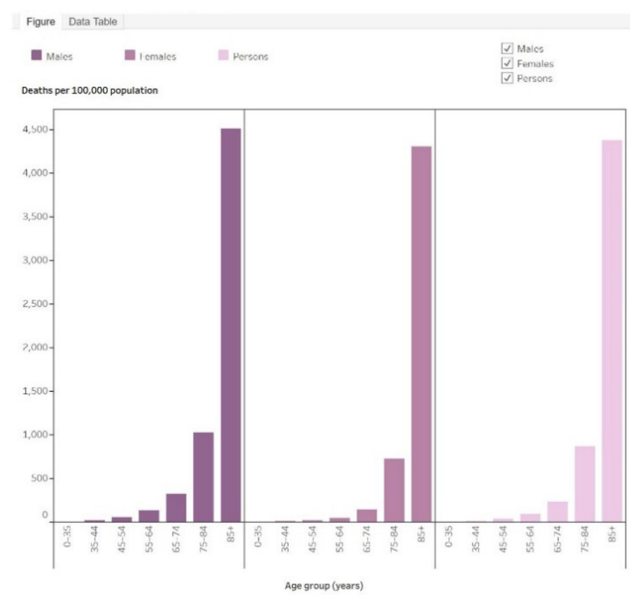

FIGURE 4: AUSTRALIAN CARDIOVASCULAR DEATHS BY AGE AND SEX [17]

As EMT Roark stated in his interview the ability to see this historical data would save precious time. A smart device connected to supporting cloud infrastructure could enable the storage of theoretically unlimited data. This is quite an improvement on the devices that do extended monitoring. These devices only record up to a certain amount of time (typically at or exceeding twenty-four hours) and are uncomfortable to wear. The electrodes may become less adhered to the body from rapid movement and perspiration resulting in signal deterioration.

An elegant solution to the signal deterioration due to movement or exercise can be accounted for by incorporating sensors other than electrodes to account for the signal noise produced by such movements [3].

These two ideas of cloud connectivity and signal correction can be encapsulated into signal collection pre-processing and post-processing. Pre-processing occurs on the smart device whereas post processing occurs on the cloud server. This can aid doctors in diagnosis by allowing analysis of real time data, collected raw data and results from artificial intelligence or algorithms ran on the collected raw data to help identify characteristic markers of the user’s electrocardiogram.

Existing technologies integrated into electrocardiogram devices will lead to better diagnostics and treatments for cardiovascular health conditions whether emergent or chronic.

Our proposed device would be focused on the emergent and high-risk chronic patients. In order to improve quality of life for those affected by cardiovascular diseases.

III. DESIGN IDEA

Our design idea is an electrocardiogram that incorporates modern technologies to enable better signal quality and the ability to store data in a centralized system separate from the electrocardiogram device.

Making the device easy to use and remote home monitoring enabled for our users is one of our highest priorities for project µ-tu. It is because of this that portability is a factor considered. With portability comes the issue of power and connectivity which both needed to enable portability.

The device incorporates a user interface that allows a user to turn it on and off, change settings and display the current real time electrocardiogram signal in its intuitive design. The centralized system has an authentication mechanism along with a visual aid to help view active and historical electrocardiogram data.

A. *Punch List*

TABLE I: PUNCH LIST

Feature	Measurable Metric
ECG signal input from electrode through digital/analog filters to STM32.	Using 7 dry electrodes. Electrocardiogram signals detected and are converted to digital binary with little to no difference seen from baseline signal while inducing electromagnetic noise from either fluorescent lights or close proximity to residential transmission power lines.
Program for filtering baseline wandering generated by movement.	Digital representation of signal is smoothed out with software to reduce the effects of normal body movement within a house environment such as walking, reaching, lifting small objects less than 100lbs. signal is also smoothed out for involuntary muscle twitch.
Display Data to User through Graphical User Interface.	**Functional feature test**: heartbeat is displayed to user using simulated data for the user interface. **End of project test**: heartbeat is displayed to the user using signals from the electrocardiogram signal input feature.
Internet Connectivity	**Functional feature test**: tested by connecting to 8.8.8.8, forced disconnect for error handling checking. Simulated data transferred to central system. **End of project test**: Data from MP157 actively transmitting to cloud centralized system. Error handling checked by making central system unavailable.
No connectivity local device storage	On connection error, data from software movement noise filtering is stored until the connection returns or until storage is full.
"cloud" centralized data processing and retention system	Historical data from the electrocardiogram device is stored in a remote database and can be displayed to a user.

B. *Addressing the Issue*

The primary issue we are trying to address is misdiagnosis caused by erroneous signals in electrocardiograms due to signal noise, also known as artifacts. There are four main types of artifacting in ECG signals: baseline wander, transmission line interference, electrode motion artifacts, and electromyographic (EMG) noise [20].

EMG noise is often caused by involuntary or voluntary muscle movement (muscle twitch) and body movement, or environmental factors such as being cold. These signals can be described as random and not easy to predict. However, what can be filtered out is done so by using signal analysis techniques like a moving average filter.

Other signal noise, such as transmission line interference, can be caused by electromagnetic fields present in the immediate vicinity of the ECG device. Most electromagnetic interference is systematic and predictable. This type of interference can be purified by use of a Finite Impulse Response (FIR) filter [20].

Baseline wander is different from EMG noise. Although both have artifacting that occurs due to the muscle, baseline wander physically raises and lowers the baseline of the signal up and down in amplitude. For this a FIR high-pass zero phase forward-backward filter with a cut-off frequency of 0.5Hz can be used to estimate and remove the artifact can be used [20].

Because of these different classes of noise, we propose both hardware and software solutions for noise detection and filtering. Hardware solutions being analog circuits such as low/high/band pass filters, and the software solution for noise filtering is slightly more complex. Our software solution incorporates other sensing devices in order to detect random noise generated by voluntary and involuntary body and muscle movement and invoke software centric countermeasures.

Another issue address is System Integration. System integration is the process of allowing multiple software systems, often from different vendors, to communicate and exchange data. The systems integration requirement will need internet connectivity to fulfil a system integration process and some supporting system software such as a database.

C. *User Interfacing: GUI and UX*

The user interfacing is the cornerstone of project µ-tu. The device itself is a new iteration on the existing electrocardiogram machines using modern technologies to help users see the active measurements taken of their heartbeat and full electrocardiograph data being recorded. Physical User Interfacing (PUI) and Graphical User Interfacing (GUI) are the aspects of this device that the user will spend the most time with. As part of the overall user interface system a display performs one of the most important rolls in the user experience (UX).

Our user interface design gives the user the ability to view their beats per minute (BPM) and electrocardiograph data simultaneously. The GUI plays a vital role in the success of a device or application. This is because of the UX metric outlined in [10] in which it states, "Usability and user experience (UX) are considered as key quality determinants of any product, system or service intended for human use." UX is the experience which includes every detail about the interaction between the user and the product from the feelings about it to how well they understand it.

As stated before, our GUI takes careful consideration to this metric in its straightforward design. In the beginning of this project our initial designs accounted for the inclusion of a combination of display and buttons, dial on the device to interact with the GUI on screen if our touch screen interface is unavailable. A physical mechanism such as a button will allow the user to command the functions in the GUI to open or close statistics, turn the power on or off and even make use of wireless connections. Other physical mechanisms like a dial will allow the user to navigate within the GUI using a button to initialize the selection process of a menu item within the GUI. The design idea included two buttons and a dial for interactions with µ-tu. The rough first draft of the mapping of which can be seen below:

TABLE II: POSSIBLE PHYSICAL MECHANISMS MAPPING

	Button Depression Timing			*Consecutive Depressions*		Combined Interactions		
						B1 & B2		B1+Dial scroll
Physical Mechanisms	<1 se	3 sec	>5 sec	2	4	3 sec	>5 sec	
Button 1 (B1)	Select/Enter	tba	tba	tba	tba	Wireless pairing	Power Off	tba
Button 2 (B2)	Menu/Open	tba	tba	tba	tba			tba
Dial (D)	Dial behavior is dependent on current GUI layer user is in							

For the final iteration we were confident in the abilities of the touch screen to handle all the UI (User Interface) needs and thus excluded the buttons.

In terms of reliability the GUI has measures in place to warn the user in the event an error has occurred in any other aspect of the device including the loss of electrocardiogram signal, inconsistent or erratic body movement that may affect electrocardiogram sensor data, system crash, and wireless connection disconnect. It is important, according to article [11] that the user be able to fix the error the message that has displayed. So, we will include helpful links/guides for the user follow to correct the errors.

D. *Connectivity*

Given the portability requirements of µ-tu, it uses Bluetooth connectivity from an STM32 to an STM32MP157 to transmit the raw ECG data to be processed by the more powerful STM32MP157 (MP157). The MP157 board is a MPU that runs Linux with a 32-bit Arm Dual Cortex-A7, a 32-bit Arm Cortex-M4 real-time coprocessor, a 3D GPU, Wi-Fi, Bluetooth, with a capacitive touch panel. This board was chosen for these features and especially the real-time coprocessing power is utilized by the µ-tu device.

Because the MP157 also has enabled Wi-Fi functionality, µ-tu is furthermore connected to a cloud-based storage. Here, data from the patient is stored and readily available to both the user and primary healthcare specialist in a centralized system. This is tested by a successful storage of data via a connection to the cloud storage. In the event of a connection loss the device stores all patient data it can until a time where connection is reestablished. To test this, a connection to 8.8.8.8 was established then forcefully disconnected. The result desired is to see a local storing of data commenced as a result. In the Spring iteration of this software feature, the test was successful.

Given information technology security requirements of hospital settings and our intended dual remote monitoring and home use, security measures were considered when first discussing wireless connections. These measures are certainly needed, but not necessarily required for a prototype. Thus, our final iteration does not utilize any security features.

E. *System Integration*

For the centralized system we are not implementing a full feature supporting software. Most common types of centralized systems are web applications with supporting software such as databases and web service application programming interfaces for 3rd party vendor software integration. For our centralized system we built a visual aid that queries historical data from a database, which contains recorded data from the device. In the fall we debated that given the amount of data that may be fed to the database from continuous monitoring a NoSQL database may be the best option for future implementations.

For proof of concept of the ability to support 3rd party vendor software integration a minimized application programming interface may be provided which is typically the demarcation point between 3rd party vendor software and an inhouse system.

F. *Data Acquisition*

1) Signal Processing- Software

There are many different software techniques for noise detection and reduction. Some of the more traditional techniques are models like the Fast Fourier Transformation, which by its nature of representing the signal is a sum of frequency sine and cosine waves that allows us to select parts of the signal that we believe to be noise and remove it from the model. This model works well for repetitive systematic noise but may require some adaptation for random non-periodic noise.

Current areas of research focus on noise reduction using machine learning techniques. One solution was using recurrent neural networks for activity prediction in electrocardiogram signals [3].

In the Fall semester, for the first iteration of the digital filtering software, we utilized Simulink function blocks to be ported to the STM32 in C++ for digital analysis of user ECG data before display and output to cloud storage. These function blocks contained a bandpass filter, differentiator, moving average filter, and QRS Detection for finding the peak, threshold, and heartrate. The plan for the spring was to bring this to the MP157 in the same way and incorporate the proposed baseline wandering elimination algorithm to it.

The next iteration of the signal processing software in the Spring semester was halted due to unforeseen circumstances. The planned baseline wandering elimination algorithm was put on hold and then indefinitely suspended. For the final iteration of the device the idea was entirely left out to meet the deadlines adhered to the project. Future development of the algorithm would include an FIR high-pass zero phase f/b filter with a cut-off frequency of 0.5Hz in order to estimate the baseline wander and remove it from the signal. The cut-off frequency of 0.5Hz is choses due to it being within the range of the baseline wandering frequency.

The process to implement this method would be through a MATLAB ported function to the MP157. In order to make use of the function at times when baseline wandering would be present, we would incorporate the use of an accelerometer sensor to act as a switch that triggers the function to perform purification of the signal. The accelerometer data would also be measured for frequency to determine the frequency of movement and therefore frequency of the baseline wander. This value is then passed to the baseline wander elimination function to adjust the cut-off frequency of the FIR filter.

2) Hardware Signal Processing

The hardware part of the solution for the elimination of baseline wandering includes the use of a triaxial accelerometer. We deduced that we could take positional data readings from various points on the body using gyroscope/accelerometer sensors and apply a mathematical solution via an algorithm to extrapolate a cleaner signal without the noise produced by the movement. The general idea is to use the FIR filter discussed earlier with the ability to allow for the adjustment of the cut-off frequency and take the correlated XYZ data from the accelerometer to actively clean up the signal by adjusting the cut-off to match the movement frequency.

As per [12] acquisition and analysis of the various kinds of noises that affect the electrocardiogram signals can be classified into three distinct categories. Those categories are Baseline Wander, Muscle Tremor Artifact, Additive White Gaussian Noises. Almost all these noises can be filtered out using some type of hardware filter scheme that includes high, low and band pass filters.

Muscle tremor artifact is a major issue in signal processing of ECG signals. A study done by [15] gives some insight as to how it is possible to detect this category of ECG noise. Muscle tremor artifacting is the result of both involuntary and voluntary movement that creates separation of the electrode from the skin or if the electrode is sensitive enough it can catch the movement in the ECG data in the form of noise. This noise destabilizes the ECG signal and produces inaccurate readings. This is where the analog filtering components come into play as setting certain cutoff values through the operational amplifiers go a long way to produce a clean signal. This type of hardware could be developed to utilize tiny-OS, a real-time operating system, so the device can be integrated into the rest of the hardware hierarchy in later development of the project.

The ADS1293 ECG system-on-a-chip provides all of these filters. Including an instrumentation amplifier (INA) and a sigma-delta modulator (SDM). The INA has a gain of 3.5 making the maximum differential input voltage ±400mV. The purpose of the sigma-delta modulator is to convert the output signal from the INA into a high-resolution bit stream that is then processes by the onboard digital filters. These digital filters are all programmable and are integrated into the ADS1293 system to reconstruct the digital signal from the SDM. They each consist of three stages of filters where each stage is a 5th order SINC filter. These stages are responsible for filtering and decimating the output SDM signal by working to reduce the output data rate (ODR) and bandwidth of signals are reduced while at the same time enhancing the resolution of the discrete signals. By the time the signal reaches the third stage it has become a 24-bit digital signal requiring no further filtering.

G. *Measurable Metrics and Unique Features*

1) GUI and UX measurable metrics

In terms of the integrated display the goals are to have the ability to display the correct information, and have no issues with screen tearing, blackouts, frame drops, or power consumption issues.

The display working and showing the correct information is contingent on the video driver being used. It must be matched by part number of the screen and the compatibility of the video driver with the display and computing electronic such as a microcontroller or single-cycle computer or even FPGA + microcontroller combo. We should be able to test this in a visual sense by observing that the display works with the animations of the GUI and how well it displays the image (image quality) and if we are getting the refresh rate, brightness, aspect ratio, resolution, etc.

The goals for the GUI are mostly survey based since according to [10], in order to measure the success of a GUI you need to have people test it and fill out a quick survey grading its effectiveness, efficiency, learnability, and satisfaction. All of which are based off the hedonic and pragmatic qualities outlined in the article. These are defined as such in the figure below:

- Pragmatic attribute (we call it pragmatic perception) means the ability of the product to provide user with task-related needs and behavioural goals (usability).
- Hedonic attribute (we call it hedonic perception) means the ability of the product to provide user with needs that are not task-related (identification and stimulation).

FIGURE 6: "FROM USABILITY TO USER EXPERIENCE" ARTICLE [15]

The goal being it is easy to use and intuitive for everyday users, is the UX in a desirable range based on the surveys of test users and to have the right amount of time allotted to interaction and animation so the user feels like the GUI is the right amount of responsive. The latter can be measured by timing the loading, button press to action time, transition, or response animation length, etc.

In order to measure the accuracy of the acquired ECG data we will need to establish a baseline ECG data set to compare to our device. This can be achieved by using and existing ECG system that provides the ideal waveform signal generation we wish to achieve with our own design, this includes the metric for positional data that affects signal clarity. The goal being to match high end standalone ECG devices implemented in hospital settings.

2) Connectivity measurable metric

Sending data via wireless connectivity through system integration can be measured by the ability for our system to send its acquired data to an off-site cloud database. If transfer is successful, we should be able to see the data recorded by our device in a web browser accessing the database or other available database structure. The goal being to succeed in transferring and accessing historical ECG data taken by the device on the user. We also want all other possible IoT (Internet of Things) devices to be able to communicate with the master device (MP157). This is measurable by verifying that the expected signal is transferring quickly and efficiently to the MP157 from the STM32.

3) On the market comparisons

In comparison to other products on the market we discovered a device that boasts similar features in a portable form factor like ours. The Wellue Checkme Pro [13] is an all-in-one solution for mobile medical use. The features it lists are infrared thermometer, ECG/EKG Holter, mini monitor display, sleep monitoring, pedometer, O2 checker, NIBP, Calendar+ Reminder function. It is a portable touch screen device that has supporting PC software and mobile phone apps to help with record tracking and has the FDA (Food and Drug Administration) and CE approval with the ability to set up multiple user accounts for one device. Essentially everything we wish for the device we are designing to do. However, we were not planning to implement a temperature reader or SpO2 reader.

A closer look at the ECG/EKG monitoring process they depict is comparably interesting. In terms of connectivity, both devices are using Wi-Fi and Bluetooth. However, we have two separate parts of the device. The electrode fitted chest strap and the handheld device which is where the Bluetooth communication is utilized, and the Wellue simply uses a single device with wires to the leads.

Also, like the Wellue, µ-tu allows for larger storage of data from continuous monitoring beyond 48hours (about 2 days) to an almost indefinite length of time by utilizing an off-site cloud database that will analyze and create a living template of the user's baseline ECG data.

The Wellue uses only a lead II or lead I system with traditional wet electrodes to get up to 3 EKG signals. We are not interested in knowing the minimal way we can take ECG readings per electrode count for this project. Because we want the µ-tu device to be intuitive to use and take on and off. The adjustments in lead configuration are not conducive to an easy-to-use device. Therefore, we are using a 6-lead system that uses dry electrodes with the lead configuration already preset and not wired like this device. With respect to signal processing, μ-tu performs a higher quality signal clean-up and the added baseline wander elimination in real time.

But all-in-all, this is a remarkably similar device that could be mistaken as our inspiration for our small wearable device, but we will be improving it where it matters with modern technologies. The improvements to the electrodes, the approach we will take to signal noise de-artifacting, and living baseline ECG data are all unique to our design and would be an upgrade to a machine such as the Wellue Checkme Pro.

H. *Preliminary System Organization*

The device **system processes** we have defined may require that multiple interdependent and dependent processes operate on our system. Some processes may be able to operate independently of other processes other than sharing data using something like producer consumer models. This could enable concurrent processes.

The system also has a need for processes to happen within a specific amount of time. The data acquired in data aquation process will become irrelevant to the user of the device or to medical workers if it takes too long to process. Because of this fact and the multiple processes running on the system; A real time operating system may be needed.

However, these constraints may still be accomplished without a real time operating system with the use of multicore micro-processors where each process is given a core to operate on. This does have the resource limitation of the number of cores available whereas a real time operating system could allow a single core to be shared by multiple processes.

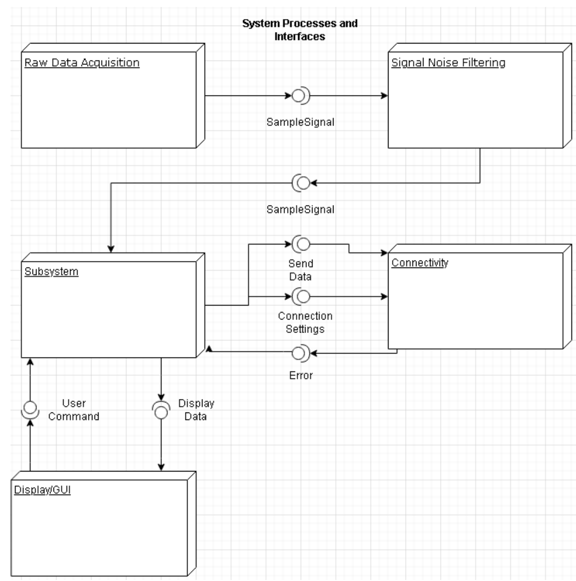

FIGURE 5: SYSTEM PROCESSING AND INTERFACES

1) Device system

- Raw Data Acquisition
  - Electrodes
  - Hardware Filtering
    - Electromagnetic interference
    - Muscle twitch
  - Analog to digital converter
  - Sampling Circuitry
- Signal Noise Filtering
  - Raw Data Input digital signal sampling
  - Output digital signal
  - Software filtering

- Baseline Wander
- Subsystem
  - Storage
  - Settings
  - Signal noise filtering Input digital signal sampling
  - Real time clock
  - Connectivity interfaces
  - Display/UI interfaces
- Display/UI
  - Display update routines
  - Input Sampling/processing
- Connectivity
  - Wi-Fi/Bluetooth
  - Data rx/tx
  - Settings routine
  - Error handling
  - Encryption

Cloud System

- Minimal Web application
  - Visual aid
  - Application programming interface
- Database(s)

I. *Design Summary*

1) Electrocardiogram signal input

Hardware needed are 6 electrodes, an analog to digital converter and pass filters. Software that may be needed is a PCB (Printed Circuit Board) designer if we end up designing our own circuit around the electrodes. Team Members will be Manish and Ryan will be working on this. They will be brining signal processing skills from the EEE120 class.

2) Software Movement Noise Filtering

Hardware need is a microcontroller. Software needed will be a compiler for the architecture we are using and a C/C++ programming environment. Team Members will be Brandon and Travis, both have software skills from computer science classes.

3) Display Data to User

Hardware needed is a microcontroller and some type of display device. Software needed will be a compiler for the architecture we are using and a C/C++ programming environment. Team members will be Brandon and Thuong, both have hardware and software skills from education.

4) Connectivity

Hardware needed is a microcontroller with connectivity support, or a separate connectivity chip. Software needed will be a compiler for the architecture we are using and a C/C++ programming environment. Team Members will be Thoung, he has both the hardware and software skills to complete this feature.

5) No connectivity storage

Hardware needed for this will be a microcontroller with storage controller support. Software needed will be a compiler for the architecture we are using and a C/C++ programming environment. Team

Member will be Travis, he has the software and hardware skills to complete this feature.

6) "Cloud" Central System

Hardware needed will be a desktop computer. Software needed will be an application server and a database. Team member will be Travis, he has the software skills to complete this feature.

The total estimated time to complete these features is about 160 to 200 hours (about 1 week 1 and a half days).

IV. FUNDING

The funding for this project, unless otherwise updated, is provided out of pocket by the team members.

TABLE III: BUDGET

Part	Quantity	Total Price ($USD - tax)
STM32	2	$21
STM32MP157C	3	$297
Electrodes	1 package (50)	$20
ADS1293	4	$40
0.5mm footprint	4	$29.56
SMD Solder kit	1	$99.14
ADS1293 Dev board	1	$99
Analog Discovery	2	$798
Real-Time Triaxial Accelerometer	1	$9
Neoprene padding	1	$17.31
Graphene Film	7	$700
	Total:	**$2103.01**

V. PROJECT MILESTONES

In this section we outlined major milestones represented by specific features necessary for the production and optimization of the desired product. The major milestones that we intend to achieve throughout the duration of our project timeline are Signal Input, Movement Noise Filtering, Display Data, Connectivity, Storage, Cloud, and Device. The Signal Input milestone will be the foundation of our device. It involves the modification of electrodes and utilization of digital and analog filters to produce an effective, readable signal. In addition, the Movement Noise Filtering milestone will enable for the digital filtration of signal distortions. Following this milestone, another important feature is Display Data. The Display Data milestone includes the essential creation of the graphical user interface (GUI), while the Connectivity milestone serves as a major improvement to traditional ECG by allowing for the transfer of recorded data from the device to an off-site cloud server. The Storage Milestone will play a significant role in handling error when an issue in connectivity occurs. The Cloud Milestone will aid in executing the selection and creation of the database structure design. Our last milestone, the Device Milestone, is intended to be open-ended, dealing with physical enhancement such as power specifications and serving as an all-encompassing milestone to the rest of the project.

The specific milestones in our project timeline, listed below, are major features discussed in the design idea portion of this report. These features are considered milestones as the full completion of one, signifies an important milestone in the project.

- Signal Input
- Movement Noise Filtering
- Display Data
- Connectivity
- Storage
- Cloud
- Device

These project milestones each represent a feature that requires the completion of work packages that include multiple tasks to meet each milestone. Some of these tasks have sub-tasks that will allow for the reduction of complexity within the specific task. Some of which are outlined in this section.

The Signal Input Milestone encompasses the completion of the modified electrodes created, digital filters utilized, and analog filters built as part of the work packages outlined with in it. Without these key components the signal sent to the microcontroller would be effectively useless, if even exists at all. With the proper filters in place to help produce a readable signal from the electrodes, said signals would be mistaken for simple noise. The effectiveness of the electrodes also plays a crucial role in this feature. This is due to them being the only means of ECG signal acquisition and because, as highlighted in our design idea statements, the electrodes are one of the primary features we intend to improve upon over traditional electrodes. Once completed, the Signal Input Milestone will be the foundation of our device and any delay in reaching this milestone will result in major setbacks for the entire project.

Supplementing the foundation is the implementation of the Movement Noise Filtering feature. As a Milestone, Movement Noise Filtering consists of a single work package with a few important tasks. The single work package focuses on utilizing an accelerometer to gather movement data. The importance of this is in the task that follows where we will utilize this data to filter out noise generated by movement seen in electrocardiogram signals. The task specifically states the team will create an algorithm to digitally filter out the signal distortion caused by muscle twitch and body movement.

Once the Movement Noise Filtering Milestone is met, parts of the team will begin to focus on the Display Data milestone. This milestone is the face of the operation, as it includes the creation of the graphical user interface (GUI). Which as state before in the design idea, is what makes or breaks the success of a product. This is why the heart rate design layout and program are the top tasks as well and why we chose the microcontroller we did. In order to keep to our design idea promise, the Connectivity Milestone was a clear milestone for us to strive for. We wholly intend the final device to have the ability to send its recorded data to an off-site cloud server. This being a major improvement over traditional ECG. The milestone's main work package defines configuring the real time operating system on our device to properly use the prebuilt stack for cloud connectivity it has built into it. Once this work package is complete, we will clearly define the cloud connectivity through connection specification. Then create the cloud data transmission program and error handling within the real time operating system.

Another key feature turned milestone, is Storage. The Storage Milestone consists of two work packages. Error handling and development of a cloud synchronization program. Error handling plays an especially significant role here, as it allows the device to know when there is an issue with the cloud connectivity and stores the recorded data on-site until connection can be re-established.

Furthermore, the Cloud Milestone consists of work packages that break down the setup of the cloud server that the recorded data is sent to and stored in. The offsite database work package focuses on the careful selection and creation of the database structure design. To supplement this work package the visual work package includes charting library selection and chart design. For the user to interface with to see their recorded and baseline data. This is where the bulk of our post-processing of the ECG data will take place.

Our last milestone is the Device Milestone. In which its work package is dependent on the physical aspects of the project, and it is broken up into iterations. One specific task in this milestone is the power specifications. This is where the iterations come into play due to the power requirements of the development board we are using for the prototype and the custom PCB intended for the final product. This milestone also requires the task completion of all peripheral devices of the project to be implemented on the product. This milestone, however, is intended to be open ended at this stage in the project.

We as a team had to make concessions as to the importance of some milestones over others for the sake of getting a prototype working in the next six weeks. It is for that reason that we labeled the Signal Input, Display Data, and Movement Noise Filtering as the most important milestones for the remainder of this semester. These three milestones completed give a presentable prototype and are further categorized by order of importance. Most important is the Signal Input milestone followed by Display Data and then the Movement Noise Filtering milestones. Reaching a completed Signal Input milestone means having all signal acquisition devices and peripherals working to give clean ECG signal input to the microcontroller. Without this there is no ECG. From this we can direct our attention to making the acquired signal visible to the user in an intuitive GUI design. From this we can make a more concentrated approach to the Movement Noise Filtering milestone as a team. It will take a significant amount of background work to get a robust algorithm working to effectively filter out the noise produced from patient movement. Thus, making this milestone important but requiring undivided attention.

From there, leading into the next semester, we can address the importance of the rest of the milestones. Connectivity being the next most important thing. As discussed before, it includes the cloud connection specifications which is a key design feature in our project. After that comes the Storage milestone that includes the error handling of when the device cannot synchronize with the cloud server. It will ensure that the data collected from the device is not lost while the connection is also lost. Which leaves the design of the cloud database in the Cloud milestone. This mostly just involves making the incoming data easily viewable and well organized which is why it is low on the priority list, but still above the class assignments in order of importance.

As part of establishing the project milestones the team established a means of tracking the progress and tasks needed to reach completion of the project. Part of this methodology is seen in the Gantt chart in Appendix F, Figure F1.

VI. WORK BREAKDOWN STRUCTURE

We broke our project into several key features. These features represent the milestones in our project. Each key feature will have a couple of packages underneath them. These packages will have multiple work items that should only take a week.

A. Signal Input

The signal input is the most critical piece of or project. Our project is entirely based on the accuracy of input signals from electrodes. This feature represents both the electrode input and the physical circuitry for filtering electromagnetic interference.

1) Electrodes

This package involves the physical sensors that detect the signals from the heart. Including, finding the specifications that are needed from the electrodes and finding part numbers for our prototype. From there this package has another task that involves building a prototype for this key feature. This task should take an estimated 30 hours and will be accomplished by Ryan Smith. We will break this package down into task as follows.

a) Specifications

In this task we will define the specific requirements of our electrodes. Frequency range, possible noise, electrode material and types are all things that should be explored.

b) Protype/proof

In this task we will test out our physical electrode selection with a wave generator and oscilloscope.

2) Filters

This package involves taking the signal from the electrodes and utilizing specific circuit designs to filter out electromagnetic interference and noise, then taking the filtered signal and digitalizing it using an analog to digital converter. There are three tasks for this package specifications, analog to digital converter selection and a protype proof of the package. This package should take around 45 hours (about 2 days) to complete and will be completed by both Thuong and Manish. We will break this package down into the tasks that follow.

a) Specifications

In this task we will define the specific requirements for our filters. Bandwidth, types of noise, types of filters, filter part numbers are all things that should be explored.

b) Analog to Digital

In this task we will decide on the correct analog to digital resolution and select a part number to convert our analog electrode signal into a digital binary signal.

c) Prototype/proof

In this task we will test out our electrodes, filters and analog to digital converter using wave generator, oscilloscope, and logic analyzer.

B. Movement Noise Filtering

The movement noise filtering is a primary improvement we are trying to make to the electrocardiogram. This feature involves other types of sensors that can detect body movement. The input from these body movement sensors is then taken and used to filter out artifacting, produced from movement seen in the electrode signal input feature, that are not part of the electrocardiogram signal.

1) Accelerometer

The accelerometer is our primary sensor for movement detection. This package has several tasks starting first with our specifications then on to a pseudo program in which we collect data from the accelerometer and put it in a format we can use in the main piece of this feature's program. We will then use that in the movement identification & filtering piece of this program. This is also the first package to have a real time operating system task because this feature will need to run on its own thread with its own CPU (Central Processing Unit) time slot. This package is estimated to take around 60 hours (about 2 and a half days) to complete and will be completed Thuong and Brandon with some help from Travis. We will breakdown this package as follows.

a) Specifications

In this task we will define the specific requirements for our accelerometer and select part numbers to order

b) Accelerometer pseudo program

in this task we will write a pseudo program to get data from the accelerometer and store it in memory.

c) Movement identification & Baseline Wander filtering program

in this task we will write the program to compare the accelerometer data to the electrode data and filter out noise from movement.

d) Real time operating system

in this task we will conform the code from the previous two task to work with our real time operating system.

C. Display Data

This feature is our communication to the user. Our initial focus will be displaying heart rate and developing a device control interface. After this initial development we will try and build in electrocardiogram wave displays.

1) Graphical User Interface

This package has several tasks. We start by selecting the proper embedded user interface library, then we design our initial screen layout and user control. After that will be programming our layout to have functionality. Finally, we will need to make sure that our GUI program conforms to our real time operating system and runs under its own thread. This package will take 60 hours (about 2 and a half days) at the very least and will be completed by both Thuong and Travis. We will breakdown this package into task as follows.

a) GUI library selection

In this task we will compare different embedded GUI libraries and select one to use in our project.

b) Heart rate and ECG layout design

In this task we will do a mockup of our GUI layout keeping the usability of the device in mind.

c)Heart rate & ECG display program

In this task we will implement the layout we designed in the previous task initially with simulated data than with signals from our signal input when available.

d) Real time operating system

In this task we will conform the code from the previous task to work with our real time operating system

D. Connectivity

Connectivity is another area where we are trying to improve traditional electrocardiogram devices. Connectivity will give us the opportunity to pass the data to more powerful machine to do further analytics.

1) Network stack

This package mostly involves configuring our real time operating system how to use the prebuilt stack it already has built in. Once it is configured, we will need to create a connection error handler to communicate to the rest of the system when a connection error occurs. This package should take around 30 hours to complete and will be accomplished by Travis. We will breakdown this package as follows.

a) TCP/ip stack configure

In this task we will configure and provide interfaces to configure the network stack that the real time operating system provides.

b) Error handling

In this task we will implement a program to notify other parts of the system when a connection error occurs

2) Cloud Connectivity

This package may be one of the last things we complete. We first need to define specifications of transporting the data our sensors connect across the network. From there we can write the program to handle the data transmission and error handling. Our last task for this package is again the real time operating system because this package will be in its own thread. This package should take 60 hours (about 2 and a half days) to complete and will be completed by Travis. This package will be broken down into task as follows.

a) connection specifications

In this task we need to decide the best approach to transport the data to the could. Common solutions are a webservice or a stream connection.

b) data transmission program

In this task we will implement the connection we specified in the previous task.

c) error handling

In this task we will handle data transmission errors such as corrupt or lost transmissions.

d) real time operating system

In this task we will conform the code from the previous task to work with our real time operating system.

E. Storage

If our planned connectivity feature fails to have a valid connection, we cannot lose the data we have collected. Our storage feature will store a finite amount of data until we have a valid connection to retransmit the data.

1) Error Handle Storage

This package will be the functional piece to the connectivity error handler that stores the data in secondary storage. There are a few tasks for this package, such as deciding the format the data should be stored in, writing the program then making sure the program conforms to the real time operating system. This package should take 45 hours (about 2 days) to complete and will be completed by both Thuong and Travis. We will break down this package into the following task.

a) Data format specifications

In this task we will decide the best method to store the data on device. Common solutions are a binary file or an embedded SQLite database.

b) store program

In this task we will implement the storage program to store the data with the data format specifications if there is no network connection.

c) real time operating system implementation

In this task we will conform the code from the previous tasks to work with our real time operating system

2) Sync

This will be the piece of code that will take data stored on connection error and re-transmit it to the cloud once a connection is restored. The main task is writing the program then conforming to the real time operating system. This package should take 30 hours to complete and will be completed by Travis. We will break down this package as follows.

a) Sync program

In this task we will write a program to synchronize the data that was previously stored on the device upon a new connection being established *b) real time operating system*

In this task we will conform the code from the previous task to work with our real time operating system

F. Cloud

The cloud system will be a server that receives data from the device and stores it. This allows us to use an interface to display the data as well as gives other processes access to the data to do secondary analysis.

1) Database

This package is where the data will be stored on the cloud. Given the amount of data we expect to produce a NoSQL database may be the best selection but there are many on the market to look at. The main task for this project is database selection, then designing the data structure “table” that the database will use, then writing the program to receive and store the data from the device. This package should take about 45 hours (about 2 days) and will be accomplished by Thuong. We will break this package into task as follows.

a) Database Selection

In this task we will research database technologies and select an appropriate database technology and implementation.

b) Table design

In this task we will design the data table for the database that will hold the data received from the device.

c) transmission/receive program

In this task we will write the program to receive data from the device and store it in the database.

2) Visual

This package will be the user facing package from the cloud. The main task is selecting a charting/graphical user interface library then designing the chart/ graphical user interface and finally writing the program. This package should take about 45 hours (about 2 days) and will be completed by Travis. We will break down this package into task as follows.

a) Chart library selection

In this task we will review different web-based chart and user interface libraries and select one to display the data in a web-based program.

b) Chart design

In this task we will design the chart and minimal user interface layout.

c) Program

In this task we will implement the supporting program for the chart.

G. Device

1) Circuit

This package we are expecting to add to but currently this package is reserved for task that involve developing peripheral devices for the prototype. Currently the only task we have here is the power specifications to power the device. At the moment, this package will only take about 25 hours to complete and will be completed by Brandon and Ryan. We will break down this package into task as follows.

a) Power specifications

In this task we will define the specifications to power our device by battery and charging requirements.

2) Miscellaneous

This package is for work tasks that do not clearly fit in a feature but support device development. Currently we have a task that involves deciding which integrated development environment to use. This package will currently only take about 15 hours to complete and will be completed by Travis. We will break down this package as follows.

a) Development environment setup

In this task we will define and setup our development environment to develop our software on our device.

H. Class Assignments

1) Fall 2020

- Individual Problem
- Team Problem
- Design Idea
- Work breakdown
- Timeline
- Risk Assessment
- Tech Eval
- Prototype Presentation
- Weekly Activity Reports

2) Spring 2021

- Problem Statement Revision
- Design Idea Review & Change Orders
- Spring Timeline Update
- Device Test Plan
- Market Review
- Feature Report & Presentation
- Mid-Term Progress Review
- Testing Results Report & Presentation
- Deployable Prototype Review
- End of Project Documentation
- Deployable Prototype Presentation
- Weekly Activity Reports

VII. RISK ASSESSMENT

One of the most important aspects of designing a product is to assess the risks involved and have contingency plans for a wide range of issues that may arise in the pursuit of bringing the product to market. Doing this can allow the development team to keep moving the project forward in the event that one of these issues arises. When these issues arise, we have to have mitigation techniques in place to overcome them. To do this we must analyze the reliability of each feature the product promises through risk assessment.

In the table below we predict some of the risks associated with aspects of the project.

TABLE IV: RISK ASSESSMENT RATING TABLE

RISK ASSESSMENT TABLE:				
Risk Rating Scale	LOW	MEDIUM	HIGH	SEVERE
	(1) Acceptable	(2) Alarm	(3) Generally Unacceptable	(4) Intolerable
Response	Ok to Proceed	Take Mitigation Efforts	Seek Support	Place Task on Hold

TABLE V: RISK ASSESSMENT TABLE

	Severity by color			
Likelihood				
Improbable (1)	Severe Weather causing blackouts	Materials becoming unattainable	Electrodes deemed unsafe for Human testing	Political Violence Societal Collapse
Possible (2)	Team members' class schedules interfere with tasks	Movement noise reduction algorithm unobtainable	Hardware Incompatibility	Team Contracts COVID-19
Probable (3)	Cloud/ Wireless Communication failure	Sensor/Component Breakage	Difficulty obtaining measurable metrics in testing	Prototype Malfunction
Likely (4)	Student Error in task	GUI malfunction/UI failure	Funding becomes an issue	Limitation of Hardware
Risk will Occur/ Common (5)	Testing Software/Hardware Malfunction	Parts order delay	Loss of STM32 Code/ Accidental Memory wipe	COFFEE SHORTAGE

A. Low Impact

The lowest impact risks are the easiest to account for as they do not fully affect the forward progression unless they stay persistent and remain unaddressed.

1) Team Members' Class Schedules Interfere with Tasks

In the event that a team member is too busy to complete a task assigned to them. They will be required to provide a thirty-minute team meeting explaining their progress so far in the task to the team. The remaining team will then decide how to approach dividing up the workload. This will increase the effectiveness of the team during the busy member's absence. It is our responsibility as a team to be understanding of all circumstances and situations and provide support to each member.

2) Severe Weather Inducing Blackouts

If weather becomes so severe as to induce blackouts, team members may have to relocate to somewhere unaffected. In a worst-case scenario, the work will be redistributed amongst the unaffected team members.

3) Cloud Communication Difficulties

It is likely that some problems will arise when attempting to integrate our device with a cloud-based service. For the rapid prototype it may be necessary to simulate cloud communication to either a local storage space or by using pre-generated data to send to our cloud storage. In the long-term the team will have to consider the power consumption and reliability of the permanent integration with wireless networks and how this may include switching from to Wi-Fi to data and back or relying solely on one or the other. This also includes considerations of what the device ought to do should the Cloud be inaccessible for assorted reasons.

4) Student Error in Task

Student errors are inevitable. Mistakes will be made, and they will be corrected. Any mistakes that are made by the team are within the power of the team to rectify. Even in the case that the team breaks components, more can be ordered, but that leads into its own set of risks.

5) Testing Software/Hardware Malfunction

While ensuring the compatibility and viability of all the moving pieces of the project there is the potential for things to go wrong. This can include anything from vital software crashing to hardware breaking down. The rapid prototype is going to be a rough sketch of a final deliverable and as such may not have the physical resilience of a final product. In this case it is necessary to be ready to rapidly troubleshoot and even repair the devices. The majority of software malfunctions can be remedied by rebooting the device and the majority of hardware failures can be solved by electrical tape. As a contingency the team may have to use other means of software and hardware testing, such as virtual environments or simulated signals.

6) GUI malfunction/UI failure

In the case of GUI failure, it should be possible to use physical buttons on the device to restart. However, a UI failure could include the physical buttons themselves as well. In this case it will be necessary to remove the power supply to hard reset. If there are UI or GUI problems along the development side, then the team will likely have to pursue alternate avenues to allow the user to interact with and manipulate the device.

B. Medium Impact

1) Build Materials Becoming Unobtainable

A main feature of the project is our implementation of modified dry electrodes. Materials that this includes are electrode pellets and patches (which are easily obtainable), and graphene film to act as the main component for skin contact. Graphene products over the years have become increasingly more affordable and efforts to produce mass quantities is ongoing for industry leaders [18]. Due to the current standing of graphene production, outlined by [18], we are confident of our ability to obtain the material. However, in the event that this is not possible to obtain in a timely manner we will need to reside to a simpler dry electrode using available products. One that will be utilized in initial testing of the signal acquisition is copper film. This was chosen due to its availability and conductive properties. Copper tape to be more precise has a measurable resistance that can be compared to its graphene counterpart through calculations. If the graphene film is unobtainable, we will utilize copper tape and perform calculations and provide supporting documentation to prove a graphene iteration would be more effective as a dry electrode contact.

Another build material that may be difficult to obtain by any number of variables is the custom PCB planned for the final prototype. We intend to create this PCB to reduce power requirements of the development board. This is a fairly integral part of the mobility aspect of our design. So, if it becomes unobtainable, we will need to reduce the power consumption by switching development boards. An option for this is the raspberry pi with a real time clock breakout board supporting ChibiOS/RT. ChibiOS/RT is a portable real-time operating system (RTOS) designed for embedded applications.

2) Parts Ordered are Delayed

The aforementioned graphene film and PCB are both parts that need to be ordered. Given the current issues with the post office and COVID-19 we have to mention the risks involved with ordering these items due to their uniqueness and low volume. If a part ordered is delayed outside of the available time, we will need to refer to the contingencies outlined in “*Build Materials become Unobtainable*”.

Other parts that might be delayed were reasonably ordered in advanced and therefore the risk sits in in common risk likelihood with medium severity.

3) Sensor and Component Breakage

The sensors of this project are the electrodes and accelerometer. Each utilized for sensing crucial components of the project. In the event these sensors break, our contingency plan is to replace them with back up components. We are able to do this due to their limited function in that they do not require onboard configuration.

Since we plan to use copper tape for the first iteration of the prototype instead of the graphene film, we can reduce the risk of breakage of the sensor in the final design. This is done through initial stress testing the first iteration.

4) Difficulty Obtaining Measurable Metrics during testing

Having measurable metrics proves the product's functionality. The signal input metric will require obtaining signals from all six dry electrodes through a string of filters and amplifiers. The result of not obtaining good metrics from these will require tweaking the design of the analog filters, re-analyzing the analog to digital converter, and ensuring the digital filters in the STM32 are functioning correctly. The contingency plan here is to find a suitable integrated circuit that incorporates all analog filters, because this is the point in the signal analysis that is most prone to error either by improper implementation or inadequate quality of component.

This risk also encompasses the health and safety aspect of testing the device on live subjects. If we are unable to adequately provide provable, safe for human metrics then the project will need to take a more proof-of-concept path and skip human trials. However, we will still provide the documentation required to show what was done wrong and what adjustments could be made to the prototype to adhere to health and safety standards.

5) Funding is Depleted or Sparse

Luckily in the event that funding becomes an issue we have already implemented a contingency. Due to the situation presented by COVID-19, we found it wise for a portion of us to get our own development boards. The development board is really the only major purchase required for the project. We do not expect funding to really become an issue, but if it does, we will take efforts to mitigate purchases associated with the project by seeking out cheaper or free alternatives.

6) Movement Noise Reduction Algorithm Unobtainable

The hope in using the accelerometer to identify movement noise in ECG signals is contingent on the ability to relate the two signals. If we find that they cannot be related at all then we will need to consider the alternative method of detecting muscle movement. This being EMG sensors which are just as easily obtained and even produce a similar signal type to ECG. If that does not work, then this risk is moved up to severe impact status and the task will have to be put on hold until we can reapproach it with more knowledge.

C. High Impact

Moving into the risks deemed to be high impact, we discuss risks that can halt a task for a short amount of time indicated by the minimal amount of research, calculations, or troubleshooting needed to complete the task. This amount of time does not exceed a period of two weeks or else it must be elevated to severe impact status.

1) Modified Electrodes deemed unsafe for Human testing.

The modified electrodes are a design idea based on a plethora of research papers that indicates graphene is perfect for biometric sensing. However, this is a relatively recent technology that we are attempting to use and therefore it is at a high-risk for error. As we attempt to get simulated metrics out of the graphene electrode, we will need to be recording every aspect of the electrode's interaction with the signal in order to check its compliance with health and safety standards.

That being said, if the electrode is deemed to not be safe for human testing. We will need to identify exactly why and provide a full report on what could have been done better in the fabrication process, implementation to signal acquisition, and any other factors that affect its safe usability on humans. We will keep the electrodes as they are in the final prototype but will not permit demonstrations. Instead offering the report on what went wrong and why the electrodes did not work as expected.

2) Hardware Incompatibility

Another high impact item is the possibility of hardware incompatibility. Though this is unlikely at this point it is still possible. In the even this happens we will need immediate correction to the components used. We will start with the smaller components that supplement the development board such as the accelerometer and analog to digital converter. Then if replacing those components with different ones does not work, we will need to consider the raspberry-pi option. This will set the project back a few weeks but is still a viable option in the event of hardware incompatibility.

3) Hardware Limitations

On the heels of incompatible hardware comes the limitations of the hardware which are likely to occur. The more testing and analysis we do might indicate that we need a higher bit rate from the analog to digital converter (ADC). One major hardware limitation is the STM32's power consumption. Due to its high-power consumption, we are unable to achieve the portability feature in the first iteration of the laboratory prototype. Our address contingency for this is to simply have it immobile for the time being until a custom PCB can be created to reduce the power consumption.

4) Loss of STM32 Code/Accidental Memory Wipe

Due to an incident that has happened to one of our members in the past we needed to account for the risk of complete loss of functioning code. However, this risk is fairly compensated for by use of a Git repository and sharing of uniform code to all team members with the development board being used. Therefore, this risk is possible but at a medium severity.

D. Severe Impact-

1) Political Violence/Societal Collapse

Due to the current political climate and level of protesting seen throughout the country we as a team felt it was necessary to create a contingency plan in the event one of these outside events occurs near us.

Political Violence has been occurring all across the country and world. From the brutality seen in China during their protests to the Black Lives Matter campaign that is sweeping across our own nation it is clear that we are living in challenging times. In these times of turmoil and uncertainty we decided that the best course of action to take in the event we are near events of political violence and societal collapse is to stay inside. Survive by any means necessary. If occurring to an individual team member we will work as a team to alleviate the stress of school for them and take on their work and tasks until a time arises when they can return to it. The same goes for the situation where a teammate become unexpectedly decease. Though they will not ever be able to return to work we will carry on, because that is what we all would want.

This risk sits at the highest risk point we have outlined: SEVERE but is admittedly an improbable situation. We hope.

2) Team Contracts COVID-19

In the event a team member contracts COVID-19 we will follow the contingency procedure outlined in Political Violence/Societal Collapse section of this risk assessment report. If it becomes necessary for group members to meet and exchange parts or perform lab tests with compiled components the meeting spot will be fully sanitized before and after, with group members wearing masks at all times. Given existing health conditions meet ups with some group members are limited to zero and if parts are necessary, the quantity is individually ordered in duplicate.

In terms of the effect of COVID-19 on development of the prototype we are not too worried to be without the on-campus labs and resources. Due to the new way to remote access the ECS computers in the engineering buildings we have access to all the available testing software needed. It is not ideal to be testing the physical components with the analog discovery over the premium signal testing equipment in the labs, but the analog discovery we are utilizing does allow us to introduce a simulated ECG waveform with noise much easier than the waveform generators on campus.

Given that this contagion is widespread and has killed hundreds of thousands of people over the course of mere months, this risk is assessed as SEVERE and possible. It is always advised for all team members to shelter in place and avoid any risky situations that may compromise their health.

3) Prototype Malfunction

On a lighter note, Prototype malfunction. As serious as it sounds it is a probability that it may occur at a varying degree. Some prototype malfunctions can be as simple as accidental power disconnection or a frozen UI all the way to more severe incidences. Such as shorted wires or burnt-out ICs, and fire. We will hope for no fire, but hope is not a strategy. Therefore, the team is intending to have more than one working prototype as a contingency with extra parts on hand.

4) Coffee Shortage

A common risk among engineers that must be addressed at the SEVERE risk level is the shortage of coffee. It can halt production, force vacation days, and produce sub-par completion of tasks. This wonder food has powered engineers for generations and society has endorsed its restorative properties ten-fold. Now you can order it on your phone and have scheduled shipments of the delicious bean sent directly to your home. We as a team believe in the powers of coffee and seek to honor it for the blessings it bestows upon you. Blessings of pure warmth coursing through every fiber of your being to the extent that you actually can resist fire and bend metal. Like a Golden apple the coffee bean is a legend in its own right. All we can do as mere mortals is appreciate its beauty in vast quantities. So therefore, each team member has stocked up to push through to the product completion.

VIII. DESIGN PHILOSOPHY

The objective of this project was to address the prominent societal problem of cardiovascular disease by development of an ECG device which utilizes many modern technologies to improve upon decades old devices in service today. Like many simple and portable ECG devices on the market currently, such as the Apple Watch and Fitbit, our team decided to embark on a journey to make a device that would further explore the portability aspects and make routine ECG diagnostic tests a more fluid, accurate, and comfortable experience for the user. Project μ-tu's philosophy was that we make our best attempt to expand upon the simplicity of the current portable devices and create a 6-lead variant that was versatile enough to be used in emergency settings as well as in at-home monitoring.

One of the major factors that influenced us taking this project was the ongoing Co-Vid 19 Pandemic. In seeing the death tolls on the news worldwide and how impactful it was towards people with preexisting conditions, such as the fear of exposure of even going to a hospital, we were motivated to take a step towards making a device that would contribute towards wellbeing of these people and everyone else around us. With this in mind it became apparent that longer periods of monitoring would be occurring. This emphasized the need of the cloud storage feature for data accrued by continuous monitoring. As well as baseline wander elimination to compensate for daily activities and dry electrodes for the long days attached to sensitive skin.

In the making of project μ-tu we, as individuals, had to remotely make progress towards completion of a physical device. Though this presented many challenges, each team member would learn to appreciate the contributions of one another through task-based teamwork. The essence of this work breakdown philosophy was to learn, show, and teach as time permitted. This gave each of the team members the opportunity to learn more about subjects not otherwise covered in coursework and in individual studies.

IX. DEPLOYABLE PROTOTYPE STATUS

Prologue:

As of the completion date, the status of the project is incomplete. This is largely due to an accumulation of delays created from a compilation of factors. Though these factors were forecasted in our risk assessment report, the accumulation of many of them was not accounted for when making project delay recovery strategies. As we are all aware of the ongoing Co-Vid 19 Pandemic, it was likely that one or more team members would be exposed due to no fault of their own. Unfortunately, despite all precautions the individual team member took, he contracted the virus. As outlined in our risk assessment it became necessary for group members to meet and exchange parts. Therefore, a drop off location was set and was fully sanitized before and after with group members wearing masks at all times. Each item exchanged was left in a box at this location for the necessary amount of time for the sanitation to be fully realized and then retrieved by receiving team member. Tasks were redelegated and the project continued with a little over two-week delay. This including other factors, set the project back to an indefinite completion date. That being said, the main object of this project was to learn and grow as future engineers.

A. ECG Signal Input

As outlined in the design idea section of this report, the signal input feature encompasses the electrodes, analog/digital signal filtering circuitry. The status of this feature is completed roughly 85%.

The dry electrode implementation utilizing graphene film became unobtainable due team error in task completion and delayed shipping times for the film itself. This resulted in the final iteration of the electrode design to include standard wet electrodes as the main contact point with the skin, supported by an electrically isolating layer of neoprene padding to help with sweat resistance and signal quality. The standard wet electrode Ag/Cl nib is wired through the pad to the rest of the circuitry on the torso compression strap.

The torso compression strap that these electrodes are adhered to was completed, however. The final iteration of this design includes a multi-layered breathable, stretchable set of fabrics. The first layer is to cover wiring and all onboard components. The second, and main layer, is a compression strap is usually marketed as a rib brace chosen for its breathability and elasticity. This is the medium which the main circuitry of μ-tu is woven through. The circuitry itself is a conductive thread coated in an electrically isolating resin.

At the heart of the wiring schematic and signal acquisition sits an STM32-nucleo and three ADS1293 ECG integrated circuits. These are 0.5mm footprint ICs that house all of the analog and digital filtering needed for raw ECG data acquisition. Each ADS1293 allows for a 6-electrode input configuration, a Wilson Central Terminal (WCT) output, common-mode peripheral, separate pacemaker detection circuitry, and lead-off detection.

Within the IC, a flexible switch routing allows for any of the EMI (electromagnetic interferences) filtered analog signal inputs to utilize any of the four instrumentation amplifiers embedded in the system. Once through the instrumentation amplifier the signal undergoes simultaneous decimation of bit rates and enhancement of resolution thanks to the sigma-delta modulator (SDM). The SDM contains a three-stage 5th order digital SINC filter all of which are programmable to perfect signal quality per application.

Though the design of the wiring was completed the Bluetooth connectivity from the onboard STM32-nucleo was never established due to unforeseen delays. The STM32-nucleo was intended to be the torso strap transmitter that would send the device to the more powerful STM32MP157 as part of the handheld monitoring system.

FIGURE 6: TORSO COMPRESSION STRAP INTERIOR SHOWING 7 ELECTRODE CONFIGURATION.

FIGURE 7: EXPOSED WIRING LAYER OF THE TORSO COMPRESSION STRAP PRIOR TO PATIENT SAFETY TESTING.

B. Baseline Wandering Elimination Program

Current status of this program is incomplete at roughly 20% of tasks completed. During one of the steps leading to the implementation of this feature, A team member contracted the Co-Vid 19 virus and caused a delay in its progress. This had a cascading effect throughout the development of project µ-tu.

The fully proposed design of the program to actively eliminate baseline-wander artifacting included a software-based FIR high-pass zero phase f/b filter with a default cut-off frequency of 0.5Hz in order to estimate the baseline wander and remove it from the signal. The cut-off frequency of 0.5Hz is chosen due to it being within the range of the baseline wandering frequency. However, because the 0.5Hz cut-off would not be enough for real-time de-artifacting. The design was to use an accelerometer to gather two main points of data: movement detection and frequency of movement.

Movement detection would have been easy enough to achieve using a function of conditions that would check for substantial changes in accelerometer data being read. This would be used as triggers to activate the baseline wander program. The frequency of movement would be derived by converting the analog signal to digital then using Discrete Fourier Transform (DFT) to simplify the signals of the accelerometer, not unlike how beats-per-minute (BPM) is traditionally derived. This frequency would further need to be compared to the default cut-off frequency of the FIR filter and included in a new value extracted from the relationship of the two frequencies. This value would then be utilized to actively adjust the cut-off frequency of the FIR filter to eliminate baseline wander in real time. This program would then exist on the MP157 portion of the μ-tu device.

C. Display Data & GUI

FIGURE 8: FINAL ITERATION OF GUI AND DISPLAY OF ECG DATA.

Status of this feature is 100% complete. Project μ-tu successfully incorporates a touch screen user interface to display BPM, active ECG signal form the user, battery plus internet connectivity indicators, as well as settings for allowing the user to establish wireless connectivity to the device. To display the BPM a program on the MP157 utilizes DFT methodology for the calculation of BPM. The user's ECG is what is being transformed to get this calculation, which is viewable to the user.

D. Internet Connectivity

Fully operational. This feature met its measurable metric after completion of development by functional testing then real-time transmission success. This entailed connection to 8.8.8.8 and a forced disconnection to see that error handling verification was working. Then the centralized system was shown to be displaying actively transmitting simulated data from the MP157 achieving the feature's measurable metric.

E. Cloud Centralized Data Processing and Retention system

This feature is also 100% completed. The measurable metric for this was met when it was clear that historical data was able to be accessed within the cloud-based centralized system.

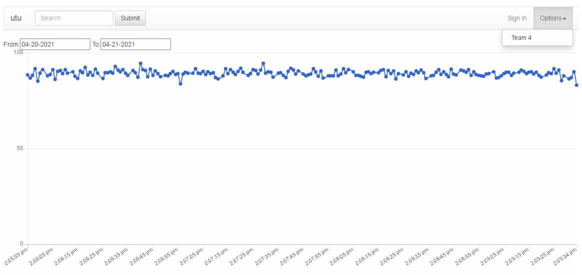

FIGURE 9: CLOUD INTERFACE

F. No Connectivity/Local Device Storage

Accompanying the internet connectivity functionality testing. This failsafe feature used to retain the user's ECG data while internet connection is not viable was 100% complete. Measurable metric achieved through verification that data being collected on the MP157 during offline usage was available on the device, intact. Additionally, able to begin retransmitting once connectivity to centralized system was reestablished.

G. Testing and Results of Analog Front End

Although the teammate who did contract the virus left no stone unturned to meet the project milestones, the device had to be quarantined for two weeks before it could be picked up for the possible testing as per the outlined schedule. However, even when the teammate recovered and required quarantine time was met, we still had to undergo a massive bureaucratic process to get our hands on the testing device that was to be loaned to us by Dr. Warren Smith. We were still not able to get clearance to get in the campus after a month of putting in the request. As a work around the team coordinated with Professor Dr. James Cottle to retrieve the device outside Riverside Hall, as there are no restrictions against meeting outside of buildings in small groups on campus while following the health guidelines, namely properly masking and social distancing.

The deployable prototype test as of typing this report was further delayed because of teammate responsible for testing the device contract the flu the day he picked up the deployable prototype and the testing device. He had to get the Covid Test done on the day he was supposed to test. The results, luckily, returned negative.

1) Current Leakage Test

As our ECG device falls under the category of the Medial devices, it was absolutely necessary for us to perform the current leakage test before it could be put safely into the human body. The testing protocol and procedure that we followed was IEC (International Electrotechnical Commission) 60601-1 (Medical device category) [21]. The purpose of current leakage test was to find out the magnitude of the current that leaks out of the devices through various flavors such as Earth leakage, touch leakage and patient leakage. The maximum leakage current is set to be around 210 µA. Hence our goal was to measure the leakage current and ensure that it was under maximum tolerable limit. Our device runs on 5VDC per chip, and the measured current leakage through the Right Arm and Left Arm leads was measured to be 0.2µA, which keeps us in the safe zone.

2) The Testing Device

The testing device used to measure the leakage current was the Safety Analyzer by Engineering Excellence. The model is 431 A. The instrument was human engineered to perform all recommended electrical testing and specifies in the California hospital association safety manual. Although it could not be found in the device manual, this device is supposed to have been manufactured in 1970's. Which makes it far before our time. The machine itself was not in the optimal condition as the chest lead plug was missing. This made the safety of the device mercurial when using it. Safety was the utmost priority as we were in the unknowns and using completely new device. The device in its full setup along with the ECG device is shown below.

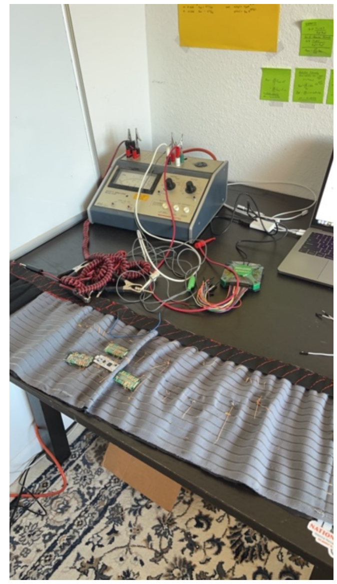

FIGURE 10: SAFETY ANALYZER SETUP WITH THE ECG DEVICE.

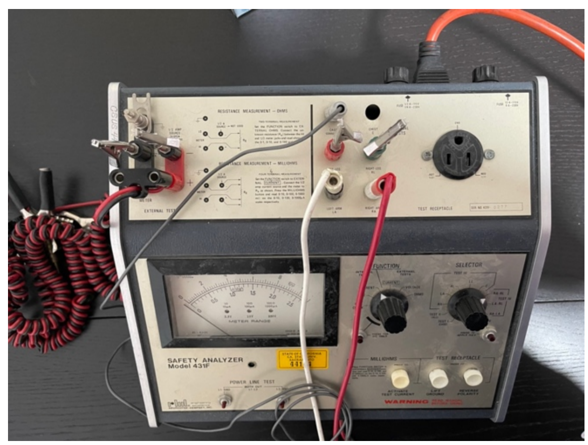

FIGURE 11: ENGINEERING EXCELLENCE SAFETY ANALYZER 431

3) Test Guidelines

The testing guidelines were followed as per the IEC 60601-1. The testing standard for the medical devices as dictated by International Electrotechnical Commission. This standard follows the testing parameters of a medical device which models the Device Under Test (DUT) with a circuit that models the human impedance. The circuit consists of 10KΩ || (1KΩ+0.1μF). It is necessary to have to capacitor in the circuit as the human signals are frequency based. The standard also dictates the testing procedures that simulates the fault conditions. This is to ensure that device can sustain the fault conditions such as open ground and reverse polarity. One of the conditions of simulating the fault condition required the device to be operated at 110% the mains voltage (i.e., 132V) in USA. Since our device is DC operated, we did not have to simulate the mains at 110%. Also, the reverse polarity test was also skipped as there is a set VDD and VSS pins for our ADS1293 and STM32Nucleo boards.

Overall, the IEC 60601-1 was a great guideline for testing our device and provided us the valuable insights into testing of the medical devices. In the process of research, we also got to learn about the current leakage test equipment and testing procedures for various kind of other devices such as IT equipment and spa machines. The underlying difference were the modelling of the impedance network of these devices.

X. MARKETABILITY FORECAST

A. Target Audience

The system is designed to serve both consumers and the healthcare sector. Specifically, it is targeted at those with chronic health concerns or other risk factors that make them especially vulnerable to cardiovascular issues. Some of these things might include those who suffer from obesity, chronic illness, or even simply advanced age. Marketing would be directed towards these groups, and additionally, it is important to ensure the device is accessible by these groups. For example, the chest strap is stretchable in order to conform to those who have a larger chest circumference.

B. Potential Clients

The groups that are considered potential clients are those who we would hope to be delivering the product to in bulk. This includes places like assisted living facilities, senior living environments, cardiovascular units, and post-acute facilities. Because the device is centralized and easy to wear, it would be convenient for mass health monitoring of mobile groups. Being more aware of patients' health in secondary health facilities would allow better reaction times to cardiovascular events or even the allow the opportunity to witness problems before they arise and time to intervene with preventative care. Within the cardiac units, the device would allow for 24/7 monitoring of the heart's condition without requiring the patient to be wired at all hours of the day. This allows the patients a better degree of mobility as well as historical data for review.

C. Competitors and Consideration

There are a few comparable products already on the market and one of them is arguably Apple. Apple has the Apple Watch, retailing at $399, which has an ECG function and is already fairly widespread. Where we have an advantage is that our device does not require the $900 iPhone to operate, our device is 6-Lead rather than 1, and will always be working, whereas the Apple Watch only works in 30 second increments when activated. More aligned with the actual intent of our device is the KardiaMobile 6L built by AliveCor for $159. However, this still requires a smartphone and only works when the user is seated and holding the device against their ankle. Finally, amongst the more general options would be a Holter Monitor, which is made by Finally, amongst the more general options would be a Holter Monitor, which is made by many companies and can be priced anywhere between $70 and $499. However, this device is typically heavy, wired, and of limited time usage. Ultimately, there are some alternatives on the market, but our product has a unique footprint that should allow it to find its own niche.

D. Economic Considerations

It is important to take into consideration the state of the economy right now when introducing a new product. For starters we are hopefully on the tail end of the pandemic. This means that while things will ideally be returning to normal, but things are still quite dampened. Speaking within a broader context, purchasing power is at an all-time low as costs continue to inflate, but wages fail to keep pace. On a brighter side some healthcare institutions are experiencing an increase in profits and may be willing to invest in recent technologies. It is also possible that the inability of hospitals worldwide to handle increased volumes of patients and will realize they need to invest in centralized systems that allow handling a higher volume of patients.

XI. CONCLUSION

Existing technologies integrated into electrocardiogram devices will lead to better diagnostics and treatments for cardiovascular health conditions whether emergent or chronic. Our proposed device would be focused on the emergent and high-risk chronic patients. In order to improve quality of life for those affected by cardiovascular diseases.

Through the various research conducted in the design idea phase of the project we were able to narrow down the specific features we desired to see in the device to be. Discovering that signal processing, connectivity, and system integration to be the most important aspects of this project we plan to allocate much of the time it will take to fully implement our design to signal processing with everything that entails. Creating the punch list gave valuable insight and direction needed to complete the project and gave a starting point for the next phase.

After defining our requirements and features in our punch list we were able to organize our work items into smaller work packages. In these, our feature set is broken into signal input, baseline wander artifact filtering, display data, internet connectivity, local storage and no connectivity error handling, and cloud centralized system. Each feature was made into a milestone for us to reach. These milestones were broken down into work packages, which in turn were made up of tasks. These tasks were allotted a certain amount of time to complete to meet the project deadline and assigned to a team member (or small group of team members) for efficiency and learning opportunities.

In order to accurately predict and track the time it would take to complete tasks the timeline was created. In this timeline we outlined major milestones represented by specific features necessary for the production and optimization of project μ-tu. In order to show progress where it was needed by the end of the fall semester the team discussed the importance of each feature. We determined that in order to achieve a working first iteration prototype by December we would focus on Signal Input, Display Data, and Movement Noise Filtering. Each of which had the highest chances of being achieved while providing the most bare-minimum representation of our overall design idea. Starting in the Spring semester we focused on refining these features and completing the remaining ones on the punch list. We attempted to intently follow and update this timeline and project task tracker to keep up to date with the tasks required to complete the device by May 2021. However, there are always risks involved in the development of a new device or product that cause delays.

As we consider our project to be demanding to some magnitude, we also have inevitable mistakes that follow and delay the project timeline and could even halt the entire project. Assessing risks in this regard is an important aspect of designing a product. It is especially important to have contingency plans for a wide range of issues that may arise in the pursuit of bringing the product to market. For such, we devised risk assessment for our project. In doing this we thought we would be giving ourselves a strong backup plan for if or when things were suddenly delayed. Doing this can allow a development team to keep moving the project forward in the event that one of these issues arises. When these issues arise, we have to have mitigation plans and techniques in place to overcome them. To do this we tried to analyze the reliability of each feature the product promises through risk assessment. The risks associated with our project are classified into low impact, medium impact, high impact, and severe impact. The merit for such classification was how much the said risk would cause the project timeline to be delayed.

Low risk is associated with minor delay in the project and could easily be filled in by other teammates. Schedule interference, local power outages, cloud connectivity, student error, and GUI/UI failure. These problems can easily be mitigated and does not affect the project timeline by considerable time. Our medium impact risks included difficulty in obtaining materials, delayed part orders, physical damage to components, lack of funding. These problems would cause our project to delay by almost a week. Whereas high impact and severe impact risk were classified if they affected our project timeline by 2 weeks or more. Although they are less likely but are high risk in nature. Given our project requires us to put electrode in human body, there are chances that safety testing could deem the device unsafe for human body. In such scenario, it would require us to start over one of our major work packages. High risks in our project are centered at hardware limitations, as breakage or loss of one would cause delay in the project by two week or more as it would require starting over the ordering process. With pandemic going on now, any damage to physical part would delay the delivery of products. Although least likely of scenarios, we thought, was a teammate contracting Co-Vid 19 and suffering severe health problems, prototype malfunction (complete loss of product), the social violence and disturbance going on now are likely to halt our project timeline for some time. Although, all in good humor, it is likely that the shortage of coffee would also definitely pose a major risk to our project as well. As it turned out, we were sorely unprepared for a multitude of these risks to occur in succession.

Project μ-tu's philosophy of design was that we make our best attempt to expand upon the simplicity of the current portable ECG/EKG devices and create a 6-lead variant that was versatile enough to be used in emergency settings as well as in at-home monitoring.

Despite all precautions and preparations through risk assessment taken by the team, we became directly the affected by the Co-Vid 19 virus which started a cascading effect of delays ultimately resulting in an incomplete project by the deadline. We take this as a learning experience and look forward the future where we can strive to do better.

Current status of each feature includes signal input and acquisition at 85%, baseline wander elimination algorithm roughly 20%, display data and GUI fully completed at 100%, Internet connectivity along with cloud centralize system and connection loss local storage backup fully operational, but Bluetooth connectivity between STM32-nucleo and MP157 was never established. This brings the total completion percentage to roughly 83% completion of attempted features.

Each of the features that made it to 100% completion met every measurable metric. The analog front end of the compression strap was also tested to meet its measurable metric, and it was crucial to examine the device for safety purposes. In order to do so, our device had to go through the through current leakage testing. The standards and the protocols of which were set by the International Electrotechnical Commission

for the medical testing device. The purpose of the testing was to ensure that the device leakage current did not exceed the set limit of 6µA. The testing of the device was performed at home setting due to campus lock down. The necessary testing equipment for this particular testing was loaned to us by Professor Warren Smith.

A special thanks to Dr. James Cottle who guided us through the excruciating final semester of this project, we would like to thank him for his dedication to his students and understanding of truly irregular struggles each team member faced. It was a pleasure to receive his knowledgeable insight and suggestions each time it was given. Thank you, professor.

<THIS MESSAGE WILL NOW SELF DESTRUCT IN 3…2…1….>

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GLOSSARY

Accelerometer: an instrument for measuring acceleration or for detecting and measuring vibrations

Accounting: the system of recording and summarizing business and financial transactions and analyzing, verifying, and reporting the results

Adhered: to hold fast or stick by or as if by gluing, suction, grasping, or fusing

Algorithms: a process or set of rules to be followed in calculations or other problem-solving operations, especially by a computer: a basic algorithm for division.

Analog to Digital Converter: a device for converting analog signals to digital form.

Analysis: a detailed examination of anything complex in order to understand its nature or to determine its essential features: a thorough study

Application Server: An application server is a server that hosts applications. Application server frameworks are software frameworks for building application servers.

Architecture: the manner in which the components of a computer or computer system are organized and integrated

Artifacting: an electrocardiographic and electroencephalographic wave that arises from sources other than the heart or brain.

Artificial intelligence: the capability of a machine to imitate intelligent human behavior.

Aspect ratio: a ratio of one dimension to another

Atrial Fibrillation: very rapid uncoordinated contractions of the atria of the heart resulting in a lack of synchronism between heartbeat and pulse beat

Authentication: the act or process of authenticating something

Bluetooth: used to certify the interoperability of telecommunications equipment utilizing UHF (Ultra High Frequency) radio waves for the close-range wireless transfer of data.

Cardiac: of, relating to, or affected with heart disease

Cardiac Abnormality: state of abnormal behavior of heart

Cardiovascular: of, relating to, or involving the heart and blood vessels.

Centralized Systems: In a centralized system, all users are connected to a central network owner or “server”. The central owner stores data, which other users can access, and also user information.

Control Interface: A control interface, or simply interface or control panel, was a means by which a person operating a particular piece of equipment could instruct the device or system as to what they desired, and the item being controlled could respond accordingly.

Convolutional Neural Network: In deep learning, a convolutional neural network (CNN, or ConvNet) is a class of deep neural network, most commonly applied to analyze visual imagery.

Data Acquisition: Data acquisition is the process of sampling signals that measure real world physical conditions and converting the resulting samples into digital numeric values that can be manipulated by a computer.

Database: A database is an organized collection of structured information, or data, typically stored electronically in a computer system.

Demarcation: the marking of the limits or boundaries of something

Demographics: statistical data relating to the population and particular groups within it.

Diagnosis: the identification of the nature of an illness or other problem by examination of the symptoms.

Durability: the ability to withstand wear, pressure, or damage.

Electrode: a conductor through which electricity enters or leaves an object, substance, or region

Electromagnetic Interference: Electromagnetic interference (EMI), also called radio-frequency interference (RFI) when in the radio frequency spectrum, is a disturbance generated by an external source that affects an electrical circuit by electromagnetic induction, electrostatic coupling, or conduction.

Embedded: fixed firmly and deeply in a surrounding mass; implanted.

Emergent: in the process of coming into being or becoming prominent.

Encryption: the process of converting information or data into a code, especially to prevent unauthorized access

Erratic: not even or regular in pattern or movement; unpredictable.

Erroneous signals: based on or containing error; mistaken; incorrect.

Fast Fourier Transform: A fast Fourier transform (FFT) is an algorithm that computes the discrete Fourier transform (DFT) of a sequence, or its inverse (IDFT). Fourier analysis converts a signal from its original domain (often time or space) to a representation in the frequency domain and vice versa.

Frequency: the rate at which something occurs or is repeated over a particular period of time or in a given sample.

Git Repository: A Git repository is the . git/ folder inside a project. This repository tracks all changes made to files in your project, building a history over time. Meaning, if you delete the . git/ folder, then you delete your project's history.

Graphical User Interface (GUI): Graphical user interface (GUI), a computer program that enables a person to communicate with a computer through the use of symbols, visual metaphors, and pointing devices.

Gyroscope: a device consisting of a wheel or disk mounted so that it can spin rapidly about an axis which is itself free to alter in direction. The orientation of the axis is not affected by tilting of the mounting, so gyroscopes can be used to provide stability or maintain a reference direction in navigation systems, automatic pilots, and stabilizers.

Hedonic: relating to or considered in terms of pleasant (or unpleasant) sensations.

High blood pressure: High blood pressure (hypertension) is a common condition in which the long-term force of the blood against your artery walls is high enough that it may eventually cause health problems, such as heart disease.

High Cholesterol: Cholesterol is a waxy substance found in your blood. Your body needs cholesterol to build healthy cells, but elevated levels of cholesterol can increase your risk of heart disease. With high cholesterol, you can develop fatty deposits in your blood vessels.

Interface: a device or program enabling a user to communicate with a computer.

Involuntary: done without will or conscious control.

IoT (Internet of Things): The Internet of things (IoT) describes the network of physical objects—a.k.a. "things"—that are embedded with sensors, software, and other technologies for the purpose of connecting and exchanging data with other devices and systems over the Internet.

Iterations: the repetition of a process or utterance

Logic Analyzer: A logic analyzer is an electronic instrument that captures and displays multiple signals from a digital system or digital circuit. A logic analyzer may convert the captured data into timing diagrams, protocol decodes, state machine traces, assembly language, or may correlate assembly with source-level software.

Machine Learning: the use and development of computer systems that are able to learn and adapt without following explicit instructions, by using algorithms and statistical models to analyze and draw inferences from patterns in data.

Measurable Metrics: A metric is a quantifiable measure that is used to track and assess the status of a specific process.

Misdiagnosis: an incorrect diagnosis of an illness or other problem

Muscle Artifact: Muscle artifacts are characterized by surges in high frequency activity and are readily identified because of their outlying high values relative to the local background activity.

Network Stack: The protocol stack or network stack is an implementation of a computer networking protocol suite or protocol family. Some of these terms are used interchangeably but strictly speaking, the suite is the definition of the communication protocols, and the stack is the software implementation of them.

Neural Networks: A neural network is a network or circuit of neurons, or in a modern sense, an artificial neural network, composed of artificial neurons or nodes.

Operating System (OS): An operating system (OS) is system software that manages computer hardware, software resources, and provides common services for computer programs.

Parsing Algorithm: Parsing, syntax analysis, or syntactic analysis is the process of analyzing a string of symbols, either in natural language, computer languages or data structures, conforming to the rules of a formal grammar.

PCB: Printed Circuit Board

Pedometer: an instrument for estimating the distance traveled on foot by recording the number of steps taken.

Physical User Interface (PUI)

Plethora: A large of excessive amount of something

Pragmatic: dealing with things sensibly and realistically in a way that is based on practical rather than theoretical considerations.

Proactive: creating or controlling a situation by causing something to happen rather than responding to it after it has happened.

Refresh rate: A refresh rate defines how many times per second it draws a new image on the screen, and it is written out in Hertz (Hz).

Sampling Circuitry: The Sample and Hold circuit is an electronic circuit which creates the samples of voltage given to it as input, and after that, it holds these samples for the definite time. The time during which sample and hold circuit generates the sample of the input signal is called sampling time.

Signal deterioration: Degradation usually refers to reduction in quality of an analog or digital signal. When a signal is being transmitted or received, it undergoes changes which are undesirable.

Signal processing: Signal processing is an electrical engineering subfield that focuses on analyzing, modifying, and synthesizing signals such as sound, images, and scientific measurements.

Systematic: done or acting according to a fixed plan or system; methodical

Thread: In computer science, a thread of execution is the smallest sequence of programmed instructions that can be managed independently by a scheduler, which is typically a part of the operating system.

Thresholds: the magnitude or intensity that must be exceeded for a certain reaction, phenomenon, result, or condition to occur or be manifested.

Usability: the degree to which something is able or fit to be used.

User interfacing: User interfaces are the access points where users interact with designs.

Video Driver: The software that links the operating system to a particular graphics card. Video drivers are typically written by the vendor of the card.

Waveform: a curve showing the shape of a wave at a given time.

WHO: The World Health Organization (WHO) is a specialized agency of the United Nations responsible for international public health

Wi-Fi - Wireless Fidelity, a facility allowing computers, smartphones, or other devices to connect to the internet or communicate with one another wirelessly within a particular area.

Appendix A. User Manual

User manual organization:

- Parts Included
- Safety Precaution
- Setup
- Instructions (How to Use)
- FAQ (Frequently Asked Questions)

Parts

- Torso Strap
- Handheld Device
- Charging Cable

Safety Precaution

- Please consult your primary care physician before use.
- If skin becomes red or irritable discontinue use and consult a medical expert.
- Before turning on the device make sure it is properly situated on the torso in order to gather accurate readings.

Setup

1. Remove torso strap and handheld from packaging.
2. Follow diagram instructions to properly situate the device on the torso.
3. Turn on handheld and torso strap and navigate through the settings to connect μ-tu to your local Wi-Fi.
4. Set up your account.
5. Press [START] on the handheld.

Instructions

The μ-tu device intuitively records your electrocardiograph allowing for the user to simply press the start after setup and relax as their heart is actively monitored.

To access your user data through the cloud portal simply log into www.MymootooHealth.com using your account username and password created at set up. For any questions please call (555)-555-1234 or email us at mootoo@mootoo.com.

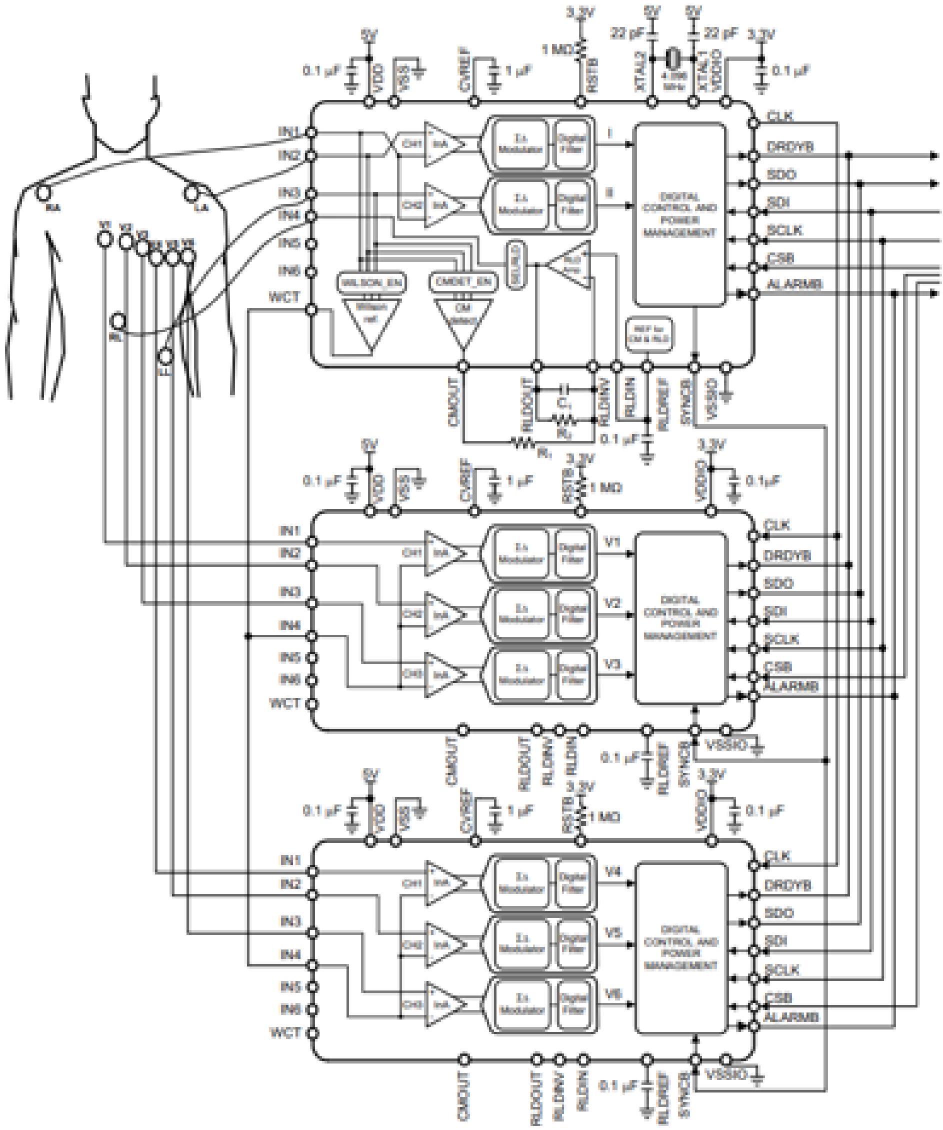
FAQ

- What if my device does not connect to the internet?
  - µ-tu will store your electrocardiograph data on the device until connection is reestablished.
- How do I connect to my Wi-Fi
  - Follow the instructions included in the packaging.
- For any further instructions or troubleshooting please email or call us!

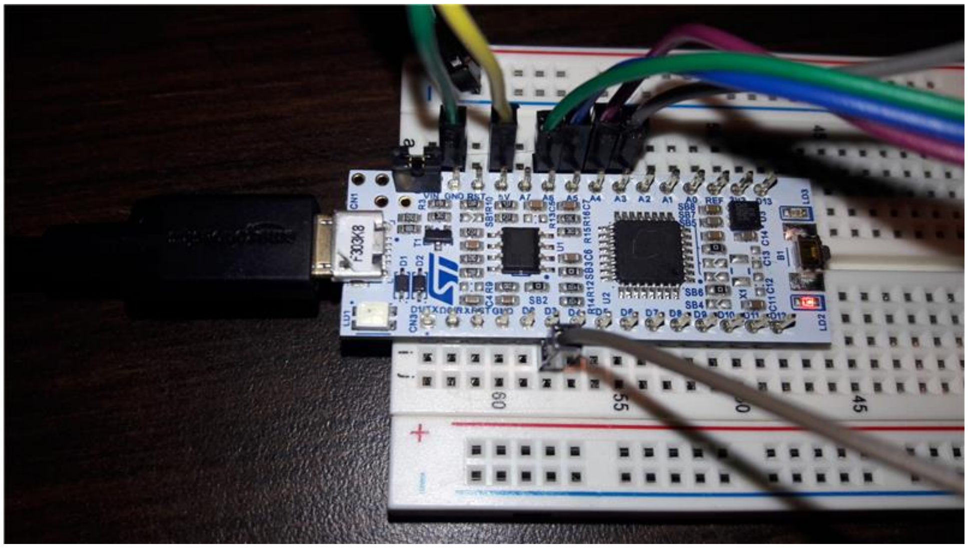
Appendix B. Hardware

ADS1293 on 0.5mm footprint

9.2.3 8- or 12-Lead ECG Application



ADS1293 Schematic [TI: ADS1293 User Manual]



STM32-Nucleo

[22] STM32MP157c-dk2

Appendix C. Software

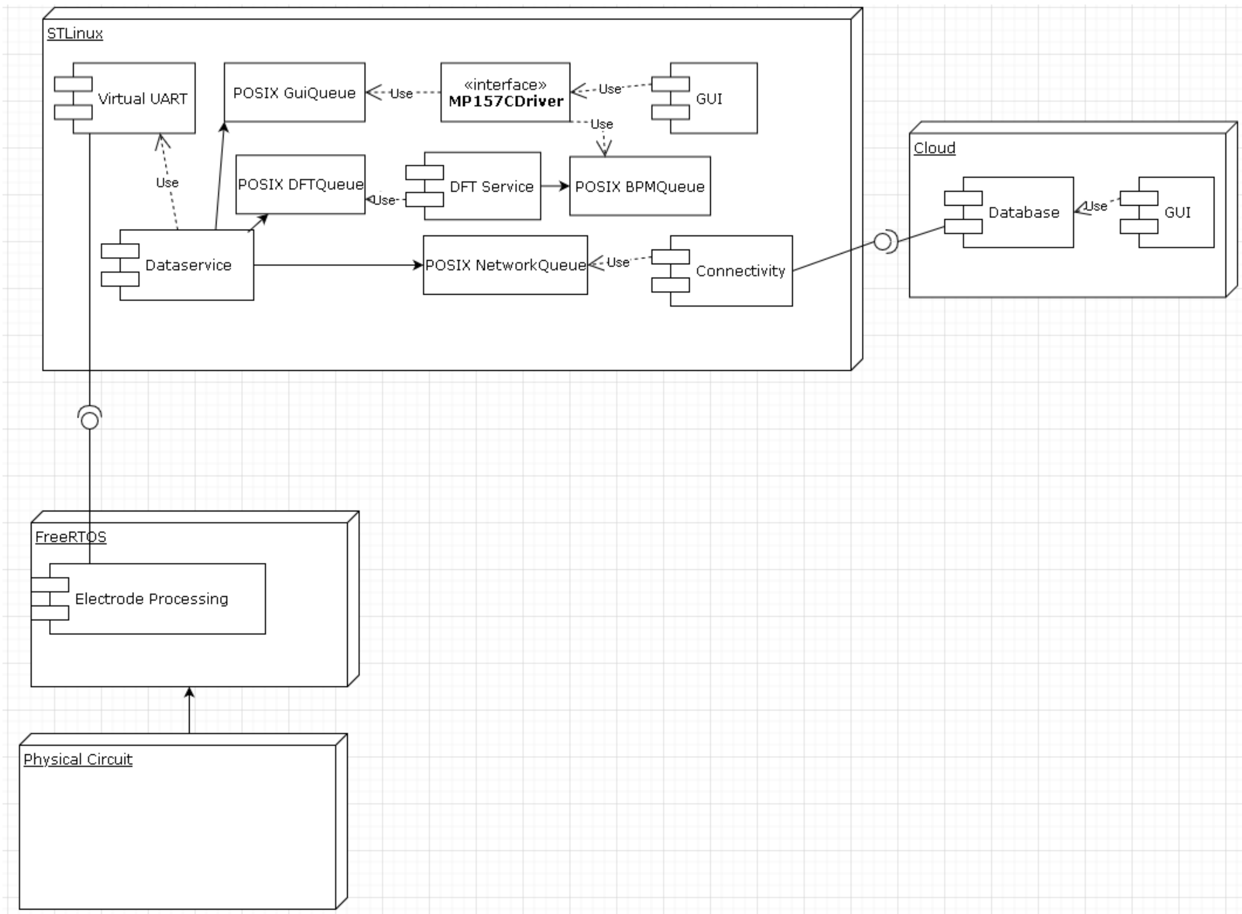


FIGURE 10: SYSTEM PROCESSING AND INTERFACES

FIGURE 12: FINAL ITERATION OF GUI AND DISPLAY OF ECG DATA.

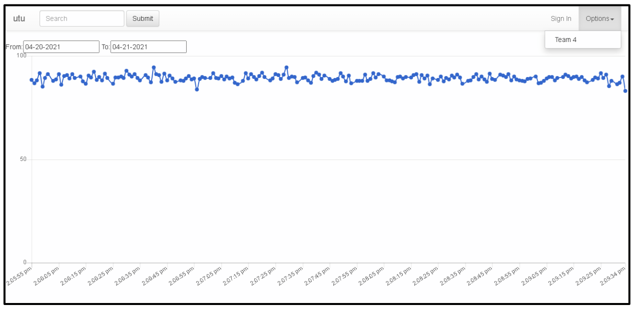


FIGURE 13: CLOUD INTERFACE

Appendix D. Mechanical Aspects

Appendix E. Vendor Contact

Appendix F. Resumes

A. Manish Mishra

MANISH JAISHI MISHRA

PROFILE

Well driven and motivated tutor with 3+ years of experience. Fluent in spoken and written English, Nepali and Hindi. With the experience from hospitality and academic work environment alike, I have accumulated experiences in various communications, public speaking and presentation skills.

EXPERIENCE

STUDENT ASSISTANT, LOS RIOS COMMUNITY COLLEGE DISTRICT, SACRAMENTO, CA – 2015-2018

MESA - Mathematics Engineering and Science Achievement is a program dedicated to excel the student in the STEM field. I had an opportunity to tutor the students of various skill levels. I developed an excellent fluency of communication and self esteem.

BAR TENDER, TOWER CAFÉ, SACRAMENTO, CALIFORNIA, 2013- PRESENT

Although Bar tender, the job was not limited to bar tending but also hosting, cashier, barista, bussing tables and extending the costumer service on the phone as well. It required me to have extended knowledge of the menu and restaurant informations that varied with the time. I also had an opportunity to learn the catering skills at various events.

SERVER, THE CHATEAU ON THE CAPITOL AVENUE; SACRAMENTO, CALIFORNIA 2019-2019

Chateau on The Capitol Avenue is an expertise of the Senior living and hospitality. I had an amazing opportunity of serving and catering the needs of the senior citizens in the dinning room of this community. Learning patience, empathy and communication skills on a different level were my biggest takeaways from this job.

EDUCATION

SACRAMENTO CITY COLLEGE, 2013-2018 - GENERAL EDUCATION

CALIFORNIA STATE UNIVERSITY SACRAMENTO – ELECTRICAL AND ELECTRONIC ENGINEERING, -2021

SKILLS

Accept responsibilities, Effective communication skills, Providing well thought out solutions, Supportive, Self-Confident, Cooperative

B. Brandon Steinlein

.

OBJECTIVE To obtain a student position in the field of Electrical Engineering, and eventually a career in Electrical Engineering

STRENGTHS

· Quick and Decisive problem solving
· Strong team asset
· Exceptional Communication Skills
· Organized and Detail Oriented

EDUCATION

AS,Math & Science Degree - Folsom Lake College
BS, Electrical Engineering - Sacramento State (2021)

KNOWLEDGE & SKILLS

- ***Communication/Organization/Leadership***
  - 1 year Management experience as President of the Math & Engineering Club at Folsom Lake College including Team Management, Project Management and Input, Member Training and Scheduling.
  - 8 years experience Communication, Organization and Leadership roles with Boy Scouts of America via various volunteer work, trip coordination planning and scheduling.
- ***Hardware/Software***
  - Rehearsed with various microcontrollers and single/bi-cycle computers such as Arduino, STM and Raspberry-Pi through several personal projects.
  - Familiar with testing and application of various electrical components using DMMs, Oscilloscopes, and Function Generators.
- ***Computer Applications Experience***
  - Inventor, Autocad, Maya, Fusion, and various other CAD/3D modeling software
  - various 3D printing slicing software
  - Multisim, PSpice/Cadence, ADS
  - Well practiced with Microsoft Office Suite and G Suite applications
- ***Proficient Programming Languages***
  - Verilog/HDL, Matlab, C/C++, Python, Assembly, Visual Basic
- ***Project/Design Experience***
  - Extensive experience with CAD/3D modeling software such as Inventor, Solidworks, Rhinoceros 3D, AutoCAD, and Fusion360.
  - Electric Skateboard with Raspberry Pi and STM32 microcontroller (Fall 2019)
  - Sacramento Micromouse chassis design
  - Pulse Detector with Operational Amplifiers (Fall 2019)
  - Portable Monitor Display (personal project)
  - Magic Mirror build and ongoing parallel application using python (personal project)
  - In-depth experience as an art student designing a piece for display at the Crocker Art Museum.
- ***Documentation***
  Created several Standard Operating Procedures for use in Folsom Lake College Lab, as well as workshop lesson plans for Folsom Lake College Innovation Center.

EXPERIENCE

Clinical Research & Data Management	**Shriners Hospital for Children**	3/12 to Present

- Assist Biomedical Engineer and Orthopedic Surgeon in data analysis techniques of gait data in a variety of studies.
- Use of Matlab to classify severe equinus cases for instant diagnosis and legacy data conversion due to some data being 7+ years old.
- Actively participating in patient interpretations for each new case.

Electrical Engineering/Drafting Intern	**M. Neils Engineering**	12/19 to Present

- Assist PE and Senior Engineer in setting up backgrounds in AutoCAD for projects and picking up redline edits to existing projects.
- Setting up equipment drawings, designing circuitry, and Title 24 documentation including power calculations.

Student Laboratory Facilitator	**Folsom Lake College, Innovation Center**	10/17 to 1/19

- Aid in teaching students new processes, machines, and techniques for them to apply to their own projects.
- Maintain all machines in the lab including; Universal Laser Systems Laser Cutter [PLS6.150D], Roland MDX-50 Multi-axis CNC, Ultimaker 2+ and 3, Various Power Tools, etc.

Asset Protection Associate	**Walmart**	4/16 to 12/19

- Detailed investigative work of shoplifting events both internal and external including hours of data sifting and extensive record keeping.
- Shrink Mitigation via deterrence of shoplifters, distribution of merchandise protection equipment to department managers, accident investigations, and upholding general safety standards.
- Open communication with local law enforcement and DA office of Sacramento County and other neighboring counties.

Assistant Manager	**Mylapore**	8/14- 7/15

- 7:00AM to Midnight six nights a week.
- Prepare food & cutlery before open hours and assist servers and waiters as needed.
- Communicate with catering requests and coordinate with chef and prep cooks.
- Balance drawer at the end of the night and distribute tips

C. Thuong Nguyen

Thuong Nguyen

EDUCATION

BS in Computer Engineering | California State University, Sacramento
09/2015 – PRESENT

Relevant Coursework

Computer Network + Internet, Electronic Laboratory and Network Analysis, Database Management Systems, Advanced Computer Organization, Signals and Systems, Electronics, Advanced Logic Design, Computer Interfacing

EXPERIENCE

Electrical Engineering Intern | Nokia of America Corporation 06/2020 – 08/2020

- Studied and gained knowledge on the importance of Network Analyzer
- Practiced coding in C++ and Python to enhance programming skills

In-Store Geek Squad Agent | Best Buys 09/2019 – 06/2020

- Removed malware, recovered and transferred data, installed and analyzed hardware
- Troubleshoot and repaired operating systems
- Provided excellent customer service

Theft-Detection Camera Prototype 11/2018 -12/2018

- Created a prototype that uses motion sensor coded in Python to detect theft

SKILLS

- Windows-based software (e.g. Microsoft Office Suite, Teams, Outlook, and OneDrive)
- Java, Python, C/C++, Verilog, and Assembly
- Tableau
- Graphic Design, Photoshop
- Bilingual: English and Vietnamese

ACTIVITIES

Event Coordinator and Vice President for Institute of Electrical and Electronics Engineers | CSU Sacramento

08/2017 – 05/2018

- Co-planned a touring event of a Tesla factory for members
- Communicated to companies to invite guest speakers to educate members about the companies and recruitment
- Coordinated and organized on-campus events by booking room, distributing flyers, setting the area
- Assisted the president in the club's matters when needed

Unit Leader, Summer Camp Secretary, and Graphic Designer| Thien Ton Vietnamese Buddhist Youth Association

11/2012 – PRESENT

- Planned and assisted children through various events including games, sports, and performances for cultural appreciation
- Taught introductory Buddhism to kids ages 6-12
  Designed logos, posters and pamphlets for special cultural and religious events

Ryan Smith

Aspiring Engineer and Lifelong Student seeking part-time internship in parallel with schooling

EXPERIENCE

Sutter Health — *Security Officer*

NOVEMBER 2018 - PRESENT

Duties included working with a wide variety of individuals including the mentally ill. Further mastered de-escalation techniques, team communication, and quick decision making.

Allied Universal Services — *Security Officer*

MARCH 2018 - NOVEMBER 2018

Position taught me de-escalation techniques as well as several forms of physical intervention in the case of failure to de-escalate.

Miraflores Winery — *Pairings Manager*

JUNE 2015 - PRESENT

Duties include directing and organizing a handful of wait staff to coordinate with an independent and varying group of chefs. Providing excellent service to high-class clientele and resolving all potential issues ranging from weather to dietary restrictions.

EDUCATION

Folsom Lake College — *Associates in Math & Science*

ALLI 2015 - FALL 2018

General Education chosen for financial reasons.

Sacramento State — *Bachelor's in Electrical Engineering*

SPRING 2019 - PRESENT

Candidate for Bachelor's Degree, expected graduation date of Spring 2021.

PROJECTS

Model Elevator Design — *Electronics Kit Display*

Created a scale elevator with 3 floors and call buttons. I then presented this display at the 15th Annual Regional STEM Fair.

SKILLS

Experienced with coding FPGAs using Verilog

Proficient with ADS, PSPICE, AUTOCAD and can quickly pick up other simulation tools

Knowledgeable of Excel, Powerpoint, and Word to display information and data

AWARDS

Boy Scouts of America Eagle Rank Required 10 years of consistent work culminating in community service project organized and carried out by myself.

Excellence and Creativity in Engineering Awarded by the Polytechnic Academy of Rancho Cordova High School.

Completed Leadership Training Awarded for completion of National Youth Leadership Training through the BSA

Perfect Attendance Awarded for 7 years of consecutive perfect attendance across middle and high school

LANGUAGES

English, Python, Java, Verilog, with enough base knowledge to pick up other languages quickly.

E. Travis Anderson

Travis Anderson
Sacramento, CA
linkedin.com/in/travis-anderson-310/

Skills: Software Engineering, UI Design, Computer Forensics, Penetration Testing, Networking, Mobile App Development, Web-Service Architecture, MVC Architecture, Big Data Architecture, Git, UML Software Modeling, Team Leadership, Microservices, DevOps, Continuous Integration/Delivery

Objectives: Software Architecture, Hardware Architecture, Enterprise Infrastructure Architecture, Security Architecture

Experience Supporting Business Processes: Workflow, Document Management, Digital Signature, Vendor Software Integration, Transaction Reconciliation, Accounting, Data Analytics/Business Intelligence

Programming Languages: Java, JavaScript, HTML5, CSS3, X86-64, ARM, MIPS, SH-3, PHP, C, C#, C++, Perl, MySql, MsSql, ASP.NET, MongoDB Shell Script, Python, VHDL, Verilog

Programming Frameworks: Windows Communication foundation (WCF), .NET MVC, Jquery, Java SWT, .NET, Jquery UI, Bootstrap, JsGrid, Apache Cassandra, Docker, Kubernetes, Apache Cordova

Programming Environments: Visual Studio, Eclipse, Netbeans, Bloodshed Dev-C++, Sourcetree, Vivado, Quartus, VI, Jupyter Notebook

Engineering Tools: Cadence, Pspice, Autodesk Eagle PCB, oscilloscope, logic analyzer, JTAG debugger, Ghidra

Education:

California State University Sacramento

Computer Engineering - Bachelor of Science (2021)
Certificate in Cyber Defense and Operations (2021)
Dean's Honor Roll - (2019, 2020)
CyberCorps (Scholarship for Service) Recipient
Department of Energy Cyberforce Competition (2019) – Team Captain (Laboratory 1st Place)

Santa Barbara City College:

Computer Science – Associate In Science Degree (2019)
Computer Science - Certificate of Achievement (2017)
Cisco Networking Associate – Skills Competency Award (2016)
Liberal Arts and Science: Science & Mathematics Emphasis - Associate In Arts Degree (2016)

Memberships:

Tau Beta Pi (California State University Sacramento - 2019)
Institute of Electrical and Electronics Engineers (2018 – Present)
Treasurer - Student Branch - California State University Northridge

Appendix G. Work Breakdown Structure and Project Timeline Gantt Chart

Figure F1: WBS diagram

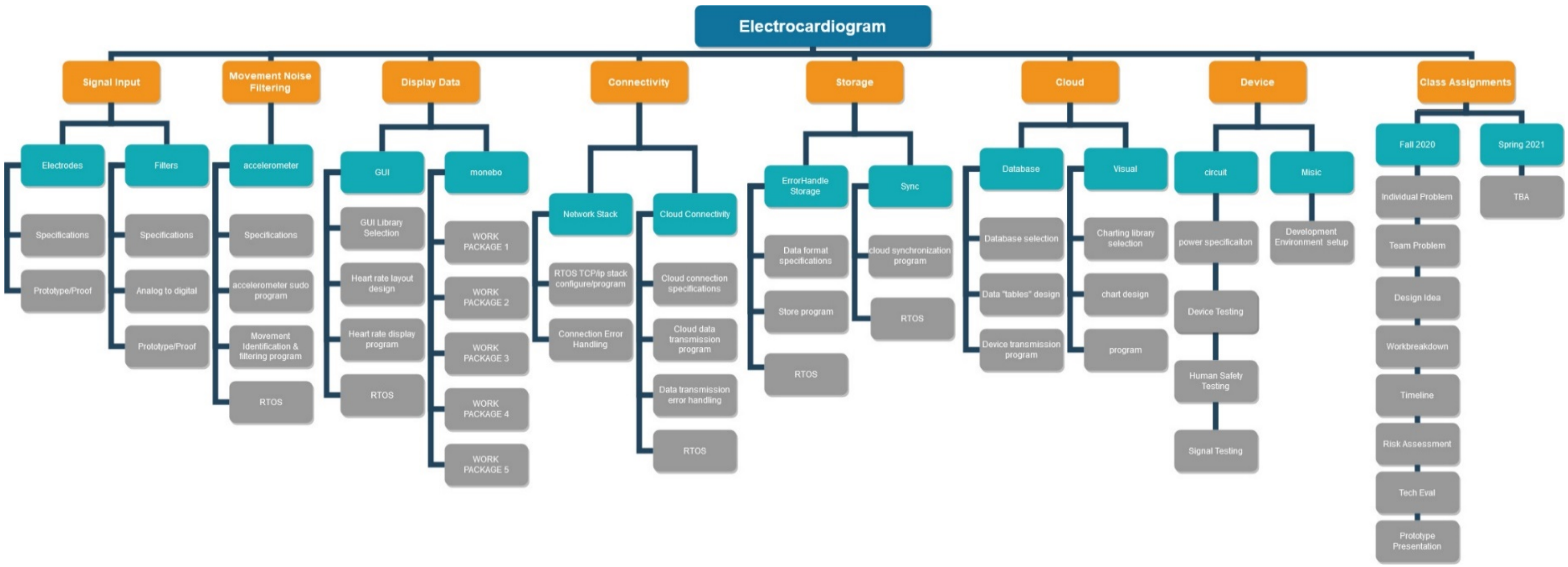


Figure F2: Pert Diagram

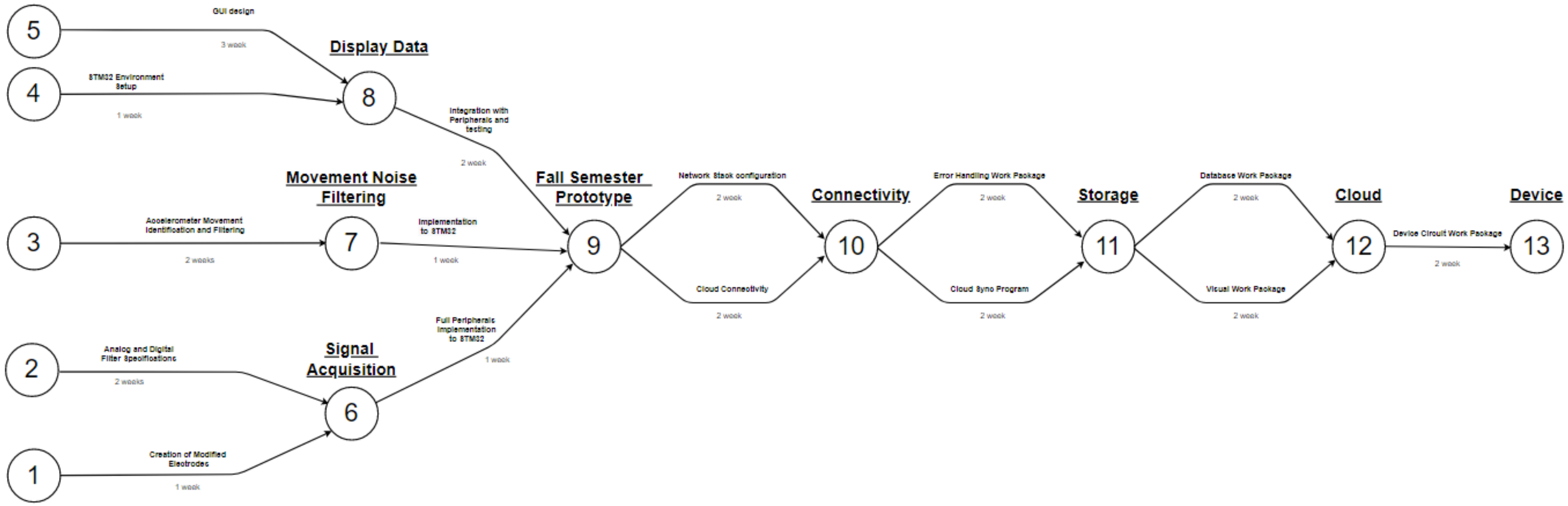
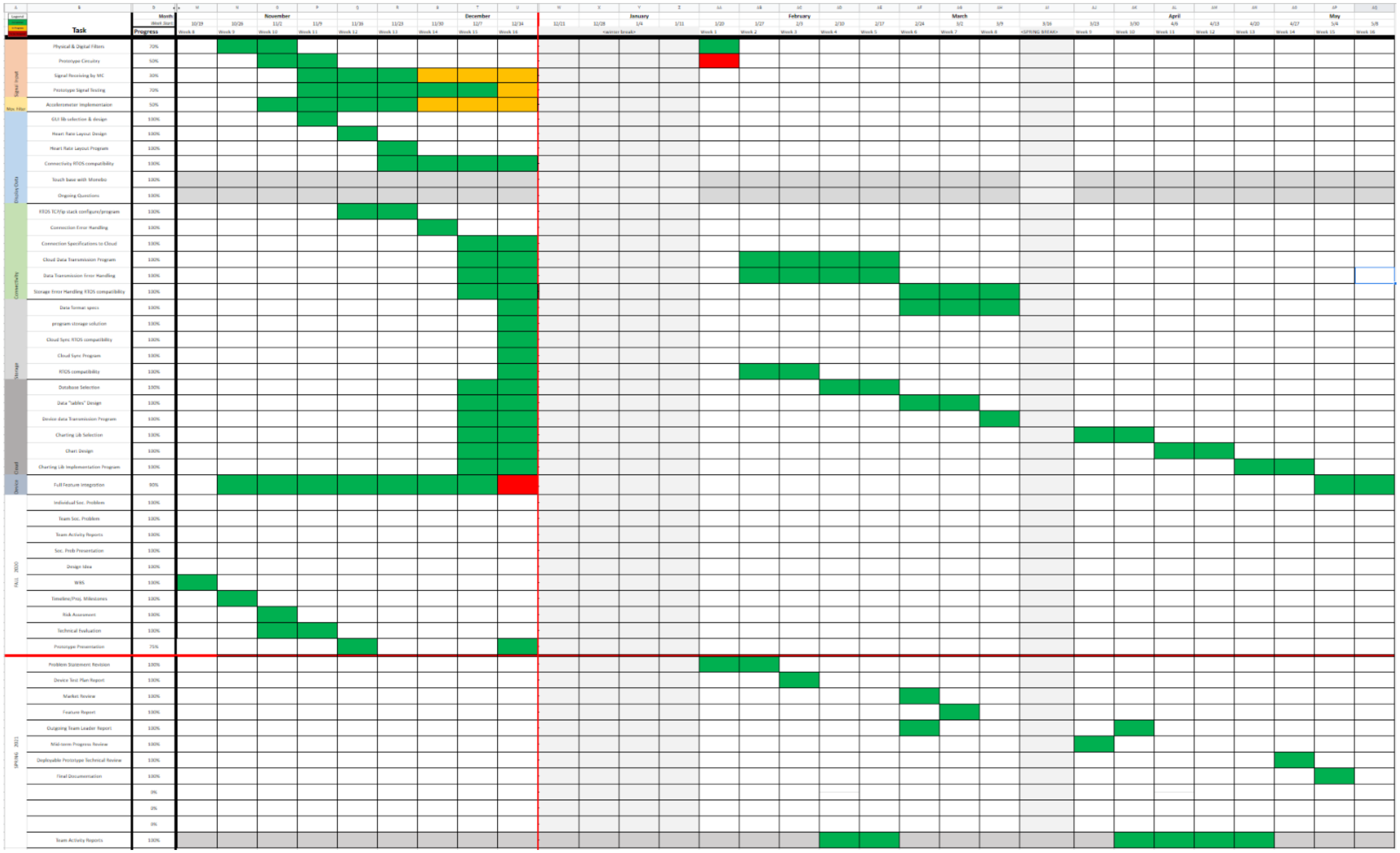


Table F1: Gantt Chart



Appendix H. Device Test Plan

A. Device Functionality

Individual component test based on expected input/output.

Product unit test

Initial test to be conducted with the expected environment being stationary.

B. Human Safety Testing

Before the device can be thoroughly tested on a person it must be tested to ensure that the device is not harmful to people. This will ideally be performed in the Signals Lab on CSUS campus, with administrator permission. The goal is to ensure that current leakage is below 100 microamps. This will be done with the equipment in the laboratory.

C. Signal Testing

Once the device is qualified as safe for human testing as per CSUS regulations, it will be attached to a willing participant. It will be assumed that the participant has an approximately standard ECG reading as a baseline. The device will be placed on and used on the participant. Success will mean that the screen device is displaying a signal that falls within 10% of the measurements as defined by Queen's University School of Medicine [19].