Rescue Device for Diaphoretic EKG Acquisition

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Authorship

The team divided up the sections of this paper and equally contributed to the writing process. No unproportionate work was completed by any team member. When going through and editing the written sections each team member took on roles of editing other sections, collaborating structural choices, as well as improving the content of the paper.

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Abstract

Emergency cardiac intervention is an important but under-researched topic within emergency medicine. Prehospital EKGs on diaphoretic, or sweaty, patients have electrode adhesion problems leading to worsened patient outcomes. Surveying local paramedics and conducting tests on simulated scenarios revealed an obvious engineering need. The KLAA delivers consistent pressure to each precordial electrode simultaneously without interfering with the EKG tracing. Designed for EMS programs in lower resource settings, the KLAA is a one-time purchase that meets universal design specifications. Clinical feasibility testing showed that the KLAA is non-inferior to normal dry EKG acquisition and provides statistically superior tracings in diaphoretic settings. With short deployment time and no interference with existing EKG acquisition the addition of the KLAA is a feasible and life saving possibility.

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1. Introduction

Emergency medical services (EMS) respond to approximately 1,000 out-of-hospital cardiac emergencies per day in the United States, with approximately 90% being fatal [33]. The first step for EMS on an emergency cardiac call is to conduct an electrocardiogram (EKG) on-scene to make a diagnosis and alert the appropriate emergency room department; however, EKG electrodes often slip or pop off of a patient's chest due to diaphoresis, leading to delayed treatment interventions. EKG readings allow for assessment of cardiac function and diagnosis of the heart condition being experienced by the patient, therefore if no EKG can be performed or if an EKG reading is delayed, treatment interventions are also delayed, increasing the risk of fatality for the patient. Time is a critical factor in treatment intervention for cardiac events. One critical cardiac diagnosis that occurs approximately 500,000 times each year in the United States is ST-segment elevation myocardial infarction (STEMI), with the majority of STEMI-related deaths occurring within 2 hours of symptom onset. Diagnosis of this life threatening condition is done with an EKG and requires immediate activation of an emergency hospital facility's surgical team to prepare for an emergency balloon angioplasty. The "door to balloon (D2B) time," or time it takes from the arrival of a patient at a hospital to receiving the emergency angioplasty, is a critical time component that needs to occur as quickly as possible to prevent patient fatality. If there is a delay in acquiring an EKG reading due to electrode slippage, this D2B time will increase, decreasing the risk of patient survival [1].

With diaphoresis (sweating) being the second most common symptom of a heart attack, electrode slippage can occur often on these emergency calls, increasing the risk of fatality for these patients [33]. Medical professionals on-scene, including paramedics and emergency medical technicians, attempt to troubleshoot this issue by continuously wiping down a patient, reapplying electrodes, or trying to hold them in place, but these actions have been described as a "continuous, frustrating cycle" that severely delays treatment. Despite the frequency of this problem occurring in pre-hospital and hospital settings, there is scarce literature highlighting the problem of electrode slippage on diaphoretic patients or outlining any attempts made to solve this problem.

The overall goal of our project was to clearly identify this gap in diaphoretic patient care in emergency cardiac intervention and propose a viable solution that can be accessible to all patients and services. To meet this goal, we developed 7 design objectives:

- accurate EKG readings;
- adhesion (of electrodes onto skin);
- timely diagnosis (after set up);
- suitable for all patients;
- user friendly;
- cost effective, and;
- universal environment (able to be used in any prehospital setting).

Upon verification testing, we validated that our device met all of these objectives with room for improvement in usability and portability. Our device design is a unique innovation that bridges the gap in diagnosis time for diaphoretic patients while being sustainable for all EMS groups as an affordable one-time purchase. Lastly, the KLAA was designed with a focus on the patient and the user, thus it is comfortable, requires minimal force to use, and works on all body types. Overall, this novel device successfully contributes to the improvement of emergency medicine, and was designed to do so in a cost-effective, patient-user-centered manner.

Our team used the materials available to us in the lab to brainstorm many design concepts and ways to hold electrodes down under diaphoretic conditions. It was important for our team to have a design that would be feasible and comfortable under all physiological conditions of the patient's chest. We formed a few different preliminary design concepts and performed a Pugh Analysis to determine which design concept to take to the next stages of prototyping. This design was a pressure delivery device, which consisted of a tubing that encased each lead and had a sled component at the ends that allowed for an equal and comfortable amount of pressure to be applied to each electrode. Each tube would be clipped into a handle component that the user will hold.

Next, our team used SolidWorks to design our pressure delivery device and printed many iterations using the 3D printers available on WPI's campus. Our team went through many iterations of this device to find the optimal thickness and length of the tubing component, without any breakage of the material once pressure was applied. It was also important for our team to find the correct material for this device to be printed in. Ideally, the material would be flexible so the user can bend each tube to reach the desired location of each electrode while being rigid enough to maintain its structure during use. Through many iterations of the pressure delivery device, our team decided to print the final handle and tubing component in ABS due to its availability and its ideal shore hardness. The sled component was printed in PLA. Both the handle and tubing components were printed completely straight, and our team later bent these components to their intended design using a heat gun.

Once our final prototype was completely fabricated, our team named this pressure delivery device, The KLAA. The next step was to conduct testing to validate that the KLAA meets all our initial design objects. Our team had three series of testing, Phase 0, Phase 1 and Phase 2. Phase 1 consisted of two benchtop tests on a mannequin and Phase 2 consisted of an IRB - approved clinical trial. After conducting these tests and performing final statistical analyses, our team was able to validate that the KLAA meets five of our seven design objects. Based on feedback from the Nurse Practitioner that performed the clinical testing, the KLAA could have further design improvements that would enhance its user friendliness and its ability to be used in all environments. Overall, the KLAA provides a novel solution to the recurring issue of performing EKGs on diaphoretic patients in emergency medical settings.

In the next chapters, we discuss the various research and testing methods conducted in depth to arrive at our current solution. Chapter 2 entails a literature review that discusses all relevant topics that correlate to the scope of this project. Detailing EKGs and their electrode

placement to physiological information regarding the heart and its associated function information in the background chapter provide useful information in understanding the project as a whole, and help showcase the knowledge our team went into designing this device with. Once initial research was done and a based knowledge established, Chapter 3 explains the approach our team took when completing this project throughout the duration of the entire academic year. This includes planning techniques, organization strategies, and understanding technical standards that relate to our project.

Moving onto Chapter 4, this chapter entails the design process for our device, and begins with a Pairwise comparison of the design objectives derived from the client statement in Section 3.1. This allowed our team to rank them based on importance when designing the device. With four initial design concepts generated and partially developed, a Pugh analysis was done to select one final design concept to iterate on and make into our final device. This being the Pressure Delivery Device, which through several different iterations discussed in depth in Chapter 4 became the KLAA.

With our final prototype, Chapter 5 discusses the series of tests that were implemented to understand the feasibility of the KLAA EKG Assist. Data from each test using the KLAA were analyzed using statistical analysis. The team created tests were divided into Phase 0, Phase 1, and Phase 2. These tests were aimed to further define the challenges associated with EKG use under a diaphoretic condition and understand if our device maintains accurate EKG readings and initial electrode placement, both on a mannequin and human subjects. Chapter 6 then discusses the results of those tests and associated findings as well as the impacts our device has on society and the device manufacturability. From there, Chapter 7 is a discussion of the project as a whole and a high level overview. Lastly, Chapter 8 discusses conclusions from the testing results, as well as other findings and future recommendations.

2. Literature Review

In this chapter, we discuss the prevalence of the electrocardiogram, its indications for use, and how it works in terms of the heart's anatomy, electrical activity, and physiology. We then emphasize how diaphoresis complicates electrocardiogram acquisition and the gap that exists in current solutions.

2.1. The Electrocardiogram (EKG)

An electrocardiogram (EKG) is a medical diagnostic tool that is utilized to see how the heart is functioning by measuring the changes of electrical signals spreading through the heart as it contracts [7]. EKGs are conducted by attaching small, sticky electrode patches to specific locations on the chest, arms, and legs of the patient. The electrical activity of the heart is detected by the electrodes and changes in the electrical activity are recorded by the EKG machine, which draws a trace onto a moving piece of electrocardiograph paper that moves at a speed of 25 mm/s [7]. The electrocardiograph paper has time plotted on the x-axis, voltage plotted on the y-axis, and larger and smaller squares dividing the axes into smaller increments [7]. A properly beating heart will be coordinated by electrical impulses to different parts of the heart in order to keep blood flowing in the direction it should. Therefore, any irregularities in an EKG reading can be indicative of heart-related conditions; for instance, narrowing of coronary arteries, myocardial infarctions, or atrial fibrillation [8]. Results from an EKG are interpreted by healthcare professionals, typically a doctor or cardiologist; however, paramedics are also trained to interpret EKGs for certain conditions in pre-hospital settings [1]. Interpretation of an EKG involves analyzing the shapes, durations, and intervals of the waves and complexes plotted by the EKG to determine if the heart is functioning normally.

2.1.1. Prevalence of EKG Use in Prehospital Settings

Prehospital 12-lead EKGs are recommended for use within emergency medical services (EMS) for early response and management of patients presenting non-traumatic chest discomfort suspected to have acute coronary syndrome (ACS) [1]. EKGs can provide critical information to inform three major components of care for these patients. This includes the prehospital treatment focus, transport to an appropriate hospital facility, and activation of a response from the receiving cardiac catheter laboratory if an ST-segment elevation myocardial infarction (STEMI) is suspected [2]. STEMI, a heart attack caused by ischemic occlusion, is the most critical and threatening subtype of ACS with the highest 30-day mortality rate [3].

Each year in the United States, approximately 500,000 ST-segment elevation myocardial infarction (STEMI) events occur, with the majority of STEMI-related deaths occurring within 2 hours of symptom onset [1], [4]. Accurate EKG interpretation is critical to patients with suspected STEMI in order to initiate immediate and appropriate care, with time being a key factor in reducing morbidity and mortality in these patients [5]. Specifically, the time to

reperfusion or “door to balloon (D2B) time” is a key determinant that has a strong influence on patient outcomes [5]. The D2B time is the time from the arrival of the patient at a hospital’s emergency department until an emergency balloon angioplasty, a surgical procedure performed in order to widen narrowed or obstructed arteries, is conducted for the STEMI in the cardiac catheterization laboratory (CCL) [6]. For patients identified or suspected to have STEMI, the goal is to decrease the D2B time and give the patient access to percutaneous coronary intervention (PCI) within 90 minutes of the onset of symptoms [1]. Each 30 minute increase in the D2B time increases the relative risk of morality within 1-year by approximately 7.5% [1].

In addition to STEMI, an EKG is important in detecting arrhythmia, electrolyte deficiency, and pulmonary embolism. An arrhythmia is defined as any deviation from the heart’s normal sinus rhythm caused by a change in the heart's electrical activity via nerve cells. Arrhythmias can vary in severity due to illness, alcohol, exercise, or caffeine, among many other lifestyle-centric factors, and is common in 1.5 to 5% of the population [2].. Signs of arrhythmia on an EKG include a narrowed or widened QRS complex width or abnormal or non-discernable P waves [2]. Electrolyte deficiency, or a lack of ions needed to stimulate electrical activity, is indicated through an EKG via peaked T waves or absence of P waves, depending on severity [3]. This occurs due to the lack of ions crossing the heart's cell membranes to generate the cardiac action potential, which in turn stimulates a heart beat.

In addition to arrhythmia and electrolyte deficiency, pulmonary embolism is diagnosed with an EKG. A pulmonary embolism is typically a block, or blood clot, in an artery in the lungs. Of about 15 to 25% of patients diagnosed, the EKG reads a specific pattern, of which is described by lead I depicting a prominent S wave, and lead II an inverted T wave.

Pre-hospital 12-lead EKG readings are also an important component when triaging or prioritizing patients and selecting the proper hospital facility for treatment [4]. While transport to the nearest PCI-capable hospital facility within 90 minutes or less is ideal for patients suspected to have STEMI, this is not always possible depending on the geographic location of the patient, particularly in rural settings [4]. When reaching a PCI-capable hospital facility is not possible in under 120 minutes, fibrinolytic therapy is required for the patient and can typically be conducted at any non-PCI-capable hospital facility [4]. Without proper and timely prehospital 12-lead EKGs, EMS providers are unable to notify hospitals to activate medical protocols accurately of the conditions their patients are experiencing.

2.1.2. Indications for Use

Policies released by several organizations worldwide including the American College of Cardiology Foundation (ACCF) and the American Heart Association Task Force (AHA) recommend a 12-lead ECG be performed in prehospital settings at the point of first medical contact (FMC) in patients presenting with signs and symptoms related to acute coronary syndrome (ACS), or more specifically, STEMI [4] [9]. Symptoms of ACS are typically sudden within the patient and can manifest in various ways including angina, pain radiating from the chest to other parts of the body, nausea or vomiting, indigestion, dyspnea, sudden and heavy

sweating, racing heartbeat, syncope, or sudden fatigue [10]. The classical symptom of ACS is substernal chest pain or angina, described most often by patients as a crushing feeling on the chest [11]. However, symptoms often vary depending on comorbidities, age, and sex [10]. Additional indications for ECGs include: cyanosis, hypotension/hypertension, hypothermia, poisoning, or blunt cardiac trauma [7].

ACS is responsible for one-third of deaths in people older than 35 and refers to a group of heart-related conditions including STEMI, non-ST elevation myocardial infarction (NSTEMI), and unstable angina [9]. Common risk factors for ACS include those of hypertension, diabetes, smoking, hyperlipidemia, male sex, obesity, physical inactivity, and poor nutritional practices [2]. Substance abuse of cocaine and family history of myocardial infarction are additional common risk factors [2]. ACS typically results from the disruption and subsequent rupture and split of plaque within coronary arteries resulting in the formation of a blood thrombus. The thrombus then blocks flow of blood to the heart muscles, causing cell death and damage in cardiac muscles due to lack of oxygen supply. While cell death does not always occur, a decrease in oxygen supply can still result in improper muscle function. When this occurs, the cardiac muscles do not function properly and results in a heart attack [8]. According to the AHA, one person every 41 seconds suffers from a heart attack, making it the leading cause of death in the United States [9].

2.2. How the EKG Works

The EKG reads a signal from the electrical current of the heart. These graphs contain information on the polarization and depolarization of the heart. Fig. 1 below is a chart which outlines each wave and interval of the EKG graph and its correlation to electrical currents in the heart.

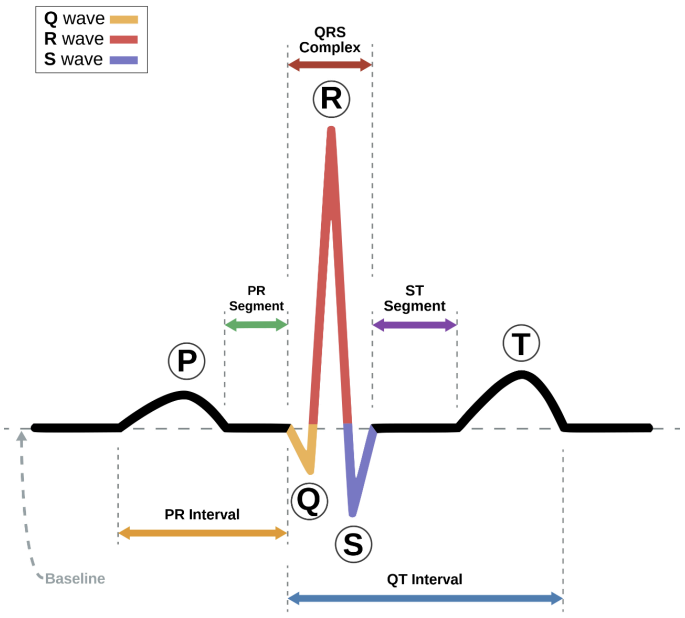


Fig. 1. Labeling the parts of the EKG reading. [22]

TABLE I
Components of a Heartbeat on an EKG Reading and Their Interpretation

Wave or Interval	**Physiological Interpretation**
P Waves	wave of depolarization that spreads from the SA node throughout the atria
PR Interval	the time between the onset of atrial depolarization and the onset of ventricular depolarization; this is the period of time from the onset of the P wave to the beginning of the QRS complex
QRS Complex	ventricular depolarization, and a relatively short duration
ST Segment	the period at which both ventricles are completely depolarized; isoelectric period following the QRS and ending at the beginning of the T wave
T Wave	ventricular repolarization that exhibits a positive deflection. The reason for this is that the last cells to depolarize in the ventricles are the first to repolarize
RR Interval	measurements of the sinus heart period in chronological or heartbeat order
QT Interval	the time for both ventricular depolarization and repolarization to occur

2.2.1. Einthoven’s Triangle

Einthoven’s triangle is a crucial principle that guides EKG lead placement. The term ‘Einthoven’s Triangle’ formed when William Einthoven discovered that cardinal limb leads in the form of an equilateral triangle can record the electrical axis of the heart [15]. This formation connects three limbs of the patient, which include the left arm, right arm, and the left leg, also referred to as standard lead I, II, and III [16]. The purpose of Einthoven's triangle is to identify correct lead placement for an accurate EKG acquisition. Fig. 2 shows a diagram with the standard leads on the body.

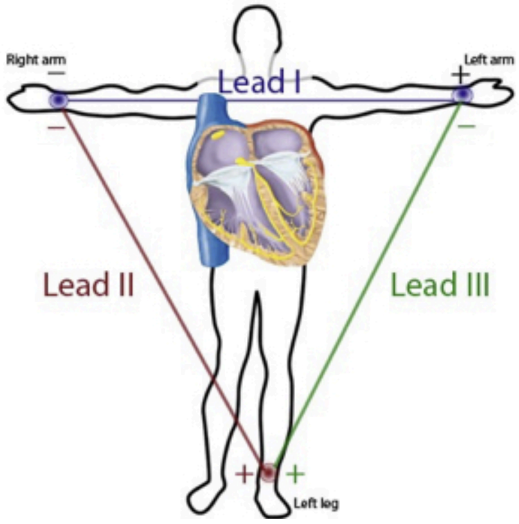


Fig. 2. Einthoven's Triangle Illustration.

This diagram shows each lead's placement and orientation on the body. Standard lead placement is defined by one negative lead on the right arm, and two positive leads on the left arm and leg. This provides a Visualizing the equilateral triangle can help aid in electrode placement to ensure proper readings.

2.2.2. Physiology of the Heart

Our heart consists of four chambers that self-regulate, these chambers are the Right Atrium (RA), the Right Ventricle (RV), the Left Atrium (LA), and the Left Ventricle (LV). Cardiac muscles or myocardium make up the middle layer of the heart and give it structure. The myocardium is surrounded by a thin outer layer called the epicardium (visceral pericardium) and an inner endocardium [4]. Fig. 3 is of the heart, visualizing the frontal section, as well as the various chambers. The numbers in the diagram represent the path blood takes and the blue shows deoxygenated blood traveling to later oxygenated blood after being pumped to the lungs and back into the heart.

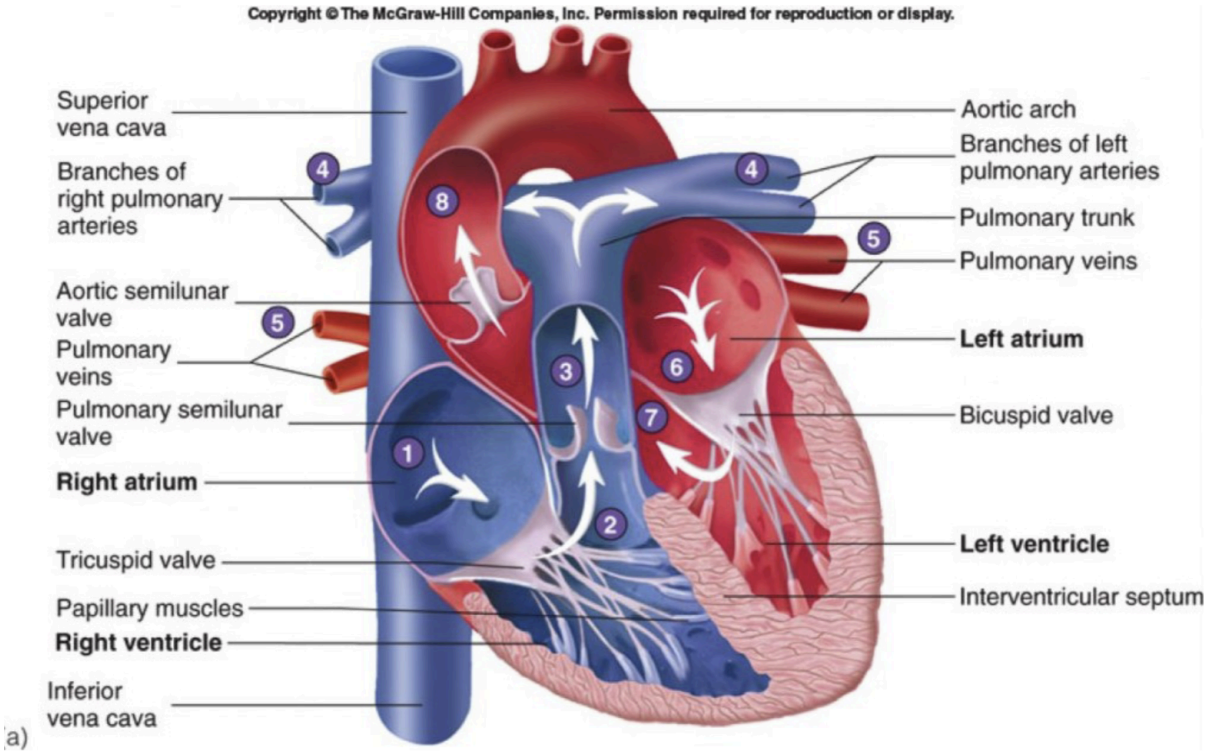


Fig. 3. Diagram of the frontal section of the heart [37]

2.2.3. Blood Flow From the Heart's Electrical System

The heart contains the cardiac conduction system, which is responsible for generating electrical impulses and distributing the signal throughout the heart [17]. The circulatory system moves blood throughout the body, and within this system is the coronary circuit. The coronary circuit supplies the heart's muscles with oxygenated blood through the heart's arteries, which is then returned to the atrium as deoxygenated blood to become oxygenated again at the lungs [23]. This system controls the rate and rhythm of the heartbeat [8]. The parts of this system are the SA node, AV node, bundle of HIS, bundle branches, and Purkinje fibers [18].

The autonomic nervous system and vascular system of the heart are crucial for proper maintenance of its electrical activity. The autonomic nervous system (ANS) works to control heart rate and blood pressure among other functions to maintain homeostasis [5]. This activity, under parasympathetic conditions, is driven by the Vagus nerve to decrease the heart rate. In contrast, under sympathetic control, heart rate is increased and triggers the "fight-or-flight" response [5]. During each heartbeat a cardiac cycle is occurring of contraction and relaxation from the beginning of one heartbeat to the next. During this cycle the systole or contraction occurs when ventricles contract while the atria relaxes, and when the ventricles relax and fill until the atria contracts is called diastole. This entire process in the heart lasts a total 0.8 seconds in the human body.

Although all cells in the heart (cardiomyocytes) can conduct electricity, only the ones part of the cardiac conduction system conduct electricity at specific speeds, which allows for certain parts of the heart to beat at specific times [16]. The electrical signal of a heartbeat travels from the top of the heart to the bottom. The heart contracts as the electrical signal travels while the chambers are squeezed in a specific order to pump blood through and create the heartbeat [8]. The electrical depolarization wave, which is the orderly passage of electrical current sequentially through the heart muscle, changing it, cell by cell, from the resting polarized state to the depolarized state until the entire heart is depolarized, travels from the SA node, through the AV node, then to the bundle of His and the Purkinje fibres [21]. P waves cause an impulse to trigger the heart's muscles to contract and pump blood [18]. The blood travels from the heart's right atrium to the right ventricle. From here, blood travels to the lungs where it can be oxygenated and re-enters into the left atrium, moves to the left ventricle, and into the rest of the body [19]. Below is a step-by-step overview of this process:

1. Pacemaker cells located in the SA node in the right atrium start the electrical signal of a heartbeat, triggered by a change in voltage or an oncoming action potential [21].
2. This electrical signal travels through the atria, causing the atrium to pump blood into the ventricles.
3. The electrical signal moves down the heart to the AV node between the atria and ventricles. During this step, the electrical signal slows to allow the ventricles to fill entirely with blood.
4. Once the ventricles are filled, the AV node creates another signal, which travels along the walls of the ventricles and causes them to contract and pump the blood out of the heart.
5. The ventricles relax and a new signal is created in the SA node. The heartbeat starts again.

2.3. Gaps in EKG Acquisition Efficiency

Abnormal or incorrect EKG readings can commonly occur due to improper EKG electrode placement [12]. Electrocardiographic artifacts are alterations and distortions of EKG readings that are not related to cardiac electrical activity and can be caused by multiple factors such as motion, loose leads, muscle tension, electromagnetic interference, and CPR compression [13], [14]. EKG placement is important to avoid failure in diagnosis or falsely ascribing pathology to electrocardiographic artifacts, possibly resulting in unnecessary utilization of resources if EMS sources activate CCLs when they are not needed [4], [12].

2.3.1. Diaphoresis

Diaphoresis is the medical definition of excessive sweating due to an underlying health condition, episode, or medication [26]. This condition can be caused by many factors, including

menopause, diabetes, pregnancy, hyperthyroidism, heart attack, substance withdrawal, cancer, anaphylaxis, and certain medications. Additionally, it is often a sign of emerging, underlying health conditions and affects many populations [15].

With diaphoresis being the second most common symptom of a heart attack, an ongoing issue faced by medical professionals is applying EKG electrodes to diaphoretic patients and reading both correct and accurate signals [31]. When a diaphoretic patient is experiencing excessive sweating, electrodes from the EKG will slide from the correct position due to the excessive perspiration on the skin. When these electrodes are misplaced, the EKG is unable to accurately read the heart's electrical signals. This frequently causes misdiagnosis of cardiac problems, which can lead to negative health outcomes for patients.

To investigate this issue, a survey was sent to ten paramedics to identify and characterize the prevalence of diaphoresis and its effect on EKG acquisition, as well as to understand existing solutions and their effectiveness. According to survey responses, indications for EKG use are mostly suspected cardiac events such as acute coronary syndrome (ACS), as well as chest pain, irregular heart rate, shortness of breath, and medical history of cardiac issues or diabetes. Other indicators are an altered mental state (AMS), abdominal pain, diaphoresis, and lastly, general weakness such as malaise, nausea, syncope, or electrolyte imbalance. Quantity of EKGs done per shift vary from zero to five per day, and one to ten per week, but all patients who are diaphoretic receive an EKG.

Six of the paramedics indicated that at least 80% of the time, slick skin from diaphoresis impacts proper placement of electrodes. Eight of the ten paramedics noted that the issue of diaphoresis is very important when compared to other factors that may complicate electrode placement. Responses described patient types most commonly known to impact electrode placement when diaphoretic as those who are obese or enduring a cardiac, respiratory, or diabetes-related event. Other conditions noted include those with nausea-vomiting symptoms, as well as fully shaved, very hairy, or very muscular patients, and patients with excess skin or breast tissue.

When asked about placing electrodes on diaphoretic patients, all paramedics surveyed indicated the electrodes do not stay in place, "pop off", or fall off with minimal connection to the skin and excessive noise in the signal. One mentioned the electrodes not registering with the system and specifically observed V3-V5 failing the most. To troubleshoot these scenarios, paramedics typically wipe down the patient with a towel and an alcohol prep pad, apply an antiperspirant, and obtain new electrodes for placement. Other methods include physically holding the electrodes in place, shaving the patient if diaphoresis is due to hair, and lastly, taping down the electrodes. These methods were indicated to work well enough "most of the time" or "sometimes" for a short duration of an initial reading, but are inherently frustrating and need to be repeated if additional readings are necessary.

When asked about current "sticky" electrodes used to combat diaphoresis, seven of the respondents noted they have never used them before or have not heard of them, while three said they work well. Reasons the paramedics have not used them before included that the clinics use

the “lowest bid” equipment and the sticky electrodes are “too costly” to purchase. Other downfalls included patient complaints during electrode removal and the potential damage removal can cause to thin or delicate skin.

2.3.2. Current State of the Art

Properly adhering EKG electrodes to diaphoretic patients is a problem that medical professionals consistently face. It is imperative to have these electrodes properly adhered in the correct placement in order to have an accurate diagnosis. To combat this issue, many companies have developed electrodes that are promised to adhere in any diaphoretic setting. These electrodes are typically “stickier” and have more gel adhesive that will adhere on diaphoretic skin. For example, 3M has an EKG electrode, the “3M Red Dot Diaphoretic Soft Cloth Monitoring Electrode”, that they ensure will stick to a patient’s skin in any diaphoretic setting (Fig. 4). The company claims this electrode has a greater adhesive and has clinical data that proves this electrode works on diaphoretic patients. In addition, they claim its low chloride content minimizes any skin irritation [24].

Fig. 4. The 3M Red Dot Diaphoretic Soft Cloth Monitoring Electrode [24].

Medline also makes an EKG electrode, the "MedGel Stress/Diaphoretic Foam Electrode”, that is claimed to stick in any diaphoretic setting (Fig. 5). Like the 3M electrode product, this Medline electrode has more gel adhesive, making it “stickier”. This product is made of foam, and is in a teardrop shape which is designed to direct the sweat around the electrode, allowing strong adhesion in diaphoretic settings [25]. This electrode is just one product that Medline makes for diaphoretic settings. They have other products such as the “MedGel Radiotranslucent Stress/Diaphoretic Foam Electrode” and many more. All of these diaphoretic electrodes have a “stronger” gel adhesive which the company claims can stick to skin in any diaphoretic setting.

Fig. 5. The MedGel Stress/Diaphoretic Foam Electrode [25].

Even though these products are all claimed to stick in any diaphoretic setting, many medical professionals find that this is untrue. The diaphoretic electrodes are also more expensive and expire after about two years after manufacturing, making it unreasonable for professionals to purchase them. Even with these diaphoretic electrodes, the users still find themselves wiping off the individual's chest, wiping with alcohol swabs, and applying pressure to the electrodes, defeating the purpose of these electrodes. Therefore, there is a prominent gap between diaphoretic patients needing an EKG and having a working electrode to help diagnose them.

3. Project Strategy

This chapter outlines the objectives and constraints generated from the client statement. In addition, this section discusses design requirements, including engineering standards and specifications, as well as our approach term by term.

3.1. Client Statement

Paramedics use EKGs for recognition of cardiac arrhythmias, ischemia, pulmonary emboli, sepsis, chest trauma, and irregular electrolyte levels. Current EKG electrodes tend to not adhere properly on diaphoretic patients, which causes various negative effects. The only current solution to this problem is creating more-adhesive electrodes; however, these are often expensive and cannot be purchased by all emergency service programs. A different approach to this issue must effectively solve this problem. This solution needs to be cost effective, easy to use, lightweight, and allow for accurate EKG readings.

3.1.1. Objectives From the Client Statement

We created design objectives based on our client statement. These objectives were used throughout the design process as criteria to take into consideration when brainstorming, narrowing down the design concepts, and developing our final design concept. Below is a list of these objectives;

- *Timely Diagnosis;* The device must enable an EKG reading in the same amount of time as a non-diaphoretic EKG or faster.
- *Accurate Readings;* The device must not interfere with the EKG reading.
- *Adhesion;* The device must keep all electrodes on the skin. Adhesion security is lost under diaphoretic conditions and causes misreading and improper diagnosis, of which our team is aiming to correct.
- *Achieve Proper Placement;* The device cannot impair the ability of emergency service providers, or other users, in placing the electrodes in the proper chest location. Using the device, proper placement of electrodes must be achieved.
- *Universal Environment;* Although our clients are primarily emergency service providers, the device must work in any medical setting. This may be in an ambulance or other prehospital and hospital settings.
- *Suitable for all Patients;* The device must work on all chest geometries of patients, and not begin to fail if patients vary in height, sex, weight, etc..
- *User Friendly;* The design of our device has to be user friendly such that minimal additional training would need to be done for emergency medical service providers.
- *Cost Effective;* Our device must be accessible to all patients, especially in low-resourced EMS groups.

3.2. Design Requirements; Technical

When designing any type of device, it is crucial for an engineering team to first consider its technical design requirements. These requirements are generalized to the overall boundaries of the human body, rather than the specific needs of the client's application. The needs of our team's application is discussed in Section 4.1. Since our team is designing an EKG acquisition device, our technical design requirements are in regards to any pressure delivery device intended to be used on humans. Below is the list of technical design requirements the team generated;

- Design does not add artifact to EKG traces produced.
- Design adheres to current EKG electrodes and EKG machine dimensions .
- Design is customizable for different sizes of patients seen (conforms to required chest geometry).
- Design is suitable for repeated use without replacement.
- Design is able to be applied to all precordial electrodes .
- Design consists of clear labels for users to read.

3.3. Design Requirements; Standards

Engineering standards were considered for the design of our prototype and guided the characteristics and technical details we chose for our device. We determined that the standards for EKG equipment is currently under the ISO/IEC and entitled, "80601, Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables, and leadwires." Under this standard, basic safety and essential performance requirements are detailed. In regard to our prototype, there are no specific safety measures or essential performance requirements, as the ISO/IEC standards apply to the electrical components of EKGs, which will not be altered within this project [30].

In addition to ISO/IEC standards for EKGs, our team investigated the Food and Drug Administration (FDA) standards for EKGs. The FDA regulates medical devices, including EKG machines, to ensure their safety and effectiveness and to set standards and requirements that manufacturers must need to market and sell EKG devices in the United States. The FDA separates medical devices into three different classes- Class I, Class II, and Class III. EKG electrodes are considered by the FDA to be Class II devices, meaning that they pose moderate risks to users. Furthermore, EKGs are determined by the FDA to be 510(k) exempt. This means that the EKG, or devices like it, are substantially equivalent to a device that is already on the market, therefore, it does not need to go through a premarket submission through the FDA. For this reason, our product would not need to go through a premarket submission, as it is similar to already-marketed devices and does not pose a significant threat to the user [26].

3.4. Management Approach

Understanding and following steps of the design process was crucial for the success of our project. The first step was identifying the need behind the project, as extensive research on EKGs used on diaphoretic patients has not been conducted yet. The team researched this by surveying paramedics who have experience in using EKGs on diaphoretic patients, as discussed in Section 2.3.1. This was important for our team as there were originally gaps in this literature. Once the need was defined and understood, our team began the brainstorming process where different design ideas were generated. This brainstorming generated nine design concepts, in which a Pairwise comparison and Pugh analysis were performed to narrow to four design concepts. With these final four design concepts, the team conducted further research to create in-depth designs and determined the feasibility of each. Again, a Pugh analysis was conducted for these four designs and the highest scoring design was chosen. Next, the final design prototyping process took place, where the team identified three main components to our final design; the tubing surrounding the EKG wires, the attachment sled piece, and the handle where the tubing comes together. The components of our prototyped design were then fabricated and tested to assess which areas needed improvements as we made further iterations to our design.

Our team used several tools to stay organized, including a group chat for communication, utilizing our Outlook calendars for scheduling purposes, and maintaining a Google Drive for documentation. The Google Drive stored all of our work, which was organized into folders for each meeting agendas and minutes, report chapters, design concepts, research materials, and more. Our team also created weekly to do lists to stay on top of our tasks as a team and individuals. Fig. 6 below show the Gantt Charts, generated in Microsoft Excel, our team created to track our progress (separated into each term).

Aterm 2023

Task	**Week 1** (08/24-08/25)	**Week 2** (08/28-09/01)	**Week 3** (09/05-09/08)	**Week 4** (09/11-09/15)	**Week 5** (09/18-09/21)	**Week 6** (09/25-09/29)	**Week 7** (10/02-10/06)	**Week 8** (10/09-10/13)
Background research								
Identify client statement and user needs								
Survey								
Literature review								
Pairwise Chart								
Concept mapping								

Bterm 2023

Task	**Week 1** (10/23-10/27)	**Week 2** (10/30-11/3)	**Week 3** (11/7-11/10)	**Week 4** (11/13-11/17)	**Week 5** (11/20-11/21)	**Week 6** (11/27-12/1)	**Week 7** (12/4-12/8)	**Week 8** (12/11-12/15)
Brainstorming Presentations								
Pugh Analysis								
Choose Final design								
Lab Prototyping								
CAD/solidworks technical drawings								
Write Report chapters: 3 4 5								
Print Tube Prototype								
Iterate Deisgn								
Draft Report								

	Cterm 2024							
Task	**Week 1** (01/10-01/12)	**Week 2** (01/16-01/19)	**Week 3** (01/22-01/26)	**Week 4** (01/29-02/02)	**Week 5** (02/05-02/08)	**Week 6** (02/12-02/16)	**Week 7** (02/19-02/23)	**Week 8** (02/26-03/01)
IRB, PLA Prototype, Training								
Create Test Procdeure, Material Selection, Final Printing								
Final Prototype complete								
Device Verification								
Draft Full Report								
Plan Study								

	Dterm 2024							
Task	**Week 1** (03/11-03/15)	**Week 2** (03/18-03/22)	**Week 3** (03/25-03/29)	**Week 4** (04/01-04/05)	**Week 5** (04/08-04/12)	**Week 6** (04/16-04/18)	**Week 7** (04/22-04/26)	**Week 8** (04/29-05/01)
Run Study								
Make Final Presentation								
Idenitify Limitations and Future works								
Final Report Done								
Final Presentation Done								
eCDR								

Fig. 6. Gantt Chart By Term**.**

Although the team had planned out what our schedule would look like for all four terms, we encountered challenges that we had to adapt to and overcome. An example of this was during C Term, the team planned to have our final prototype complete by the end of week three but instead was a challenging task that took until D-term to be completed. Our team adapted to this change by completing other tasks while we waited for our final prototype to be finished.

4. Design Process

This section describes our design concept selection process as well as our final 3D printed prototype. Each of our initial designs are illustrated along with a list of their advantages and limitations, and later sections look into our final design concept and how it's intended for use. Lastly, prototyping and material selection of our device are discussed in this chapter, as it was a key portion of the final design itself.

4.1. Needs Analysis

Determining the needs and wants for the device is crucial to its function and usability. Needs are aimed to ensure the device is created for its intended purpose. Wants, on the other hand, describe design aspects that would improve the overall design, but are not necessary for optimal function. Our team worked to prioritize the needs and wants for our device using a Pairwise Comparison Chart of our design objectives, detailed below in Table 2.

In order for the device to function as intended, the design requirements, or “needs” are detailed below:

- The device should not cause bodily harm to any patient’s body, especially the chest and ribs.
- The material used to manufacture the device should not interfere with any EKG readings.
- The material used to manufacture the device should not conduct any current.
- The material used to manufacture the device should not cause any inflammatory responses or allergic reactions to the patient’s skin.
- The device must work for patients of all ages and body types.
- The device must work under all diaphoretic conditions simulated.
- The force exertion of the entire device must not exceed 3N to keep electrodes on the skin.
- A length of 356.00 mm is required to reach V1 and V2 electrode placements.
- A length of 251.00 mm is required to reach V3, V4, V5, and V6 electrode placements.
- An inner diameter of 5mm to surround the lead encases the lead with room for length adjustment.
- An outer diameter of 9mm to maintain flexibility and structure.

The “wants” for our device are listed as follows:

- One-time set up should not exceed five minutes.
- The device is ergonomically efficient for the user.
- The weight of the device must not exceed three pounds.

The Pairwise Comparison Chart shown below ranked each objective so that our team could prioritize certain design aspects. Accurate readings and achieving proper placement proved

to be the most important objectives, thus our final design must demonstrate this through our verification and validation testing, as described in Sections 5 and 6.1.

TABLE II
Pairwise Comparison Chart.

Design Requirement	Timely Diagnosis	Accurate Readings	Adhesion	Achieve Proper Placement	Universal Environment	Suitable for all Patients	User Friendly	Cost Effective
Timely Diagnosis	0	1	1	1	1	1	0	-1
Accurate Readings	-1	0	0	0	-1	0	-1	-1
Adhesion	-1	0	0	0	-1	0	-1	-1
Achieve Proper Placement	-1	0	0	0	-1	0	1	-1
Universal Environment	1	1	1	1	0	1	0	0
Suitable for all Patients	-1	0	-1	0	-1	0	0	-1
User Friendly	-1	1	1	1	0	0	0	0
Cost Effective	1	1	1	1	0	1	1	0
Total	**-3**	**4**	**3**	**4**	**-3**	**3**	**0**	**-5**

4.2. Conceptual Designs

Due to the wide variety of electrodes on the market, our team decided to create a device that could be used universally on all electrode types. Through brainstorming and preliminary prototyping in the lab, our team finalized a few realistic design concepts. These initial design concepts are discussed in the subsequent section.

4.2.1. Initial Design Concepts

Once the team created the Pairwise chart in Section 4.1., a Pugh Analysis was created to narrow down our nine initial design concepts. A Pugh Analysis is a decision matrix that has weighted specifications listed on the Y axis and the design concepts on the X axis. A baseline, which consists of the existing method for EKG use on diaphoretic patients, is used and all other design concepts are compared to it. For our analysis, the design concepts were ranked on a scale of 0 - 5, in which 0 signified the design concept did not meet design requirements, and a score of 5 signified the design requirements were fully met. These concepts consisted of a Weight, a Wrap, Suction Cup, Pressure Delivery Device, Vest, Levered Suction Cup, Sticky Gel, Blanket, and Conductive Gel. The table shown below illustrates this initial Pugh Analysis and its results.

TABLE III
Pugh Analysis of Initial Design Concepts.

Design Requirement	Current Solution	Weight	Wrap	Suction Cup	Pressure Delivery Device	Vest	Levered Suction Cup	Sticky Gel	Blanket	Conductive Gel
Timely Diagnosis	0	4	3	3	4	5	3	2	5	4
Accurate Readings	0	3	2	5	5	2	5	5	2	4
Adhesion	0	3	4	4	4	4	4	5	4	3
Universal Environment	0	5	3	4	4	5	4	4	4	4
Suitable for all Patients	0	4	2	4	3	2	4	5	2	5
User Friendly	0	5	1	4	4	5	3	4	5	4
Cost Effective	0	4	2	3	3	1	3	4	2	4
Total	**0**	**28**	**17**	**27**	**27**	**24**	**26**	**29**	**24**	**28**

Based on the Pugh Analysis, our team's final design concepts were the Weight, Pressure Delivery Device, Sticky Gel, and Conductive Gel. These chosen design concepts are discussed in further detail in the following section. Although the Suction Cup design scored comparably high, we decided to forego this idea based on potential trauma to the patient's skin from the suction.

4.3. Final Four Designs

The final four designs chosen in the previous section are described below in more detail. To conceptualize these ideas, each team member brainstormed individually and created sketches. Then, each team member presented to the group and discussed pros and cons of their design. This process allowed the team to combine ideas and assess the feasibility of each one.

4.3.1. Weighted Electrodes

One solution entailed adding weight to EKG electrodes in order to enhance the downward force to prevent electrode slippage. This design allows for no change to the standard procedure for EKGs and would help ensure accurate readings with proper EKG electrode placement and increased adhesion. Additionally, this would be suitable for all patients and help with timely diagnosis, as it eliminates the need to readjust electrodes that are slipping due to perspirant on the skin's surface. While this solution has the potential to work on the electrodes on

the top surface of the body, the additional downward force of the electrode may promote slippage on areas on the body with prominent curvature or on the side of the chest. This design concept would not provide a way in which the force could be redirected towards the body to hold all the 12-lead electrodes in place. which wouldn't achieve our team's design objectives.

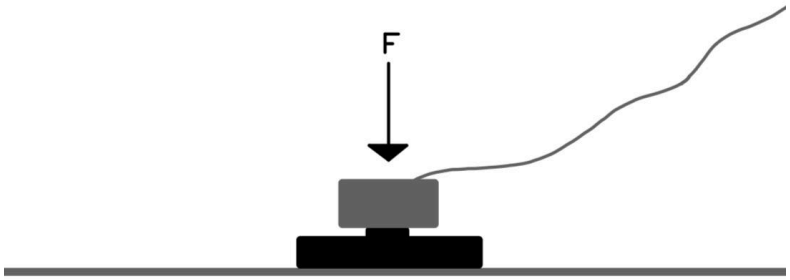


Fig. 7. Weighted Electrode Design Concept Illustration.

4.3.2. Pressure Delivery Device

Another design identified was a pressure delivery device. This device would have one central point held by the user and protruding retractable and bendable arms that could be moved to the placement of the electrodes on the patient. The user would then apply force to the central point and this force would be dispersed through the bendable arms and onto the electrodes to hold them in place. This device would increase both the accuracy of EKG readings and the adhesion of the electrodes on the patient through the applied pressure. The potential drawbacks to this solution include the additional time required to move the bendable arms over each electrode and the increased difficulty of the user to apply the device, as this could be difficult for a single user to accomplish.

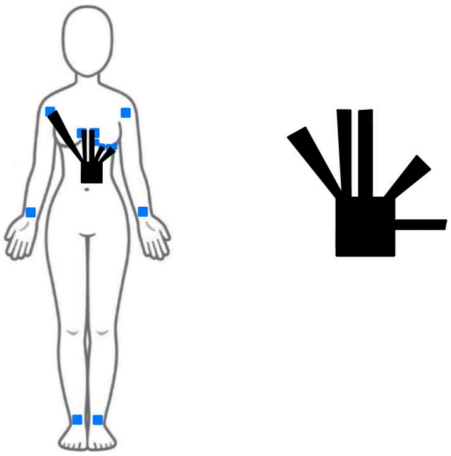


Fig. 8. Pressure Delivery Device Design Concept Illustration.

4.3.3. Sticky Gel

The sticky gel is a design in which there are no changes to the standard of care in performing EKGs. With this alternative design, the EKG-user would notice an electrode is slipping on a diaphoretic patient and the sticky glue would be applied around the electrode. The glue would dry within a short timeframe and the electrode would then be held in place on the patient. This approach would increase accurate readings and adhesion of the electrodes to the patient; however, there are multiple drawbacks. First, this approach would not be user-friendly for either the patient or the EKG-user. The EKG user would have to spend additional time utilizing the sticky glue on all the slipping electrodes and would have to manage the clean-up of the sticky glue. The glue may also be painful to the patient, as there is currently no known sweat-resistant glue that is also easily removable from the skin of the patient. The time needed to apply the glue could lead to increased time to diagnose a patient.

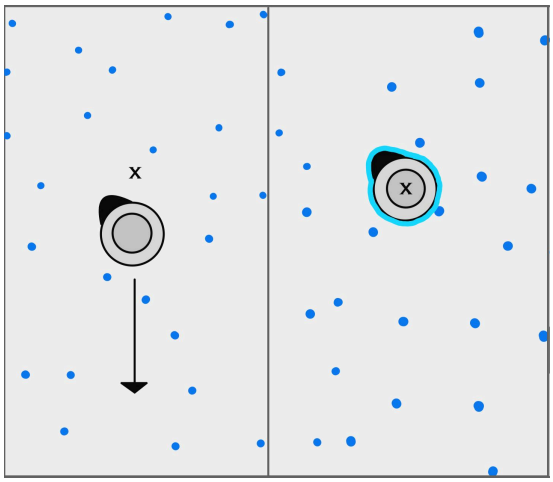


Fig. 9. Fast Drying Glue Design Concept Illustration.

4.3.4. Conductive Gel

This is a design in which a conductive gel would be applied where the EKG electrodes would normally be placed on a patient. All lead wires would be redesigned and thinner, to then be placed within the gel to produce an EKG reading. If this conductive gel was sweat resistant and had a thick viscosity, the gel would theoretically stay in place on the human body and eliminate the problem of electrode slippage. This would increase the accuracy of the EKG readings. Due to the properties of the gel and additional need to redesign the EKG wires; however, this design solution cannot be met within the time and budget scope of the project. Additionally, our team decided this solution over-complicates the client's need to prevent

electrode slippage by redesigning the entire concept and process of current EKGs used in pre-hospital settings.

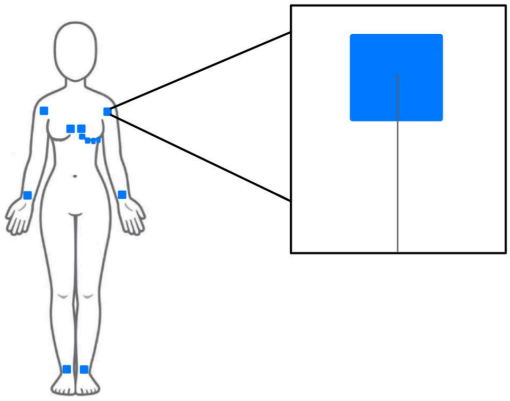


Fig. 10. Conductive Gel Design Concept Illustration.

4.3.5. Final Design Selection

To determine our team's final design to prototype, a final Pugh Analysis was performed with our four finalized design concepts. The baseline comparison was the existing method for EKG use on diaphoretic patients. The design concept receives a score of 0 if it meets the baseline. A score of 1 is received if the design concept exceeds the baseline, and a score of -1 is received if the design concept does not meet the baseline. The representative Pugh Analysis for these final four design concepts can be seen below.

TABLE IV
Pugh Analysis of Final Design Concepts.

Designs	Accurate Readings (5)	Adhesion (4)	Suitable for all Patients (4)	User Friendly (4)	Timely Diagnosis (3)	Universal Environment (3)	Cost Effective (2)	*Total Score (weighted)*	*Total Score (unweighted)*
Pressure Delivery Device	1	0	0	1	1	0	1	3	14
Weight	1	0	0	1	1	0	0	3	12
Sticky Gel	1	1	0	-1	0	0	-1	0	3
Conductive Gel	1	1	0	-1	0	0	-1	0	3

From this Pugh Analysis, the Pressure Delivery Device was selected as it had the highest score amongst all other final design concepts. Our team found that combining aspects of the weighted design to the pressure delivery device would produce the strongest overall design to move forward with, as the weighted design also scored significantly higher than other design concepts.

4.4. Final Design Concept

Our final design is a device that consists of rigid tubes that enclose each EKG lead with corrugated sections. All the tubing components are connected to one central handle where the user applies a downward force to distribute force on all the electrodes simultaneously. Electrodes are placed on the patient as normal. The rigid portions of the tubes allow for the force from the handle to travel to the electrode and prevent slipping while the corrugated sections allow for the user to bend the tubing to reach the specific placement needed for the patient. Our team identified three main components that construct this final design which are (1) the handle, (2) the sled, and (3) the tubing, as depicted below in Fig. 11.

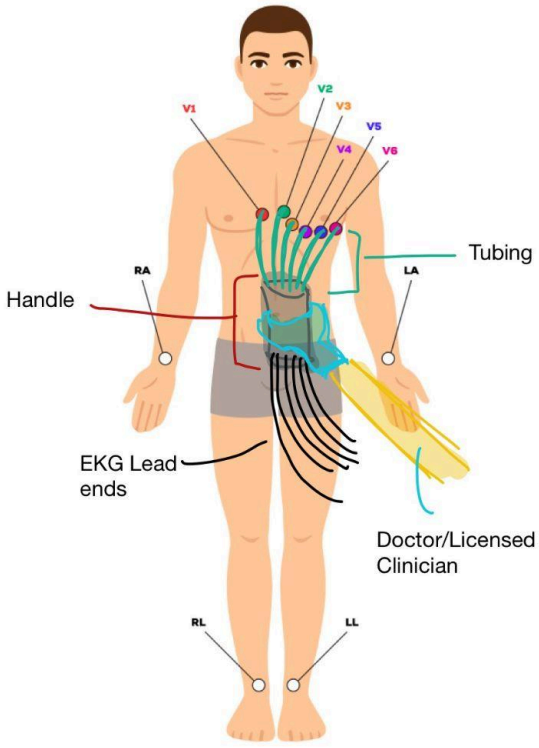


Fig. 11: Final Concept Selection.

4.4.1. Final Design Concept; Handle Component

We conceptualized the handle design through multiple drawings. These drawings helped the team visualize how the handle would connect to the tubing component and how it would fit into the user's hands. Fig. 12 below shows our drawing iterations.

A B C

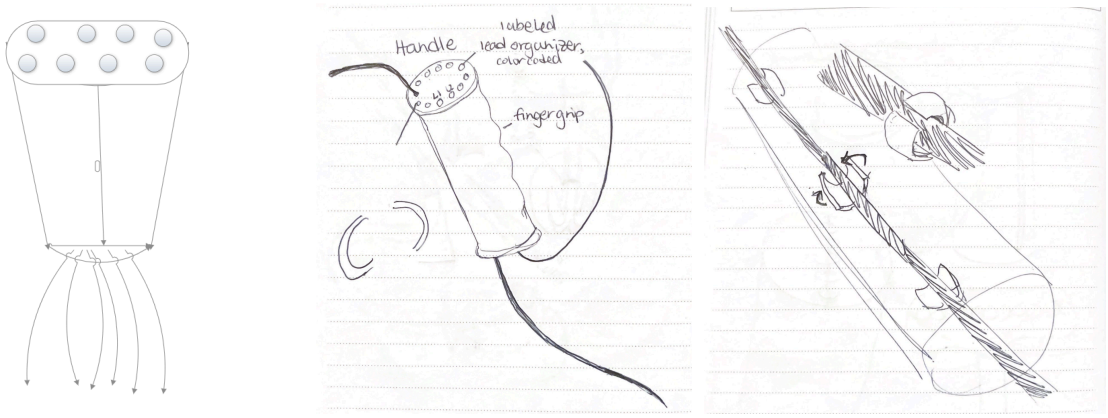


Fig. 12. Handle design drawings.

The handle was conceptualized to sit in the user's hand comfortably while also keeping the leads organized with labels. The handle also could withdraw or retract each lead for proper placement onto the patient by having the leads snap into place with enough room to pull the lead in either direction to reach its desired length.

4.4.2. Final Design Concept; Sled Component

To further solidify our final design concept for the sled component, we assembled iterations of a mock prototype, using materials such as bendy straws and pipe cleaners along with an EKG. This process allowed us to visualize our ideas and understand where there is need for improvement. Fig. 13 shows our iterations, where we discussed different aspects of each design to continue finalizing our ideas.

It was important for our team to design a component that could evenly distribute pressure along the electrode so that it can be in constant contact with the skin without interfering with the electrical signal. The sled places the force on the edges of the electrode not the wire component connected to the lead as in field techniques consist of paramedics putting two fingers on the electrodes to hold them down. The sled final design concept accomplishes this by having two “fingers” that branch out from the tubing and have a rounded edge to hold down the electrode by distributing the pressure to either side of the electrode, and was ultimately denoted the name “sled”. The rounded edges make for the sled to have the ability to move while still accomplishing a secure connection, as shown in Fig. 13(d) and 13(e). Another benefit of the sled

design is the mechanism of force, where it can be applied gradually instead of at a straight angle as seen in Fig. 13(a). The design shown in Fig. 13(e) was selected to be 3D printed and iterated on as described in Section 4.5.3.

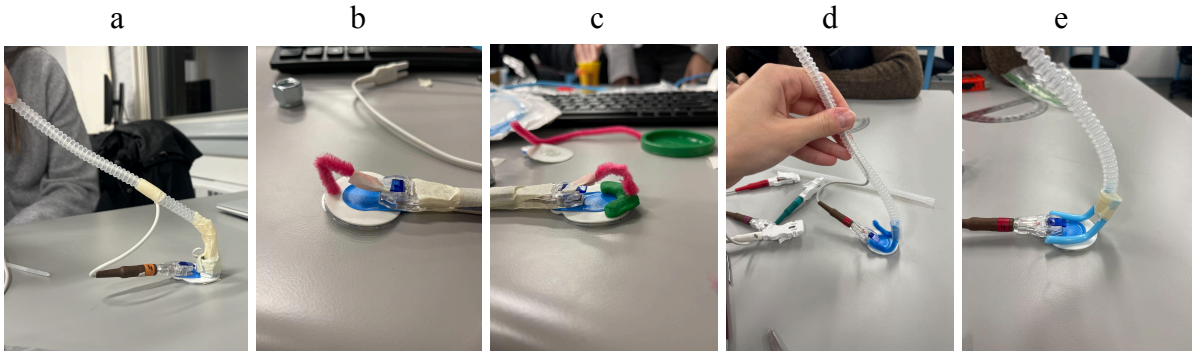


Fig. 13. Mock straw prototype iterations.

4.4.3. Final Design Concept; Tubing Component

The main component of the pressure delivery device is the tubing component that encases each EKG lead. Each lead will be thread through its own tube, giving the wire structure and a method to deliver pressure from the handle to the sled component. Each tube will have a small slit on its underside to thread the lead through, with a hole to allow the wire to come out of the tube and ultimately snap onto its electrode (See Fig. 13(a) and 13(d)).

An essential part of the tubing component is the corrugated sections on the top and/or bottom of each tube. These corrugations are designed so the user can bend each tube to reach its respective electrode. In addition, the proximal ends of the tubing has two protruding parts that allow each tube to be clipped into the handle without any room for movement. Fig. 14 shows our team's first tube design (with the sled component attached).

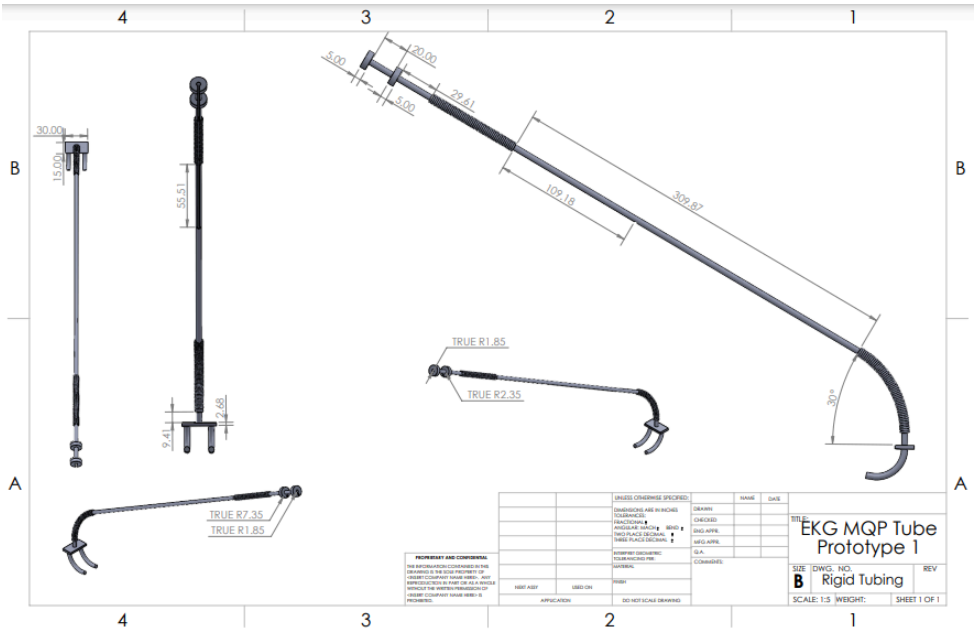


Fig. 14. Solidworks drawing of tubing component concept.

4.5. Prototype Iterations

Once the team selected the final design concepts for each of the components of our device, we began making edits to these designs after further consideration. These iterations of our designs are detailed below and are broken down by each competent; handle, sled, and tubing.

4.5.1. Handle Iterations

The handle component of our device was constructed using Solidworks and consists of two parts, a top and bottom. The material used to 3D print the handle was PLA. A top and a bottom part were needed to allow for the tubing of our device to be put into the bottom part of the handle, with the top part holding them in place. The initial iteration of the handle did not have rounded edges, as shown in Fig. 15.

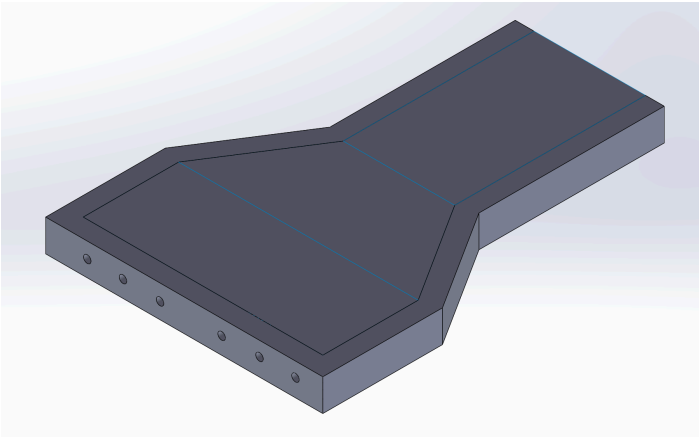


Fig. 15. Handle Prototype, Iteration 1.

The second iteration of the handle, shown in Fig. 16, included labels for each lead and rounded edges. Rounding the edges of the handle allowed for more comfort and a better grip on the handle. To close the two portions together, we attempted the use of snaps. The snaps were not able to be secured to the prototype due to the glue coming off of the prototype when the top portion was pulled off the bottom portion. The second method that was attempted was the use of velcro strips. The velcro strips were successful, allowing the top portion to be secured to the bottom portion and also allowed for easy opening and closing of the handle.

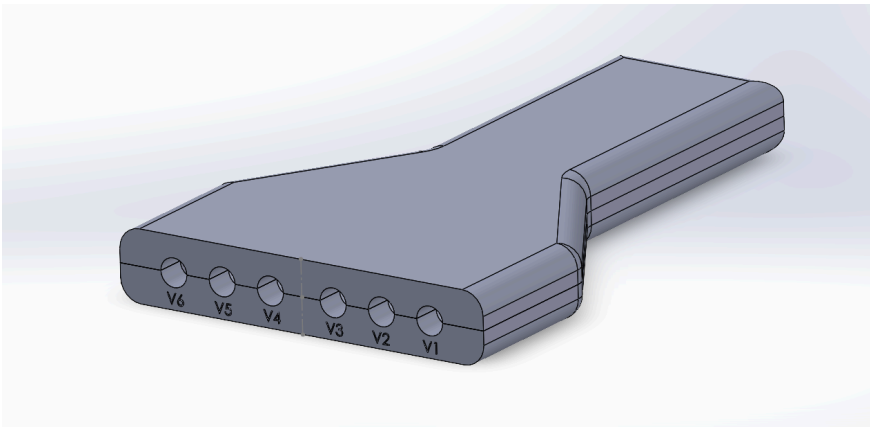


Fig. 16. Handle Prototype, Final Iteration.

4.5.2. Sled Iterations

The final design of the sled component of our device was constructed in Solidworks, therefore it could be 3D printed using PLA. The first 3D technical drawing of the sled can be seen below in Fig. 17.

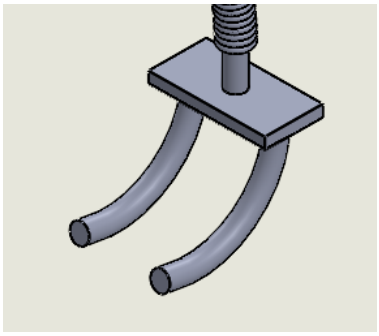


Fig. 17. Sled Prototype, Iteration 1.

The initial prototype was similar to the final design concept, which was outlined previously in section 4.4.1, as it has the two “fingers” to hold down the sides of the electrode and is connected to the end of the tubing. Due to 3D printer limitations, the two fingers needed to be printed individually, and all components of the sled had to be glued together. Our team aimed to improve the overall efficacy of this design, as well as add a mechanism to connect the sled to the rest of the tubing. This led the team to create a second iteration for our prototype where the sled had threads so it could screw into the tubing part and was a more streamlined y-pipe. Fig. 18 shows the 3D Solidworks drawing made for this iteration.

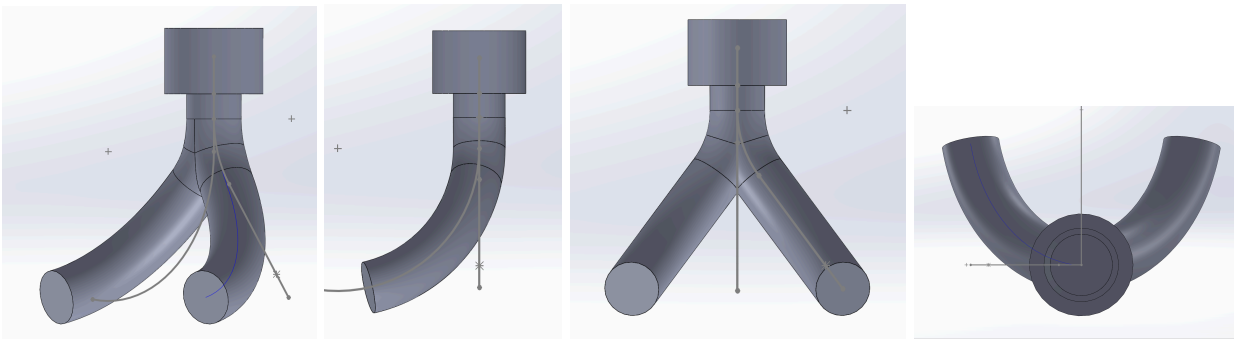


Fig. 18. Sled Sled Prototype, Final Iteration.

Following the Y pipe iteration, the team decided in order to get the desired angle for each of the sled components it would need to be manually bent. This was accomplished by using PLA to 3D print straight Y pipes with a threaded head to connect to the tubing. The sled was later bent to the desired shape using a heat gun. The figure below illustrates that process and the final sled iteration.

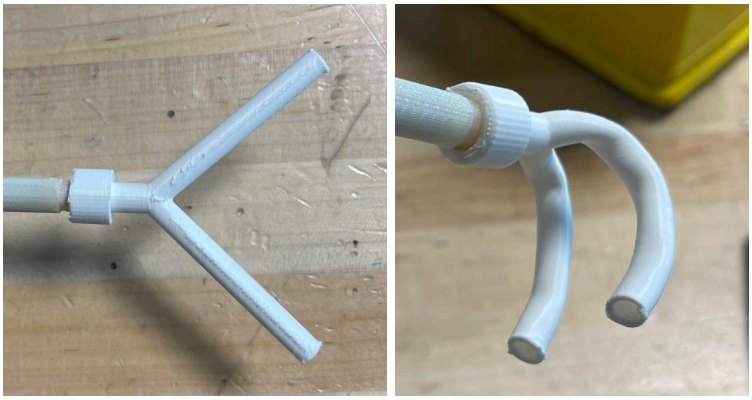


Fig. 19. Sled Prototype, Final 3D Print in PLA.

4.5.3. Tubing Iterations

The dimensions of the tubing component is based upon the dimensions of the EKG lead. To begin prototyping, our team first took all the applicable dimensions of a lead, such as its diameter and the length and width of the component that clips into the electrode. The applicable dimensions are shown in Table V below.

TABLE V
Applicable dimensions of an EKG lead.

Wire Component	**Dimension**
Lead Diameter	2.65 mm
Width of end piece that clips into electrode	15.75 mm
Length of end piece that clips into electrode	7.53 mm
Diameter of end piece that clips into electrode	9.75 mm

The first iteration of the tubing component started as one long tube with two corrugated components at either end, with one of the components already bent downwards to reach the electrode, as shown in Fig. 14. Due to limitations with available 3D printers, the tube component could not be printed in one single piece. Therefore, the component was split in half with threads added to each side in order to screw the pieces together. The beginning half is identical for each lead, however, the last half has a different length depending upon the lead's location on the body. In the beginning stages of prototyping, Leads 1, 2, and 3 were shorter than 4, 5 and 6, as shown below in Figure 20. On the last half of each lead, there are two additional circular components allowing the tube to latch into the handle. These circular components are 13.00 mm in diameter with 10 mm in between. This allows the tube to clip into the handle without sliding around.

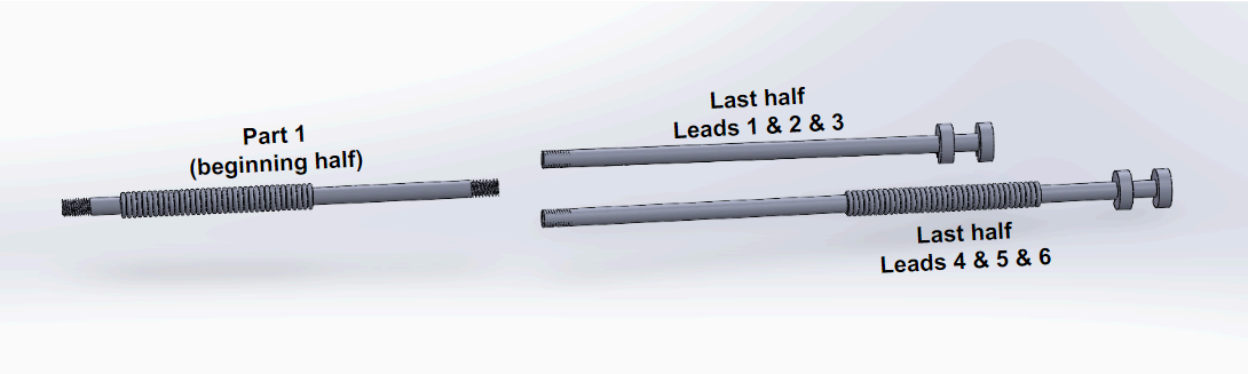


Fig. 20. Tubing Prototype, Iteration 2.

Upon further consideration of electrode placement compared to the handle, our team decided the tubing for leads 3, 4, 5, and 6 required a shorter length than leads 1 and 2. Also, Lead 3 did not need an additional corrugated component on its last half, because it is directly in line with the device and handle. The final dimensions of the tubing component are listed in Table VI.

TABLE VI
Length dimensions of each tube component.

Lead Number	**Final Tube Length (mm)**
1	356.00
2	356.00
3	257.00
4	251.50
5	251.00
6	251.00

*The thickness of each tube is 2.0 mm.

This iteration also included a change to the design of the corrugated component. This section was initially designed as straight hinges that could stretch or compress as needed. Upon further consideration into the design of drinking straws, this design changed to become a sickled/hook shape so the component can bend easier. To ensure our design is strong enough to avoid cracking or snapping, our team increased the thickness from 0.75 mm to 2.0 mm. Our team's final prototype iteration was designed to be completely straight, with a thickness of 2.0 mm. Our team's final tubing prototype is shown below in Fig. 21.

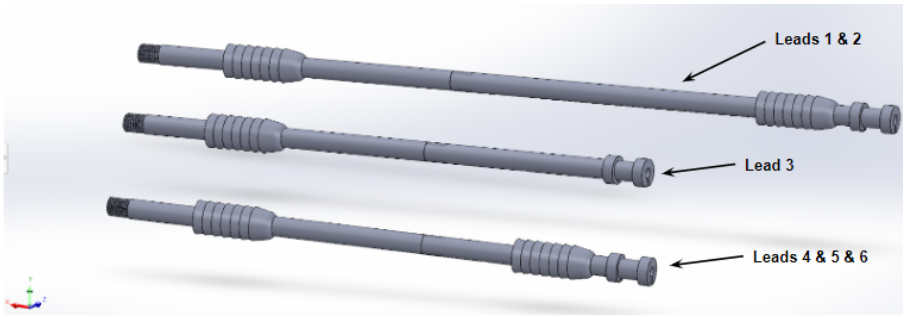


Fig. 21. Tubing Prototype, Final Iteration.

Fig. 22. Tubing Prototype, Final 3D Print in ABS.

4.5.4. Material Selection Process and 3D Printing

Material selection was necessary to meet the desired objectives of our overall design, and went hand-in-hand with the component design process. Materials were chosen separately for each design component. The tubing material needed to bend in certain areas, maintain a rigid structure, and withstand stress without failure or snapping. The sled component needed to be rigid and able to withstand stress resulting from force applied by the handle. Lastly, the handle component must be rigid and strong enough to carry the weight of the EKG lead system as a whole and withstand the grip of the person using it. Printer selection was also important, as our device required high resolution from its thin, long, detailed design.

To start, our team used polylactic acid (PLA) for all three components. While sufficient for the final handle prototype and sleds (Fig. 23), it was too brittle and snapped easily while

inserting the leads for the tubing component. Also, the resolution was too low to reach our desired print for the threads to connect the sled component, as shown in Fig. 24. Lastly, the LulzBot TAZ Workhorse printer used PLA as the support material, which was difficult to break off of the prototype as the support structures were found on the inner diameter of the tubing where the leads needed to fit.

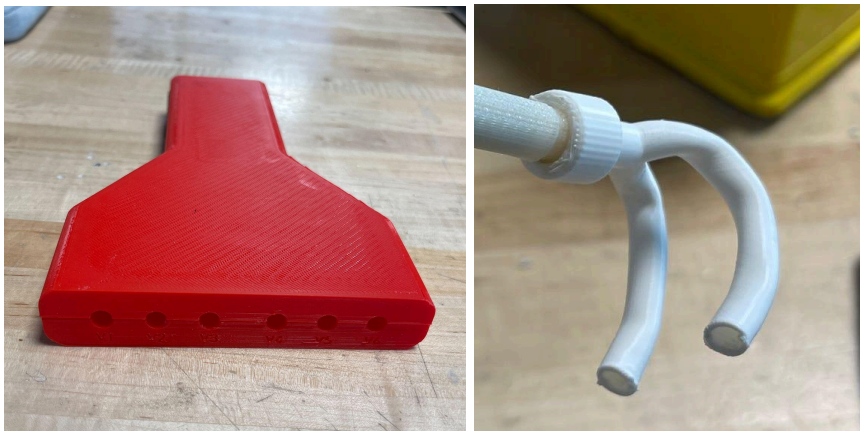


Fig. 23. PLA Handle and Sled Prototype.

Fig. 24. PLA Tubing Component Threads.

Next, we printed the tubing component using the Stratasys J826, with Vero and Agilus materials. The J826 allowed for a higher resolution than the LulzBolt TAZ and used gel as the support material. Vero seemed suitable based on its high strength and stiffness, while Agilus was flexible and bendable for the corrugated portions of the prototype. Once printed, we encountered multiple issues, as shown in Figure 25. The support gel tore the Agilus while being removed, and the Vero portions snapped fairly quickly once inserting an EKG lead into the device. The Agilus portion broke off of the Vero where they connected, and the Agilus proved to be much too flexible, as it was loose and did not maintain a bent shape.

Fig. 25. Tubing Component Material Failure with Vero and Agilus.

Our team tried printing the corrugated portion of the tubing in the Vero material using the Stratasys J826. We hypothesized that if we make the walls of the section thinner, it could help it bend to our desired degree. Ultimately, the corrugated portion snapped when bending (as shown in Fig. 26) and this material was forfeited.

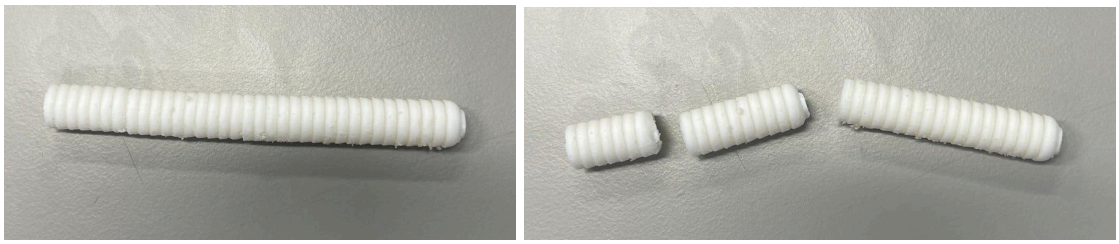


Fig. 26. Corrugated Tubing Component Failure with Vero.

Lastly, our team decided to choose acrylonitrile butadiene styrene (ABS) for the tubing component using the Dimension SST 1200es. ABS has a shore hardness of 82 D with a heat deflection temperature range of 80°C to 100°C, which was suitable due to its rigidity and its ability to bend under high temperature. Therefore, we were able to bend the tubing to the angle necessary to reach each electrode, both on the distal and proximal bent-sections, as shown in Fig. 27. This property of ABS alleviated the means of finding a flexible, shape forming material that was not easily accessible given our resources. In addition, we determined a flexible material is intended for the manufactured product, while this design phase is solely prototyping and proof of concept.

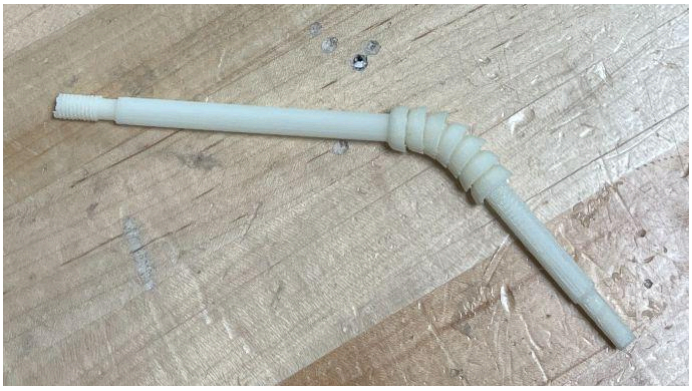


Fig. 27. Bended portion of ABS tubing via heat gun.

4.6. Final Prototype - The KLAA EKG Assist

Our final prototype was complete with each component including the handle, sled, and tubing that was bent to each electrode location. The tubing was fitted and snapped in at its proximal end into the handle, and the distal end of the tubing was threaded into the sled. Both parts of the handle were secured together by velcro. The ABS tubing and sleds were successfully bent under heat to reach their final shape according to EKG standard placement on a mannequin. Below depicts our prototype in Solidworks and later 3D printed and fabricated based physical prototype.

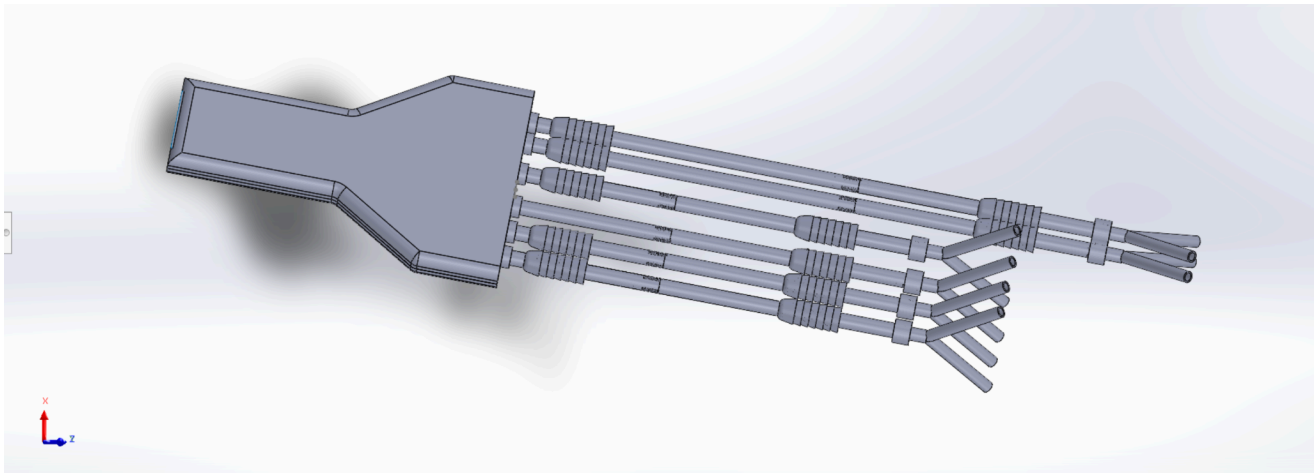


Fig. 28. Final Solidworks Assembly.

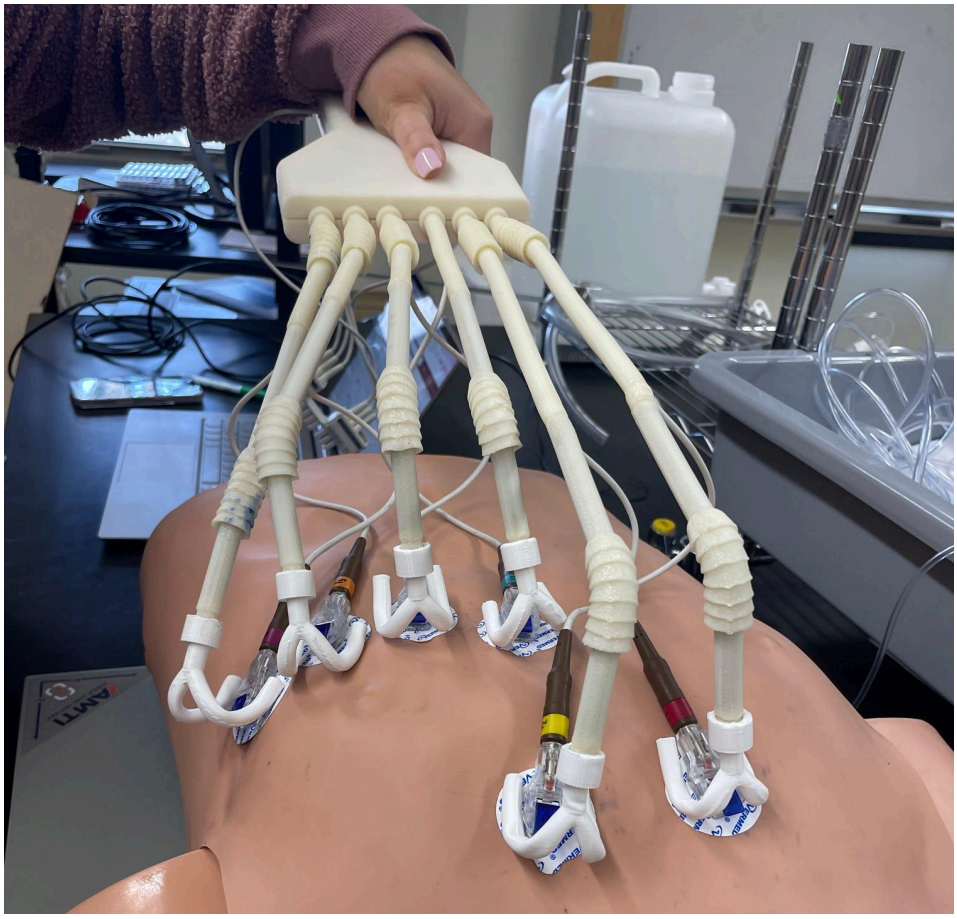


Fig. 29. 3D Printed Assembly.

As seen in Fig. 28, the KLAA prototype handle, tubing, and sleds were printed as straight components. The final handle and sleds were printed with PLA, while the tubing component was printed in ABS. Fig. 29 shows we bent each tubing corrugation and sled to its appropriate location on the body using a heat gun and mannequin as a guide.

5. Final Design Verification

A series of tests were conducted to understand the feasibility of the KLAA EKG Assist and verify our final design meets our design objectives. Data from each test using the KLAA were analyzed using statistical analysis. In this section, we describe each test and their results.

5.1. Methods

Our team devised a series of tests to validate the objectives of the KLAA. These tests were divided into Phase 0, Phase 1, and Phase 2. These tests are aimed to further define the challenges associated with EKG use under a diaphoretic condition and understand if our device maintains accurate EKG readings and initial electrode placement, both on a mannequin and human subjects. Phase 0 testing aimed to further investigate diaphoresis using electrodes without the KLAA, while Phase 1 was KLAA verification testing on a mannequin, and lastly, Phase 2 was a clinical study with human subjects. The human subjects test was performed under Institutional Review Board (IRB) approval, with proper consent forms signed. This material can be found in Appendix A.

In all tests, the control was the mannequin or human subject with no change made to the skin surface and a normal EKG was performed, whereas the experimental unit was a simulated diaphoretic environment, including a 50 mmol NaCl solution spray and petroleum jelly. The magnitude of diaphoresis was also considered, where 1 spray of solution defined a low-magnitude, 3 sprays defined a high magnitude, and petroleum jelly spread defined maximum magnitude of diaphoresis, as shown in Fig. 30.

a b c

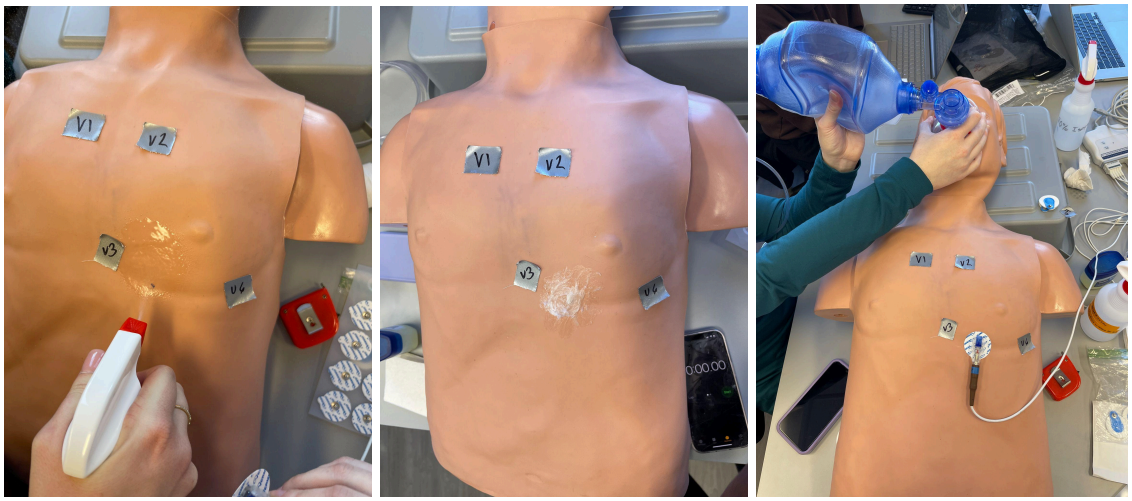


Fig. 30. Mannequin Set Up.

(a) shows NaCl spray, (b) shows petroleum jelly spread at V4. (c) shows the final set up with the bag valve mask to simulate breathing.

5.1.1. Phase 0 - Electrode Slip Test

The purpose of this test method is to further define the problem that diaphoresis causes for EKG acquisition in terms of electrode movement. An electrode will be placed on a mannequin at V4 according to the EKG standard along with a control condition and a simulated diaphoretic condition. Diaphoresis magnitude will be varied in terms of salt sprays and a petroleum jelly spread. A mock EKG will be run at each condition, and the final electrode position will be marked. The distance between the electrodes initial and final placement will be recorded. The step-by-step procedure can be found in Appendix B.

5.1.2. Phase 0 - Electrode Pull Test

The purpose of this test method is to further define the problem that diaphoresis causes for EKG acquisition in terms of electrode skin adherence. How much does diaphoresis affect electrode adherence to the skin? An electrode will be placed on a mannequin according to the EKG standard at V4 along with a control condition and a simulated diaphoretic condition. Diaphoresis magnitude will be varied in terms of salt sprays and a petroleum jelly spread. A mock EKG will be run at each condition, and the electrode will attempt to be pulled off using a spring scale. The force of the pull will be recorded. The step-by-step procedure can be found in Appendix B.

5.1.3. Phase 1 - KLAA Pass or Fail on Mannequin

The purpose of this qualitative test method is to show whether or not the KLAA EKG Assist works to keep electrodes in place. A mannequin will be suited with either no diaphoretic condition or with a simulated diaphoretic condition of varying magnitudes. Electrodes will be placed on the mannequin according to EKG standards. The user will connect all leads to the KLAA EKG Assist and use it on the mannequin and attempt to secure the electrodes in place. The user will record a pass or fail. A pass is defined by the following parameters; (1) all tubing reaches electrodes, (2) no observed electrode lifting or sliding, (3) the sled makes full contact with the electrode, and lastly, (4) no device failure or cracking. For the device to receive a pass for each of the parameters all electrodes under the conditions must satisfy the specified parameter. The step-by-step procedure can be found in Appendix C.

5.1.4. Phase 1 - KLAA Force Exertion on Mannequin

The purpose of this test method is to find the amount of force exerted on a mannequin while using the KLAA EKG Assist. This will indicate the amount of pressure a patient can expect on their body from the device, as well as how much force the clinician will use. A

mannequin with electrodes previously placed will be zeroed onto a force plate with varying degrees of diaphoresis. The user will connect all leads to the KLAA EKG Assist and use it on the mannequin until the electrodes are secured in place. The force of this action will be recorded. The step-by-step procedure can be found in Appendix C.

5.1.5. Phase 2 - Human Subjects Non-Inferiority

Phase 2 compared the KLAA to the control of current practice on human subjects in a private clinical setting. The main objective was to verify that KLAA-assisted EKG readings were equivalent to the control readings. Five female and five male subjects were enrolled to include different chest geometries and ensure the KLAA is suitable for both male and female anatomies. A licensed clinician performed an initial standard EKG test utilizing current clinical practice, and then performed an EKG with the KLAA Assist. This was not a diagnostic test, so the clinician did not interpret or share the results from the EKG test. The results were compared to examine any clinically-relevant differences between the regular EKG and the EKG with the KLAA Assist. A complete test method utilized in Phase 2 can be found in Appendix D.

5.1.6. Phase 2 - KLAA Pass or Fail on Human Subjects

The goal of Phase 2 was to determine the efficacy of the KLAA Assist in preventing electrode slippage on diaphoretic patients. This phase was also completed on five female and five male human subjects in a private and secure clinical setting. Use of the EKG machine and the KLAA Assist was carried out by a licensed clinician. This again was not a diagnostic test, meaning the physician did not interpret or share the results of the EKG test with the test subject. To begin the test, participants were asked to remove outer layers of clothing in order to expose the chest area to allow for application of the EKG and KLAA Assist. The NaCl solution was then sprayed in different magnitudes to simulate different levels of diaphoresis and the clinician performed an EKG. During the test, our team took notes and observed the process. In addition to the human subjects testing, our team devised a list of questions to ask the clinician regarding the readings, device usability, and ergonomics, of which are found in Appendix E.

5.2. Results

In this section we review the outcomes from the experimental procedures and both the quantitative and qualitative tests conducted to validate the project's objectives. Test results include data sheets, collection of figures, associated graphs, statistical analysis, and discussions of findings.

5.2.1. Phase 0 - Electrode Slip Test

Based on the data table found in Appendix F, there was no magnitude of distance the electrodes traveled under any of the conditions the team simulated. Despite this finding, the team observed that the electrode adhesion security was lost under various magnitudes of simulated

diaphoresis. As the electrodes lift at the edges, the conductive piece on the underside of the electrode loses contact with the skin, and electrical signals cannot be captured by an EKG. This was observed where the sweat solution pooled and/or the petroleum jelly clumped under the electrode, causing the electrodes to release off the mannequin's body during the simulated breathing. Below are pictures captured during various magnitudes of simulated diaphoresis, showing the subsequent electrode behavior;

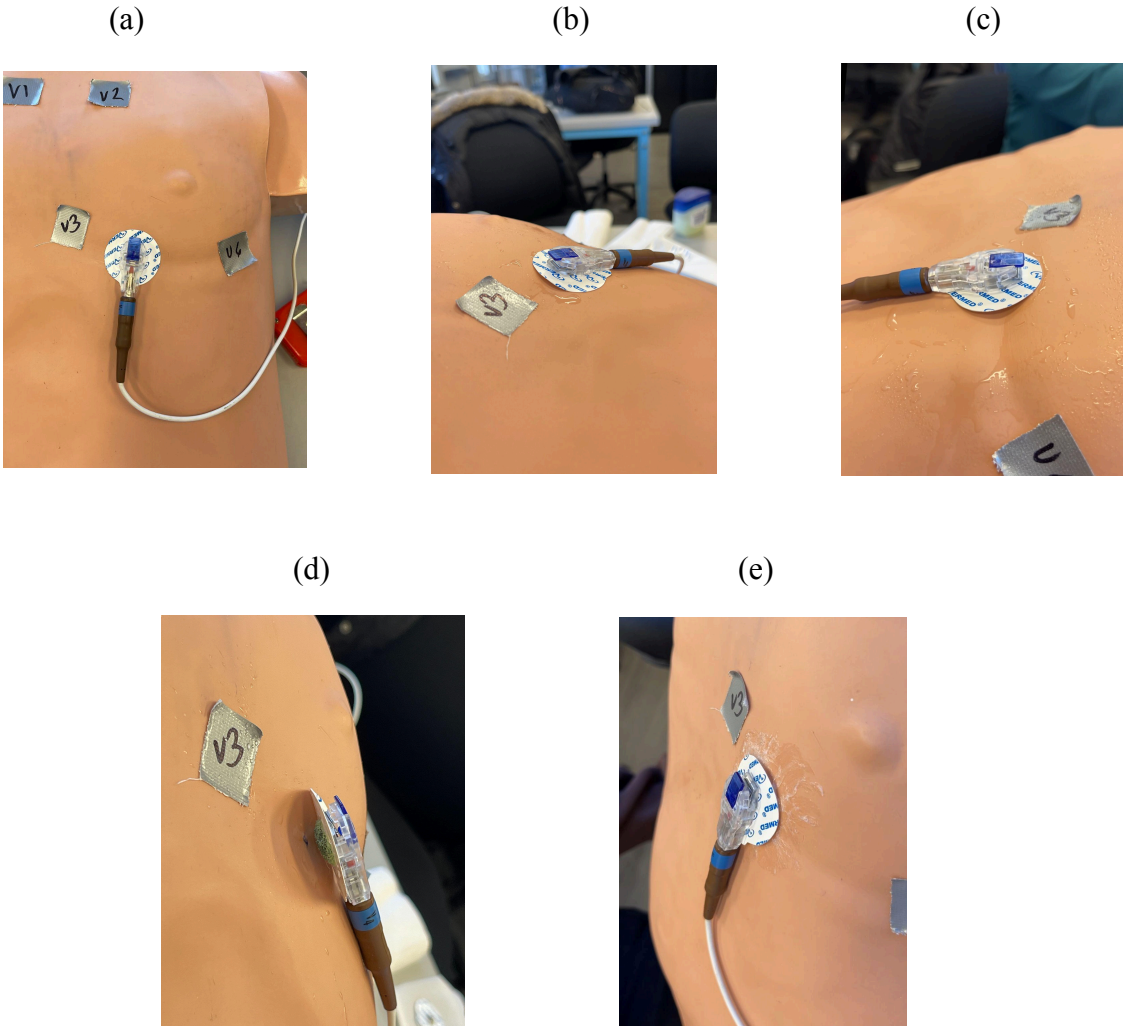


Fig. 31. Phase 1 - Electrode Slip Test.

(a) normal conditions. (b) diaphoresis magnitude, level 1. (c) diaphoresis magnitude, level 2, (d) diaphoresis magnitude, level 3. (e) diaphoresis magnitude, level 4.

The figure above illustrates the correlation the team observed of the electrode security being affected by the magnitude of diaphoresis simulated, such that the more severe the diaphoresis condition the poorer the electrode security is. From that the team was able to validate

that the electrode adhesion is not secure under diaphoretic conditions, therefore impeding proper EKG readings.

5.2.2. Phase 0 - Electrode Pull Test

Fig. 32 shows the results from the electrode pull test trials. In comparison to the control condition with zero saline sprays or application of petroleum jelly, less force was needed to remove the electrode in the diaphoretic state. The force needed to hold the electrode in place on a diaphoretic patient can be assumed to be equal but opposite to the forces required to pull the electrode off of the mannequin. Therefore, the force needed to hold the electrodes in place ranges from less than 1N to approximately 3N in the diaphoretic condition. The data sheet can be found in Appendix F.

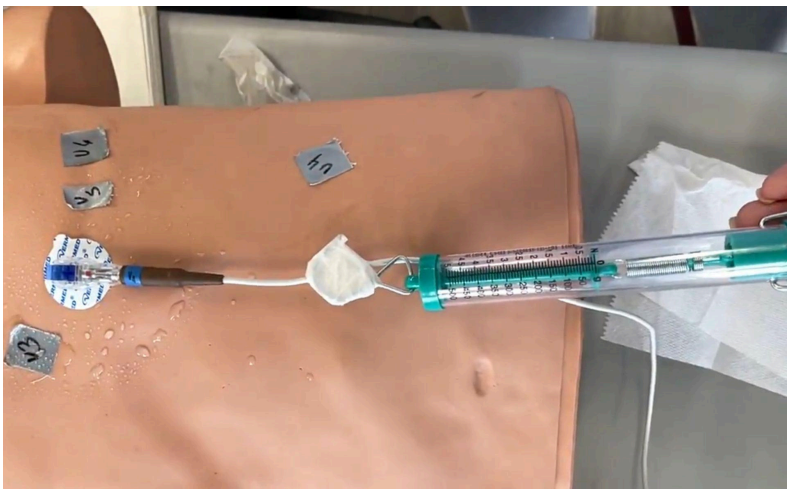


Fig. 32. Electrode Pull Test set up.

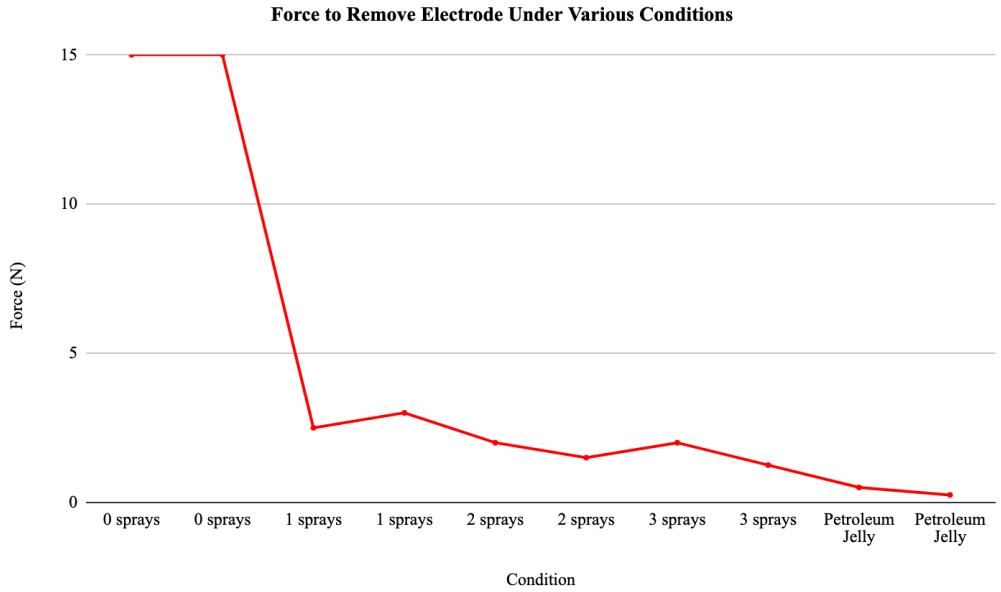


Fig. 33. Relationship between force required and level of diaphoresis.

5.2.3. Phase 1 - KLAA EKG Assist Pass or Fail

Results indicated that the KLAA EKG assist successfully kept electrodes on the mannequin, as shown in the data sheet in Appendix G. Prior to KLAA use, electrodes placed under all magnitudes of diaphoresis slipped or popped off, as shown in Fig. 34. Placement of the KLAA device re-adhered the electrodes for the entirety of the test, as shown in Fig. 35. Lead V6 failed at 2 sprays and under the petroleum jelly condition, but this was assumed to be attributed to the rigidity of the device and the angle at which V6 is located on the mannequin. If the device were freely bendable, the sled could have been manipulated to touch the electrode at an ideal angle, thus preventing it from slipping as seen with the other leads. Similarly, lead V5 did not fully adhere at 3 sprays, which was most likely again due to the rigidity of the KLAA prototype.

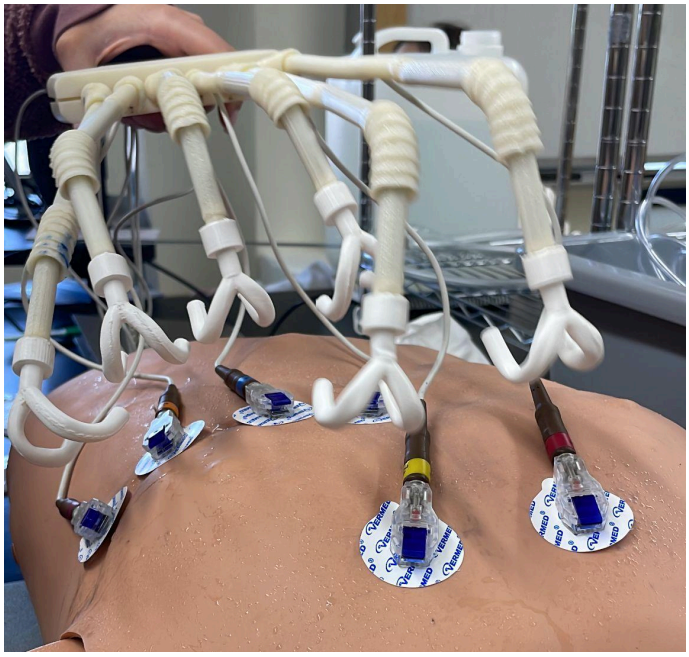


Fig. 34. Electrodes before KLAA use diaphoretic magnitude of 2 sprays.

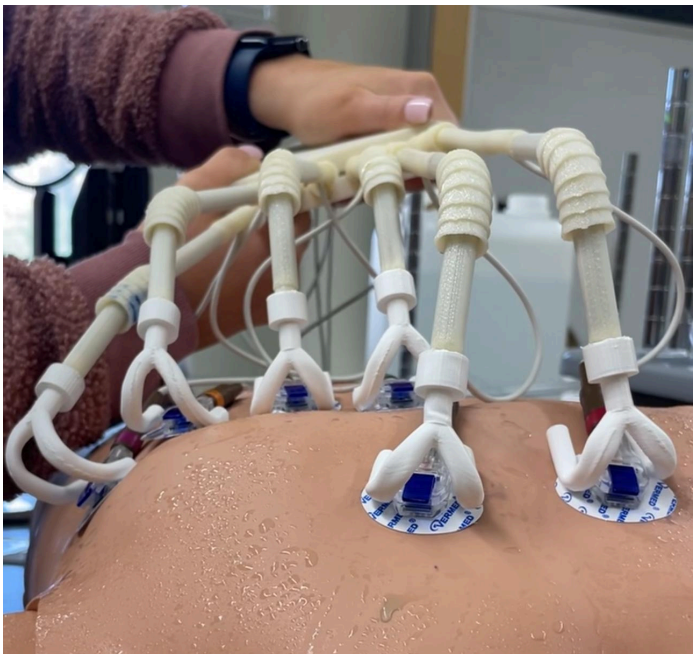


Fig. 35. KLAA EKG Assist, diaphoretic magnitude of 2 sprays

5.2.4. Phase 1 - Force Exertion of Entire Device

The mean forces and standard deviations were calculated for each set of trials within a diaphoretic condition. The mean force across all 15 trials was calculated to be 2.43 Newtons,

verifying that the KLAA device does not require an excessive amount of force from the user in order to keep electrodes in place that isn't overbearing for patient experiences. Additionally, the pressure exerted by the KLAA onto a patient will not cause additional harm or discomfort to a patient.

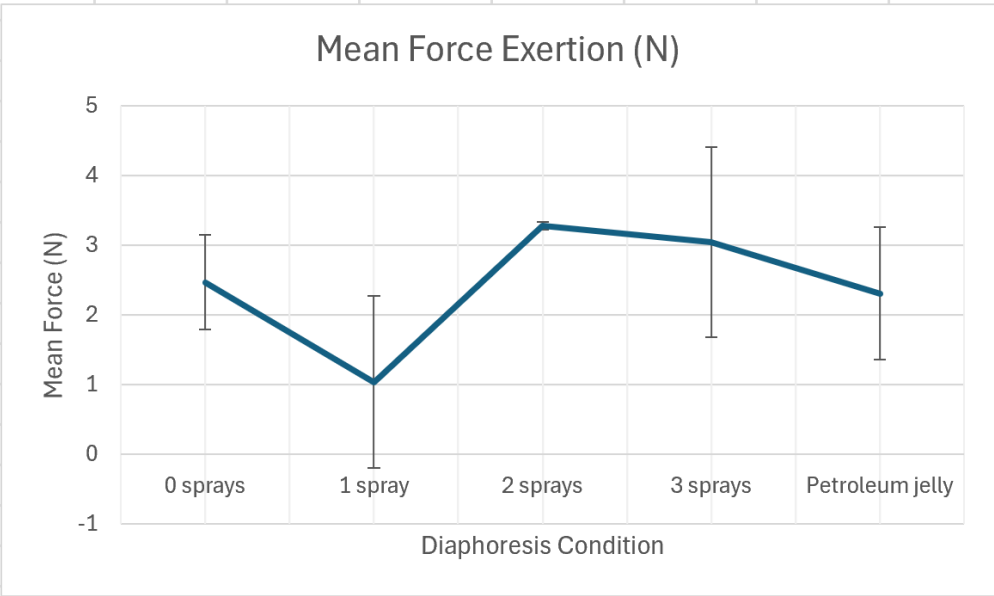


Fig. 35. Mean force, Force Exertion Test

To determine the significance in the differences between average force, a One Way ANOVA statistical test was performed. One Way ANOVA tests are ideal to determine if the differences in average values between three or more groups are statistically significant or not. When running this statistical test, a *p value* is obtained. If $p > 0.05$, there is no statistically significant difference between the average values of the groups being analyzed, while a $p < 0.05$, determines a statistically significant difference between the groups, meaning these differences are likely not due to random sampling. The results from this One Way ANOVA yielded a p value of 0.11821, meaning there is no statistically significant difference between the mean values of force values at different levels of diaphoresis. This is further detailed in Section 6.1.

5.2.5. Phase 2 - Human Subjects Non-Inferiority

Based on our human subject's testing, the KLAA was determined to yield EKG readings that are non-inferior to running an EKG under normal conditions. Each participant had three EKG readings taken, once with normal EKG acquisition (control group), once with the KLAA under normal conditions, and a third time with the KLAA under diaphoretic conditions. The clinician blindly compared the KLAA readings for each participant to their control, and pointed out any clinically significant differences or superiorities. In order to quantify this data, our team

gave each control reading the value 5. Each KLAA reading was given a +1 for every superior difference, and a -1 for every inferior difference. This table can be found in Appendix H.

The KLAA readings show minimal clinically significant differences that are inferior to the control readings. After the testing was completed, all EKG readings for each participant were blindly analyzed against each other under the three testing conditions based on the ratings in the table. The control group was compared against both the KLAA (non diaphoresis conditions) and KLAA (diaphoresis conditions) independently. An unpaired t-test was performed to determine if there were any statistical differences in these groups. This test is used to compare differences in two independent groups (such as the control vs. KLAA, and control vs. KLAA + diaphoresis). The results of an unpaired t - test will yield a *t value* that will determine if the mean of the two groups are statistically significant or not. If the $t > 0.05$, the results are not statistically significant. If $t < 0.05$, the results are statistically significant. When performing an unpaired t-test between the Control group and the KLAA (no diaphoretic conditions), $t = 1.0000$. This means the mean values of the group are the same, and there is no statistical difference between the EKG readings. When performing this test between the control group and the KLAA (diaphoretic conditions), $t = 0.6882$, also meaning there is no statistical difference between the groups. This is discussed further in Section 6.1.

In addition to interpreting the clinician's feedback on each EKG reading, our team wanted to better quantify the differences in results. The clinician noted that participant C had higher P waves in the KLAA readings, while participants A and K had higher T waves in the KLAA readings. When interpreting any EKG reading, it is useful to look at the scale of the paper. Typically, the length of each small square is 1mm, which is equal to 0.1mV of voltage (see Fig. 36).

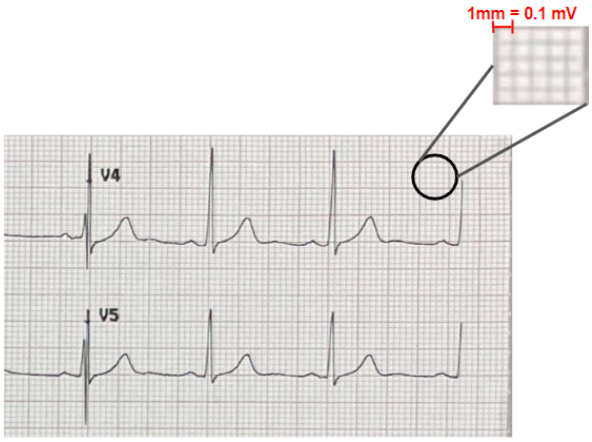


Fig. 36. Scale of an EKG reading related to voltage.

A higher voltage suggests there is better electrode adhesion to the skin, allowing for the EKG to better read the heart's electrical current. Our team quantified the differences in P and T waves in applicable participants using ImageJ to measure the amplitudes. Fig. 37 shows the

mean voltage of P waves in Participant C under all three EKG conditions, in leads 4 and 5, observed from participant C (N=6).

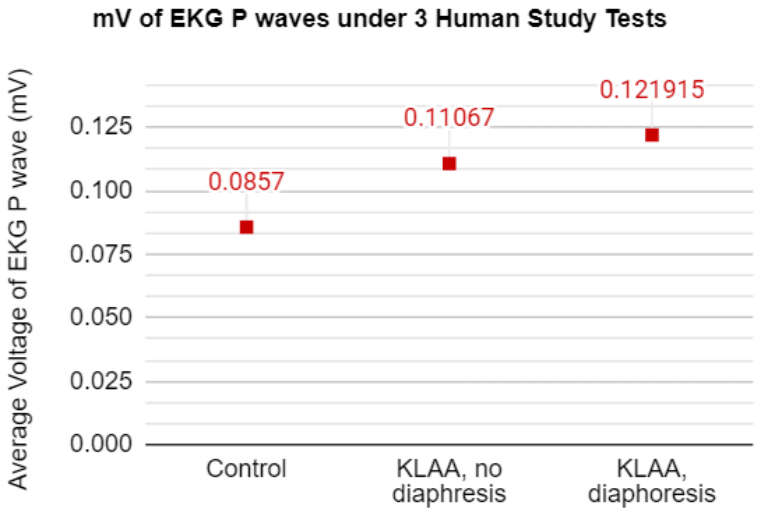


Fig. 37. Average voltage of P waves.

The trend in Fig. 37 shows that using the KLAA in both normal and diaphoretic conditions yielded a higher voltage value. This further proves that the KLAA allows for better adhesion of electrodes to the skin under all conditions. This same process was completed for the T waves in participants A and K. Fig. 38 shows the average voltage of T waves in leads 3, 4, 5, and 6, observed from participants A and K (N=15).

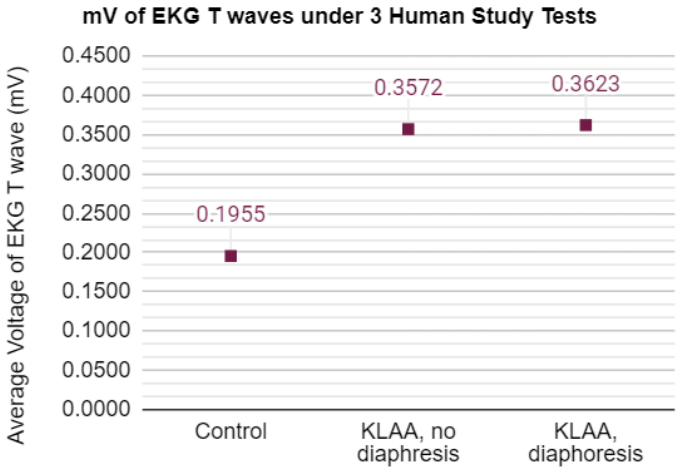


Fig. 38. Average voltage of T waves.

The same trend was observed for the T waves. In general, the voltage readings from the KLAA in both conditions are higher than in the control group. This again proves that the KLAA

allows for better adhesion to patients under any condition. To further illustrate this point, our team performed a One Way ANOVA statistical test for both the P and T waves against all the EKG conditions. First, the voltage from each P wave was measured from participant C, and all the conditions were analyzed against each other. This statistical analysis yielded a $p = 0.00012$, meaning the mean voltages between each condition is statistically significant. When this test was performed for all the T waves, the results yielded a $p = 0.0000$. The differences in voltages between the three conditions for the T waves were also statistically significant. These results are further interpreted in Section 6.1.

5.2.6. Phase 2 - KLAA Pass or Fail on Human Subjects

The KLAA passed all specified parameters for all the diaphoretic simulated testing. From some observations, a few participants did not have full sled contact on lead 6, however it was still enough to hold the electrode down without any slippage. Therefore, the KLAA was able to effectively hold each electrode down without any slippage on all the participants under diaphoretic conditions. A crucial observation during this test was the time it took to make a diagnosis. The nurse practitioner noted that it was quick to use the KLAA and get an EKG reading. Setting up the KLAA initially did take some time due to lack of practitioner training and the rigidity of the prototype, but once the leads were encased into the KLAA it was not taken apart after every use. Therefore, this was not a challenge for the nurse practitioner.

6. Final Design Validation

Design validation is done to ensure our design meets the intended objectives for use as determined, and any discrepancies must be discussed. Our objectives consisted of accurate readings, adhesion, timely diagnosis, suitable for all patients, user friendly, cost effective, and that the device works in a universal environment.

6.1. Statistical Analysis Interpretation

A statistical analysis was conducted after Phase 1 and Phase 2 of the KLAA's verification testing. The results from the One Way ANOVA test after Phase 1 - KLAA Force exertion are detailed in Table H. Since the p value > 0.05, the results of this test are not statistically significant, meaning that the KLAA exerts a consistent pressure amongst all magnitudes of diaphoresis and the user can push downward with the same amount of force no matter the patient's diaphoresis levels.

TABLE VII
Results from One Way ANOVA test for Phase 1 - KLAA Force Exertion.

Test	**P value**	**Significance**
Mean force exertion by KLAA for all diaphoresis levels	0.11821	Not statistically significant

An unpaired t test was performed after the Human Subjects Non-Inferiority testing to compare each KLAA condition against the control condition. The results of this analysis are displayed in Table R. Both KLAA conditions showed to be not statistically significant from the control conditions, suggesting that EKG readings produced with the KLAA are non-inferior to any normal EKG reading. These results also show that the KLAA will not produce EKG readings with any clinically significant differences to normal EKG readings.

TABLE VIII
Results from Unpaired t-test for Human Subjects Non-inferiority test.

Test	**T value**	**Significance**
Control vs. KLAA (normal)	1.000	Not statistically significant
Control vs. KLAA (diaphoresis)	0.6882	Not statistically significant

A One Way ANOVA test was also performed after the Human Subjects - Non Inferiority test to compare the differences in voltage in the P and T waves of all three simulated conditions. These results are in Table J. Both the P and T waves under all conditions are shown to be statistically significant amongst one another. This suggests that these differences are due external reasoning (like the KLAA) and not just from the sample of participants.

TABLE IX
Results from One Way ANOVA test for analysis of EKG P and T waves.

Test	**P value**	**Significance**
Voltage of P waves	0.00012	Statistically significant
Voltage of T waves	0.0000	Statistically significant

6.2. Meeting Our Client Needs

Our verification testing revealed that our design meets 5 of 7 objectives, as shown in Table X. A discrepancy was found with user friendly, as the clinician needed assistance with device set-up in the human subjects testing. Another discrepancy was found in the universal environment objective, in which the KLAA could take up more space in an ambulance than what is already available, thus a smaller, more portable design was recommended.

TABLE X
Validation Against Client Needs.

Objective	**KLAA Validation Criteria**
Accurate Readings	Passed Non-Inferiority (T Values of 1.00 and 0.6882)
Adhesion	Passed Non-Inferiority (T Values of 1.00 and 0.6882)
	Passed Phase 1 & 2 Pass/Fail Tests
Timely Diagnosis	Once set up, no additional time needed to make diagnosis
Suitable for all patients	Passed on all 10 participants
	Passed Non-Inferiority (T Values of 1.00 and 0.6882)
	Passed Phase 1 & 2 Pass/Fail Tests
Cost Effective	One time fabrication and reusable product

User Friendly*	NP needed assistance during application
Universal Environment*	Ambulance size and condition concerns

*objective not fully met

6.3. Ethics & Societal Impact

The KLAA device could positively impact health outcomes and safety of people across the world. As previously mentioned, EMS teams respond to approximately 1,000 out-of-hospital cardiac arrests in the United States alone, with nearly 90% of these incidents being fatal [10]. Having early intervention from EMS teams requires timely and accurate diagnosis of the heart condition using EKGs; however, EKG diagnosis can be delayed from patients who have some degree of diaphoresis, causing electrode slippage. With this complication, time on scene by the EMS team can delay transport to an appropriate hospital facility and at the hospital facility, as they will not be alerted of the cardiac event and will not have ample time to activate cardiac and operating room teams. Having the KLAA device incorporated into the equipment of EMS teams will allow for quicker cardiac event diagnosis by EMS teams and a potential decrease in the fatalities caused by cardiac events.

Cost, sustainability, and equity were considerations throughout the entire design process. The device is reusable, eliminating the need to constantly replace the device with every use. With the device being cost-effective, the goal is for every EMS company to be able to purchase the device to aid with EKG acquisition. This would allow the device to be fully accessible to all individuals who would benefit from the device.

It is imperative to make ethical considerations when designing a biomedical device that will have a direct impact on patients. Throughout the duration of this project, our team considered how we could prevent healthcare disparities potentially resulting from our device and how it might impact medical ethics. As a result of our device being designed for diaphoretic patients in pre-hospital settings, our main considerations were EMS environments and patients our device will be used on.

With patients being the center of focus when designing a biomedical device, our team also considered medical ethics and how our device was directly going to benefit the patient. We ensured our device would not harm patients throughout the design and testing phases of this project. During the design phase, we ensured the device would do no harm to the patient and provide a benefit to the patient. Tests were completed to ensure the force exerted by the device would not cause discomfort or bodily harm to the patient.

Cost is a major factor that can impact accessibility to medical services, including medical devices. If our device is too expensive, it is possible that only well-funded EMS groups will be able to purchase it, resulting in disproportionate benefits amongst patient populations. During the design phase of this project, we worked to ensure all EMS groups would have the ability to

afford our device by keeping its cost low and ensuring it would be reusable. In addition to cost, we also ensured our device had the ability to be used on all patients, regardless of anatomical differences. While our academic institution was only able to provide our team with a standard, male mannequin to test our device, other aspects within our design methodology ensured equal accessibility. All engineering diagrams depicting the device being used on a human were drawn on both male and female body types. Additionally, we made our device adjustable in order to account for potentially varying anatomical features on a patient's torso such as breasts or excess adipose tissue. Finally, in the testing phase of this project we tested on both male and female test subjects to account for anatomical differences between biological males and females.

6.4. Device Sustainability

The device we created has several qualities that allow it to be a sustainable option for paramedic programs we are targeting as our clients. It is sustainable as the device itself is a one time purchase, there would be no need to buy replacement or additional parts. The device can be reused on all patients seen until it is broken or damage to any of the components impairs its proper function. As components do experience damage that causes it to need to be discarded it can be thrown in the trash and no additional biohazard or special sharps trash is needed in the proper discarding of the device. As the device is further manufactured and material selection expands outside of ABS there still is no foreseeable need for special steps to dispose of the device.

6.5. Device Manufacturability

The manufacturability of our device is crucial when looking to bring this product to the market, in terms of design, cost, and distribution requirements. The design of our device lies heavily in both the material selection and changes our team would make. Ideally, the device would be made of a material that allows for the tubing components to be bent into position and then hold that position while pressure is being distributed to the electrodes. While the device was printed in several different components that were threaded together, our plan would have the tubing and sled be one continuous print if manufactured, and the handle would consist of an improved snapping mechanism that held the top and bottom portions together. The cost of the device for our team to print was not significant and depending on material selection and 3D printing capabilities further devices would also be relatively low in cost. Once the device is printed it doesn't need to be stored in special conditions, or transported within a specific time frame making the distribution requirements easily achievable. Together this all makes our device able to be effectively manufactured.

7. Discussion

We designed and tested a medical device that solves the problem of electrode slippage on diaphoretic patients, leading to successful adhesion of electrodes on human patients and accurate EKG readings. This device has the potential to be used alongside all EKGs in order to promote electrode adhesion on all skin conditions, decrease the amount of time needed to collect EKG readings, and provide a way for all patients to have better medical outcomes. The KLAA uniquely provides a unit to centralize all EKG leads and position them over the proper location of electrodes placed on the body. With a few improvements to the usability of the device, the KLAA is optimized to be cost-effective and accessible to all patients, making the device applicable in all medical scenarios requiring an EKG.

Three phases of testing allowed for quantification and verification of the KLAA to meet design requirements, as supported by the results of this project. Phase 0 testing made it possible to define and quantify the problem of electrode slippage on diaphoretic patients, and verified that the KLAA prototype met testing criteria on a mannequin model. A survey completed by 10 paramedics with experience working with EKGs in pre-hospital settings reported electrodes fall, slip, or pop off on patients who are diaphoretic, leading to minimal skin-connection, excessive noise on an EKG reading, or failure of an EKG to produce a reading. Additionally, current methods to solve this problem in the field only work “sometimes” or are “too costly” to be afforded by all EMS companies. Results from the survey displayed the gap in literature defining the problem of electrode slippage and showed the need for a solution to solve this problem.

In Phase 1, testing of electrode adherence on a mannequin model in the Force Exertion Test led to quantification of the force required to be applied by the KLAA and verification that the KLAA successfully prevented electrode slippage. The force test revealed the average force applied by the KLAA under various diaphoretic conditions was 2.43 Newtons. Statistical analysis was completed to verify that there were no significant differences between the mean values of each testing group. A one-way ANOVA analysis of variance test with a significance level of 0.005 resulted in a p-value of 0.11882, revealing there were no statistically significant differences between the means of the testing groups and that our data was consistent across all trials. Additionally, the KLAA Pass/Fail test revealed the KLAA successfully reached all electrodes, kept the electrodes in place, and no critical failures were observed. It was observed that while all electrodes had increased contact with the mannequin when the KLAA was being used, the V6 electrode was seen to have minimal slippage and decreased adherence to the mannequin, particularly on the right side of the electrode. It can be reasoned that this occurred due to the electrode’s placement on the most lateral portion of the ribcage with the highest observed curvature. The electrodes are designed as flat and circular, and while they are mostly successful at conforming to changes in geometry on the body, they encounter problems with adherence to more pronounced changes in geometry.

With the KLAA successfully passing Phase 1, Phase 2 testing on human subjects was completed to confirm the KLAA did not interfere with EKG readings during a control condition

and the KLAA successfully produced accurate EKG readings on a simulated diaphoretic environment. A total of 10 participants - 5 male and 5 female - with varying chest geometry were used as human participants. A nurse practitioner with experience using EKGs was recruited to use the KLAA on various diaphoretic conditions on all participants to produce EKG readings.

The three conditions used were: (1) A typical EKG with no diaphoresis and no KLAA utilized (control), (2)EKG with no diaphoresis and KLAA utilized, and (3) EKG with simulated diaphoresis and KLAA utilized. The control used for comparison was the typical EKG with no diaphoresis and no KLAA used to demonstrate how a typical EKG should appear. EKGs from each testing condition were collected, with the nurse practitioner being blind to the condition used for all EKG readings. The control condition was compared to the EKGs obtained from the EKG with no diaphoresis and KLAA utilization to ensure the KLAA did not interfere with the current practice of EKG acquisition on non-diaphoretic patients in a private clinical setting.

All electrodes were observed to adhere to the patient under diaphoretic conditions, allowing for successful acquisition of an EKG. As with the mannequin testing, electrode V6 was noted to have minimal slipping and decreased adherence to the patient. It can again be reasoned that this is due to its placement on the most lateral portion of the ribcage. The nurse practitioner reported that there were no observed or clinically significant differences between the control and the KLAA condition, demonstrating the KLAA successfully passed.

The non-inferiority testing was completed after acquisition of EKG readings from all conditions on each patient within the human testing protocol. All EKG readings were labeled and organized by participant with a phonetic and numeric combination, not known to the nurse practitioner. The nurse practitioner was then asked to compare the EKG readings and note any clinically significant differences between the readings. The nurse practitioner reported that the KLAA led to a “cleaner tracing,” particularly observing more defined P and T waves. To further quantify this unexpected finding, our team calculated the area under the P and T waves across all three testing conditions and completed a one-way ANOVA test to reveal statistically significant differences in the measured voltage when the KLAA was in use. The p-values obtained to compare the voltage for P-waves and T waves across the control, KLAA with no diaphoresis, and KLAA with diaphoresis were 0.00012 and 0.0000, respectively. These results reveal that in a trial of human subjects with diaphoretic conditions, the KLAA may have been superior to controls, as shown by the nurse practitioner’s observations and the more defined P and T waves on EKG readings. Further research is needed to investigate if increased electrode adherence results in increased voltage and therefore, “better” EKG readings.

8. Conclusions and Recommendations

8.1. Conclusions

Our team was able to create a medical device prototype that successfully prevented electrode slippage on diaphoretic patients and produced accurate EKG readings. Additionally, the device was suitable for all patients, cost-effective, and would lead to increased efficiency of cardiac event diagnosis in pre-hospital settings. Two phases of testing allowed for device characterization and verification on a mannequin model and on human participants. Due to the gap in research and data on the problem of electrode slippage on diaphoretic patients, Phase 1 trials on a mannequin allowed our team to define the parameters of electrode slippage on diaphoretic patients. We quantified the differences in force required for an electrode on a dry condition versus a diaphoretic condition, verifying the problem of electrode slippage on diaphoretic patients. Additionally, we quantified the amount of force needed to keep electrodes in place on various diaphoretic conditions. The KLAA was also used on the mannequin with simulated diaphoretic conditions to validate proper electrode adherence with the applied force of the KLAA.

Phase 2 of testing allowed our team to confirm the KLAA's ability to be used on human patients with varying chest geometries in both non-diaphoretic and diaphoretic conditions. Medical device testing of the prototype by a nurse practitioner within a clinical setting on patients with simulated diaphoretic conditions allowed us to verify the ability of the KLAA to successfully solve the problem of electrode slippage. The nurse practitioner reported the KLAA device could be successful in helping to prevent electrode slippage, organize EKG wires, and lead to better health outcomes for diaphoretic patients needing EKGs. In addition to device verification in the clinical trials, unexpected outcomes were observed by the nurse practitioner. While our goal was to verify non-interference of the KLAA on EKG readings, the nurse practitioner reported that the KLAA produced a "cleaner tracing," potentially indicating increased adherence, and therefore more pronounced readings, of EKG electrodes on patients. With these findings, the KLAA demonstrated the ability of a low-cost, accessible device to be used in pre-hospital settings, leading to better health outcomes across all patients experiencing a cardiac event.

8.2. Limitations

Various limitations were encountered throughout the prototyping process of the KLAA. Material selection and 3D capabilities at WPI were two major limitations faced. A set budget for MQPs required our team to work within the confines of the materials and 3D-printing capabilities at WPI. While we sought out a material that was both rigid and flexible, allowing for an appropriate degree of bending in real-time to correctly be adjusted to the geometry of a patient, none of the available materials at WPI fulfilled our material needs. While materials do

exist with the proper material properties for our device, we were not able to purchase these materials to be used with the WPI printers, as students are not authorized to do so. Additionally, the 3D printers available to use had limited capabilities that did not allow us to accomplish printing the tubing and sled component as one complete piece, rather they were printed as separate pieces, which led to slower prototyping time.

8.3. Recommendations

Further iterations and development of the KLAA device is needed to create a fully-functional medical device to be used together with an EKG to not only prevent electrode slippage for diaphoretic patients, but to increase the timeliness of all EKG acquisition. A natural progression of this work is further material analysis in order to select a material that meets the criteria for adjustable tubing to allow for proper contact of the KLAA with all electrodes applied to a patient receiving an EKG. A further study could work to outsource the device to a company with material and printing capabilities that allows for proper material properties of all components of the device and development of a fully-functional prototype.

Observations made within this research project also suggest the entire device could be designed to be shorter so that force can be applied more directly to the electrodes and for increased ease of use. Further iterations should explore creating this shorter device, while also investigating other design changes to make it easier for one user to access and place electrodes, such as a design with retractable leads, a paddle design for the handle, and bluetooth capabilities to eliminate wire connections to the leads.

9. Implementing The American Rescue Plan Act Grant at Free Medical Programs

In furthering the mission of accessible healthcare for both providers and patients, an additional project initiative was completed alongside the development of the KLAA. Free Medical Programs are an important health safety net for uninsured or under-insured individuals, who do not have access to a primary care doctor or other medical care. They can provide basic and preventative medical services to these patients, while also alleviating the stress on emergency room departments by limiting the amount of non-life threatening visits. Partnering with the United States Department of Treasury to implement and disperse the American Rescue Plan Act (ARPA) Grant money to free medical programs within the Worcester Care Collaborative Inc, this project helped fund clinics and improve patient experiences. Epworth Free Medical Program was the clinical setting for testing the clinical feasibility of the KLAA and where ARPA Grant was implemented, highlighting the importance of gaining funding for free medical services.

Abstract

This project worked with three programs allied with The Worcester Free Care Collaborative: Epworth Methodist Free Medical Program, Akwaaba Free Medical Program, and Worcester Islamic Center Social Services (WICSS). These Free Medical Programs (FMPs) are an important health safety net for individuals who are uninsured, underinsured, or are otherwise hindered from having access to medical care. In response to the COVID-19 pandemic, fiscal recovery funds were used to create the American Rescue Plan Act (ARPA) Grant for the reimbursement of vital community services across the country. The three programs were awarded a grant from this program in Fall 2023. Research has shown that populations belonging to specific geographical, racial, and economic demographics that use free medical services were disproportionately affected by COVID-19, and the ARPA Grant aims to help reimburse the FMPs who were placed under extra strain during the pandemic. Our team reviewed deliverables from the United States Department of Treasury which outlined the purpose of the grant, the parameters that qualified patient visits, the need to track forms for unduplicated submissions, and the timeline of the grant implementation. This project's goal was to create iterations of documentation that met the needs of each FMP to ensure smooth implementation of the grant funding process. After six months of work, the team raised approximately $10,000, or one-third of the reimbursement-based grant. The implementation strategy included a sustainability plan that enables the three FMPs to continue with the grant program until their full reimbursement targets are met. Throughout this project, writing was used as the main tool to support grant implementation and sustainability.

Chapter 1: An Introduction to Free Medical Programs

Section 1.1 The Establishment of Free Medical Programs (FMPs)

The Haight-Ashbury Medical program was the first free medical program (FMP) established in the United States during the height of the "Summer of Love" in 1967 [38]. The 1960s marked a time of social, cultural, and political change in the United States as a result of the ongoing Vietnam War, leading to many counterculture ideals. Paralleling the Summer of Love in 1967 was the widespread experimentation and use of drugs such as LSD and marijuana, leading to increased health concerns and the need for accessible medical care [39]. The district of Haight-Ashbury in San Francisco, California was a focal point within the counterculture movement, attracting an influx of young citizens to the district. In response to the increasing population and emerging drug epidemic, the Haight-Ashbury Medical program was established by Dr. David Smith and healthcare volunteers, centered around the new ideal that "healthcare is a right, not a privilege [38].

The Haight-Ashbury Medical program influenced additional FMPs to open in the region and eventually nationwide. Within the same year of the Haight-Ashbury Medical program's opening, five additional FMPs opened in the region, and 28 more by 1968 [40]. As more FMPs were established across the region and spread across the country, the National Free Program Counsel was formed in 1975, encompassing 400 free programs nationwide [38].. Early FMPs struggled to obtain licenses to practice medicine. This often resulted in relying on a lead physician to claim the FMP as a private practice operating under their medical license which risked potential liability for the program [38]. Additionally, medications often came from drug representatives' samples and all equipment and supplies were donated from local hospitals. Despite these challenges, FMPs have continued to grow across the US and are still widely utilized by patients without access to formal medical care, underserved communities, and un-or-underinsured populations. It has been documented that more than 1200 free programs are currently in practice across 49 states [38].

Approximately 1.8 million Americans nowadays receive care from these programs annually, with no trends indicating a decrease in the use of their services [41]. The private health care insurance system within the United States limits access to quality, equitable, and affordable healthcare. As a result, over 8.4% of Americans or approximately 27.6 million people reported not having health insurance in 2022 [42]. Further, a Commonwealth Fund survey conducted before the COVID-19 pandemic revealed 27% of non-geriatric adults were underinsured, 24% struggled to pay medical bills, 12% initiated a change to their "way of life" to pay a medical bill, and 23% were enrolled in long-term plans to pay off medical bills [43]. With rising costs of healthcare and insurance plans, an increasing number of Americans are unable to afford basic healthcare needs which highlights the need for alternative healthcare options like FMPs across the country.

Section 1.2 The Need for Free Medical Programs In The U.S.

In the United States in 2022, 11.5% of Americans lived in poverty as reported by the U.S. Census Bureau [44]. For American citizens living in poverty, federal programs like Medicaid and CHIP (Children's Health Insurance Program) exist to help provide insurance options [45]. In 2011, Medicaid was expanded under the American Care Act, yet states were allowed to opt out of the Medicaid expansion which eroded some people's ability to obtain affordable health care covered by insurance [46].

For new immigrants and non-US citizens living in the United States, they must wait five years after acquiring legal residence status to qualify for Medicaid and CHIP which prolongs the possibility of having no health insurance [47]. Those who are living in the United States as undocumented cannot qualify for Medicaid [45]. However, some states such as Massachusetts still provide state assistance to undocumented residents through programs like MassHealth [48].

Due to factors like poverty and residence status, millions of people in America are uninsured, which directly impacts their ability to receive medical care [46]. With the average cost of life saving medicine like an Epipen costing upwards of $600.00 without insurance, people who cannot afford to pay out of pocket or who do not qualify for government-aided insurance are at a disadvantage in their health outcomes [49].

Free medical programs provide a healthcare option for those without insurance, as well as those who still may not be able to pay for uncovered costs with certain insurances like Medicaid. In 2010, 1.8 million people utilized FMPs in the United States showcasing the need for this health safety net [50]. At FMPs, patients can receive a variety of services through volunteer professional health providers trained in primary care, preventative medicine, physical therapy, and ophthalmology [51]. Patients can also receive physicals or vaccines that are required for a job or school, or medications like insulin. With those who are uninsured having worse health outcomes than insured people, FMPs can help vulnerable populations have continuous access to healthcare when they need it [52].

Section 1.3 Exploring the Current State of Free Medical Programs

According to the National Association of Free & Charitable Clinics (with clinics functioning similarly to free medical programs), there are currently over 1,400 Free & Charitable Clinics in the United States [53]. Each FMP is unique in the services they offer, funding means, and access to a volunteer network. Yet despite this, all FMPs often fill a healthcare gap identified by medical professionals or community members and share a mission to serve a majority of uninsured patients [50]. The network of FMPs in the U.S. has much variety in both the size and associated funding of each program; this plays a large role in the types of services each program can offer and the number of medical providers and/or volunteers at their disposal [54].

Section 1.4 Addressing Limitations of Free Medical Programs

FMPs have a wide variety of services they offer to patients, with most conducting general physical exams and providing testing and treatment for chronic conditions (e.g., diabetes and high blood pressure) and minor medical problems (e.g., headaches, sore throats, cough/colds, stomach issues). Some programs may also provide prescription assistance programs, pharmacy services, and certain gynecological services [55]. Program-to-program disparity in services is affected by the general lack of specialty care stemming from the inability to access specialists, medicine, and malpractice coverage [54]. Specialist services include psychiatrists, orthopedists, urologists, rheumatologists, and dentists. This leaves programs only able to provide certain services, with some being dictated by the surrounding community's needs [50].

Since FMPs operate under a non-profit organizational format, they primarily rely on volunteers to stay open and provide services to patients [56]. These volunteers come from a variety of backgrounds that help fulfill all functions in a medical program. This staff may be made up of volunteer physicians, licensed healthcare professionals, and non-licensed medical personnel. It's also common for nurses, nurse practitioners, physician assistants and, on a smaller level of frequency, social workers and psychologists to volunteer at FMPs [55].

Funding of FMPs primarily can be categorized into categories of; sponsorship, fundraising, grants, and donations to stay open. Sponsorship of a FMP can be done by individuals or organizations such as hospitals, medical associations, secular community organizations, faith-based entities, and foundations that were established as a result of a hospital sale. Sponsorship may also dictate the mission and services provided at the program. Fundraising for FMPs often includes community outreach through annual fundraising drives and outreach to individuals, businesses, and other organizations. A major source of funding for FMPs is through grants, which can be from businesses, foundations, and government organizations. Grants however require a proposal, budget, and narrative, as well as compliance with the terms of the grant and any related agreements, making them less accessible for all programs [55]. The funding of FMPs is unique to each program, and often various levels of funding emerge for different FMPs, with some even "living hand to mouth" [55,56].

Section 1.5 Benefits to the Community Free Medical Programs Provide

There is a large uninsured population in the United States, making up approximately 46 million people, who are often forced to forego needed healthcare due to prohibitive costs. FMPs, which make up part of the "health safety net" for uninsured people in need of healthcare, offer basic services for little or no cost to patients. Although FMPs are one of the few options available to uninsured and underinsured people, they have been widely overlooked and rarely studied.

Through the surveying of free programs in this study conducted by the Agency of Healthcare Research and Quality from 2010, found that free programs provide both preventative

and general medical care for approximately 10% of the uninsured, working-age adult population that seek care [57].

Due to the understudied nature of free health programs, it remains a challenge to quantify the impact that free health programs have on communities that utilize them. However, patients of free health programs report high degrees of satisfaction with primary care and routine women's health services received at free programs, especially when compared to the degree of satisfaction with other, traditional, health care options available with insurance. Patients of free programs report a high degree of intent to continue seeking care at free programs. Free programs also help to alleviate some of the strain on emergency rooms, as patients of free programs reported that the emergency room was their only other option for primary healthcare [58].

There is a large array of types of FMPs in the United States, the majority of which are located in the South. Independent free programs are usually better staffed, open more days of the week, and have larger budgets than other types of FMPs including church-run and student-run programs. These different types of free programs offer different types of care depending on the resources available to them, which can be limited due to staffing constraints. Student-run programs are mostly evenly distributed throughout the country, instead of being primarily located in areas with higher need, most likely due to the distribution of medical schools throughout the country [58].

Chapter 2: The Project

Section 2.1.0 Need Statement

In Worcester, Massachusetts, three FMPs—Epworth, Akwaaba, and WICCS—operate locally, providing essential services to uninsured individuals. These programs are part of the Worcester Free Program Coalition, a group of seven free medical programs that serve as a vital health safety net for the community. Their primary goal is to offer medical assistance to those facing obstacles in accessing conventional healthcare systems.

In response to the COVID-19 pandemic, fiscal recovery funds were allocated by the federal government to establish an American Rescue Plan Act (ARPA) Grant. A component of the grant reimburses community programs for essential services provided during and after the COVID-19 pandemic. The three programs we partnered with, Epworth, Akwaaba, and WICCS, received a $49,230 grant from the City of Worcester, in partnership with the ARPA program to reimburse services provided during and in the reconstruction period after the COVID-19 pandemic. The grant reimbursed the programs for services provided for Worcester residents who have been disproportionately impacted by the COVID-19 pandemic. The grant's guidelines, as outlined by the documentation provided by the Federal Office of the Treasury and the City of Worcester, specify various criteria for program visits to qualify for coverage. These criteria include ethnicity, race, address, household income per size, participation in government

programs, and specific services received during the visit. For each qualifying visit, the free medical program will be reimbursed $128.24 until the full $49,230 is exhausted.

Despite each program being unique in their size, patient volume, funding and more, this network of FCs needed our team to design and implement a documentation system within the constraints of the ARPA grant to secure federal funding.

Section 2.1.1 Mission Statement & Project Objectives

When the team began this project we created a mission statement that encapsulated what we hoped to accomplish and embody during the duration of this project. It is as follows;

Mission Statement:
To support accessible, sustainable and free healthcare in Worcester for populations disproportionately affected by COVID-19.

In addition to our broader mission statement to guide our efforts our team identified a technical goal statement. This technical goal statement is derived from the more quantitative aspect of our project to give the team tangible aspirations. It is;

Technical Goal Statement:
To design and implement a documentation system within the constraints of an ARPA grant to secure federal funding for three free public health programs in Worcester, Massachusetts.

Our technical goal statement and mission statement both are aligned with the primary goals of the FMPs. To further develop the scope of our project the team created project objectives we wanted to fulfill by the conclusion of the project. With these project objectives the team achieved both our technical goal and mission statement. These objectives are identified below:

1. Determine a reasonable fiscal end goal through identifying trends from data taken at each of the three programs.
2. Determine how each program functions via assessing the means of organizing information and administrative procedures, leadership approaches and who will take responsibilities of the ARPA forms.
3. Identify the ways in which writing can be and is applied through our project.

As previously discussed in section 2.1, the ARPA grant was created in response to the disproportionate effects of the COVID-19 pandemic on Worcester, MA residents. This grant is derived from fiscal recovery funds and aims to reimburse free medical programs for qualifying medical visits. The FMPs involved in the grant include; Epworth, Akwaaba, and WICCS. As noted above, the total amount for this grant is $49,230.00 and $128.24 per participant allowing for 384 unduplicated qualifying individuals' visits at any of the three Worcester Free Medical Services to be reimbursed to the program. The grant's guidelines specify various criteria for program visits to qualify for coverage. These criteria include ethnicity, race, address, household

income per size, participation in government programs, and specific services received during the visit. Included in appendix I is the ARPA grant form used in the free programs.

Our project was responsible for the implementation of the grant as well as the tracking of patients seen by all programs under the grant to ensure no duplicate patients are covered by the grant. This is accomplished by the group via a “crosswalk” stored on the secure WPI browser. The crosswalk is an excel sheet where data entry is completed for collected forms from programs that have been checked and qualify for the grant. This data entry properly guarantees the programs can use the grant under the state’s guidelines, such that no duplicates will be sent to the state for reimbursement. The crosswalk holds the following information from each qualifying patient; date of visit, patient number, name, patient identification number, and program visited. In appendix L there is a blank version of the crosswalk to showcase its format.

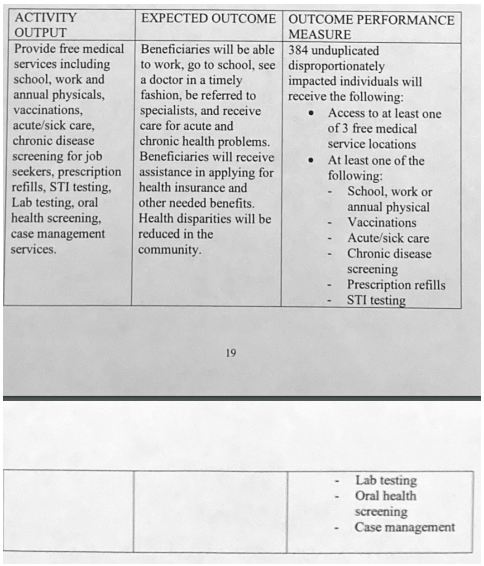
Once the crosswalk was developed the team created an additional cover page to be used alongside the forms at the three FMPs to assign patients an identification number and obtain their name. This cover page contains information explaining what the form is for and helps patients make informed decisions on their participation in the grant. Although the cover page contains their name, it is not sent to the City with the actual ARPA grant forms but is shredded once the patient information is archived in the crosswalk. In appendix I is the cover page without any of the fields filled out.

Despite having data entry means and privacy concerns covered, the team had to account for variation in each free medical service and how that variation impacted the successful implementation of the grant forms. This stemmed from various functional formats of the FMPs, their staff involvement and even the program’s ability to distribute the grant forms. Our team created long-term solutions for the three medical service programs; this meant that although our project concluded at the end of this spring, the FMPs participating in the grant are still able to operate while collecting reimbursement money through their own means. In doing so, the team had to account for the unique struggles each FMP has to implement a sustainable solution.

Section 2.2.0 Methodology/Approach Overview

Section 2.2.1 Iterations of the Form

The original ARPA Grant outlines a “Performance-Based Payment Plan” in which the beneficiaries of the grant- the three free programs- will provide select services to 384 unduplicated eligible patients living in Worcester, who have been impacted or disproportionately impacted by the COVID-19 public health emergency or its negative economic impacts. The Performance-Based Payment plan lays out specific activities, outcomes, and performance measurements that ensure the grant is directly benefiting the appropriate patients. Figure X displays the eligibility requirements for a patient visit, with each eligible patient visit equating to a total of $128.24 per participant every month for successful completion of the outcome performance measure.



ACTIVITY OUTPUT	EXPECTED OUTCOME	OUTCOME PERFORMANCE MEASURE
Provide free medical services including school, work and annual physicals, vaccinations, acute/sick care, chronic disease screening for job seekers, prescription refills, STI testing, Lab testing, oral health screening, case management services.	Beneficiaries will be able to work, go to school, see a doctor in a timely fashion, be referred to specialists, and receive care for acute and chronic health problems. Beneficiaries will receive assistance in applying for health insurance and other needed benefits. Health disparities will be reduced in the community.	384 unduplicated disproportionately impacted individuals will receive the following: • Access to at least one of 3 free medical service locations • At least one of the following: - School, work or annual physical - Vaccinations - Acute/sick care - Chronic disease screening - Prescription refills - STI testing - Lab testing - Oral health screening - Case management

Fig. 39. A summary of eligibility requirements directly from the state for each patient visit under "Outcome Performance Measure".

A method to track patient visits and evaluate the eligibility of patients for the grant was developed by the team based on the criteria outlined in Fig. 39. Due to the distinct operational and cultural considerations at each FMP, the medical programs were first observed by the team to gather information on how each program operated, the cultural and linguistic considerations at each program, and the patient and healthcare team workflow. It was observed that while each program had distinct cultural considerations, patient populations, and overall workflow, the general structure of how a patient arrives at the program, receives care, and exits the program were similar at each site. Due to this observation, a form regarding grant funding eligibility was created to be completed by patients, or a patient's guardian, at the time in which that patient arrived to receive care from either Epworth, WICs, or Akwaaba.

Layout, language, and word choice were carefully considered when developing and iterating on the form throughout the grant implementation process. Due to the differing patient populations at each program, it was important to ensure the form was written in a way that was comprehensible and in language that was easy to read and understand. This included not using overly technical or complex terms but instead, using laypeople's terminology. Additionally, it needed to be made clear to the patient that any sensitive information would be kept confidential. See Appendix I for our full grant form.

Section 2.2.2 Implementing Sustainability Practices

Implementing a sustainable process each program could follow to correctly gather and report eligible visits was important to establish as a result of the student team's graduation being prior to the end of the grant implementation period. To assist the programs with this process an infographic, instructional document, and "grant importance" document were developed. The

infographic and supporting documents represent three ways to communicate how to fill out the form and why the form is important for the programs to allow them to receive grant funding without the help of the MQP team.

Infographic
The infographic created by the team is a collection of imagery and instructional language that provides five steps to follow in order for the programs to fill out and complete the grant-eligibility form without outside assistance (See Appendix J). The form includes two main sections: purpose and process steps. The purpose section is a small text box that briefly explains the rationale and importance for the programs to complete the forms. The process steps section outlines the five steps in an easy-to-follow format, including imagery and color coding.

Instructional Document
The instructional document included by the team is a written step-by-step procedure for the programs to follow that details how the program can complete the grant eligibility form. The form includes two main sections: purpose and steps by program. The purpose section is a short, five-line paragraph that again outlines the importance and rationale for the programs to complete the forms in order to receive funding (see Appendix K).

"Grant Importance" Document
Due to feedback from Akwaaba that the program was struggling to fill out the forms without MQP team assistance, a one-page "Grant Importance" document was developed by the team. The document is titled "What the ARPA Grant Can Do For Your Medical Service" and uses both written language, varying font settings, and visual graphics in order to easily display the importance of receiving grant funding for the program by completing the form. The written component explains that eligible visits will award the program with $126.24 per visit, with each form taking less than five minutes to complete. Figure X displays the visual graphic used within the Grant Importance document that shows how one eligible form completed by the program will gain $126.24 towards the program. See Appendix L for the Grant Importance document.

Section 2.3.0 Results

Section 2.3.1 Quantitative Results

Over the time of this project (November 2023 to March 2024), 94 patients' visits qualified for the ARPA grant. With each qualified visit equaling $128.24 in grant funds, the three programs collectively have been awarded $12,054.56. As the maximum amount of funding available through the grant is $49,230, this means that 25% of available ARPA grant funds have already been distributed to the programs over the course of four months. If the rate of qualifying

form acquisition and submission to the government remains the same from this point in time onwards, the grant should be fully distributed to all programs within 12 months. With the grant ending in July of 2025, there should be ample time for form collection and submission so the grant can be fully distributed if our methodology is followed.

The Worcester Free Care Collaborative, which includes the health programs of Akwaaba, WICS, and Epworth, cares for over 5,000 patients annually (WFCC, 2024). These programs run entirely on private donations and grants, like the ARPA grant our project focused on (WFCC, 2024). Although not all 5,000 patients qualify for the ARPA grant, their care is improved by the funds the program receives from those visits that do qualify.

Section 2.3.2 Qualitative Results

Through volunteering at the programs, team members of this project observed the structure and organizational methods of each FMP. From there, a grant form including a top explanation sheet in different languages was developed (appendix I). After the initial attempt to implement this grant form into the admission process of each program, it was clear that each program would have different needs. It was initially challenging to implement the form due to the program's volunteer workers' requiring a greater understanding of the grant form and its purpose. The team created additional written resources in order to increase effective communication between us and the program volunteer workers. These additional written resources took the form of an infographic (appendix J), an instructional document for implementation (appendix K), and a document explaining the importance of the grant to FMP volunteers (appendix L). Ultimately, the team learned that communication was increased with the FMPs through clearly written, well-distributed infographics and instruction sheets.

Writing in non-profit settings is challenging due to the vast amount of genres utilized in this type of organization. For example, non-profit writing includes genres such as memos, instruction manuals, grant proposals, grant reports, annual reports, media-related documentation, and more [59]. Non-profit organizations' success relies heavily on effective communication internally, with those who utilize their services, as well as with partners in the private sector and the government.

Section 2.3.3 Impacts on the Community

After implementing the grant for the government and finding patients who qualify, we could see the effect the grant would have on both the free programs and the greater Worcester community. The money raised has the potential to enable the programs to continue to run and acquire necessary resources, allowing them to continue to serve populations in Worcester that were disproportionately affected by COVID-19 and those that rely on free programs as their primary source of healthcare. The grant provides support for the free programs and makes it possible for the free programs in Worcester to operate as a healthcare safety net as they were intended. With more funding, FMPs can purchase medical supplies they need. They could also

start additional programs running out of their spaces such as food banks and free clothing supply centers. More funding for FMPs means improved patient health and wellbeing, all of which also help the entire Worcester community.

In addition to the funding allowing the FMPs to continue to run and acquire necessary resources, the patients have a direct effect from the implementation of the grant. Many patients across all free clinics were able to receive work and school physicals, vaccinations, tuberculosis testing, prescription refills, and other crucial services like dental and dermatological care. With the patients being able to have increased access to these services provided by the FMPs, they are able to return to work, which might have been affected by the COVID-19 pandemic, school, and be in better health.

Chapter 3: An Anthropological Lens on Writing for Non-Profit Programs

Section 3.1 Project Impacts Through Writing

Our project had the unique ability to combine our written skills developed from coursework into a tangible outcome that touched many people in the Worcester community. Unlike what most assume writing is capable of, our project helped to change the city around us that we have spent the last four years living in, and will have a lasting impact even after the conclusion of this project. Most notable is the way the three free programs we worked with are impacted in both their ability to take on such roles in the grant process, as well as the benefits from such work to keep their programs open and improve the experiences of the individuals who visit.

To highlight the impact of this project, our team helped the three free Worcester night programs receive $128.24 per qualified visit in reimbursement funding to the programs. This number only includes patients who qualified for grant reimbursement; however, there are many more people being served by the grant implementation and who will feel the positive effects of this grant. This funding provides the Worcester Care Collaborative Inc. the necessary means to better serve their patients and improve patient experiences. Writing has the ability to turn the possibility of grant funding for the local free programs into reality and create sustainable practices for all types of programs. Several different aspects of writing can be seen throughout the process of this project and although some may seem obvious others constitute further thought and reflection to see their impacts. Further discussed in the following sections is the way in which writing through the teams' experiences and perspectives made our project both successful and impactful.

Section 3.2 Writing as Negotiation

A large part of this project was communication back and forth with the City of Worcester and negotiation the team completed as a means of writing. At the start of the project, the City provided deliverables on information regarding the guidelines of the grant, initial forms to be filled out, and other information surrounding the grant and its purpose. The team had to negotiate back and forth in developing a form that both was usable in the program's setting but satisfied the needs and requirements the City had for the grant. This process was in part negotiation with the programs, figuring out what worked and what didn't work for them through assessing the needs of each individual program to create a form that would be usable. And as that negotiation with the City settled, the next negotiation with the programs began to be at the forefront as we helped them use the forms and take responsibility for their use. Asking already struggling, or understaffed, programs to do more work was difficult, understandably. The team had means of negotiating with the programs to increase their use of the forms through making the how-to guides for the program staff as well as helping them understand all the grant can do for their program. Where this negotiation moved next was between the patients and the form, helping them to understand what they are filling out is not as easy when there are language barriers present. Also asking personal questions like income, ethnicity, government programs used, reason for visit, to all be later sent to the City can feel invasive and takes communicating the non-identification of each patient to the City as well as conveying the positive intent of the grant. When proper negotiation was implemented the team found success and both the programs and patients were on board with participation in the grant.

Section 3.3 Writing for Instantiating Need

In some ways, writing can constitute a form of reality. People sign legal contracts that bind them to work for a company for a set time, prevent them from disclosing information about sensitive issues, or marry another person. When writing in the free health program setting, documenting patient visits through the grant qualification form helps to prove that there is a need for free programs. By gathering other information through standard patient intake forms at the front desk, programs can prove that their patients need their services. Programs can gather data on why exactly their patients are using their programs, what illnesses or health problems are most often encountered, and how frequently people come back to the same program.

Without the forms and documentation systems we implemented in our MQP, the City would not be able to track qualified visits. In this way, our documentation systems help instantiate the need for grant money, and therefore the need for free health programs that heavily rely on grant money. In the future, the data from our documentation systems could be analyzed to determine if there are other populations that may benefit from alternate grants from the government. These grants may not cover the same qualifications as this ARPA grant, but instead cover other currently under-resourced populations that also utilize Worcester's free health programs.

Section 3.4 Writing Constitutes Culture

Writing documentation for free programs helps to put sensitive issues into perspective. Writing about how some people do not have the same access to healthcare as others, or how many people were disproportionately affected by COVID-19, makes systematic flaws in the healthcare industry known to a wider audience, ultimately increasing awareness of systematic issues and improving cultural sensitivity.

The three FMPs eligible for the COVID-19 relief ARPA grant- Epworth Clinic, Worcester Islamic Center Clinic, and Akwaaba Clinic- serve patients from distinct and varying cultural backgrounds. Adapting to the cultural and linguistic needs of each FMP was extremely important to maximize the effectiveness of the form and respect the patients at each clinic.

Section 3.5 Writing is Disincentive

As a means of communication in this project, writing needed to be understandable to individuals with varying levels of literacy and education. Complex language can disincentivize and discourage a patient from participating in filling out the form. Due to the complex technical language used within the original ARPA Grant, the team needed to develop a rewritten version of the ARPA Grant through a simplified Grant Eligibility Form. Word choice and formatting were carefully considered to ensure the form was understandable for all patients at each of the free programs. Additionally, language can disincentivize patients from filling out a form if it is not in their first language. The team also translated the form into multiple languages as an option for patients at the free programs.

Section 3.6 Writing is Ethics

Deliberate verbiage and word choice within the Grant Eligibility form were necessary to ensure all patients had an equal understanding and opportunity to complete the form. When writing is too complex or not understood by all audiences, some individuals may not be able to access the benefits resulting from the written work. Complex language and certain words or phrases can also insinuate biases within the written work and wrongfully assume the work will be understood. Additionally, if not all audiences have an understanding of a written work, writing can effectively be used against certain populations and decrease equity. For example, having a written work translated into only one language can effectively limit all individuals speaking other languages to read and benefit from the written work.

10. References

[1] J. L. Funder, L. Ross, and S. Ryan, “How Effective are Paramedics at Interpreting ECGs in Order to Recognize STEMI? A Systematic Review,” *Australasian Journal of Paramedicine*, vol. 17, pp. 1–9, Jan. 2020, doi: 10.33151/ajp.17.772.

[2] M. Rehman and N. U. Rehman, “Precordial ECG Lead Mispositioning: Its Incidence and Estimated Cost to Healthcare,” *Cureus*, vol. 12, no. 7, p. e9040, doi: 10.7759/cureus.9040.

[3] I. Rehman and A. Rehman, “Anatomy, Thorax, Heart,” in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Sep. 04, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK470256/

[4] A. Singh, A. S. Museedi, and S. A. Grossman, “Acute Coronary Syndrome,” in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Dec. 19, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK459157/

[5] X. Wei, S. Yohannan, and J. R. Richards, “Physiology, Cardiac Repolarization Dispersion and Reserve,” in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Dec. 18, 2023. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK537194/

[6] “3M™ Diaphoretic Foam Monitoring Electrode, 2200 Series.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.3m.com/3M/en_US/p/d/b00037601/

[7] “3M™ Diaphoretic Foam Monitoring Electrode, 2200 Series.” Accessed: Apr. 18, 2024. [Online]. Available: https://www.3m.com/3M/en_US/p/d/b00037601/

[8] “3M™ Red Dot™ Diaphoretic Soft Cloth Monitoring Electrode.” Accessed: Dec. 18, 2023. [Online]. Available: https://www.3m.com/3M/en_US/p/d/b00037603/

[9] “Accurate interpretation of the 12-lead ECG electrode placement: A systematic review - Kirti Khunti, 2014.” Accessed: Sep. 04, 2023. [Online]. Available: https://journals.sagepub.com/doi/full/10.1177/0017896912472328

[10] “Cardiac conduction system - Health Video: MedlinePlus Medical Encyclopedia.” Accessed: Dec. 18, 2023. [Online]. Available: https://medlineplus.gov/ency/anatomyvideos/000021.htm

[11] “CV Physiology | Electrocardiogram (EKG, ECG).” Accessed: Dec. 18, 2023. [Online]. Available: https://cvphysiology.com/arrhythmias/a009

[12] “EKG Interpretation Primer - Full Text.docx,” Google Docs. Accessed: Sep. 04, 2023. [Online]. Available: https://drive.google.com/file/d/0B7j619WxqXF_NUtfQ21GNFhYRndnQU0yempwMnY2d1NuTl93/view?usp=embed_facebook

[13] “Electrical conduction in the heart: Video & Anatomy,” Osmosis. Accessed: Dec. 18, 2023. [Online]. Available: https://www.osmosis.org/

[14] “Function of the Heart’s Electrical System,” Cleveland Clinic. Accessed: Dec. 18, 2023. [Online]. Available: https://my.clevelandclinic.org/health/body/22562-electrical-system-of-the-heart

[15] “General Review.” Accessed: Dec. 18, 2023. [Online]. Available: https://www.unm.edu/~lkravitz/UNM%20Pages/generalrev.html

[16] “How the Heart Works - What the Heart Looks Like | NHLBI, NIH.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.nhlbi.nih.gov/health/heart/anatomy

[17] “Lead systems – how an ECG works | CardioSecur.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.cardiosecur.com/magazine/specialist-articles-on-the-heart/lead-systems-how-an-ecg-works

[18] “Mapping Blood Flow Through the Body,” Verywell Health. Accessed: Dec. 18, 2023. [Online]. Available: https://www.verywellhealth.com/blood-flow-through-the-heart-3156938

[19] “Understanding an ECG | ECG Interpretation | Geeky Medics.” Accessed: Dec. 18, 2023. [Online]. Available: https://geekymedics.com/understanding-an-ecg/

[20] “Anatomy and Function of the Heart’s Electrical System.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.hopkinsmedicine.org/health/conditions-and-diseases/anatomy-and-function-of-the-hearts-electrical-system

[21] “How the Heart Works - How the Heart Beats | NHLBI, NIH.” Accessed: Dec. 18, 2023. [Online]. Available: https://www.nhlbi.nih.gov/health/heart/heart-beats

[22] E. A. Ashley and J. Niebauer, “Conquering the ECG,” in *Cardiology Explained*, Remedica, 2004. Accessed: Sep. 04, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK2214/

[23] A. Dupre, S. Vincent, and P. A. Iaizzo, “Basic ECG Theory, Recordings, and Interpretation,” in *Handbook of Cardiac Anatomy, Physiology, and Devices*, P. A. Iaizzo, Ed., Totowa, NJ: Humana Press, 2005, pp. 191–201. doi: 10.1007/978-1-59259-835-9_15.

[24] M. Elgendi, A. Mohamed, and R. Ward, “Efficient ECG Compression and QRS Detection for E-Health Applications,” *Sci Rep*, vol. 7, no. 1, p. 459, Mar. 2017, doi: 10.1038/s41598-017-00540-x.

[25] C. for D. and R. Health, “Class I and Class II Device Exemptions,” *FDA*, Aug. 2023, Accessed: Apr. 24, 2024. [Online]. Available: https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions

[26] A. Marketing, “12-Lead ECG Placement Guide,” Vitali. Accessed: Sep. 04, 2023. [Online]. Available: https://www.vitalipartners.com/blog/2023/01/12-lead-ecg-placement/

[27] A. Marketing, “12-Lead ECG Placement Guide,” Vitali. Accessed: Sep. 04, 2023. [Online]. Available: https://www.vitalipartners.com/blog/2023/01/12-lead-ecg-placement/

[28] R. Pura, “Einthoven’s Triangle: A Piece Of Medical Device History,” ClearPath Medical. Accessed: Sep. 04, 2023. [Online]. Available: https://clearpathmedical.com/medical-device-history-einthovens-triangle-ecg-electrocardiogram-willem-einthoven/

[29] C. and Sensors, “12 Lead ECG Placement Guide | Cables & Sensors,” Cables and Sensors. Accessed: Sep. 04, 2023. [Online]. Available: https://www.cablesandsensors.com/pages/12-lead-ecg-placement-guide-with-illustrations

[30] H. Yang *et al.*, “Adhesive Biocomposite Electrodes on Sweaty Skin for Long-Term Continuous Electrophysiological Monitoring,” *ACS Materials Lett.*, vol. 2, no. 5, pp. 478–484, May 2020, doi: 10.1021/acsmaterialslett.0c00085.

[31] B. Young, “New standards for ECG equipment,” *J Electrocardiol*, vol. 57S, pp. S1–S4, 2019, doi: 10.1016/j.jelectrocard.2019.07.013.

[32] “Introduction - Cardiology Teaching Package - Practice Learning - Division of Nursing - The University of Nottingham.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.nottingham.ac.uk/nursing/practice/resources/cardiology/introduction/index.php

[33] “Medscape For You.” Accessed: Apr. 24, 2024. [Online]. Available: https://www.medscape.com/for-you

[34] “The Heart’s Electrical System,” ucsfbenioffchildrens.org. Accessed: Sep. 04, 2023. [Online]. Available: https://www.ucsfbenioffchildrens.org/education/the-hearts-electrical-system

[35] “Anatomy and Function of the Heart’s Electrical System.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.hopkinsmedicine.org/health/conditions-and-diseases/anatomy-and-function-of-the-hearts-electrical-system

[36]“12 lead ECG placement | Research | ADInstruments.” Accessed: Sep. 04, 2023. [Online]. Available: https://www.adinstruments.com/blog/correctly-place-electrodes-12-lead-ecg

[37] G. Karki, “Human Heart-Gross structure and Anatomy,” Online Biology Notes. Accessed: Apr. 24, 2024. [Online]. Available: https://www.onlinebiologynotes.com/human-heart-gross-structure-and-anatomy/

[38] “The 1960s, Drugs and the Birth of the Free Clinic - ProQuest.” Accessed: Apr. 25, 2024. [Online]. Available: https://www.proquest.com/docview/1709136088/abstract/F1EECEC676AD42E5PQ/1?sourcetype=Wire%20Feeds

[39] “The Free Clinic Movement in the United States: A Ten Year Perspective (1966–1976) - David E. Smith, 1976.” Accessed: Apr. 25, 2024. [Online]. Available: https://journals.sagepub.com/doi/10.1177/002204267600600404

[40] D. J. Fletcher, “15 years later, free clinic still thriving: Haight-Ashbury Free Clinic still alive and well,” *Am Med News*, vol. 25, no. 21, pp. 11–12, Jun. 1982.

[41] A. Hu, “Reflections,” *Otolaryngology–Head and Neck Surgery*, vol. 155, no. 2, pp. 197–198, 2016, doi: 10.1177/0194599816649361.

[42] “U.S. Uninsured Rate Dropped 18% During Pandemic.” Accessed: Apr. 25, 2024. [Online]. Available: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2023/202305.htm
[43] “Health Care Crisis Unabated: A Review of Recent Data on Health Care in the United States - David U. Himmelstein, Steffie Woolhandler, 2021.” Accessed: Apr. 25, 2024. [Online]. Available: https://journals.sagepub.com/doi/10.1177/0020731420981497
[44] E. A. Shrider and J. Creamer, “Poverty in the United States: 2022”.
[45] “Medicaid Eligibility | Medicaid.” Accessed: Apr. 25, 2024. [Online]. Available: https://www.medicaid.gov/medicaid/eligibility/index.html
[46] S. L. Dickman, D. U. Himmelstein, and S. Woolhandler, “Inequality and the health-care system in the USA,” *Lancet*, vol. 389, no. 10077, pp. 1431–1441, Apr. 2017, doi: 10.1016/S0140-6736(17)30398-7.

[47] “Health coverage for lawfully present immigrants,” HealthCare.gov. Accessed: Apr. 25, 2024. [Online]. Available: https://www.healthcare.gov/immigrants/lawfully-present-immigrants/

[48] “Information for immigrant patients and their health care providers on immigration enforcement | Mass.gov.” Accessed: Apr. 25, 2024. [Online]. Available: https://www.mass.gov/info-details/information-for-immigrant-patients-and-their-health-care-providers-on-immigration-enforcement

[49] “Connecticut General Assembly,” Connecticut General Assembly. Accessed: Apr. 25, 2024. [Online]. Available: https://www.cga.ct.gov

[50] “An Assessment of the Health Care Safety Net: Performance Evaluation of Free Clinics - Lynn M. VanderWielen, Yasar A. Ozcan, 2015.” Accessed: Apr. 25, 2024. [Online]. Available: https://journals.sagepub.com/doi/10.1177/0899764013520235

[51] D. J. Arenas, R. Noche, A. Thomas, D. Hallak, and S. Raman, “Systematic Review of Patient-Centered Needs Assessments Performed by Free Health Clinics,” *Journal of Student-Run Clinics*, vol. 5, no. 1, Art. no. 1, Jun. 2019, doi: 10.59586/jsrc.v5i1.79.

[52] A. P. Wilper, S. Woolhandler, K. E. Lasser, D. McCormick, D. H. Bor, and D. U. Himmelstein, “Health Insurance and Mortality in US Adults,” *Am J Public Health*, vol. 99, no. 12, pp. 2289–2295, Dec. 2009, doi: 10.2105/AJPH.2008.157685.

[53] “National Association of Free & Charitable Clinics | NAFC.” Accessed: Apr. 25, 2024. [Online]. Available: https://nafcclinics.org/

[54] S. L. Isaacs and P. Jellinek, “Is There A (Volunteer) Doctor In The House? Free Clinics And Volunteer Physician Referral Networks In The United States,” *Health Affairs*, vol. 26, no. 3, pp. 871–876, May 2007, doi: 10.1377/hlthaff.26.3.871.

[55] “The Free Medical Clinic: A Practical Handbook for Health Care Providers” Accessed: Apr. 25, 2024 [Online]. Available: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/ama-foundation/free-medical-clinic-handbook.pdf

[56] “What is the Role of Free Clinics in the Safety Net? | Request PDF.” Accessed: Apr. 25, 2024. [Online]. Available: https://www.researchgate.net/publication/51725304_What_is_the_Role_of_Free_Clinics_in_the_Safety_Net

[57] “Free Clinics in the United States: A Nationwide Survey | Health Care Delivery Models | JAMA Internal Medicine | JAMA Network.” Accessed: Apr. 25, 2024. [Online]. Available: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/416041

[58] A. M. Gertz, S. Frank, and C. E. Blixen, “A Survey of Patients and Providers at Free Clinics Across the United States,” *J Community Health*, vol. 36, no. 1, pp. 83–93, Feb. 2011, doi: 10.1007/s10900-010-9286-x.

Appendix

Appendix A - IRB Material

Written Consent From - Participants

Written Consent Form

Investigators: Lauren Averka, Kellie Bushe, Abby Gallagher, Abbi Poland
Contact Information: Email: gr-ekgmqp@wpi.edu
Title of Research Study: EKG MQP Feasibility Test

Sponsor: Worcester Polytechnic Institute, Advised by Brenton Faber

Introduction:

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks, or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of Study:

The purpose of this study is to test our prototype, the "EKG Assist". The purpose of this prototype is to help properly adhere electrodes to diaphoretic (sweaty or perspiring) patients when running an electrocardiogram (EKG). An EKG is a diagnostic tool used to measure the electrical activity, or rhythm, of the heart. Our team hopes to verify that our design works by testing its usage on willing participants.

Procedures to be Followed:

Participants will be asked to arrive at the Epworth Clinic for this study. Participants will lay down on their back on an examination table.
From the British Journal of Nursing; Procedure for recording standard 12-lead EKG
The following procedure will be followed when recording the EKG (Jevon, 2007; 2009)

1. The participant will be in a comfortable position, ideally at a 45 degree angle. The head should be well supported; the backrest of the bed and pillows will be helpful.
2. Participants' wrists must be close to, but not touching, the waist.
3. Clinician will apply the limb electrodes in accordance with the EKG setup diagram
4. Clinician will apply the chest electrodes in accordance with the EKG setup diagram
5. The participants lie still and breathe normally.
6. Once complete, the clinician will remove electrodes from the participant.

A licensed clinician will conduct an EKG under the typical clinical methodology, then will conduct an EKG using the EKG Assist. This process will be repeated under diaphoretic conditions, simulated via 2 sprays of saline spray. No diagnostic interpretation of the EKG will occur. EKGs from both procedures will be compared for equivalence but not for diagnostic results. Any incidental findings will not be discussed with the participant.

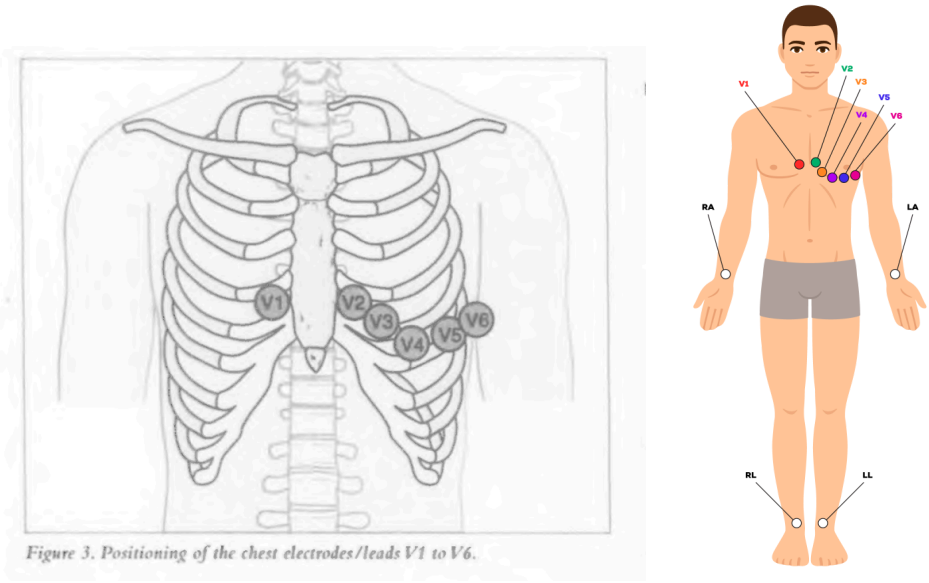


Figure X. 12 lead EKG electrode placement diagram from BJN and Cardiac Direct

Privacy:

Participants in the research study must expose the chest for proper placement of both the EKG and the EKG Assist. There is an option to wear a loose fitting bra that will not interfere with the EKG placement. Those who sign this consent form are aware that this process is necessary for the study to take place. Participants understand this study will take place in a closed room, with only the necessary team members and clinician in the room to observe for qualitative and quantitative data collection and feedback. There are female and male clinicians available for the study upon participant request.

Risks to Study Participants:

Using an Electrocardiogram (EKG) poses generally minimal risk as they are a common and non-invasive diagnostic tool. The EKG being used in the study is calibrated and currently in use at the clinic. A licensed clinician will be responsible for the placement and use of the EKG on all participants so there is generally no risk associated. The electrodes used to attach to the skin for EKG monitoring may cause mild skin irritation or allergic reactions in some individuals. Participants may experience discomfort or anxiety during the placement of electrodes or the recording process. This is usually temporary and mild. And finally, EKGs are

non-invasive, participants are exposed to electrical equipment but the risk of electrical shock or malfunction of the equipment is extremely low but is still considered as a potential risk. If the clinician reads any concerning results from the EKG tests, the participant will be notified. The clinician will assist the participant in getting help if needed.

Participants are asked to disclose any pre-existing conditions that may be discovered during this study. This is done so that the clinician on site does not discover any conditions during the study that would raise concern for the patient's health. By answering the following question you are not disqualified from the study nor will this information be traced back to you as an individual: Have you ever been diagnosed with a cardiac arrhythmia? Please check the corresponding box below for your answer;

- ☐ Yes
- ☐ No
- ☐ I prefer not to answer.

Benefits to Study Participants and Others:

Participants in this study are assisting the WPI EKG Acquisition Device MQP team in development of a device that will aid paramedics and other emergency service personnel by preventing electrode slippage on diaphoretic patients. Use of this device will ensure proper diagnosis of potentially life-threatening conditions through more accurate and timely EKG readings.

Record Keeping and Confidentiality:

Results from the study will be publicly available in the final report, which includes information on EKG similarities and differences between EKG readings using our device and not using our device. Confidential information about the study participant will not be collected so there is no risk of breaching privacy through the publishing of the study findings in our report. Any publication or presentation of the data will not identify you. The final report will be available on digital.wpi.edu. Signed consent forms will be saved in a manner that keeps the information secure, in a locked cabinet in our advisors office.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:

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IRB Manager - Ruth McKeogh (Tel. +1 508 831 6699, Email: irb@wpi.edu). Human Protection Administrator - Gabriel Johnson (Tel. +1 508 831 4989, Email: gjohnson@wpi.edu).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the test at any time they see fit.

Photography:
Any photographs taken may be used to show test results, and may be included in the final report and/or final presentation. There will be no photographs of faces, or any other identifying information/features. Does the participant consent to having photographs taken during testing?

- ☐ Yes, I consent to having photographs taken during testing.
- ☐ No, I do not consent to having photographs taken during testing.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____
_____
Study Participant(s) Signature Date

_____
_____
Study Participant(s) Name (Printed) Date

_____
_____
Signature of Person who Explained Study Date

Written Consent Form - Nurse Practitioner

Written Consent Form

Investigators: Lauren Averka, Kellie Bushe, Abby Gallagher, Abbi Poland
Contact Information: Email: gr-ekgmqp@wpi.edu
Title of Research Study: EKG MQP Feasibility Test

Sponsor: Worcester Polytechnic Institute, Advised by Brenton Faber

Introduction:

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks, or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of Study:

The purpose of this study is to test our prototype, the "EKG Assist". The purpose of this prototype is to help properly adhere electrodes to diaphoretic (sweaty or perspiring) patients when running an electrocardiogram (EKG). An EKG is a diagnostic tool used to measure the electrical activity, or rhythm, of the heart. Our team hopes to verify that our design works by testing its usage on willing participants.

Procedures to be Followed:

You, the licensed Clinician, will be asked to arrive at the Epworth Clinic for this study. You are asked when placing the EKG electrodes to follow the procedure below as described in the British Journal of Nursing.

From the British Journal of Nursing; Procedure for recording standard 12-lead EKG

The following procedure will be followed when recording the EKG (Jevon, 2007; 2009)

1. Wash hands with bacterial soap and water bactericidal and dry
2. Identify the correct patient for the procedure
3. Explain the procedure to the patient. This ensure that the patient understands the procedure and able provide valid consent.
4. Prepare the patient and environment
5. Ask the patient lie down comfortable position, ideally at a 45 degree angle, the head should be well supported, the back rest the bed and pillows will be helpful. To help ensure standardization and interpretation of serial EKGs, the patient should adopt the same position for each recording
6. Ensure the inner aspects the wrists are close to, but not touching, his/her waist

7. If necessary, prepare the skin. wet gel electrodes are used, shaving and abrading the skin not necessary; solid gel electrodes are used, clean/degrease and debrade the skin and shave necessary
8. Apply the limb electrodes/leads:
    - red right inner wrist
    - yellow left inner wrist
    - black right inner leg, just above the ankle
    - green left inner leg, just above the ankle. (Upper arms
    - upper legs are sometimes used instead ankles/wrists.)
9. Apply the chest electrodes/leads
    - V1 (white/red lead) fourth intercostal space, just the right the sternum
    - V2 (white/yellow lead) fourth intercostal space, just the left the sternum
    - V3 (white/green lead) midway between V2 and V4
    - V4 (white/brown lead) fifth intercostal space, midclavicular line
    - V5 (white/black lead) mid-clavicular line, the same horizontal line as V4
    - V6 (white/violet lead) mid-axillary line, same horizontal line as V4 and V5
10. Ensure the EKG cables are not pulling on the electrodes lying over each other; this will help minimize electrical artifact and improve quality and accuracy the EKG trace
11. Check the calibration signal the EKG machine ensure standardization. This normally paper speed25 mm/s and EKG size mV/10 deflection
12. Ask the patient lie still and breathe normally during the procedure.
13. Record the 12-lead EKG following the manufacturer's recommendations
14. Remove the EKG electrodes/leads. Clean as necessary following the manufacturer's recommendations. If serial 12-lead EKGs are needed, electrodes are usually left on the patient.
15. Label the EKG correctly. Report and store the EKG the notes, adhering to local policy.

You, the licensed clinician will conduct an EKG under the typical clinical methodology as described above, then will conduct an EKG using the EKG Assist. This process will be repeated under diaphoretic conditions, simulated via 2 sprays of saline spray. No diagnostic interpretation of the EKG will occur. EKGs from both procedures will be compared by you on a scale of 0-100 for equivalence but not for diagnostic results. Any incidental findings will not be discussed with the participant. After the conclusion of the readings on the participants you the Clinician will be asked questions regarding your experience using the device, these questions are attached to the appendix of this consent form. Your name will not be attached to your answers or your work affiliation.

Privacy:

Your name will not be attached to your answers of the questionnaire or your work affiliation. You will also not be included in any of the possible photos the team will be taking.

Risks to Study Participants:

Risks regarding your participation in this study as the licensed clinician running the EKGs for this study are minimal. The most notable one will be the interactions with the participants while running an EKG on them. Although unlikely, we do not foresee any risk of significance being faced by you if you participate.

Benefits to Study Participants and Others:

Participants in this study are assisting the WPI EKG Acquisition Device MQP team in development of a device that will aid paramedics and other emergency service personnel by preventing electrode slippage on diaphoretic patients. Use of this device will ensure proper diagnosis of potentially life-threatening conditions through more accurate and timely EKG readings.

Record Keeping and Confidentiality:

Results from the study will be publicly available in the final report, which includes information on EKG similarities and differences between EKG readings using our device and not using our device. Confidential information about the study participant will not be collected so there is no risk of breaching privacy through the publishing of the study findings in our report. Any publication or presentation of the data will not identify you. The final report will be available on digital.wpi.edu. Signed consent forms will be saved in a manner that keeps the information secure, in a locked cabinet in our advisors office.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:

Team members - Lauren Averka (Tel. +508 581 0667, Email: lbaverka@wpi.edu), Kellie Bushe (Tel. +508 340 0503, Email: klbushe@wpi.edu), Abigail Gallagher (Tel. +508 369 8640, Email: acgallagher@wpi.edu), Abbi Poland (Tel. +401 649 0095, Email: alpoland@wpi.edu)

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By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____
_____
Study Participant(s) Signature Date

_____
_____
Study Participant(s) Name (Printed) Date

_____
_____
Signature of Person who Explained Study Date

Appendix B - Phase 0 Test Methods for Design Verification

Appendix B shows each step for design verification tests for Phase 0 as discussed in Chapter 5.

Test Method - Characterizing electrode movement due to diaphoresis on a mannequin model using an NaCl solution and petroleum jelly

Objective

The purpose of this test method is to further define the problem that diaphoresis causes for EKG acquisition in terms of electrode movement.

Test Method Overview

An electrode will be placed on a mannequin at V4 according to the EKG standard along with a control condition and a simulated diaphoretic condition. Diaphoresis magnitude will be varied in

terms of salt sprays and a petroleum jelly spread. A mock EKG will be run at each condition, and the final electrode position will be marked. The distance between the electrodes initial and final placement will be recorded.

Materials

- Duct tape
- Mannequin
- Marker
- Camera
- Bag valve mask
- Stopwatch
- Measuring tape
- Electrodes
- EKG
- NaCl solution spray
- Petroleum jelly
- 70% isopropyl alcohol

Set-Up

Mannequin Set-Up

1. Attach tubing to its respective bag on the mannequin
2. Attach bag valve mask
3. Prop up mannequin to 30 degrees
4. Mark proper electrode placement locations with duct tape according to EKG standards
5. Remove V4 tape
6. Mark initial location of electrode with a marker at V4 location

EKG Set-up

1. Attach V4 lead to electrode

Procedure

1. Spray desired magnitude of diaphoresis on V4 location, 4 inches away from mannequin
    a. NaCl solution: 0, 1, 2, or 3 sprays
    b. Petroleum jelly spread: max diaphoresis
2. Take photo of diaphoresis magnitude
3. Immediately place electrode on the properly marked area of mannequin at V4
    a. Take photo of initial placement
4. Record a video and perform mock EKG for 60 seconds
    a. Simulate breathing using bag valve mask
    b. Record observations

5. Remove electrode
6. Mark final placement with a marker if electrode moved
7. Take photo of final placement
8. Measure distance with a measuring tape if electrode moved
9. Wipe with area isopropyl alcohol
10. Repeat one more time for a total of two trials per diaphoresis magnitude
11. Repeat for all diaphoresis magnitudes

Clean-Up

1. Wipe mannequin and device with isopropyl alcohol
2. Dispose of electrodes

Data Sheet

Trial	Diaphoresis Magnitude	Lead Number	Time (s)	Distance (mm)	Photo end time	Notes/Observations
1	0	V6	60			
2	0	V4	60			
3	1	V4	60			
3	1	V4	60			
4	2	V4	60			
5	2	V4	60			
6	3	V4	60			
7	3	V4	60			
8	Petroleum jelly	V4	60			
9	Petroleum jelly	V4	60			

Test Method - Characterizing electrode-skin adherence under diaphoretic conditions on a mannequin model using a spring-scale

Objective

The purpose of this test method is to further define the problem that diaphoresis causes for EKG acquisition in terms of electrode skin adherence. How much does diaphoresis affect electrode adherence to the skin?

Test Method Overview

An electrode will be placed on a mannequin according to the EKG standard at V4 along with a control condition and a simulated diaphoretic condition. Diaphoresis magnitude will be varied in terms of salt sprays and a vaseline spread. A mock EKG will be run at each condition, and the electrode will attempt to be pulled off using a spring scale. The force of the pull will be recorded.

Materials

- Spring scale
- Duct tape
- Mannequin
- Marker
- Camera
- Electrodes
- EKG
- NaCl solution spray
- Petroleum jelly
- 70% isopropyl alcohol

Set-Up

Mannequin Set-Up

1. Prop up mannequin to 30 degrees
2. Mark proper electrode placement locations with duct tape according to EKG standards
3. Remove V4 tape
4. Mark initial location of electrode with a marker at V4 location

EKG Set-up

1. Attach V4 lead to electrode
2. Attach spring scale to electrode with tape

Procedure

1. Spray desired magnitude of diaphoresis on V4 location, 4 inches away from mannequin

    a. NaCl solution: 0, 1, 2, or 3 sprays
    b. Petroleum jelly spread: max diaphoresis
2. Take photo of diaphoresis magnitude
3. Immediately place electrode on the properly marked area of mannequin at V4
4. Wait for 30 seconds using a timer
5. Record a video in slow motion including spring scale
6. Pull electrode off mannequin in parallel
    a. Record any observations
    b. Stop timer once pulled off completely
7. Record maximum force on spring gauge
8. Wipe with area isopropyl alcohol
9. Repeat one more time for a total of two trials per diaphoresis magnitude
10. Repeat for all diaphoresis magnitudes

Clean-Up

1. Wipe mannequin and device with isopropyl alcohol
2. Dispose of electrodes

Data Sheet

Trial	Diaphoresis Magnitude	Lead Number	Force (N)	Photo end time	Notes/Observations
1	0	V4			
2	0	V4			
3	1	V4			
4	1	V4			
5	2	V4			
6	2	V4			
7	3	V4			
8	3	V4			
9	Petroleum jelly	V4			
10	Petroleum jelly	V4			

Appendix C - Phase 1 Test Methods for Design Verification

Test Method – Understanding the feasibility of the KLAA EKG Assist in control and diaphoretic conditions on a mannequin

Objective

The purpose of this qualitative test method is to show whether or not the KLAA EKG Assist works to keep electrodes in place.

Test Method Overview

A mannequin will be suited with either no diaphoretic condition or with a simulated diaphoretic condition of varying magnitudes. Electrodes will be placed on the mannequin according to EKG standards. The user will connect all leads to the KLAA EKG Assist and use it on the mannequin and attempt to secure the electrodes in place. The user will record a pass or fail. A pass is defined by the following parameters; (1) all tubing reaches electrodes, (2) no observed electrode lifting or sliding, (3) the sled makes full contact with the electrode, and lastly, (4) no device failure or cracking. For the device to receive a pass for each of the parameters all electrodes under the conditions must satisfy the specified parameter.

Materials

- Marker
- Mannequin
- Electrodes
- EKG
- KLAA EKG Assist
- NaCl solution spray
- Petroleum jelly
- 70% isopropyl alcohol

Set-Up

Mannequin Set-Up

1. Marker proper electrode placement locations according to EKG standards

Prototype Set-Up

1. Insert each lead into its respective KLAA tubing
2. Open handle casing
3. Insert leads into casing and thread the lead through the back
4. Close handle casing securely

5. Clip leads into their electrodes and align the sled along the front of the clip

Procedure

1. Spray desired magnitude of diaphoresis
    a. NaCl solution: 0, 1, 2, or 3 sprays
    b. Petroleum jelly spread: max diaphoresis
2. Place electrodes on the properly marked areas of mannequin
3. Manipulate KLAA to proper alignment with electrodes using corrugated portion of lead
4. Apply a force onto the device until the electrodes are secure in its proper location
5. Record any notes or observations
6. Record a pass or fail
7. Spray 70% isopropyl alcohol to clean mannequin of any residual electrode gel
8. Repeat steps 1-7 with all diaphoresis conditions

Clean-Up

1. Wipe mannequin and device with isopropyl alcohol
2. Dispose of electrodes

Data Sheet

Diaphoresis Magnitude	Pass / Fail Tubing reached location	Pass / Fail electrode stays in place	Pass / Fail Sled full contact	Pass / Fail no observed failure	Notes/Observations about certain lea
0					
1 spray					
2 sprays					
3 sprays					
Petroleum jelly					

Test Method – Force exertion of KLAA EKG Assist on a mannequin
Objective

The purpose of this test method is to find the amount of force exerted on a mannequin while using the KLAA EKG Assist. This will indicate the amount of pressure a patient can expect on their body from the device, as well as how much force the clinician will use.

Test Method Overview

A mannequin with electrodes previously placed will be zeroed onto a force plate with varying degrees of diaphoresis. The user will connect all leads to the KLAA EKG Assist and use it on the mannequin until the electrode is secured in place. The force of this action will be recorded.

Materials

- Force plate
- Marker
- Mannequin
- Electrodes
- EKG
- KLAA EKG Assist
- NaCl solution spray
- Petroleum jelly
- 70% isopropyl alcohol

Set-Up

Force Plate Set-Up

1. Plug in USB cord to side of force plate and USB into the computer
2. Open NetForce software on the desktop
3. Zero hardware before the test. Setup→hardware→zero
4. Enter a weight for your subject (kg). Just type it in, do not press anything after that
5. Settings: acquisition settings. Set duration for recording to 30s and data sets per second (200, use drop down) press okay

Mannequin Set-Up

1. Marker proper electrode placement locations according to EKG standards
2. Spray desired magnitude of diaphoresis
    a. NaCl solution: 0, 1, 2, or 3 sprays
    b. Petroleum jelly spread: max diaphoresis
3. Place electrodes on the properly marked areas of mannequin

Prototype Set-Up

1. Insert each lead into its respective KLAA tubing
2. Open handle casing
3. Insert leads into casing and thread the lead through the back
4. Close handle casing securely
5. Clip leads into electrode and align the sled along the front of the clip
6. Manipulate tubing to proper alignment with electrode using corrugated portion of lead

Procedure

1. Spray desired magnitude of diaphoresis in one lead location (V1-V6)
    a. NaCl solution: 0, 1, 2, or 3 sprays
    b. Petroleum jelly spread: max diaphoresis
2. Place electrode on each location from step 1
3. Repeat steps 1 and 2 for all electrodes
4. Manipulate KLAA to proper alignment with electrodes using corrugated portion of lead
5. Zero the force plate
6. Start recording on NetForce
7. Apply a force onto the device until the electrode is secure in its proper location
8. Record any notes or observations
9. Stop recording on NetForce after 30s
10. Save: file → export data file → save as bsf file
11. Spray 70% isopropyl alcohol to clean mannequin of any residual electrode gel
12. Repeat steps 1-12 for each magnitude of diaphoresis
13. Record each force from exported data file

Clean-Up

1. Wipe mannequin and device with isopropyl alcohol
2. Dispose of electrodes

Data Sheet

Trial	Diaphoresis Magnitude	Force (N)	ForceNet File Name	Timestamp of pictures	Notes/Observations
1	0				
2	1 spray				
3	2 sprays				
4	3 sprays				
5	Petroleum jelly				

Results

Table 9. Force Exertion of KLAA Device on Mannequin with Force Plate

Diaphoretic Condition	**Mean Force (N)**	**SD**
0 sprays	2.47	0.68

1 spray	1.04	1.23
2 sprays	3.28	0.052
3 sprays	3.05	1.37
Petroleum jelly	2.31	0.95

Appendix D - Phase 2 Test Methods for Design Verification

Test Method - Determining Non-Inferiority of EKG readings using the KLAA EKG Assist on non-diaphoretic human subjects

Objective

The purpose of this test is to verify that the use of the KLAA EKG Assist does not interfere with normal EKG readings on human subjects.

Test Method Overview

Participants will be identified by their initials. An EKG will be done on a human subject by a licensed clinician, once with a regular EKG set up and once with the KLAA EKG Assist. Our team members will label the normal EKG readings with a lowercase letter, and the KLAA readings with an uppercase letter. The clinician will not be aware which reading corresponds to which EKG set-up. The clinician will determine if the readings are equivalent and this result will be recorded. No diagnosis will be made.

Procedure

1. Participants arrive at the Epworth Methodist Free Medical Program in Worcester, MA and are shown to the examination room in the clinic where the testing will occur.
2. Participants will remove outerwear and associated clothing so the chest area is accessible.
3. Participants lay down on the examination table.
4. An EKG is placed on the participant by a licensed clinician.
5. A reading is taken without the “EKG Assist” and recorded by the licensed clinician.
6. Repeat steps 1-5 for a total of 3 trials.
7. The EKG is taken off the participants.

8. A licensed clinician places the EKG Assist device on the participants.
9. A reading is taken with the “EKG Assist” and recorded by the licensed clinician.
10. Repeat steps 7-9 for a total of 3 trials.
11. The licensed clinician verifies the two readings are the same (checking for noise in the results, etc..) and correlating data recorded

    Scale - for EKG equivalence testing, the clinician reads the same reading 3 times

    i. Give an equivalent reading (3)
    ii. Completely different (0)
    iii. Some equivalence (2)
    iv. Minimal Equivalence (1)

Data Sheet

Trial	Participant	Pass (Equal) or Fail (Inferior)	Notes

Test Method - Determining the feasibility of the KLAA EKG Assist on human subjects in a diaphoretic environment

Objective

The purpose of this test is to verify that the KLAA EKG Assist works to maintain electrode placement on a human subject with simulated diaphoresis.

Test Method Overview

Participants will be identified by their initials. Diaphoresis will be simulated with 3 sprays of the NaCl solution. An EKG will be done on a human subject by a licensed clinician with the KLAA EKG Assist.

Procedure

1. Participants arrive at the Epworth Methodist Free Medical Program and are shown to the examination room in the clinic where testing will occur.
2. Participants will remove outerwear and associated clothing so the chest area is accessible.
3. Participants lay down on the examination table

4. A licensed clinician will spray the participant 3 times with a salt solution that mimics that of human sweat.
5. An EKG is placed on the participant by a licensed clinician using the KLAA EKG Assist.
6. Record pass or fail
7. EKG is then removed and the chest area cleaned off with sterile wipes, and the chest is sprayed again with salt solution.
8. Repeat steps 1-6 for a total of three trials

Data Sheet

Trial	Participant	Diaphoresis Magnitude	Pass or Fail	Notes

Appendix E - Nurse Practitioner Questionnaire

Questionnaire
Pre-Trial Questions What has your experience been with EKGs on patients? (how often do you do them, etc..) Do you run EKGs on diaphoretic patients? **Phase 1 Questions** What is the quality of the tracing the EKG produces with the device? Is there any noise present? Do any of the leads show discrepancy in the readings? Are some less quality tracing? Are you able to tell the difference between the two trials in the blinded study? **Phase 2 Questions** What is your overall feedback on the set up of the device? What is your overall feedback on the design of the device? What is your overall feedback on the application of the device?

Is the device feasible in a clinical setting?

Appendix F - Phase 0 Data Tables

Phase 0 Electrode Slip Test Data Sheet					
Trial	**Diaphoresis Magnitude**	**Lead Number**	**Time (s)**	**Distance (mm)**	**Notes/Observations**
1	0	V6	60	0	Switch to V4 based on where the most breathing movement comes from.
2	0	V4	60	0	Stayed in place, no areas folded up
3	1	V4	60	0	Ends of electrode started to fold up
3	1	V4	60	0	Middle part of electrode wasn't on the mannequin
4	2	V4	60	0	Less movement, didn’t lift as much
5	2	V4	60	0	No lifting or movement
6	3	V4	60	0	Lifted up, water pool underneath the lifted area
7	3	V4	60	0	Lifted where water pooled
8	4 (petroleum jelly)	V4	60	0	Lifted where water pooled
9	4 (petroleum jelly)	V4	60	0	Lifted off, comes off very easily, is not stuck on

Table X: Electrode Pull-Test Data Sheet

Phase 0 Electrode Pull Test Data Sheet					
Trial	**Diaphoresis Magnitude**	**Lead Number**	**Force (N)**	**Photo end time**	**Notes/Observations**
1	0	V4	15.0	12:24pm	

2	0	V4	15.0	12:29pm	Changing the spring scale to smaller rated one for more accurate readings for following tests (50N→ 20N)
3	1	V4	2.5	12:38pm	Switching to 5N spring scale for following trials
4	1	V4	3.0	12:46pm	
5	2	V4	2.0	12:48pm	
6	2	V4	1.5	12:50pm	
7	3	V4	4.0	12:52pm	
8	3	V4	2.0	12:56pm	
9	Vaseline	V4	0.5	1:01pm	
10	Vaseline	V4	0.25	1:03pm	

Appendix G - Phase 1 Data Tables

Phase 1 KLAA Pass or Fail Data Sheet						
Trial	**Diaphoresis Magnitude**	**Pass / Fail Tubing reached location**	**Pass / Fail electrode stays in place**	**Pass / Fail Sled full contact**	**Pass / Fail no observed failure**	**Notes/Observations about certain leads**
1	0	pass	pass	pass	pass	Lead from V2 is tangled in V3
2	1 spray	pass	pass	pass - 80%	pass	Multiple electrodes slipped off before KLAA use. KLAA worked best on electrodes where the force point was closest
3	2 sprays	pass	pass	pass	pass	All electrodes popped off before KLAA use. Lead V6 failed due to the angle, not full contact

4	3 sprays	pass	pass	pass	pass	V5 never fully stuck down
5	Petroleum jelly	pass	pass	pass	pass	Electrodes were spinning during lead placement before KLAA use. V6 slipped with KLAA use (could be due to sled placement that may be pushing it away) did not slip too far, could still be readable.

Phase 1 Force Exertion Data Table		
Diaphoretic Condition	**Mean Force (N)**	**SD**
0 sprays	2.47	0.68
1 spray	1.04	1.23
2 sprays	3.28	0.052
3 sprays	3.05	1.37
Petroleum jelly	2.31	0.95
Avg. Mean F (N)	2.43	

Appendix H - Phase 2 Data Tables

Phase 2 Non-Inferiority Data Sheet		
EKG Reading	**Clinician Feedback**	**Rating**
A (control)	-	5
A1 (KLAA, normal)	V3 - V6 have higher amplitude of T waves	6

Aa1 (KLAA, diaphoresis)	V3 - V6 have higher amplitude of T waves	6
C (control)	-	5
C1 (KLAA, normal)	P waves have higher amplitude	6
Cc1 (KLAA, diaphoresis)	V1 has higher amplitudes, P waves have higher amplitude	7
F (control)	-	5
F1 (KLAA, normal)	V1, V2 has more artifact	4
Ff1 (KLAA, diaphoresis)	Consistent with control (F)	5
K (control)	-	5
K1 (KLAA, normal)	T waves have higher amplitude	6
Kk1 (KLAA, diaphoresis)	T waves have higher amplitude	6
L (control)	-	5
L1 (KLAA, normal)	Consistent with control (L)	5
Ll1 (KLAA, diaphoresis)	Consistent with control (L)	5
B (control)	-	5
B1 (KLAA, normal)	V3 has lower amplitude of P waves	4
Bb1 (KLAA, diaphoresis)	V3 has lower amplitude of P waves	4
E (control)	-	5
E1 (KLAA, normal)	Consistent with control (E)	5
Ee1 (KLAA, diaphoresis)	Consistent with control (E)	5
T (control)	-	5
T1 (KLAA, normal)	Consistent with control (T)	5

Tt1 (KLAA, diaphoresis)	Consistent with control (T)	5
P (control)	-	5
P1 (KLAA, normal)	Consistent with control (P)	5
Pp1 (KLAA, diaphoresis)	Consistent with control (P)	5
M (control)	-	5
M1 (KLAA, normal)	Little artifact	4
Mm1 (KLAA, diaphoresis)	Little artifact	4

Phase 2 KLAA Pass or Fail Data Sheet					
Participant	**Pass / Fail Tubing reached location**	**Pass / Fail electrode stays in place**	**Pass / Fail Sled full contact**	**Pass / Fail no observed failure**	**Final Result**
A	pass	pass	pass	pass	PASS
C	pass	pass	pass	pass	PASS
F	pass	pass	pass	pass	PASS
K	pass	pass	pass	pass	PASS
L	pass	pass	pass	pass	PASS
B	pass	pass	pass	pass	PASS
E	pass	pass	pass	pass	PASS
T	pass	pass	pass	pass	PASS
P	pass	pass	pass	pass	PASS
M	pass	pass	pass	pass	PASS

Appendix I - Grant Form

In English

This free medical program is participating in a City of Worcester grant that can reimburse us for your visit. Your identifying information will not be shared with the city, but we do need to ask you some questions on page two to see if your visit qualifies.

My visit can be used towards the grant.

Print name: _____ Date: _____

Participant Identification Number: _____

En español

Este programa médico gratuito participa en una subvención de la ciudad de Worcester que puede reembolsarnos su visita. Su información de identificación no se compartirá con la ciudad, pero necesitamos hacerle algunas preguntas en la página dos para ver si su visita califica.

Mi visita se puede utilizar para la subvención.

Nombre impreso: _____ Fecha: _____

Número de identificación del participante: _____

Em português

Este programa médico gratuito é subsidiado pela cidade de Worcester e pode oferecer reembolso pela sua visita. As suas informações pessoais não serão compartilhadas com a cidade, mas precisamos fazer algumas perguntas na segunda página para determinar se a sua visita é elegível para o subsídio

Minha visita pode ser usada para a concessão.

Nome impresso: _____ Data: _____

Número de identificação do participante: _____

—---------- PAGE 2 BEGINS —----------

City of Worcester in partnership with Worcester Evening Free Medical Service Program Inc (Epworth), Worcester Islamic Center Social Services, WICSS) Free Medical Program, Akwaaba Free Health Program

COMMUNITY PROJECTS AND PROGRAMS COMPLIANCE FORM FOR SLFRF FUNDING

The participant/guardian should complete this form regarding program eligibility. Several regulations require that we determine eligibility for participants receiving services paid for, in part, but the State and Local Fiscal Recovery Funds (SLFRF), which are provided by the United States Department of the Treasury. The service, or contract, provider should retain this form for monthly reporting requirements as well as for on-site monitoring visits.

INFORMATION PROVIDED ON THE FORM IS KEPT CONFIDENTIAL AND IS NOT SHARED WITHOUT YOUR PERMISSION EXCEPT AS REQUIRED BY THE US DEPARTMENT OF THE TREASURY TO CONFIRM INCOME ELIGIBILITY OF PARTICIPANTS IN SLFRF FUNDED PROGRAMS. THE CITY OF WORCESTER HAS THE RIGHT TO VERIFY ELIGIBILITY.

PARTICIPANT INFORMATION

Address: _____

(Street, City, and Zip Code required)

SELF-DECLARATIONS

Please state your ethnicity and race from the boxes below.

Ethnicity *(please select only one)*

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Race *(please select only one)*

- ☐ White
- ☐ Black/African American
- ☐ Asian
- ☐ American Indian/Alaska Native
- ☐ Native Hawaiian/Other Pacific islander
- ☐ American Indian/Alaskan Native *and* White
- ☐ Asian *and* White
- ☐ Black/African American *and* White
- ☐ American Indian/Alaskan Native *and* Black/African American
- ☐ Other Multi-racial _____

HOUSEHOLD INCOME INFORMATION

1) Circle the household size below and proceed to question 2.

Household size	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Income Limits	$50,310	$59,160	$74,580	$90,000	$105,420	$120,840	$136,260	$151,680

2) For the household size circled above, is your income **below** the income amount listed?
Please Circle **YES** or **NO**

—------- PAGE 3 BEGINS —----------

Do you partake in any of the following government programs? Please check *ALL THAT APPLY*

- ☐ Children's Health Insurance Program (CHIP)
- ☐ Childcare Subsidies through the Child Care and Development Fund (CCDF) Program
- ☐ Medicaid
- ☐ National Housing Trust Fund (HTF), for affordable housing programs only
- ☐ Home Investment Partnerships Program (HOME), for affordable housing programs only
- ☐ Temporary Assistance for Needy Families (TANF)
- ☐ Supplemental Nutrition Assistance PRogram (SNAP)
- ☐ Free and Reduced-Price Lunch (NSLP) and/or School Breakfast (SBP) programs
- ☐ Medicare Part D Low-income Subsidies
- ☐ Supplemental Security Income (SSI)
- ☐ Head Start and/or Early Head Start
- ☐ Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)
- ☐ Section 8 Vouchers
- ☐ Low-Income Home Energy Assistance Program (LIHEAP)
- ☐ Pell Grants

PARTICIPANT CERTIFICATION

I certify that the above information is true and correct to the best of my knowledge,

Participant/Guardian: _____ **Date:** _____

(signature)

==========

TO BE COMPLETED BY THE MEDICAL PROGRAM

SERVICES PROVIDED

The following is to certify that the patient received a service eligible for City of Worcester reimbursement under SLFRF. By signing below, this certifies that the patient received one or more of the services below while at the free medical program listed. Individuals that can certify on behalf of the program(s) include licensed providers, RNs, medical students, dental technicians, case managers, and registration personnel.

Participant Identification Number: _____

Seen at

- ☐ Epworth (WEFMSP Inc)
- ☐ WICSS
- ☐ Akwaaba

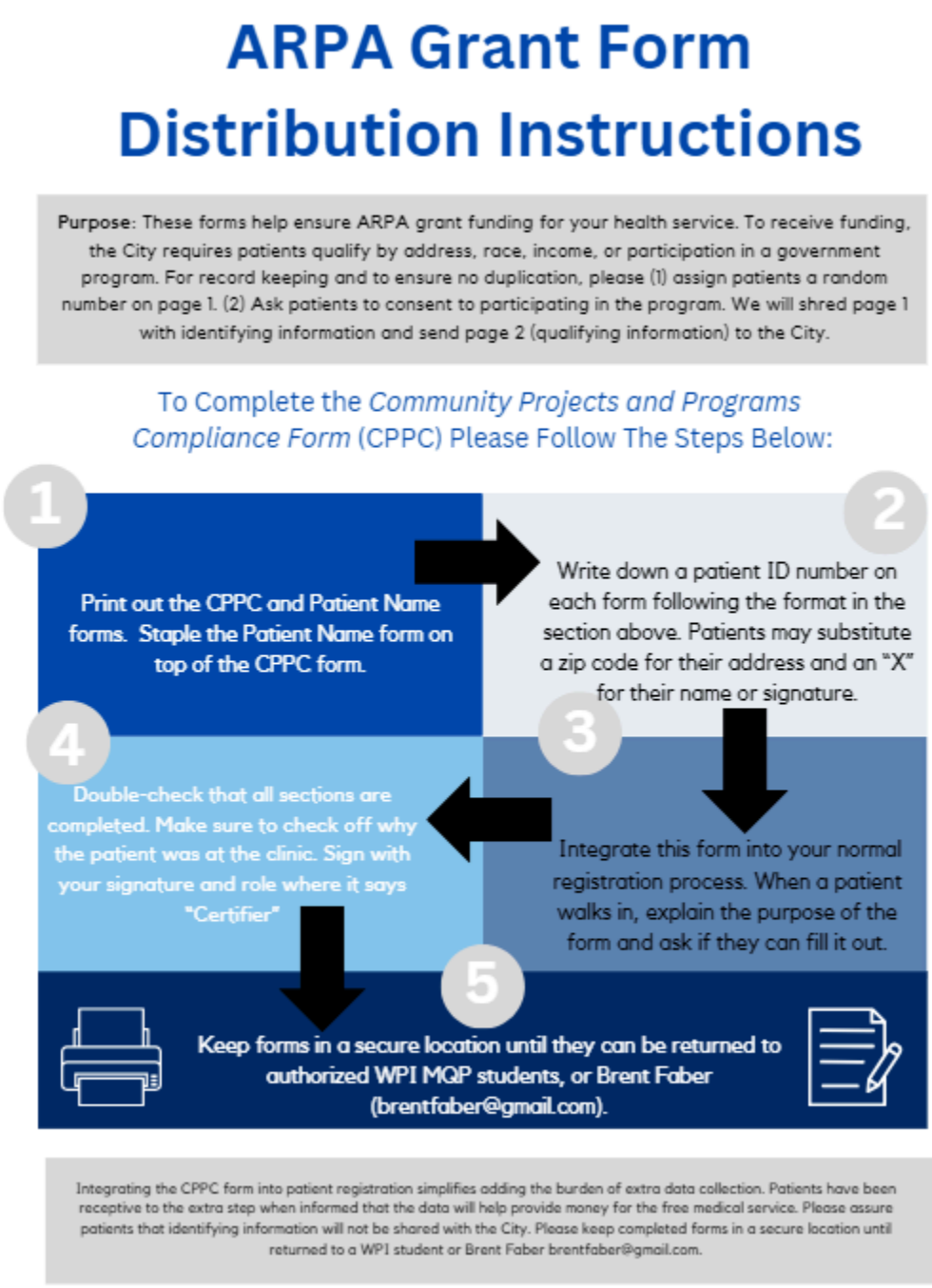
Care Provided

- ☐ School, work, or annual physical
- ☐ Vaccinations
- ☐ Acute/sick care
- ☐ Chronic disease screening
- ☐ Prescription refills
- ☐ STI testing
- ☐ Lab testing
- ☐ Oral health screening
- ☐ Case management

Certifier Name _____ Title _____

Signature of Certifier _____ Date _____

Appendix J - Infographic



Appendix K - Instructions for program

ARPA Grant Form Distribution Instructions

Purpose

By distributing these forms, you are helping to ensure ARPA grant funding for Worcester's free public health programs. To receive funding, the state requires patients at the program fill out the Community Projects and Programs Compliance Form (CPPC). Patients need to be assigned a random number upon being handed the two forms so the form can be entered into a secure database. This number should follow the format (month-day-year-starting number of the day).

EX) If starting on January 25th, 2024, write 1252401 for the first patient, 1252402 for the second, etc.

Steps by Program

1. Print out both the CPPC and Patient Name forms.
2. Staple the Patient Name form on top of the CPPC form.
3. Write down a patient ID number on each form following the format above.
4. When a patient walks into the program, explain the purpose of the form to them and ask if they would like to fill it out. Integrate this form into your normal registration process.
    a. Example script to explain this form: “I am helping to secure more governmental funding for this program. If you would like to, you can fill out this form which will go to the government. If your visit qualifies, the program here will receive money from the government to continue serving the community. Filling out this form is completely optional and you can stop at any time you do not feel comfortable. Nothing is required of you, and by filling out this form you will not have to give money to the program. This only helps to support more funding for the program from the government.” Make sure to ask for their consent and ensure they know they can stop filling out the form if they want to. Choosing to not participate in this will NOT impact their medical care.
5. If they say yes and would like to fill it out, you can give them a pen and clipboard if necessary. If they have any questions, you can explain as they go through it or sit next to them and help them fill it out.
6. Once they have completed the form (double-check that all sections are completed properly), ask them why they are visiting today.
7. Fill out the back section of the CPPC form. Make sure to check off why the patient was at the program, and sign off with your signature where it says “Certifier”.
8. Keep forms in a secure location until they can be returned to authorized WPI MQP students, or Brent Faber (brentfaber@gmail.com).

Appendix L - Importance Document

What the ARPA Grant Can Do For Your Medical Service

The ARPA Grant gives the Worcester Evening Free Medical Service Program, Inc. the opportunity the receive reimbursement for patient visits that qualify according to specific grant-defined deliverables. These qualifiers include; ethnicity, race, address, household income per size, participation in government programs, and specific services received during the visit. Completed forms will be collected by ARPA grant team and submitted to the city. Money will be reimbursed to the clinic.

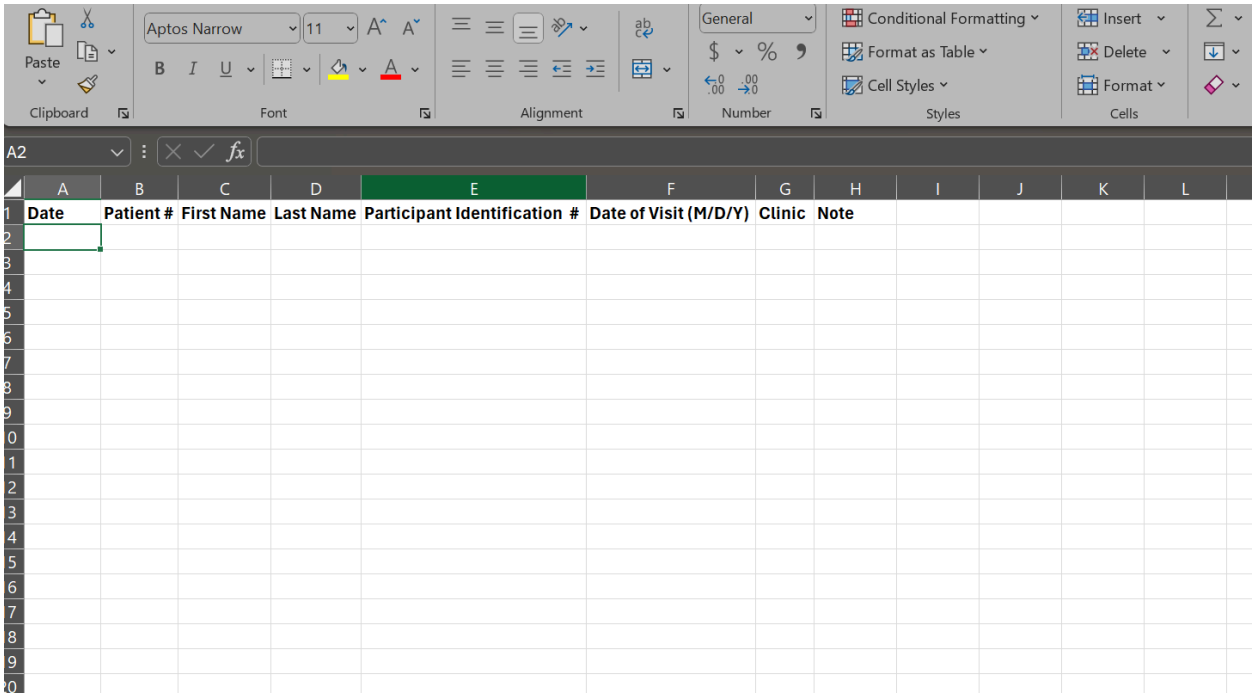
- **$49,230 total** Grant money available to receive **by 2025.**
- **$128.24 per qualifying form**
- **Less than 5 minutes** to fill out the form
- Clinics are only responsible for the completing the forms and holding them until they are collected

1 Eligible Completed Form

=

$126.24 towards clinic

Appendix M - Blank copy of crosswalk format



Date	Patient #	First Name	Last Name	Participant Identification #	Date of Visit (M/D/Y)	Clinic	Note