

Worcester Polytechnic Institute
Major Qualifying Project

PhleAidTM
Automated Phlebotomy Assistant

Authors:

Gabriela Morales-Castillo¹

Angelina Nicolella²

Carlos Pacheco¹

Armando Zubillaga^{1,2}

*Department of Mechanical Engineering¹, Department of Electrical and Computer
Engineering²*

Primary Advisor:

Gregory Fischer

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Abstract

The goal of this project is to minimize pre-analytical errors and simplify the phlebotomy process. PhleAid™, the Automated Phlebotomy Assistant, implements a combination of three subsystems: a vial selection system, a vial handling and labeling system and a blood verification system. The vial selection system chooses the appropriate vial for each test through a graphical input and decision-making system that utilizes a microprocessor and database. The vial handling and labeling system minimizes user contact with the blood specimen by implementing our designed hardware, stepper motors and proximity sensors. Additionally, a barcode scanner is implemented to identify each blood vial. Finally, the blood volume verification system utilizes a series of photodiodes, LEDs and amplifiers to detect the level of blood inside the vial. This system ensures that the volume of blood obtained is sufficient for testing. Overall these subsystems work together to achieve our goal.

Authorship & Contributions

Every member of our team contributed to the completion of this report in both writing and realization. When writing the report, every team member acted as the main editor for the sections they were responsible for. During the construction of PhleAid™, the tasks were divided accordingly to fit each team member's strengths to produce the best possible end product. The detailed list of contributions each team member was responsible for is given below:

Writing

- Gabriela Morales wrote the abstract, section 2.3 Lab Testing and Pre-Analytical phase, section 2.4 part a. Blood Vial Supply Technology, all of chapter 3 Project Strategy and Design Overview, Sections 4.1 Integrated System Description and section 4.2 Blood Vial Selection Subsystem, all of chapter 5 Final Design Verification, and section 6.1 Final Performance.
- Angelina Nicolella wrote section 2.1 Practice of Phlebotomy, section 2.4 part b. Labeling Technology, the Electronic Component part of section 4.4 Blood Vial Handling Subsystem, Section 4.4 Blood Vial Labeling Subsystem, and Section 6.4 Project Impact.
- Carlos Pacheco wrote the Introduction, the Executive Summary, section 2.4 part c. Blood Vial Handling Technology, section 4.3 Blood Vial Handling Subsystem, and the Conclusion.
- Armando Zubillaga wrote the Executive Summary, section 2.2 Blood Sampling Tests and Requirements, the Electronic Component part of section 4.4 Blood Vial Handling Subsystem, section 4.5 Blood Vial Volume Verification Subsystem, section 6.1 Final Performance, section 6.2 Limitations, and section 6.3 Recommendations.

Realization

- Gabriela Morales created the graphical user interface for the Blood Vial Selection Subsystem, and led the design and construction of Blood Vial Handling subsystem.
- Angelina Nicolella incorporated the barcode scanner for the Blood Vial Labeling Subsystem, designed the various PCBs that controls the device, and assisted in the software programming.
- Carlos Pacheco led the design and construction process of the device, ensuring that all the predetermined standards for the Blood Vial Handling subsystem are met.
- Armando Zubillaga programmed the software of the electronic components used in the each of the subsystems in PhleAid™ and designed the various PCBs.

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Executive Summary

Every year, around 0.5% of laboratory test results turn out erroneous and negatively affect the healthcare of around 2,000,000 people. Inaccurate results often come from mistakes that occur before or during the blood collection process. Some of these errors include: selecting an incorrect vial, mislabeling a vial, damaging the blood sample because of poor vial handling or drawing an insufficient amount of blood. There are many solutions in the market that aim to minimize these errors, but most only focus on one specific error. There is a gap in the market for robotic technology that provides a solution to reducing all the aforementioned errors. Incorporating technology into phlebotomy has the potential to remove human error that may lead to an inaccurate laboratory tests.

To reduce the occurrence of preanalytical errors, our team created PhleAid, an automated assistive device whose mechanisms address these errors and minimize human contact with the blood vials. Overall the goal of this project is to simplify and support the phlebotomy process as well as reduce the incidence of pre-analytical errors. This device is divided into four main subsystems to ensure every error that occurs during phlebotomy is addressed. The subsystems are:

- Blood Vial Selection Subsystem: correctly selects the blood vials to be filled according to the tests needed by the patient.
- Blood Vial Labeling: labels each vial by linking a patient's information with his or her corresponding vials.
- Blood Vial Handling: minimizes the phlebotomists contact with the vial while steadily positioning the vial during blood collection.
- Blood Vial Volume: verifies the sample is adequate by means of sensor readings.

The Blood Vial Selection subsystem has four major components: a microprocessor, a blood test database, a patient database and a graphical user interface. A Raspberry Pi was selected as the main processor to run the program, which receives the patient name as input and then outputs the appropriate blood test and vials. The graphical user interface makes it easier for the phlebotomist to access patient information and warns them if the patient is not fasting.

The Blood Vial Labeling subsystem consists of a barcode scanner in a position where it can read the pre barcoded labels on vials. The barcode scanner is connected to the main controller and it sends information to the patient database.

The Blood Vial Handling subsystem ensures the vials do not experience aggressive shaking or a hard impact when landing. During the design process, the team divided the device into three different mechanisms: the vial dispensing mechanism, the first inverting mechanism and the final inverting mechanism. Each mechanism was constructed using transparent acrylic, 3D printed parts

and motors to assist the movement of vials. Every mechanism is held together by a network of aluminum extrusions bolted together so each mechanism is lined up correctly to ensure mishandling vials.

The Blood Vial Verification subsystem ensures the phlebotomist draws the required amount of blood for the lab analysis to be successful. This subsystem consists of a series of LED's that are attached to the first vial inverter, an optical sensor board with a series of photodiodes that are aligned with the LED's and a buzzer that goes off when the phlebotomist has collected a sufficient amount of blood.

PhleAid's final design consists of four major subsystems: Blood Vial Selection, Handling, Labeling and Volume Verification, assembled together with a series of aluminum extrusions. The figure below depicts the final design.

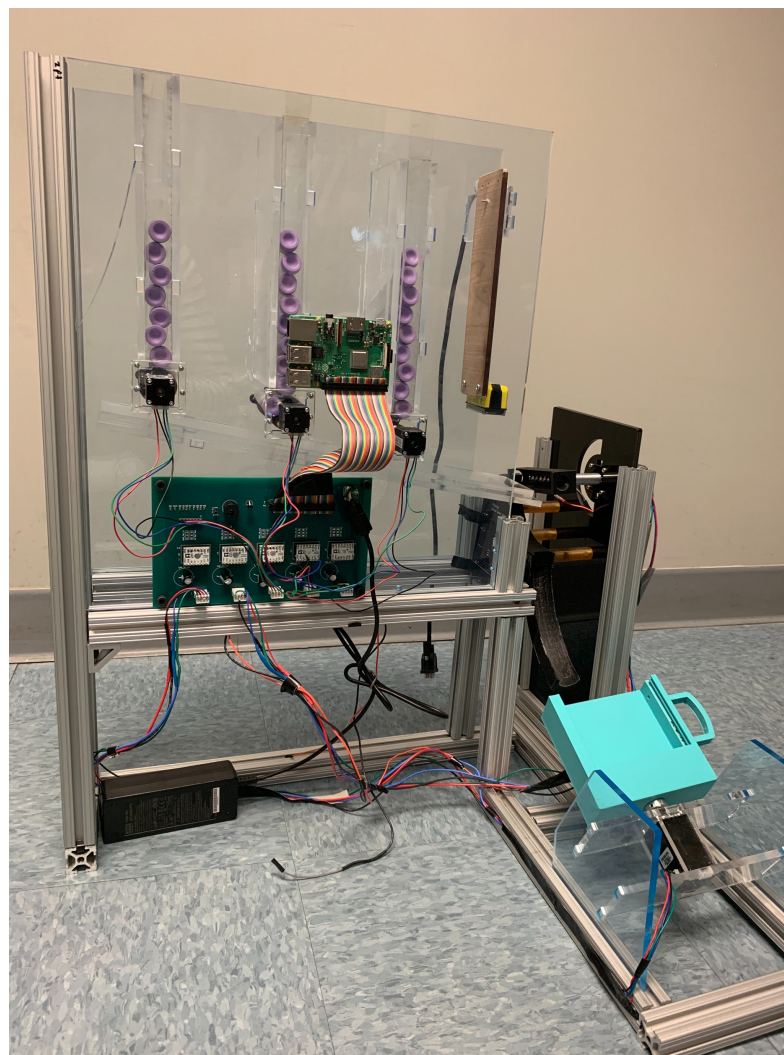


Figure: PhleAid Final Prototype

Based on initial functionality testing, the team determine that PhleAid did not meet all the system requirements. The Blood Vial Handling Subsystem did not move vial into position for labeling and blood collection with 100% reliability. Additionally, the Blood Vial Labeling Subsystem did not

always scan barcode when vials were rolling. However, the team conducted performance testing to determine and fix the parameters that were affecting these system requirements.

Testing was conducted to determine what factors were affecting the performance of PhleAid. Test I was performed to increase the success of the vials rolling into the collection position. After performing this test I, the data showed that the ideal wheel dispensing direction is counterclockwise with an angle of rotation of 120 degrees and a rotation of speed of 83 steps/ms. Tests II was design to test this ideal parameters with a modification of the ramp. In all three wheels, the dispensing and rolling mechanism had a success rate of over 86%. Test III was performed to evaluate different camera heights impact the percentage of barcode that are successfully scanned. With a height of five inches from the ramp, the Cognex Camera achieved 100% functionality over the samples tested.

Based on time and budget constraints and testing, the team determine a set of limitations that affect the functionality of PhleAid. However, for each of these limitations, a recommendation was evaluated to improve the overall performance of PhleAid, so it can successfully minimize pre analytical errors. The recommendations and limitation per subsystem are the following:

- Blood Vial Selection Subsystem
 - Limitations
 - The system is not capable of checking the number of vials that are inside each of the dispensers. This eventually can lead into errors along the phlebotomy process and additional steps for the phlebotomist.
 - Recommendations
 - Incorporate a sensor in order to detect if there are vials inside the dispensers, so the system can alert the phlebotomist if the dispenser is empty.
 - Incorporate current lab management software and patient databases such as LabCollector LIMS [53] and Prolis [54], instead of using a mock patient database that is limited to five tests per blood vial.
- Blood Vial Handling Subsystem
 - Limitation
 - The dispenser's design affects how the vials are filled. If the vial is not dropped correctly, there is a possibility that the vials' rubber lid touches the inner walls of the dispenser and then gets stuck or changes position due to friction with the wall.
 - The ramp's design affects how the vial rolls into the flipping mechanism. When the rubber lid lands on the ramp, it causes the blood vial to bounce and immediately gets stuck with the next wheel.

- Recommendations
 - Integrate an additional stepper motor and a conveyor belt to create a more reliable way to dispense the vials without them depending on rolling perfectly into the 1st flipping mechanism.
 - Redesign the dispensers, so it is easier to place vials, to hold more vials and to remove vials if they get stuck inside the dispenser.

- Blood Vial Labeling Subsystem
 - Limitation
 - Vials need to be pre-barcode by hand, so this process can be very tedious for phlebotomists. Moreover, if vial does not roll down perfectly down the ramp, the camera will not scan the vial.
 - Recommendation
 - Integrate an automatic labeling solution that can print and place the labels on the vials instead of doing the process by hand, so it is faster and more automated.

- Blood Vial Volume Verification Subsystem
 - Limitation
 - The optical sensor pcb design limited the maximum baud rate the serial communication between the ATmega328 microcontroller, and the Raspberry Pi has to 9600 bits per second. The PCB needs to be redesigned to read, process and send data quicker.
 - The location of the photodiodes and op amps on the board need to be changed to reduce the size of the board, so there is no interference between the photodiodes and the flipping mechanism base.
 - Recommendations
 - The optical sensor PCB board needs to be redesigned to increase the baud rate for the serial communications. Some changes that should be done are creating a ground and a power planes to eliminate unnecessary traces on the top and bottom layer and making the traces of the board more symmetric.
 - Add some type of filter so the photodiodes do not detect the ambient light. This can significantly aid the output voltage change detection once blood vials are in the process of being filled.

Chapter 1

Introduction

Accurate laboratory tests results are pivotal in making medical decisions and can severely impact a patient's healthcare. Obtaining accurate tests results is often challenging due to errors that occur in the pre-analytical phase, specifically before and during the phlebotomy process. The pre-analytical phase encompasses all the processes that occur before blood samples are analyzed in laboratories. Some common errors seen during this phase are incorrect vial selection, mislabeled vials, damaged blood samples due to coagulation, hemolysis or lipemia, and insufficient sample volume. There are some marketed solutions that attempt to minimize the amount of errors that occur during the pre-analytical phase. These solutions can solve one specific pre-analytical error. For example, some companies have products such as, small labeling machines to avoid vial mislabeling, and vial dispensers to ensure proper vial selection. In addition, there are quality control measurement systems and procedures in place.

However, there is a market gap for solutions that use robotic technology to reduce many pre-analytical errors all at once. There are solutions already in the market to handle these problems, and incorporating them into one device can be a simpler approach to help minimize the occurrence of errors. Incorporating technology into the the phlebotomy process can also help reduce any human error present, such as mishandling, mislabeling or skipping a step in the process of blood collection.

By combining a team of engineering students with backgrounds in mechanical and electrical engineering, we created PhleAid: a automated robot that can reduce the occurrence of the aforementioned errors during the process of phlebotomy by limiting human contact and combining various mechanisms that address the problems. In other words, our project's main goal is to develop an automated device that simplifies and supports the phlebotomy process as well as reduces the incidence of pre-analytical errors.

To achieve our goal we developed four different subsystems that address pre-analytical errors:

- Blood Vial Selection Subsystem: correctly selects the blood vials to be filled according to the tests needed by the patient.
- Blood Vial Labeling Subsystem: labels each vial by linking a patient's information with his or her corresponding vials.
- Blood Vial Handling Subsystem: minimizes the phlebotomists contact with the vial while steadily positioning the vial during blood collection.
- Blood Vial Volume Verification Subsystem: verifies the sample is adequate by means of sensor readings.

The result was PhleAid, a device that can fully carry out the phlebotomy process within 4 subsystems. A graphical interface assists Phlebotomists to begin the procedure, and starts the automated blood selecting, handling, labeling, and verification processes.

Chapter 2

Literature Review

2.1 Practice of Phlebotomy - An Overview

Phlebotomy – the drawing of blood – has been practiced for centuries and is still one of the most common invasive procedures in health care. However, this practice varies considerably between countries, and between institutions and individuals within the same country. These differences include variations in blood-sampling techniques, training (both formal and “on-the- job”), use of safety devices, disposal methods, reuse of devices and more. According to the World Health Organization the procedure for drawing blood follows these steps[1]:

1. Assemble equipment (Choose proper blood vial, syringe, tourniquete, alcohol, swabs, gauze, lab forms and vial labels)
2. Identify and prepare the patient by verifying patient identity, allergies and fasting. Obtain verbal consent of test to be performed.
3. Select the blood extraction site. Prepare site by applying tourniquet and locate vein.
4. Perform hand hygiene and put on gloves
5. Disinfect the entry site with alcohol swab
6. Puncture vein with needle. Collect blood. Release tourniquet before withdrawing the needle
7. Fill the laboratory sample tubes. Before dispatch, invert the tubes containing additives for the required number of times (as specified by the guidelines)
8. Draw samples in the correct order
9. Clean contaminated surfaces and complete patient procedure. Recheck labels on to vials before dispatch.
10. Prepare samples for transportation
11. Clean up spills of blood or body fluids

During phlebotomy procedures, the greatest concern is the safety of health workers and patients; therefore, guidance for staff on best practices is critical. It is important for the Phlebotomy procedure to be done very precisely. If a blood sample is poorly collected, the results may be inaccurate and misleading to the clinician, and the patient may have to undergo the inconvenience of repeated testing. The three major issues resulting from errors in collection are hemolysis, contamination and inaccurate labeling. These errors are all part of the pre-analytical process[2]. The ISO 15189:2012 standard for laboratory accreditation defines the pre- analytical phase as “steps

starting in chronological order, from the clinician's request and including the examination requisition, patient preparation, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins”[3].More details and key aspects of the Phlebotomy process will continue to be discussed within the following sections.

2.2 Blood Sampling - Tests and Requirements

The previous section describes the phlebotomy process. Nonetheless, one of the key phases of a successful phlebotomy process is selecting the correct blood vial for the corresponding blood test. Additionally, the blood specimen obtained should be verified to ensure accurate test results. This section outlines how each blood vial is selected and how the blood is verified.

Blood Vial Selection

The blood vials, or vacutainers, are usually made of plastic or glass and have different color caps depending on the additive inside. During the collection phase, blood is drawn inside the vacutainer by either the use a vacuum blood vial or the use of a plunger to slowly aspirate the blood [4]. The vacuum technique is very convenient because the blood is drawn automatically into the vial. The difference in pressure between the point of puncture and the blood vial allows the blood to circulate through the tubing and into the vial.

The following table summarizes different colored caps, with their corresponding additives, and the typical tests in which each blood vial is used:

Table # 1: Additive, Number of Inversions and Test per colored Vacutainer.

Sources: [5],[6],[7],[8],[9],[10],[11],[12],[13],[14],[15]

| Color | Additive | Inversions (#) | Tests |
|---|---|----------------|---|
| Red | <ul style="list-style-type: none"> No additive in glass tube. Clot activator in plastic tube – enhance clotting of blood. | 5 | <ul style="list-style-type: none"> ABO/Rh Testing Indirect Antiglobulin Test (IAT) Type and Screen (T&S) |
| SST (Serum Separation Tubes) <ul style="list-style-type: none"> Red and black Gold | <ul style="list-style-type: none"> Silicone/gel to separate serum from cells permanently. | 5 | <ul style="list-style-type: none"> Vitamin A, D-(25-OH) or E CMV Immune Status EBV Immune Status |
| Blue (light) | <ul style="list-style-type: none"> 3.2% or 3.8% buffered sodium | 3-4 | <ul style="list-style-type: none"> Prothrombin Time (PT) |

| | | | |
|--------------------------------------|--|------|---|
| | citrate solution | | <ul style="list-style-type: none"> • Partial Thromboplastin Time (PTT) • Thrombin Time (TT) |
| Lavender | <ul style="list-style-type: none"> • Spray-coated K2EDTA (plastic) (ethylenediamin tetraacetic) - scavenging metal ions. • Liquid K3EDTA (glass) | 8-10 | <ul style="list-style-type: none"> • Complete Blood Count • ABS Neutrophil Count • HB A1C |
| PST (Plasma Separation Tubes) | <ul style="list-style-type: none"> • Sodium heparin or Lithium heparin and a polymer gel. | 8-10 | <ul style="list-style-type: none"> • Basic Metabolic Panel • Electrolytes • Hepatic Function Panel • Lipid Panel |
| | <ul style="list-style-type: none"> • Green • Green and black | | |
| Grey | <ul style="list-style-type: none"> • Potassium oxalate and sodium fluoride. • Lithium iodoacetate and heparin. | 8-10 | <ul style="list-style-type: none"> • Glucose Levels • Blood Alcohol Levels • Lactate • Bicarbonate |
| Black | <ul style="list-style-type: none"> • Buffered Citrate. | 8-10 | <ul style="list-style-type: none"> • Westergren sedimentation rates (SDR) |
| Royal Blue | <ul style="list-style-type: none"> • K2 EDTA | 8-10 | <ul style="list-style-type: none"> • ABO grouping • Rh typing • Antibody screening |
| Tan | <ul style="list-style-type: none"> • K2 EDTA or Sodium Heparin | 8-10 | <ul style="list-style-type: none"> • For Lead determination test. |
| Yellow with white label | <ul style="list-style-type: none"> • Sodium polyanethol sulfonate (SPS) • Acid citrate dextrose additives (ACD)- anticoagulant. | 8-10 | <ul style="list-style-type: none"> • SPS for blood culture specimen collections in microbiology. • ACD for use in blood bank studies, HLA phenotyping, DNA and paternity testing. |

Blood Sample Verification

The specimen obtained from phlebotomy should be verified through a blood verification process. The blood verification process is an essential step for generating accurate and precise test results. Therefore, it is critical to ensure a proper blood vial collection. The important issues with the blood samples are discussed in this section:

- **Coagulation**

For each blood test, there is a corresponding top that contains a certain additive to prevent the blood from coagulating [16]. Coagulation produces errors when testing. Tests need to be rejected if the blood samples are coagulated. The main reasons for coagulation are leaving blood in a syringe for too long before placing it in tubes (no anticoagulation additive inside syringe), delay of placing blood in tubes, and improper mixing of anticoagulated tubes [16]. Therefore, creating a system that can properly invert the filled blood vials is ideal to prevent coagulation.

- **Insufficient Blood Vial Volume**

Every blood test has a minimum volume of blood that needs to be drawn in order to generate accurate results during the laboratory testing phase. Insufficient filled blood vials generate incorrect results due to an improper additive to blood ratio [17]. Moreover, after the blood is collected, the blood vials must be gently inverted 180 degrees to properly mix the blood with the additive. Failure to perform this step will cause the blood specimen to coagulate or generate hemolysis, which also leads to inaccurate lab results [18]. It is essential to incorporate a system that can alert the phlebotomist once the required blood volume has been reached. Consultation with phlebotomists revealed that blood vials are commonly filled to their maximum capacity regardless of the blood volume needed for that test.

- **Hemolysis**

Hemolysis occurs with the rupture of erythrocytes (red blood cells) [19]. Typical erythrocytes live around 110 to 120 days, before they start to break down naturally [20]. During the blood collection process, hemolysis happens with inadequate specimen collection, such as using an intravenous catheter, extended use of a tourniquet (long-lasting constriction of the blood vessels), vigorously shaking of blood vial, and errors during transportation for testing [21]. Currently, the used practices to detect hemolysis in blood samples are visual inspection and automated laboratory analyzers. In order to minimize the chances of hemolysis, a system needs to be designed that helps

phlebotomist to properly handle filled vials, such as reduce vial to vial contact and vial drops. Furthermore, incorporate in this system a process that gently mixes the filled blood vial.

- **Lipemia**

Lipemia is physical phenomenon in which the blood sample becomes accumulated by lipoprotein particles [23]. The main cause of this problem is the inadequate time of blood sampling after a meal (fasting) [23]. To successfully conduct fasting, the patient is not allowed to eat or drink any food for 12 hours and water consumption is the only liquid permitted. Intense exercising, smoking cigarettes, drinking alcohol and caffeine- beverages are also not allowed [23]. Besides inaccurate fasting, some physical conditions can induce lipemia, such as multiple myeloma, diabetes mellitus, acute pancreatitis, kidney failure or hypothyreosis [18].

The current methods done to detect lipemia are very similar to the hemolysis detection techniques. Visual detection is used in many labs; however, it is very unreliable to detect accurately the presence of lipemia. Some laboratories use triglyceride concentration measurement method, but it is not very effective because the proportion of triglycerides differs among lipoprotein subclasses and ranges. The most reliable method is using analytical platforms to assess the degree of lipemia. It is based on diluting the sample in saline and measuring the spectra in a wide range of wavelengths. Like the hemolysis detection platforms, each different manufacturer uses a different range of wavelength for the calculation of the degree of lipemia, making the entire process poorly standardized [23].

Nonetheless, some prevention measures can be taken before the blood specimen is collected. Asking the patient if proper fasting was conducted or if they have any of the conditions mentioned above, reduces the overall collection rate of unusable samples due to lipemia [24].

To summarize, the phlebotomy process requires meticulous considerations of how the blood specimen is obtained, which vacutainer it is stored in and what conditions should be flagged in order to obtain accurate and reliable test results.

2.3 Laboratory Testing and Pre-Analytical Errors

Accurate laboratory test results are extremely important because the patient's healthcare depends on them. This section details the impact of inadequate test results, the errors that cause them and measures that can be taken to prevent such errors.

Laboratory tests have a major impact on medical decisions. Approximately, 70% of all medical decisions are based on diagnostic test results, which include blood tests [25]. However, the presence of errors is relatively common in clinical laboratories [26]. Up to 0.5% of all laboratory tests results have estimated to be erroneous [26]. Which, considering the average 451 million lab tests performed per year[27], 0.5% can negatively impact the healthcare of around 2 million patients.

Errors at any phase of the laboratory testing process can lead to a misdiagnosis and mismanagement, and represent a serious hazard for patient health. However, the majority of these

errors can be traced to the pre-analytical phase [28]. The pre-analytical phase encompasses all the procedures that occur before the blood sample is tested. It includes patient preparation, phlebotomy (blood collection), specimen transportation, and storage. For the purpose of this project, the pre-analytical phase will be defined as the process that involves selecting the appropriate blood vials, labeling the blood vial and collecting and handling the blood specimen.

Various researchers have reported that 46-68.2% of laboratory errors occur in the pre-analytical phase [29]. This is probably caused by the greater number of steps that are performed by professionals in different disciplines before the testing process. Additionally, the lack of standardised protocols for defining and measuring pre-analytical variables significantly increases the amount of pre-analytical errors.

The direct cause of pre-analytical errors is uncertain. However, the most common errors include [30]:

- Inappropriate vacutainer selection.
- Vacutainer improperly labelled or mislabelled.
- Insufficient sample volume.
- Inadequate sample due to clotting, hemolysis and lipemia.

These errors have consequences for the patient, which include a delayed test result or new sample collection, but may also have a life threatening impact, such as the administration of unnecessary treatments [31]. Additionally, pre-analytical errors can also have a significant economic impact. Errors can increase time, resources and supply waste. These cost money and decrease the lab's overall efficiency [32].

Overall, there are many initiatives to avoid the negative consequences of pre-analytical laboratory errors. Quality control measures [33] such as procedures, staff training and workstations [30] are set in place to prevent mistakes. Information technology and robotics are also powerful tools that reduce errors in specimen collection and pre-analytical blood sample handling. Nonetheless there is a gap in the current market for solutions that implement robotic systems to reduce pre-analytical errors before and during the specimen collection process.

2.4 Prior Art

There is a lack of robotic solutions intended for all stages of the phlebotomy process itself. However, robotics and automation after the phlebotomy process have had some progress. Some examples include: the Accelerator p540 created by Abbott [34]. The Accelerator has barcode reading capabilities and automates the aliquoting, sorting and centrifuge of blood vials. Similarly, The Beckman Coulter AutoMate 2500 includes a family of products that sort, detect the label and aliquot blood vials after the sample is collected [35]. There are also numerous automated solutions for the

post-analytical phase. One example includes Aim Labs' Path Finder[36]. This product handles post analytical management of blood vials by capping sorting and archiving the vials into storage racks. Overall, most of the products available focus on automating the process after the phlebotomy has occurred.

On the contrary, the pre-analytical phase and the errors that occur here remain a challenge that robotics and automation has not yet tried to fully solve[37]. There is a lack of robotic solutions that attempt to minimize pre-analytical errors in the entire phlebotomy procedure. Nevertheless, there are some solutions that solve individual problems in specific stages of phlebotomy. These technologies will be discussed in more detail in this section of the report

a. Phlebotomy Assistive Technology

There is one commercially available product that targets the reduction of errors during the manual preparation before the phlebotomy process begins. This product is called GNT5 and is made by a company called Energium [38]. The GNT5 receives patient information (inputted in the system by a receptionist), selects the right type and number of blood vials for the indicated test, labels the blood vials and then finally sends the labelled vials to a test tube tray ready for the phlebotomist to use. Figure 1 illustrates the GNT5 system.



Figure #1: GNT5 Standard [38].

In summary, this system prevents blood vial mislabeling and reduces waiting time. It can also interface with hospital information systems to record patient information. The main limitation of the GNT5 system is that it doesn't target errors during the phlebotomy process; such as insufficient sample volume or inadequate specimen collection. Additionally, the large size of this system might hinder its installation in smaller phlebotomy exam rooms. A more compact system would be more suitable for such environment.

Another technology available on the market today is the ProTube Suite by Inepco. Different than the GNT5 this solution focuses on automating the blood sampling collection phase. It assists

phlebotomists in the draw phase by detecting manual errors at the blood collection point. It scans for positive patient identification, correct blood tube selection, and optimal order of blood draw. It applies vial labels at the time of collection, and after drawing the blood sample it checks by reading barcodes. By doing so, ProTube assesses process compliance and even records the time of collection [39]. Similarly to the GNT5, the main limitation for this device is that it does not target errors during the phlebotomy process, such as blood sample handling and verification.



Figure #2: ProTube Suite

b. Labeling Technology

As mentioned before, there are no solutions that integrates all phases of the phlebotomy process. However, there are several products in the market that can label blood vials automatically. Specifically, we analyzed three types of products that differ in the way that they differentiate the blood vials per patient: inkjet products, label making products, and barcode scanners. The inkjet solutions directly etch the patient information to the vial's surface while the label making solutions print out a label, with the information, that can be pasted on the vial. We also analyzed pre-barcoded solutions along with a barcode scanner. This section describes the most relevant labeling solutions in both categories; as well as their advantages and limitations.

- **Inkjet Solutions: TubeWriter™ and VideoJet™**

There are a few products to consider within the inkjet option. The first is the TubeWriter™, a high-speed inkjet technology specifically designed for blood vial labeling and tube printing for medical purposes including clinical labs and cell banks. This provider offers two different devices: the Tubewriter 360™[40] and TubeWriter Standard™[41]. Both devices are shown in Figure 3 and 4.

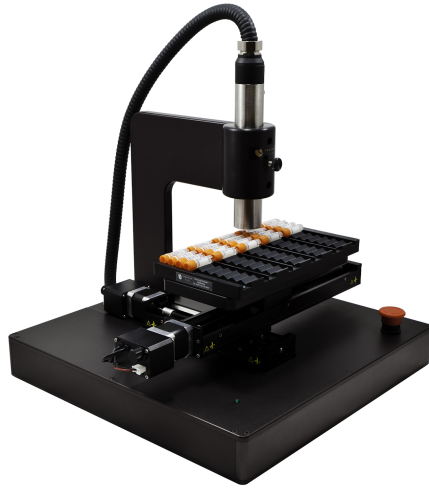


Figure #3: TubeWriter 360. *Source:* [40]

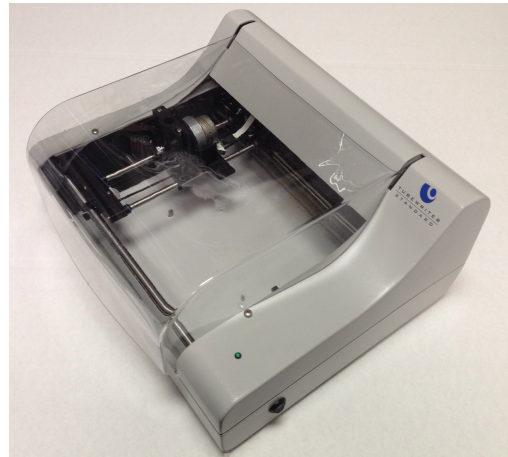


Figure #4: TubeWriter Standard. *Source:* [41]

The TubeWriter Standard™ has less capabilities than the 360 Machine, but due to size restriction, it is a better integration for smaller devices. It also has compliance with Microsoft Excel which can be easily integrated using a microcontroller.

The second inkjet option is from VideoJet™ printing technologies[42]. This company creates devices to label many types of products, including plastic bottles, pharmaceutical products, and more. Moreover, one of these devices could be implemented to into the pre-analytical process. This company has various products that can label vials.

The CIJ solution shown in Figure 5 is the most versatile of all technologies, combined with a portfolio of over 175 inks, CIJ prints on nearly any material and shape[43].

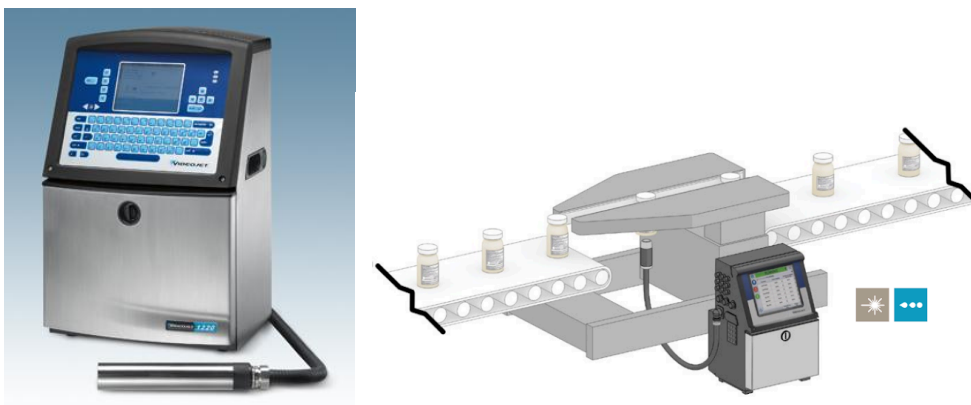


Figure #5: CIJ Laser Inkjet Models. *Source:* [43]

- **Label Printing Solutions:**

Printing labels individually for each patient’s blood vial is another solution that minimizes labeling errors in the phlebotomy process. Several options will be described below. The downside to printing a label is that it creates the need for sticking the label onto the vials, an extra step to be considered.

The first product would solve the problem of having to create a subsystem that sticks the label to the vial. The first solution analyzed was the Label Printer Applicator™ (LPA), also from VideoJet™ technologies[44]. It prints customized labels and applies them directly onto the desired application. An image of the product is shown in Figure 6 below.

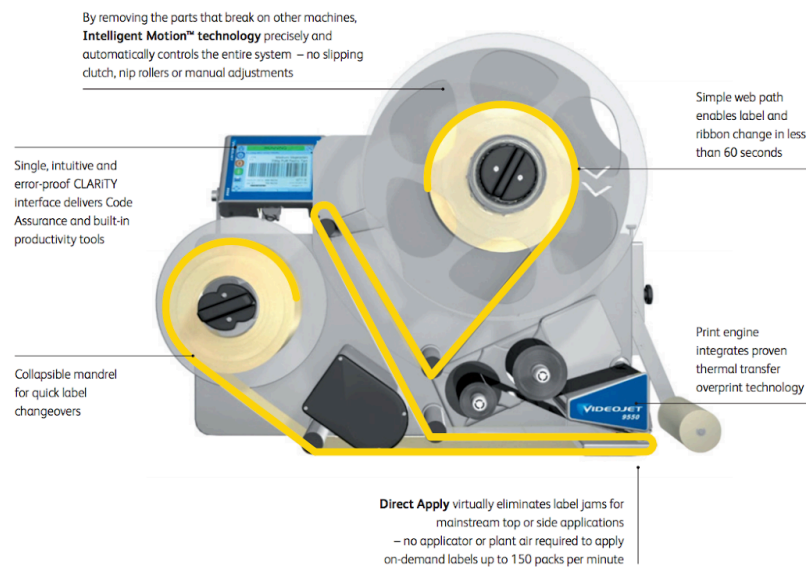


Figure #6: Label Printer Applicator™ (LPA) . Source: [44]

The second labeling option consists of a regular label printer as shown in the figure below (Figure #7). It is the Clarisafe Medical Color Label Printer[45] This label printer is designed for pharmaceutical purpose and can be easily integrated with any device , by using their label printing software to design our label template.



Figure #7: Clarisafe Medical Color Label Printer . Source: [45]

Aside from the Clarisafe printer, other more inexpensive options like regular label printers can also be considered. However, most easy to purchase low-cost label printers do not have software available to easily integrate with our user interface which is a problem for the users input. One option that can interface with a PC is the small DYMO LabelWriter which includes MAC or PC compatible software to create custom labels[46]. This software could integrate with a user interface and a microprocessor. This product is shown in the figure below.



Figure #8: DYMO LabelWriter . Source: [46]

- **Scanning solutions**

The last option was to use prelabeled vials, specifically pre barcoded vials, and implement a scanner to read and register the barcode numbers. The first solution is an Arduino compatible barcode scanner available on Adafruit Figure 9. This scanner is camera based, so it can be held further away than laser based scanners, and takes 100 photos per second which means its less likely to result in errors. It decodes nearly any kind of 1D striped barcode in this compact module [47].

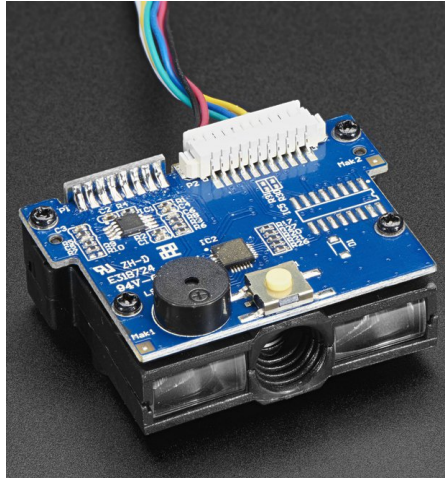


Figure #9: Adafruit Scanner. Source: [47]

Another solution considered was a camera from Cognex Corporation, which is an American manufacturer of machine vision systems, software and sensors used in automated manufacturing to inspect and identify parts, detect defects, verify product assembly, and guide assembly robots[48]. Their products are compatible with this project's purpose. Specifically, the Cognex Dataman 50, which is the simplest camera yet, meets our project's requirements. The Cognex Dataman 50 Camera is displayed in Figure 10.

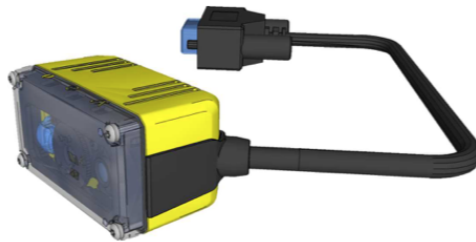


Figure #10: Cognex Camera[48]

c. Blood Vial Handling Technologies

Proper handling is important when moving a vial into its proper position, especially when the vial is full of blood. Mishandling or aggressive shaking of the vial can cause coagulation and hemolysis in the blood specimen[21]. To avoid mishandling, it is crucial to keep vials stored in a way that each one will be held in place and will not interfere with another. The most common solution seen in most laboratories is a simple tray tube rack that can hold various vials at the same time. An example of such rack can be seen below in Figure 11.



Figure #11: Phlebotomy Tray Tube Rack. Source: [49]

There are several marketed technologies that are able to extract one vial at a time from a large container by means of a rotating wheel with dents that are just wide enough to fit a blood vial inside[50]. As seen in Figure 11, the vials are cluttered in a way that the one at the lowest point will be the one picked up by the wheel to be sent down the chute at the end. At the end of the chute, the space gets just narrow enough to position the vial in an upwards direction contrary to its horizontal position when it is inside the dispenser. One drawback is that this device was intended for vials with plastic lids because there is barely any friction between them, making them easier to pull apart and less likely to get stuck. The vials used in this project have rubber lids. This will be a challenge because not only they can get stuck because of friction with a wall, but also because rubber lids have a larger diameter, making them roll in a curved direction.

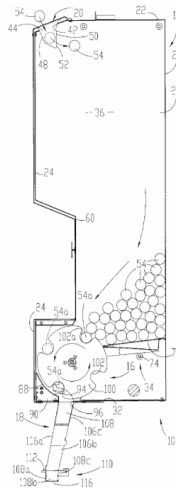


Figure #12: Medical Vial Dispenser. Source: [50]

There is also fully automated robot that stores, dispenses and delivers patient-specific medication ready to be administered named PillPick (Figure #13). The PillPick Automated Packaging and Dispensing System is about 10 feet wide, 5 feet deep and slightly taller than most humans, so it can store over 50,000 medication units [51]. It also includes its very own verification system in which

items are placed in labeled bags and a barcode scanner ensures they are being delivered to the right place. Similar to our project, it is a robot that aims to reduce the number of human errors during a process although it is focused on drug delivery for patients in a setting as big as a hospital or pharmacy.

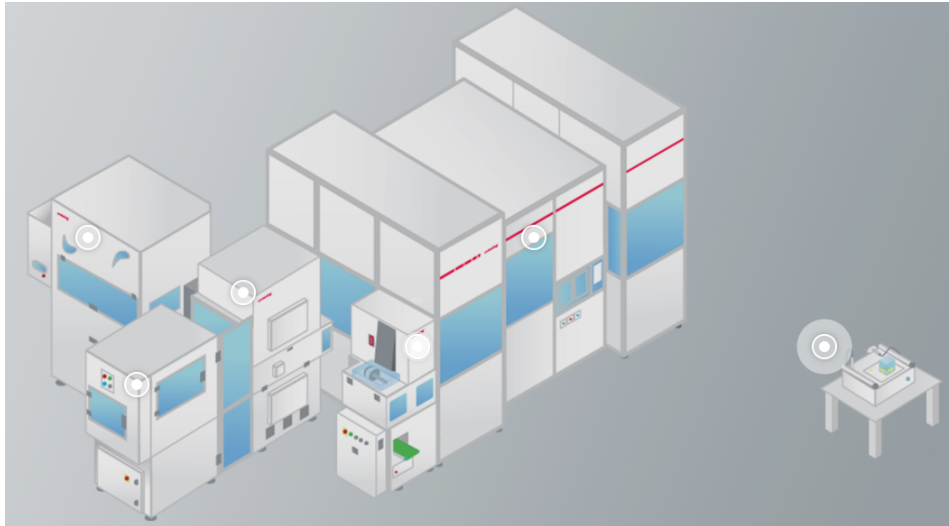


Figure #13: PillPick Automated Packaging and Dispensing System. Source: [51]

Although this device seems ideal because of its various automated components, it has many features that do not apply to the scope of this project. First, the PickPill includes a separated station where the nurse can start the selected operation. Second, it can store and handle multiple objects such as pills, vials, syringes and ampoules [51], but our focus is only blood vials. Third, the size of PillPick is very large and it is very hard to implement this in a room within a laboratory.

Chapter 3

Project Strategy - Design Overview

This chapter gives an overview on how the project scope, design requirements and overall strategy were developed for PhleAid. To be an improvement to the current healthcare and phlebotomy practices, PhleAid needed to be designed to fight tight specifications.

3.1 Overall Project Goals and Design Requirements

PhleAid’s efficiency and utility can only be valuable if it is able to meet the current deficiencies before and during the phlebotomy process. Furthermore, the device should easily integrate with two things: First it should fit within the phlebotomists routine in a way that they find acceptable. Second, it should be able to work alongside other robotic technologies that focus on the phlebotomy and blood analysis process,

Our goal is to develop a robot that simplifies and supports the phlebotomy process as well as minimizes pre-analytical laboratory errors. The design requirements were determined after considering primary and secondary stakeholders in such system. The following context diagram displays the relationship between PhleAid and those relevant stakeholders.

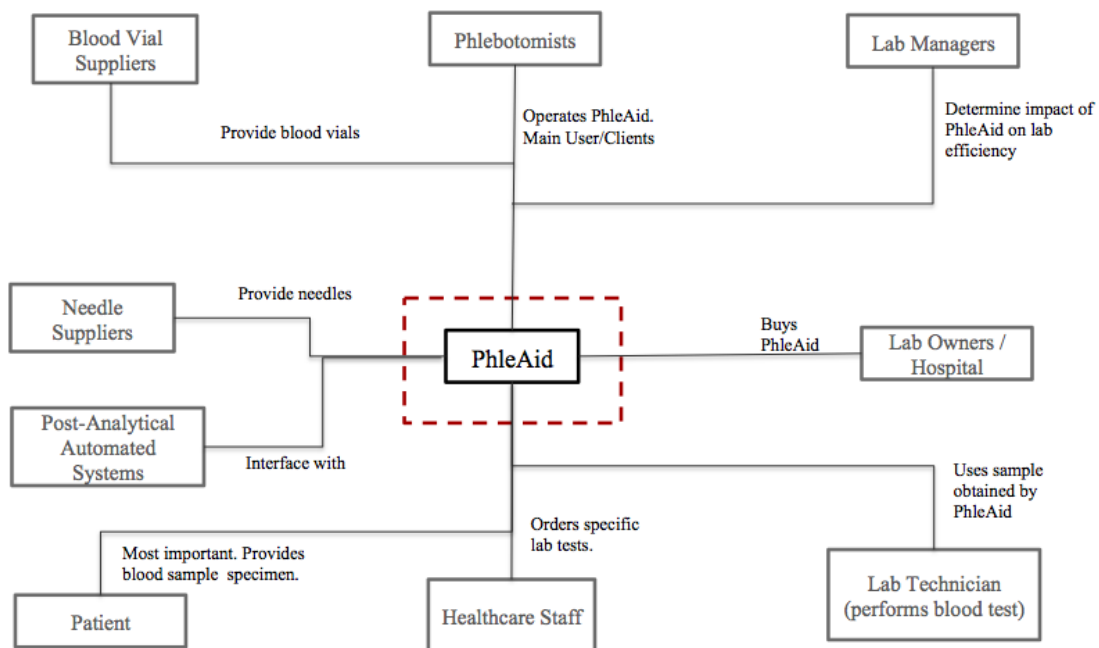


Figure #14 : Project Context Diagram. System and Stakeholders.

After focused research and long discussions, the pairwise comparison chart, displayed in Table 2, was used to rank the design requirements of greatest importance for the design of the PhleAid. The requirements were determined based on the most common pre-analytical errors and consideration of the environment PhleAid was going to be used in.

All team members individually compared and ranked each design requirement individually. If the requirement in the row was more important than the requirement in the column, the team member should place a 1. If it was less important, they placed a 0. If the team members considered both requirements to be equally important, they place a 0.5 The final comparison chart displays the averaged values of the team's responses.

Table #2 : Design Requirement Pairwise Comparison Chart

| Design Requirements | Fits on top of a table. | Ensures blood sample quality through sensor readings | Invert blood vial after specimen collection | Min user's contact with blood vial | Select appropriate vials for indicated test | Links each blood vial with the patient's file/information |
|--|-------------------------|--|---|------------------------------------|---|---|
| Fits on top a table | - | 0.375 | 0.25 | 0.125 | 0.75 | 0.5 |
| Ensures blood sample quality through sensor readings | 0.5 | - | 0.75 | 0.875 | 1 | 1 |
| Invert blood vial after specimen collection | 0.25 | 0.5 | - | 0.25 | 0.875 | 0.5 |
| Min user's contact with blood vial | 0.5 | 1 | 0.625 | - | 1 | 0.5 |
| Select appropriate vials for indicated test | 0 | 0.125 | 0.125 | 0.5 | - | 0.375 |
| Links each blood vial with the patient's file/information | 0.125 | 0.5 | 0.375 | 0.25 | 0.625 | - |
| TOTAL SCORE | 1.375 | 2.5 | 2.125 | 2 | 4.25 | 2.875 |

The team determined that all design requirements listed would be considered for the development of PhleAid. However, the higher ranking design requirements would have greater priority in the design and decision-making process. These include: 1) Select Appropriate Blood Vials for Indicated Test. 2) Verify Blood Volume. 3) Label Blood Vials Properly. 4) Invert Blood Vials after specimen collection.

Taking both the requirements and most common pre-analytical errors into consideration, the team divided the project into four major subsystems:

- I. **Blood Vial Selection Subsystem:** selects the appropriate vial for each test through a graphical input and decision-making software.

- II. **Blood Vial Handling Subsystem**: inverts blood vials after collection and minimizes user contact with blood specimen through a robotic vial handling mechanisms.
- III. **Blood Vial Labeling Subsystem**: links each blood vial with the patient file/information.
- IV. **Blood Vial Volume Verification Subsystem**: ensures blood sample quality through sensor readings.

The development of each subsystem and how they interact with each other to achieve PhleAid's ultimate goal is explained in Chapter 4 of this report.

3.2 Project Progression - Timeline

Our project timeline was divided into eight main milestones that will lead to the successful development and construction of the robot. Each milestone includes a list of tasks and subtasks to guide us in the completion of each milestone. Once the objectives were determined by the group, a timeline was created to help visualize the team's priorities at a given time and determine how much time should be spent for each task. The timeline also shows how some tasks depend on the completion of other tasks, regardless of if they are under the same milestone or not. The timeline can be seen below in Table 3.

Table #3 : Proposed Project Timeline

| ID | Sub-ID#s | Depends on the completion of: | Estimated time | Milestone | Task | Sub Task 1 | Sub Task 2 |
|---|----------|-----------------------------------|------------------|-----------|--|------------|------------|
| ETRDS | | | | | | | |
| Establish team roles, duties & schedule | | | | | | | |
| | 1 | no dependency | 10 min | | Meet as a group to discuss strengths and weaknesses of team members | | |
| | 2 | ETRDS.1 | 1 min | | Set up committees for the mechanical design and electric components of the robot | | |
| | 3 | ETRDS.2 | 10 min | | Schedule weekly meetings for each committee, team only and team plus advisors | | |
| FOOP | | | | | | | |
| Figure out our plan | | | | | | | |
| | 1 | no dependency | 15 min | | Define our challenge | | |
| | 2 | FOOP.1 | 15 min | | Propose a solution | | |
| | 3 | ETRDS.3 | 15 min | | Establish deadlines | | |
| CMD | | | | | | | |
| Complete mechanical design | | | | | | | |
| | 1 | ETRDS.2 FOOP.2 | 90 min / meeting | | Draw potential designs for each component | | |
| | 1 | ETRDS.3 | | | In mechanical group meetings, members will brainstorm design ideas | | |
| | 2 | CMD.1.1 | | | As a group, we select the most adequate design | | |
| | 3 | CMD.1.2 | | | Determine the necessary subsystems for each component | | |
| | 2 | CMD.1 | 2 terms | | Use CAD software to design the device | | |
| | 3 | CMD.1 CMD.2 | 2 terms | | Determine the material needed for each part. | | |
| FP | | | | | | | |
| Finish prototypes | | | | | | | |
| | 1 | CMD.1 | 3 weeks | | Begin prototype planning | | |
| | 2 | FP.1 | 3 weeks | | make simple prototypes | | |
| | 3 | FP.2 CMD.1 | 2 terms | | Prepare for making more advanced prototypes | | |
| | 4 | FP.3 | 2 1/2 terms | | Build advanced prototypes | | |
| IED | | | | | | | |
| Incorporate electronic devices | | | | | | | |
| | 1 | ETRDS.3 FOOP.2 FP.4 | 30 min | | Coordinate with rest of the team to determine where electronic devices will be incorporated in the robot | | |
| | 1 | IED.1 | | | Determine which devices will be needed | | |
| | 2 | IED.1 | 3 weeks | | Design & order PCB | | |
| | 3 | | 2 weeks | | Begin to create database for patients | | |
| | 4 | IED.3 | 1 week | | Integrate database with our mpu | | |
| BTR | | | | | | | |
| Build the robot | | | | | | | |
| | 1 | CMD.3 | 4 weeks | | Create the parts of the device by laser cutting, 3D printing or machining | | |
| | 2 | IED.1.1 IED.2 IED.4 | 3 weeks | | Order all electronic components required | | |
| | 3 | BTR.1 BTR.2 | 1 1/2 terms | | Assemble the robot by uniting its components | | |
| | 1 | BTR.1 | | | Construct each mechanism separately | | |
| | 2 | BTR.3.1 | | | Join each mechanism using a network of aluminum extrusions | | |
| | 3 | BTR.3.2 BTR.2 | | | Incorporate electronic devices in the robot | | |
| TTR | | | | | | | |
| Test the robot | | | | | | | |
| | 1 | BTR.3 | 1 1/2 terms | | Begin iteration process | | |
| | 1 | TTR.1 | | | Aim to improve with each iteration | | |
| | 2 | TTR.1.1 | | | Continue until no error is seen | | |
| | 2 | BTR.3 | 1 1/2 terms | | Have all sensors communicating | | |
| FTP | | | | | | | |
| Finish the paper | | | | | | | |
| | 1 | no dependency | 1 term | | Write the background section | | |
| | 2 | CMD.2 IED.2 | 3 terms | | Write the design process sections | | |
| | 1 | can be done as project progresses | | | Document each step of the process | | |
| | 2 | CMD.2 BTR.3 | | | Include visual representation of the robot's components | | |
| | 3 | FTP.2 | 1 1/2 terms | | Write the verification sections | | |
| | 4 | FTP.3 | 1 week | | Write the introduction and conclusion | | |
| | 5 | FTP.4 | 2 weeks | | Add appendix, references and list of figures | | |
| | 6 | FTP.5 | 1 week | | Review paper before submission | | |

3.3 Research and Development Cost

The team's members have been exposed to various classes about mechanical and electrical design and some have had prior hands-on experience constructing semi-automated systems. By utilizing our campus' facilities such as rapid prototyping, machining labs, and our project advisor's AIM lab, we will construct various iterations of the robot's subsystems until they are functioning and can be assembled. The proposed/preliminary and actual for the expenses of the projects are given below, which was estimated to account for the additional purchases necessary.

Table #4 : Estimated Budget

| Category | Description | Proposed Development Cost (\$) | Actual Development Cost (\$) |
|-----------------------|--|---------------------------------------|-------------------------------------|
| Mechanics | 3D Printing, Machining, Raw Materials | 350 | 115.35 |
| Electronics | Motors, Motor Driver, Processing Unit, Circuit Boards and Components | 150 | 417.01 |
| Sensors | Optical and Weight Sensors | 150 | 286.53 |
| Blood Vial Labeling | Barcode Scanner, Labels | 150 | 10 |
| Passive Hardware | Enclosure, supports | 200 | 221.87 |
| Accessories | Blood Vials | 50 | 30 |
| Information Resources | Books, Articles | 50 | 0 |
| | Total (\$) | 1,000 | 1,080.76 |

Table #4 above depicts the total cost of prototyping PhleAid. In addition, certain components used in the development process were donated to the team, like the Cognex Dataman Camera. These donations are not reflected in the actual development cost. It provides information on how the budget was allocated for the development of this project. This total cost does not reflect the price of the device itself.

Chapter 4

Design Process

As mentioned in Chapter 3, PhleAid™ has four subsystems that each have a separate function: a Vial Selection Subsystem, a Vial Handling Subsystem, a Vial Labeling Subsystem and a Blood Sample Verification Subsystem. This chapter details how each of the subsystems that comprise PhleAid™ was defined and developed.

4.1 Integrated System Description

PhleAid’s four subsystems were developed in parallel to achieve our project goal: to simplify and support the phlebotomy process as well as minimize pre-analytical laboratory errors. The following Figure 15 depicts what functions occur in each subsystem to achieve the ultimate goal. Each subsystem and its respective functions are color coded in the figure below.

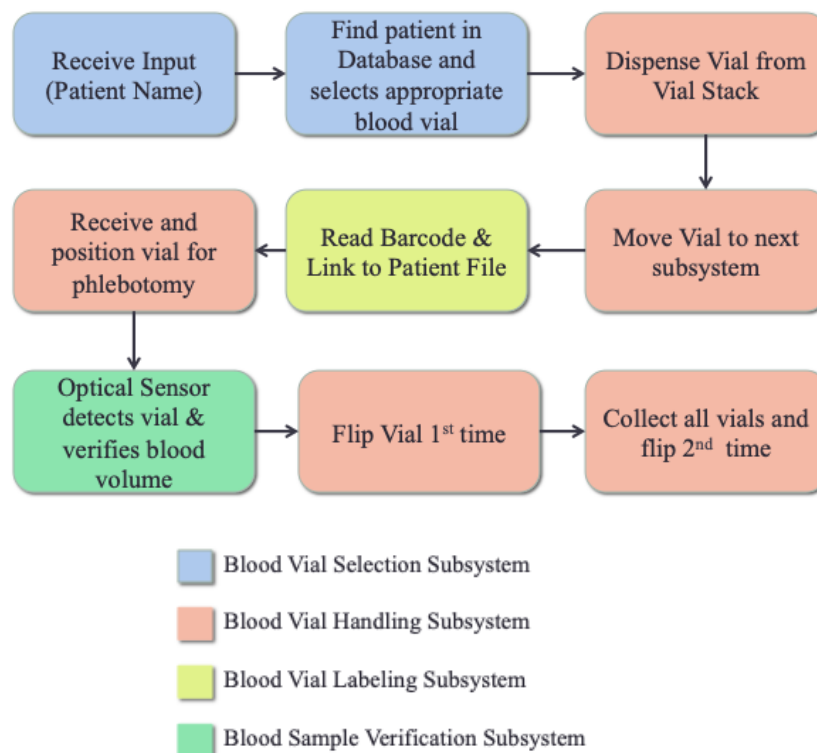


Figure #15 : PhleAid™ Subsystems and Functions

To begin, the phlebotomist inputs the patient’s name into the Vial Selection System of PhleAid. Then the program matches the name with the tests required by that patient; and then extracts

the specific information for each test. For example, what type of blood vial is appropriate for that test and how many inversions are necessary. Following the vial selection, the Blood Handling Subsystem dispenses the appropriate vial and moves the vial into the sample collection site. While the vial is moving, the Blood Vial Labeling Subsystem reads the generic barcode printed on the vial and matches that barcode with the patient file. Subsequently, the Blood Vial Handling Subsystem receives the vial and places into position for collection. Here the Blood Vial Volume Verification System detects the presence of the vial and instructs the phlebotomist to insert the butterfly needle into the vial. While the blood is collecting, the Blood Vial Volume Verification Subsystem measures the blood volume inside the vial and a buzzer sounds when the vial has been filled with sufficient blood. After the sample is collected, the Vial Handling Subsystem inverts the vial once and moves it into a second inverting mechanism where it is inverted multiple times. Finally, the phlebotomist can collect all the blood vials after the procedure is completed and all samples were collected.

The following sections explain in more detail how each subsystem was developed.

4.2 Lab Test and Proper Blood Vial Selection Subsystem

a. System Background

As mentioned in previous sections, inappropriate blood vial selection is one of the most common pre-analytical errors. Each laboratory test utilizes a specific blood vial containing a certain additive that must be mixed with the blood specimen. Therefore, when a sample is collected for a specific test in the wrong vial, it becomes waste.

In addition, the phlebotomist is required to ask the patient certain screening questions that prevent the collection of inadequate blood samples. As explained in Section 2, a blood sample can be inadequate due to lipemia, which is caused by improper patient fasting and certain health conditions. Screening the patients allows the phlebotomist to know if the blood sample will be adequate for testing.

b. System Requirements

Dispensing vials automatically for each patient depending on the necessary blood test reduces the possibility of human error. Vials need to be dispensed and filled in a particular order to meet phlebotomy procedure requirements. Screening the patient to see if they met their physician's requirements decreases the risk of obtaining inaccurate lab results.

Therefore, there was a need to implement, within PhleAid™, a subsystem that selects the appropriate blood vials and screens the patient for fasting requirements. The design requirement of the Blood Vial Selecting Subsystem is to select the appropriate vial for each test through a graphical input and decision-making software.

To do so, the following system requirements were defined:

- Receives Patient Name as Input.
- Extracts Patient Information and correlates the tests needed to what vials should be dispensed.
- Determine appropriate dispensing order.
- Assist in patient screening process before phlebotomy.

The system requirements will be considered met if a graphical user interface and program are developed that achieves the tasks listed above.

c. System Development

To develop such system, four major components were considered. First, a microprocessor to run the program. The team evaluated using an Arduino Mega or a Raspberry Pi as the main processor (Figure 16). Both options were evaluated based on memory, computational power, input and output options. The Raspberry Pi was selected because of its greater computing capacity. The microprocessor receives the patient name as an input and then extracts the appropriate blood tests and blood vial from two major databases: Blood Test Database and Patient Database. Both are stored in the microprocessor's memory.

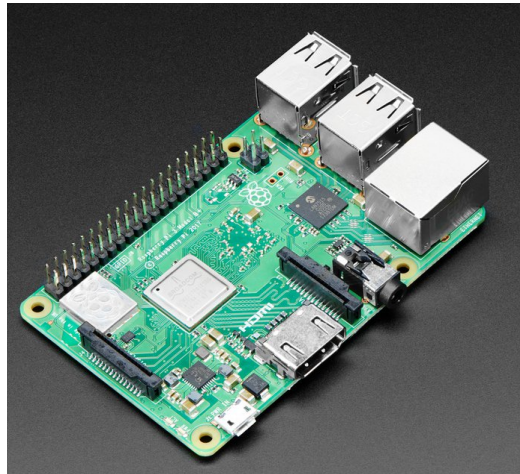


Figure #16: Raspberry Pi module [52]

The Blood Test Database contains the specific tests that can be performed with each blood vial. This database has the capability to include multiple possible blood tests and vials. It also contains information on what additive is inside each blood vial, how many inversions it requires and the appropriate blood vial filling order. However, for the scope of this project, the system was limited to three different blood vials and the most common tests that are performed in the U.S. with those vials. The three blood vials selected were reviewed and approved by phlebotomists.

The Patient Database contains the test information for each patient. For development and testing purposes, the team implemented a mock database with random patient names and tests.

Finally, a Graphical User Interface (GUI) was developed to facilitate patient and information search. The GUI also provides warning messages to the phlebotomists if the patient has not met the appropriate fasting requirements before the test. A first iteration of the GUI was created and subsequently modified after a series of interviews with phlebotomists. Figure 17 & 18 show the multiple GUI design developed.



Figure #17: Graphical User Interface 1

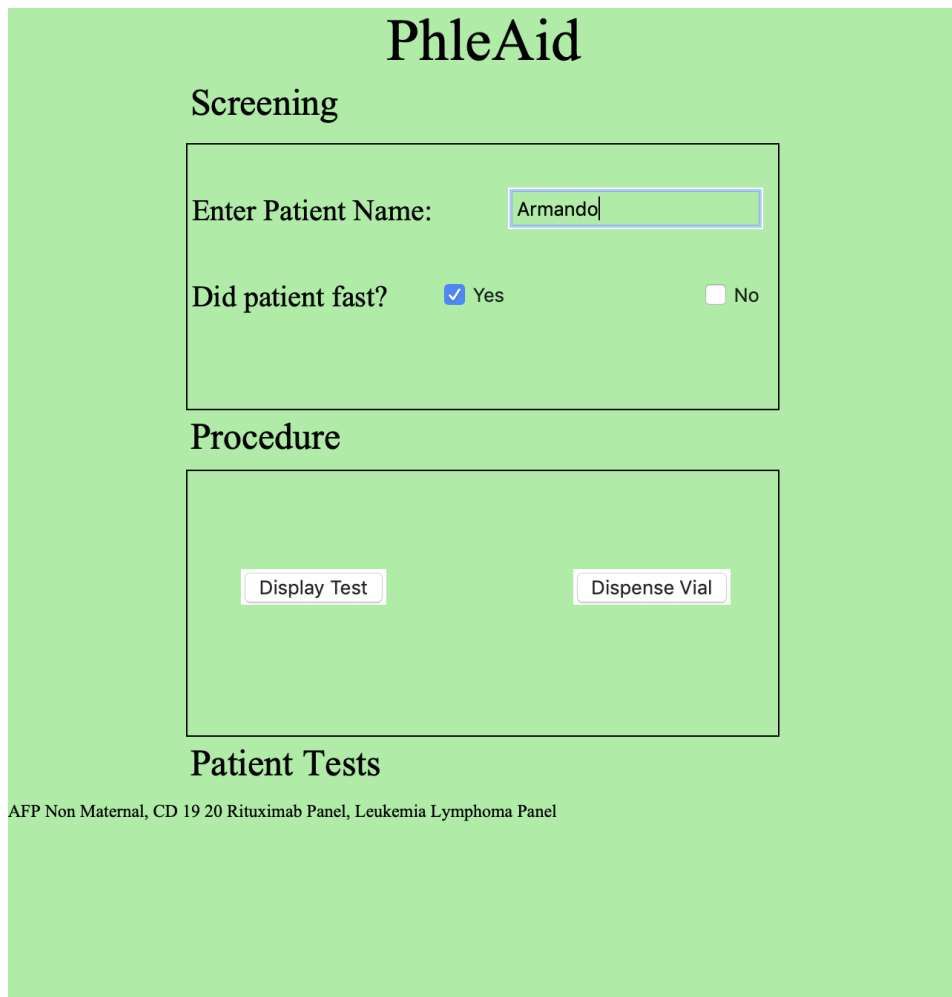


Figure #18: Graphical User Interface 2

d. Future Direction

For further system development certain measures should be considered.

First, to expand the test database. Currently, the test database used by PhleAid supports 15 different lab tests that are performed with three different vials. In the future, this database could include a broader variety of test options and blood vials.

Second, to conduct another round of interviews to improve the Graphical User Interface. So far, a prototype of the GUI has not been tested with phlebotomists. More interviews focusing on user interaction would provide valuable feedback about the GUI's functionality and aesthetics.

Third, to integrate our program to current lab management softwares and patient databases. There are several laboratory management softwares, such as LabCollector LIMS [53] and Prodis [54] that are implemented in phlebotomy laboratories and hospitals. Instead of using a mock patient database, our system would extract patient test information directly from the lab's management

system. Additionally, it could input the barcode on each vial with the patient's file automatically. In other words, the program would perform the same functions but it would extract information from current softwares implemented in laboratories.

4.3 Blood Vial Handling

a. System Background

Proper vial handling is an important requirement for this project because mishandling the vial can cause improper test results due to clotting and hemolysis. Minimizing the phlebotomist's contact with the blood vial can reduce the possibility of mishandling.

On another hand, to prevent clotting, phlebotomists are responsible for inverting the vial a certain amount of times to ensure that the blood sample mixes with the additive inside the vial. The phlebotomy process would benefit from an automated device that can properly keep a vial steady and minimize phlebotomist contact with the vial.

b. System Requirements

The objective of the Blood Vial Handling Subsystem is to successfully carry out some of the steps that make up the pre-analytical phase of the laboratory testing process while limiting the phlebotomist's contact with the vial. The purpose of this subsystem is to prevent the vial from experiencing aggressive shaking or a hard impact against a solid surface. The design requirements for this subsystem are to invert blood vials after collection and minimize user contact with blood specimen through a robotic vial handling mechanisms.

To do so, the following system requirements were defined:

- Store each vial in independent dispensers separated by vial color. All dispensers should be equal and wide enough to keep them at a horizontal position while stacked. The dispenser must have a mechanism that draws out the bottommost vial for it to roll to the next subsystem component.
- Move the vial into position for labeling and blood collection. The design for this component should consist of multiple mechanical subsystems that help move vials from point A to point B, and also include ramps to assist gravity with the movement of the vials.
- Hold the vial steadily for blood collection. Regardless of the position it is in during collection, the orientation of the vial is not a requirement because blood flows towards the vial due to pressure differential[55].
- Invert the blood vial the appropriate amount of times after blood sample collection.
- Easily remove vials altogether after procedure is complete.

c. System Development

This section outlines the development of both Mechanical and Electrical components of the Blood Vial Handling Subsystem.

Mechanical Components

After multiple discussions, the team developed various solutions to meet the predetermined subsystem requirements. The team took commonalities present in the proposed solutions and developed a set of standards to act as specific design guidelines. The standards agreed upon were:

- The vials starts at a horizontal orientation to roll from one section to the next. This simplifies the design process because gravity facilitates the vial movement.
- The robot mates with butterfly needles. The phlebotomist punctures the patient with one side of the butterfly needle and inserts the other side into the vial as seen in figure 19.



Figure #19: Butterfly needle [56]

- The vial is placed in a slot that holds the vial during collection. This support counters the force of the phlebotomist when inserting the butterfly needle into the vial.

During the design process, the team decided to divide the device into three main mechanisms that carry out different functions during the blood collection process. These are the vial dispensing mechanism, the first inverting mechanism and the final inverting mechanism. A flowchart of the order of how they operate is shown below and each mechanism is further explained in the remainder of this section.



Figure #20: Main Mechanisms of Blood Vial Handling Subsystem

Mechanism I: Vial Dispensing Mechanism

Considering similar technologies discussed in Section 2, our team agreed to have our design mirror the procedure used by the PillPick [51] to store and select blood vials. However, the PillPick device is too large and it is more practical in a hospital setting. This is a concern because one of our predetermined design requirements was that PhleAid™ should fit on top of a table. Therefore, the other analyzed solution, the automated vial dispenser [50], was a more feasible solution since it had a wheel that could draw out one vial at a time. The only drawback to this device is that the vials would end in a vertical position and would not be able to roll to the next section.

After further discussion, the team designed a mechanism similar to the vial dispenser which stores vials but positions the vial horizontally. The hand sketches below present the two ideas that seemed most feasible for dispensing one vial at a time. The first drawing, Figure 21, consists of a pair of latches that separate one vial from another. Both latches retract: the lower one first to release the vial and the upper one second to place the next vial into position to dispense. Each latch's movement can be controlled by actuators.

The second idea, displayed in Figure 22, utilizes a wheel that has space to separate one vial at a time. This wheel can be controlled by a motor that can be programmed to stop after only one vial is released. Ultimately, the team decided to go with the wheel to be the mechanism that draws out vials because it requires only one motor to operate instead of two actuators. By reducing the number of moving components, we simplify the programming and reduce the risk of failure. A table with all the pros and cons of each idea is given below the figures

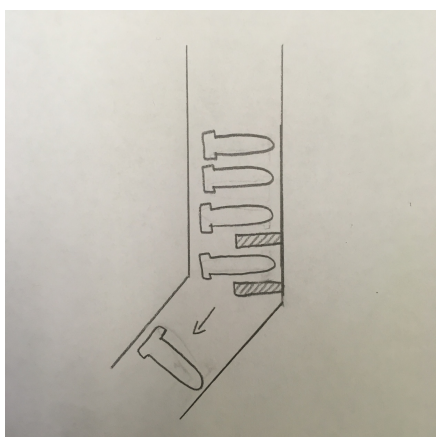


Figure #21: Sketch of latches

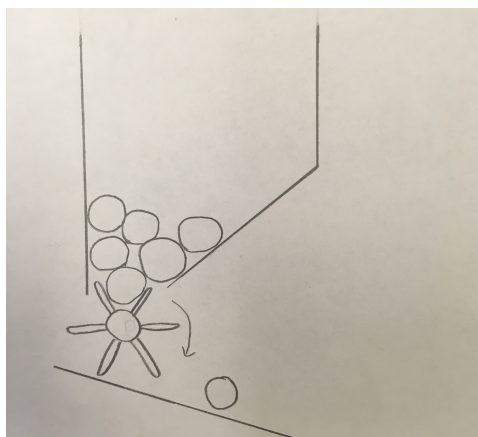


Figure #22: Sketch of wheel

Table #6 Pros and Cons of Latches and Wheel

| Latches | | Wheel | |
|----------------|---------------------------|-------------------------------|---------------------|
| Pros | Cons | Pros | Cons |
| Simpler design | Two electronic components | Only one electronic component | More complex design |
| | More programming required | Simpler programming | |
| | Higher chance of risk | Lower chance of risk | |

The figure below shows the first iteration of the wheel inside the vial dispenser. After testing, this first iteration presented several flaws such as not having additional room for the vial caps and not fitting in the motor shaft. Also, we found that if the programming of the stepper motor was not accurate the wheel could travel a few extra steps, causing the system to dispense two vials instead of one.

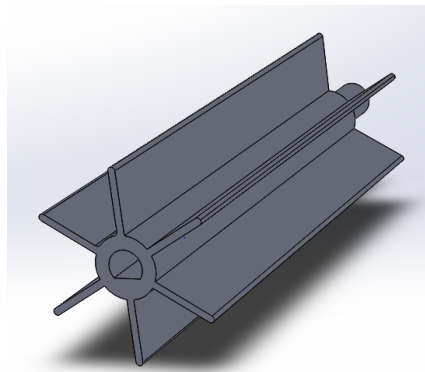


Figure 23: Original design of wheel

The second iteration of the wheel is shown in Figure 24. This design addressed the flaws of the previous iteration by successfully extracting one vial at a time. By only having space for one vial, the new wheel prevented more than one vial from being dispensed. Vials are dispensed onto a ramp and move on to the blood collection mechanism. Since more than one type of vial is used for the project, multiple dispensers are required. Additionally, since all vials use the same ramp, the dispensers must be placed one in front of the other. The height of the drop should be low enough to reduce the impact of the vial with the ramp, but also high enough for the vials coming from previous dispensers to roll through uninterrupted.

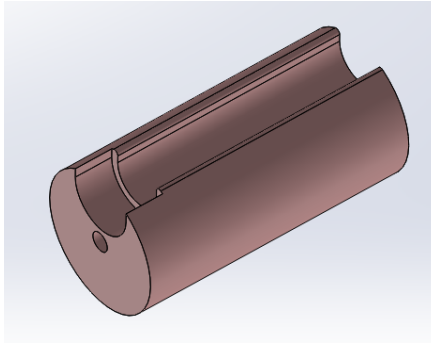


Figure 24: Second iteration of wheel

Figure 25 below shows the original SolidWorks model of the first assembly, where blood vials are stored and dispensed. Three separate vial dispensers aligned with one another and a ramp that will lead the vial to fall into a slot where blood collection will take place are the components that make up this subsystem. The ramp has a lower platform towards one of its edges to leave space for the lid of the vial. This makes the body of the vial be the only surface in contact with the ramp, allowing the vial to roll down in a straight direction. Prior to having the ramp, two rods were placed underneath the dispensers for the vials to roll down them. The reason for having rods was to prevent contact between the vial's lid and the surface to ensure the vial travels in a straight path. This idea was discarded after the team tested dropping a vial into two rods because the vials would bounce and misalign their path. A ramp with a lower platform on its side made with two pieces of scrap acrylic yielded the desired result when tested because the vials did not bounce upon impact with the surface and would roll down in a straight path. The dispensers in the updated model shown in figure 26 were reduced in a way that only one vial will fit on top of another to avoid cluttering of vials when they are close to the wheel.

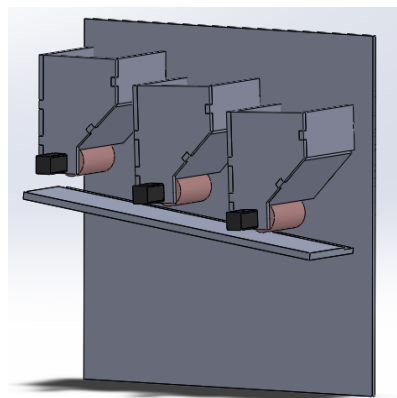


Figure 25: First iteration of vial dispensers

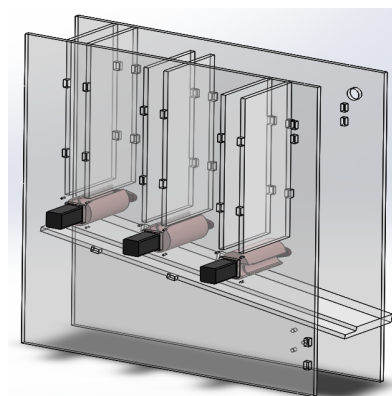


Figure 26: Second iteration of vial dispensers

Mechanism II: First Inverting Mechanism

After the vials are dispensed, they will roll down the ramp into a slot that will position the vial for blood collection. It is pivotal that the vial is held still at this point to avoid mishandling of not only the vial but the butterfly needle itself. Part of the vial should also be exposed for a system to verify the correct amount of blood is drawn. Similar to the previous system, the team's proposed solutions were drawn on paper, as seen in the figures below, and then discussed altogether. Figure 27 shows how the vial will be held still by mechanical clamps while figure 28 shows the vial held in place by means of four small arms applying pressure against the vial.

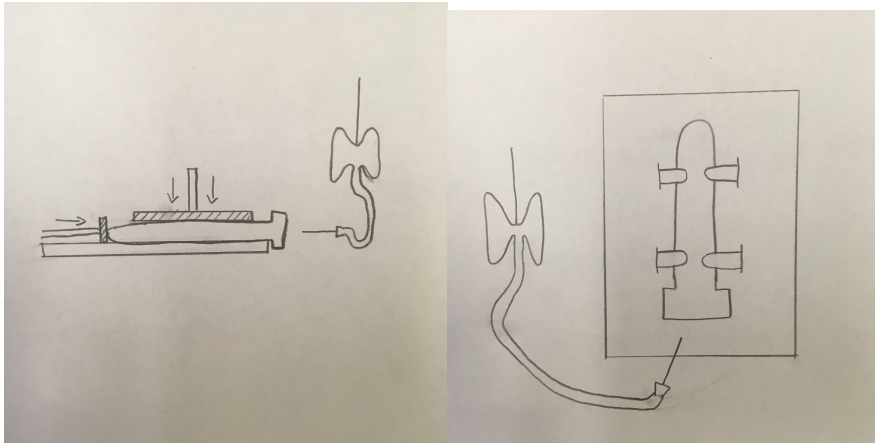


Figure 27: Sketch of clamps holding vial Figure 28: Sketch of robotic arms holding vial

After discussing the proposed sketches, the team decided that both designs were considered feasible for holding the vial in place, but complicated because of the need for more space, motors and sensors. A new solution for holding the vial in place was proposed later and designed as a SolidWorks model. Figure 29 shows our proposed solution for holding the vial in place for blood collection and the inversions needed afterwards. The part needed just enough open space for the vial to land and be verified by LED's while having enough support so the vial doesn't fall during the inversions. A hole was added on each end of the object. The smaller one acts as a path for the male end of the butterfly needle to reach the lid of the vial and the larger one is for the vial to go through to the next system in the robot.

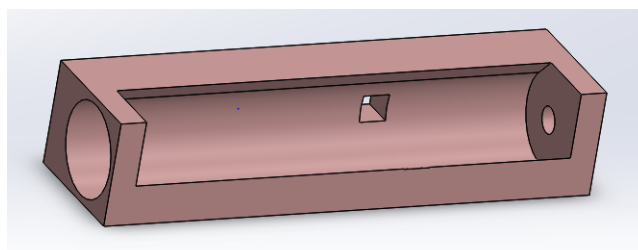


Figure 29: First iteration of inverting hold

To determine which solution would be used in the device, the team overlooked the benefits of each design to determine which would be the most feasible. Table 7 below presents the pros and cons

of each, which led us to select the inverting hold as the part that will hold the vial in place during blood collection.

Table #7 Pros and Cons of Blood Collection Mechanism

| Clamps | | Robotic Arms | | Inverting Hold | |
|---------------|---|------------------------|--------------------------------|--------------------------------------|------------------------------|
| Pros | Cons | Pros | Cons | Pros | Cons |
| Simple design | Requires 2 electric components | The vial is held still | Requires 2 electric components | Requires only one electric component | The vial has space to wiggle |
| | Requires very precise coding to prevent too much or too little pressure on the vial | Simple programming | Complex design | Can invert the vial. | Complex design |
| | Higher risk | | Higher risk | Lower risk | |

The Inverting hold was then 3D printed and tested to see if the vial is stable enough to insert the male end of the butterfly needle without the person having to support the vial. The test yielded the desired results so the team was able to move forward with this design. However, a new design was proposed where the LED's are behind the inverting hold to save up space. To do so, a large rectangular hole was cut out from the original design. The resulting part that allows space for LED lights to go through can be seen in figure 30 below.

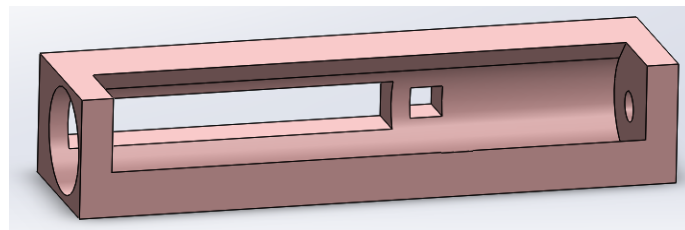


Figure 30: Second iteration of inverting hold

After a first round of testing this object to see if it would drop the vial in the desired manner, the team discovered that not all tests resulted successful. Oftentimes the vial would fall off the empty space by which it came in by instead of going through the hole intended to be a pathway for the vial. To address this problem, a new inverting hold was designed that has a reduced angle of entry and a longer surface preventing the vial from falling off the side when held in position for dropping through the hole. Figure 31 below, shows the third iteration of this part with the aforementioned changes.

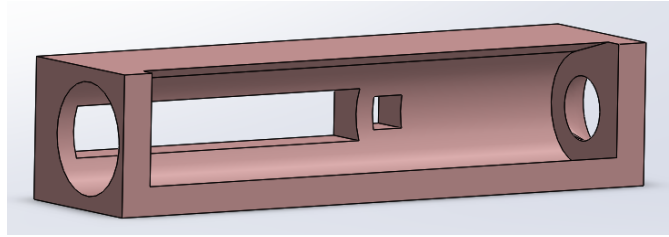


Figure 31: Third iteration of inverting hold

The axis of rotation for this part is at the small square hole located towards the center of the part. This hole is aligned to the shaft of a NEMA 11 stepper motor, which acts as the turning mechanism for this subsystem. A mounting hub with three screws is attached to the inverter by means of three heat inserts in the inverter. The mounting hub has a 5mm diameter rod through the center held together by a set screw. This rod goes into a cylindrical adapter that holds the rod on one side and the motor shaft on the other side with set screws. Figure 32 below shows an image of the mounting hub used, and figure 33 shows how the inverter is mounted to the motor.



Figure 32: Mounting hub for NEMA 11 motor shaft

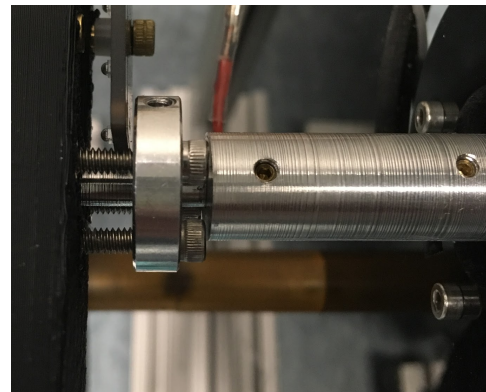


Figure 33: Fully mounted inverter

Once the vial lands in the inverter, it is rotated 90 degrees counterclockwise to align the vial vertically for the blood collection process. While the vial is being filled, it is also going through the larger hole at the end of the inverting hold, creating the need for a part that prevents the vial from falling when oriented vertically. To address this problem, we designed an arc whose radius is slightly larger than the distance between the square shaped hole and the end of the object with the larger circle. This arc was designed to prevent the vial from sliding out of the inverting hold while keeping the lid at a short distance from the other end to allow the butterfly needle to reach it. The arc also has a hole at the bottom of its path right next to the space holding the vial when it is vertical. After blood collection, the inverting hold aligns with the hole so the vial can slide down into the next mechanism. Multiple iterations for this part were necessary because various tests were conducted to determine the ideal dimensions the hole should have. Three mounting holes on the side of the arc were also added to hold the arc in place so it can be aligned with the inverting hold. The final design was then 3D printed, and its holes were sanded from the inside to ensure the screws that would hold it in place would fit.

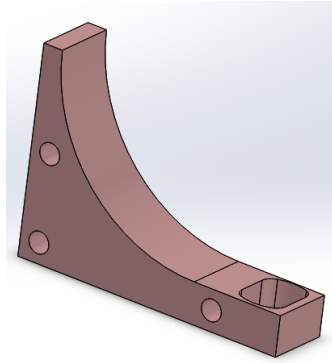


Figure 34: Vial holding arc

Next, our team had to determine how the vials would go to the final inverting mechanism and how this mechanism would look like. The first idea proposed was to have the vials to free fall from the arc into a large bucket-like object that would invert all the vials at once. Although this design would be very simple, it is not ideal vial handling because the impact upon landing can shake the blood and cause hemolysis. An alternative solution was to create a slide that would lead the vials into the next mechanism. Since it is a complicated shape, we determined that this part would also need to be 3D printed. It was also intended to be glued to the bottom of the arc in a way that the path for the vials is aligned with the hole in the arc. Figure 35 shows the first design of the slide, which was quickly disregarded because the shape had no flat surfaces. This is a problem because the part would have no stable surface to rest upon when being printed. Our next iteration of this slide was designed with flat sides to facilitate the 3D printing process (Figure 36). After printing and testing it, we observed that the part followed our set guidelines to achieve proper vial handling, meaning that we could move forward with the idea of having a slide for the vials.

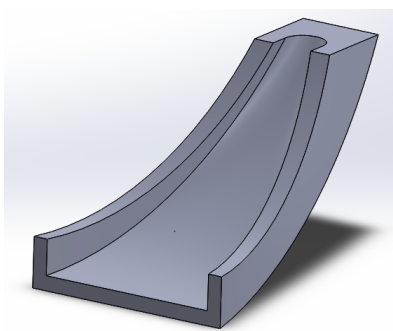


Figure 35: First iteration of vial slide

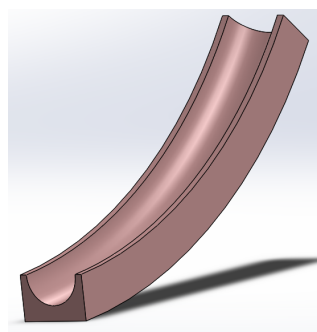


Figure 36: Second iteration of vial slide

Next, we decided that the height and length of the slide should be reduced to prevent the final product from being too tall. We also decided that an additional structure with mounting holes should be added to the slide. The purpose of this structure is to be screwed into the same acrylic wall that is supporting the arc. We then redesigned the slide accordingly to reflect these discussed changes. The resulting design is seen in figure 37 below.

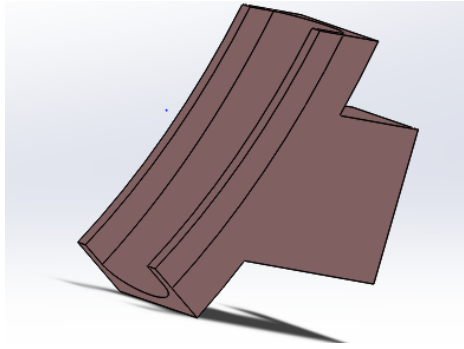


Figure 37: Third iteration of vial slide

This small slide was printed and mounted on the wall, along with the entire inverting subsystem, to test if it would function the way we intended. Oftentimes the vial would get stuck between the inverting hold and the side of the slide because there was not enough space for the vial to go through. To address this problem, we redesigned the vial supporting arc and added a slide at the end that oriented differently compared to the previous slide. With this new part, the vials would slide in a direction parallel to the acrylic wall instead of away from it. Figure 38 below shows the SolidWorks model of this new part.

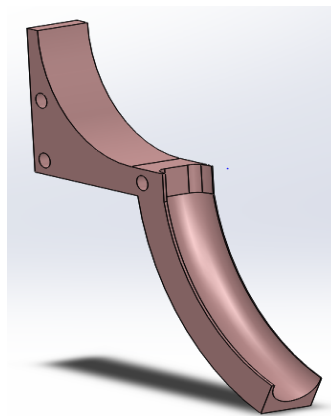


Figure 38: Vial holding arc with slide

Mechanism III: Final Inverting Mechanism

For our last system, we needed to create a bucket-like object that could hold every vial that was filled and give them their required multiple inversions, as previously suggested. Such object should also have an opening at an angle that can catch vials as they are dropping from the slide. Instead of drawing our proposed ideas for this part on paper, we made various SolidWorks models because this part would have been complicated to visualize using only a two-dimension sketch. We also agreed that this part should also be 3D printed because it would be a difficult part to machine and we would need a light material that can be held by a motor. This part is supported by a mounting hub, shown previously in figure 32 below, that is screwed into the part and mounted into a NEMA 11 stepper motor by a set screw that is pressing against the flat surface of the motor shaft.

Our first design, shown in figure 39, is an open box with a slanted back wall. The purpose of the back wall being slanted was to prevent the vials from landing on a flat surface. Instead, the bottom of the vial should slide towards the corner so the vials rest in a horizontal position. This part also has a slot for inserting a thin acrylic lid to prevent the vials from falling.

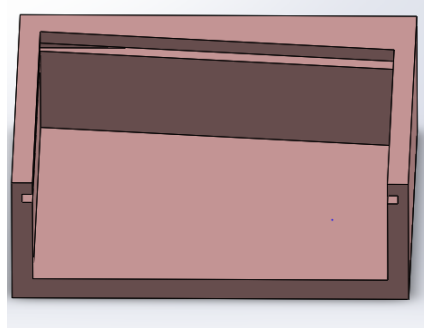


Figure 39: First iteration of large inverting hold

A second design was then proposed that had a roof and an empty space on the side. The purpose of the empty space was to allow the vials to be removed by the phlebotomist after the inversions. A drawer that could fit inside this object was also designed to prevent the vials from falling during the inversions. The problem with this drawer was the difficulty to print a part that could fit perfectly inside the inverting hold due to the higher clearances needed when 3D printing. To address this issue we kept printing drawers until we had one that just barely fit, then we used sandpaper to scrape off the outer surface until it would fit.

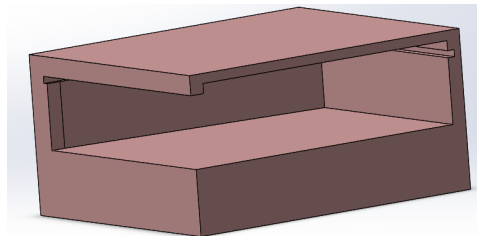


Figure 40: Second iteration of large inverting hold

Our next iteration, shown in figure 41, was a combination of our two previous ideas because it has space for an acrylic lid and has open space on the side so the phlebotomist can remove the drawer full of vials. For this design, a slot was added at the bottom of the empty space on the side to prevent the drawer from falling off. We also reduced the height of the object by removing excess material on the bottom. Figure 42 shows how this mechanism will be positioned. The slide discussed earlier was designed to have an angle that leads the vials directly into the opening of the large inverting hold.

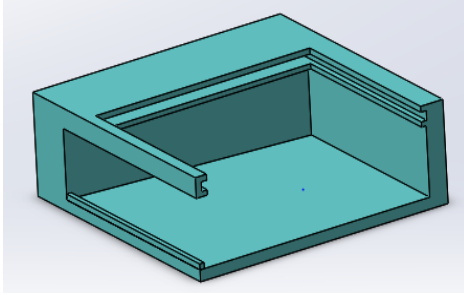


Figure 41: Third iteration of large inverting hold

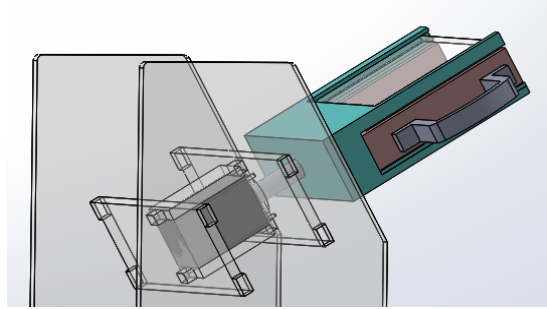


Figure 42: Final inverting assembly

Electrical Components

A circuit was created to control all moving elements of the Blood Vial Handling SubSystem. Such circuit includes a series of motors, motor drivers, microcontroller and PCB. The general layout of how the circuit operates and motor placement in the PhleAid structure are depicted in the figures below:

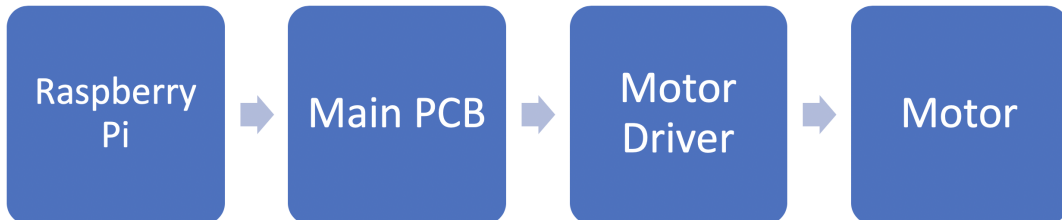


Figure 43: Block Diagram of Motors and Motor Control

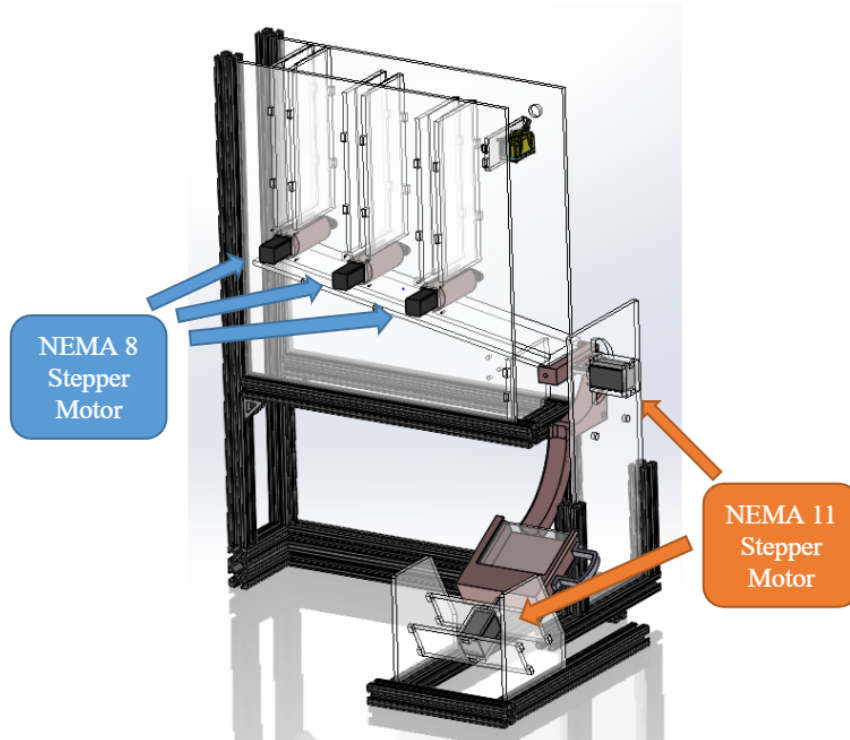


Figure 44: Motors Placement in PhleAid

- **Motor Selection**

The team’s priority for selecting a motor was that angle of rotation could be easily controlled since most of the moving components/systems are rotating around a shaft. Controlled rotation is what allows the blood vials to move from one subsystem to another. Among multiple rotary motor samples considered, stepper motors were selected because they divide their entire rotation into equal steps. Therefore, programming precise motion is simple.

Two different stepper motors were selected: NEMA-8 and NEMA-11. Both are hybrid bipolar stepping motors.

Three NEMA-8 (Figure 43) motors control the three wheels for the vial-dispensing mechanism. These have a 1.8° step angle (200 steps/revolution) and draw 600 mA at 3.9 V per phase, allowing for a holding torque of 180 g-cm (2.5 oz-in).



Figure 45: Stepper Motor NEMA 8 [57]

Two NEMA -11 (Figure 44) motors control the first and second vial inverting mechanisms. This model has an equal step angle than NEMA-8. The key difference is that for the NEMA-11 each phase draws 670 mA at 3.8 V, allowing for a holding torque of 600 g-cm (8.3 oz-in). The additional torque was needed due to the higher mass of the mechanisms that rotate.



Figure 46: Stepper Motor NEMA 11 [58]

- **Motor Driver**

All five motors use a DRV8834 driver (Figure 45), which operates from 2.5–10.8 V, allowing stepper motors to be powered with voltages that are too low for other drivers. The drivers are programed to control the amount of steps and the direction of rotation performed by the stepper motor.

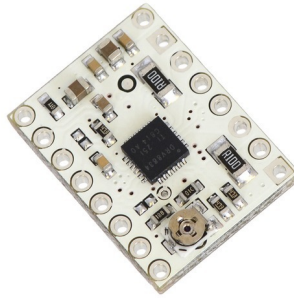


Figure 47: Stepper Motor Driver [59]

- **Motor Driver Control**

The drivers are connected to the Raspberry Pi, which is the main microcontroller in our system. In order to incorporate these devices, a main PCB was created. It would contain a header for the stepper motor coils and Raspberry Pi, the connections for the motor driver and the power supply for all the PCBs (refer to the appendix section for PCB schematic). In respects to the power supply, the main PCB is connected to the wall and a regulator is placed to provide the required five volts all PCBs need to function.

d. Future Direction

As previously stated, PhleAid can expand its database to allow more types of tests, meaning that more types of vials will be necessary. That being said, more vial dispensers behind the ones already present will probably result in a longer ramp and an larger device, allowing the vials to pick up more speed. When expanding PhleAid, the same predetermined requirements should still be taken into consideration.

In terms of new additions to this device, the ability to detect a mishandled vial and stop the process could be implemented. To do so, additional sensors would be integrated into PhleAid.

4.4 Blood Vial Labeling

a. System Background

Labeling Blood Vials is a crucial part of the Phlebotomy process and errors in labeling can lead to serious health hazards for patients. Each vial should be labeled and confirmed by the phlebotomist before the blood is collected.

b. System Requirements

This system has to match each blood vial to a patient before blood is collected. In order to be compliant with PhleAid, all barcodes should be pre-barcoded in order to be registered into the database. After a vial is dispensed, it should be quickly scanned on the ramp before entering the blood volume verification subsystem. Since the transition between the dispensing and verification

mechanisms is quite short, scanning has to be done in a matter of seconds. For this reason we found the need to look for solutions that would meet this very specific requirement.

The design requirement for the Blood Vial Labeling Subsystem is to link each blood vial with the patient file/information. To do so, PhleAid requires a system that can read the barcode on the vials as they are rolling down the ramp.

c. System Development

For this subsystem the team considered various options mentioned previously in Section #2, but many were discarded because they failed to meet the requirements of our project. The options previously considered included inkjet products, label making products, and barcode scanners. Even though the inkjet solutions were a great option for labeling vials due to their ink efficiency and speed, these were not feasible due to their high costs and large size. The label makers were also a viable option because they were customizable and relatively low cost; however, it would be inconvenient for the phlebotomist to manually print and place labels on each vial. Since we are trying to minimize preanalytical errors, including mislabeling, this was not a feasible option.

Finally, we decided that the barcode scanner with pre barcoded vials was the best option for two main reasons: First, it was easier to integrate into our mechanical system within the size and space constraints of PhleAid. Second, the scanner offers privacy where the others didn't by just having a barcode directly scanned into the system instead of a physical name on the label. Last, image based barcodes are not only comparable in price to other technologies, but are also more powerful.

When debating which image based barcode scanner to use, either the Adafruit option or the Cognex Camera, we ended up choosing the Cognex camera because of its higher read rate performance. Cognex Corporation designs, develops, manufactures and markets machine vision sensors and systems, or devices that can “see.”

DataMan® 50 is a compact fixed-mount barcode reader providing the highest read rates for 1D label-based barcodes. With advanced image formation and a small footprint, DataMan 50 is the ideal solution for our automated device. DataMan 50 is small enough to fit in the tightest spaces, and with IP65 rated housing, it can also handle harsh environments. Taking this into advantage, the DataMan 50 will fit perfectly into our PhleAid device as shown in the figure below.

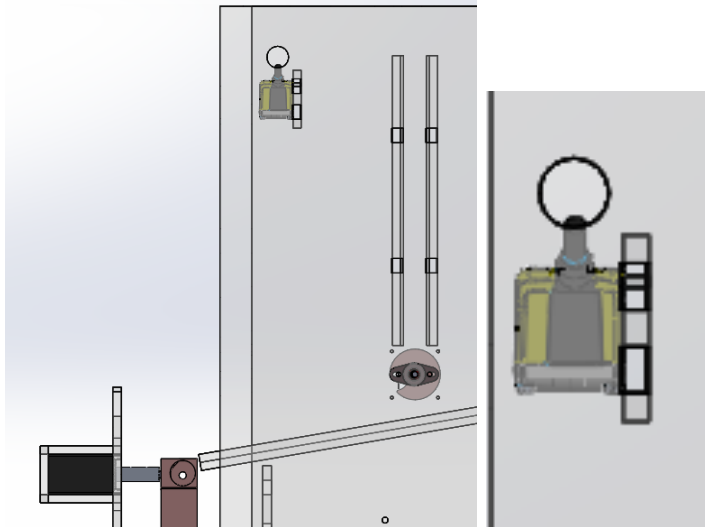


Figure 48: Cognex Camera mounted onto final design

The Dataman is placed right in between the vial dispensers and the first vial flipping mechanism. This way, the released vial can be scanned and registered with that barcode in our database. The DataMan Setup Tool software made it easy to configure the DataMan 50 for our high-speed 1-D label-based barcode reading. Using the setup software, the Cognex camera was put into keyboard mode which allows the camera to scan and output a number directly onto the program.

The camera turns on and begins reading once the program starts, after it scans one vial, the camera shuts off. We used a Raspberry Pi as the main controller for our device. The Cognex camera is connected to our main PCB and transmits information directly to the controller. Our program uses a large for loop that repeats the whole dispensing, scanning, and flipping process for each vial. Once one vial is at the end of the process, the program continues on to the next patient. Therefore, if a patient has more than one blood test to be completed, several barcode numbers will be identified to one patient.

d. Future Direction

Even though the Cognex camera is already on the market, it's integration to our design was crucial and, Nonetheless, there are still modifications that can be made in the future. It could have an input to the camera that lets it know if there was an issue in the Phlebotomy process and start or stop. There also might be issues with the camera, for example if there is something wrong with the process and the vial should be discarded, the camera should be notified to scan again, a new vial barcode. There are also other Cognex Cameras with more power and better features which could provide more resources to work with than the selected camera.

4.5 Blood Vial Volume Verification Subsystem

a. System Background

As mentioned in Section #2, there are multiple biological phenomena that can affect the blood specimen if certain steps in the phlebotomy process are not followed precisely. In particular, coagulated blood samples can lead to inaccurate test results. As explained before, coagulation can occur when insufficient blood volume is collected because the additive to blood ratio is not correct. Therefore, creating a volume system that detects proper blood sample volume is essential for the development of PhleAid.

b. System Requirements

Verifying that the collected blood volume has been reached is essential to minimize laboratory errors. Insufficient volume samples lead to incorrect results due to an improper additive to blood ratio. The design requirement of the Blood Vial Volume Verification Subsystem is verify that the required blood volume has been reached. To do so, the requirements of this system are:

- Measure the collected blood volume.
- Alert the phlebotomist once the blood vial is fully filled.

c. System Development

The team considered multiple solutions to ensure that the phlebotomist collects the required minimum draw volume for each blood test. The first option is using level sensors to determine the height of the blood column. These types of sensors detect the height of a liquid inside an encase because some liquids, like blood, form a horizontal layer due to gravity [60]. There are multiple types of lever sensors, such as optical level switches, capacitance, ultrasonic, microwave/radar, vibrating, conductivity or resistance and float switch. The level sensors option was discarded mainly because they are invasive. This means that the sensor must be in contact with the blood [61]. This cannot occur in order to avoid contaminating the blood sample.

Our ultimate solution was using photodiodes and LEDs to determine the height of the blood column. A photodiode is a solid-state device that converts incident light into an electric current [62] and a LEDs converts electric current into a monochromatic light [63]. Therefore, our solution is to generate a monochromatic light from the LED and cross the filled blood vial. Then, the photodiode collects the photon energy to generate an output voltage. We are setting thresholds for the output voltage. Therefore, the system can determine whether or not a blood vial is present and the blood vial

is being filled. Once the minimum required blood volume is reached, the phlebotomist is alerted with a signal to stop drawing blood from the patient.

The team researched on possible components that we could use as the photodiode and the LEDs. The team decided to use the Excelitas Technologies VTB Process Photodiode [64]. The team chose this product because it has large active area of 5.16mm² [64], which is ideal when input signals are weak [65]. Additionally, the viewing angle of the device is very open [64], allowing for more LED emitted light to be sensed even if the light is refracted when passing through the blood vial. For the LED, the team determined to use the SunLED Chip Led Lamp [66]. The team chose this product because of a low current consumption of 20 mA and forward voltage of 3.3V, and a high millicandela rating of 1195 to cross the filled blood vial. Moreover, the LED has an emission wavelength of 470 nm [66].

Even with the high light luminosity of the LED and high sensibility of the photodiode, the signals are weak and have a negative effect in detection system. Therefore, the team decided to design a transimpedance circuit to augment the output of the photodiode (Figure 49). Furthermore, the photodiode is set to zero biased meaning that the voltage across it equals to zero volts. Therefore, the diode is set to photovoltaic mode to build up the output voltage and to eliminate the possibility of dark current [67]. The figure below displays the layout of this type of circuit.

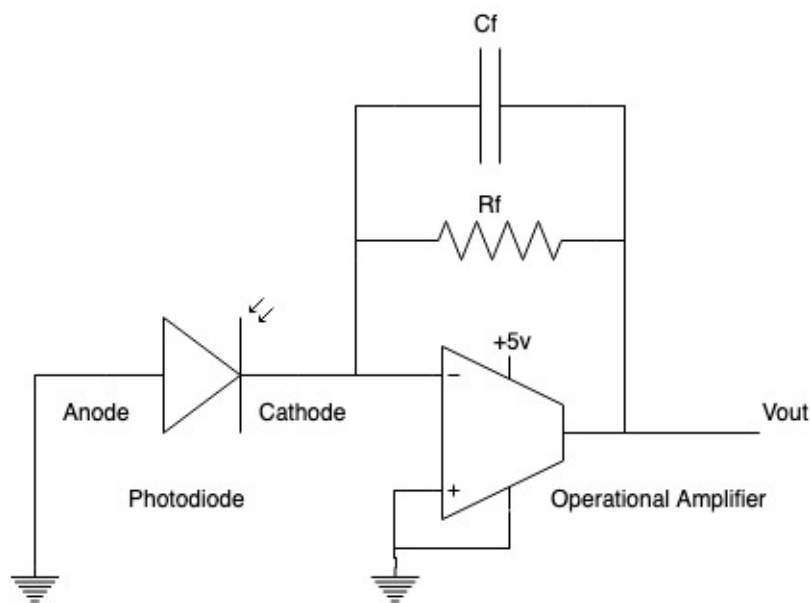


Figure 49: Zero Biased Transimpedance Operational Amplifier Circuit

For our circuit design, the team decided to use the MCP6492 operational amplifier because of its low-input bias current of 150 pA, low quiescent current of 530 μ A/amplifier (typical), low-input offset voltage of \pm 1.5 mV (maximum) and it is recommend for our application by the manufacturer [68]. The selected load resistance (R_f) was one MOhms to apply the small current going across the photodiode. Additionally, the capacitance (C_f) chosen was of 100 nF to reduce risk of noise [69].

With this circuit design, the photodiode output voltage was amplified from an average of 400 millivolts at ambient to average of 1.8 volts at ambient light. This gain shows how great this op amp works.

Once the signals is amplified, the output voltage has to pass through an analog to digital converter (A/D converter), so the team can program the system with the Raspberry Pi. Therefore, ATMEGA328P-AU microcontroller was determined to serve as the A/D converter. Then, the collected data is analyzed to determine the blood sample volume. Finally, the data is transmitted to the Raspberry Pi via the Rx/D and Tx/D UART serial ports. Furthermore, the system proceeds to alert the phlebotomist by activating the buzzer and sample continues to the inversion mechanism to end the whole process.

In order to account for the different required blood volumes, seven LEDs and five photodiodes are used, so there are two LEDs per diode, to account for one to five milliliters of blood. A 85 Ohm resistor was placed in series to create a voltage drop from 5V to 3.3V, which is required for the XZFBB55W-3 to function. The team proceeded to develop two PCBs for the LEDs circuit. Detailed PCB Schematics are included in the Appendix Section. Additionally, these PCBs are powered using the main PCB that contains the power supply connections to the wall (see section 4.3).

d. Future Direction

This system only accounts for two PCBs. Therefore, new versions of these PCB can be created, in order for high speed communication and very high precision analog signals reading. Examples of updates are: placing the capacitors very close to the ports they are decoupling, creating symmetric traces, and adding a ground and power planes to eliminate unnecessary traces in the bottom and top layer.

Chapter 5

Final Design & Verification

PhleAid's final design consists of four major subsystems: Blood Vial Selection, Handling, Labeling and Volume Verification, assembled together with a series of aluminum extrusions. Figure #53 below depicts the final design.

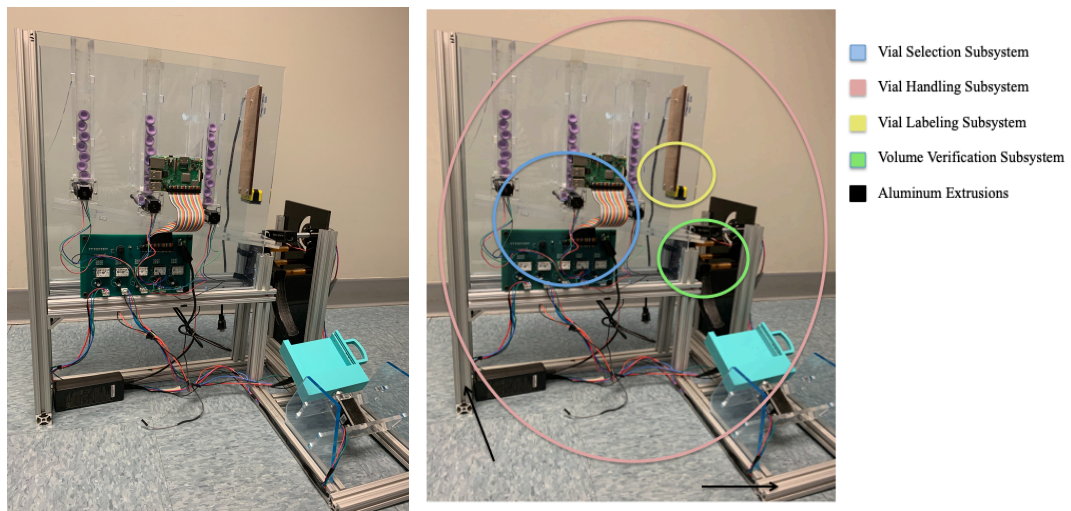


Figure 53: Final PhleAid Design

The mechanisms that dispense and invert the blood vials are depicted in Figures #54 and #55 respectively. These are both part of the Blood Vial Handling subsystem. The vial dispensing mechanism includes three NEMA-8 stepper motors that control the three wheels that dispense blood vials.

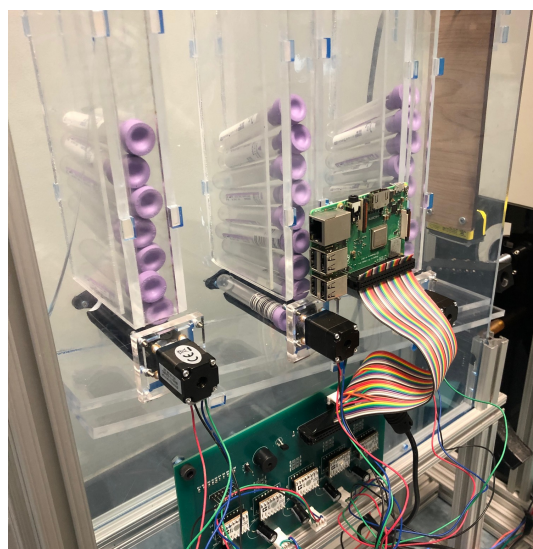


Figure 54: Mechanism that dispenses the vials.

The vial inverting mechanism includes two NEMA-11 stepper motors that 3D printed components that flip the mechanism and hold in place for collection.

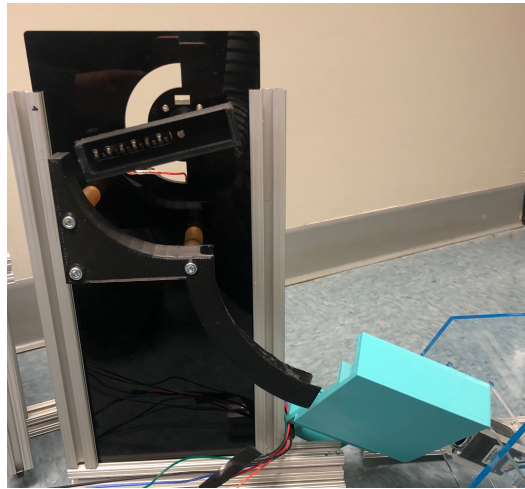


Figure 55: Mechanism that holds the vial for blood collection and inverts them after collection

The PCBs used across PhleAid™ with all the components soldered in place are shown in Figures #56, #57 and #58 respectively. The Main PCB provides power to all of the PCBs and the entire device. The five motors are controlled by the 5 motor drivers shown below. Each of these have their independent circuit which includes a capacitor of 100 uF. There are also 5 connectors which can be connected and disconnected to the different motors. This PCB also connects to the Optical Sensor PCB through a 7 pin connector, a 4 pin connector for the Cognex camera and two pin for the LED PCB. All of the small resistors at the upper left of the PCB are part of the circuit. The long connector is a 40 pin connector for the Raspberry pi. The green to terminal block connects the PCB to power through a 5 Volt adapter. There is also a small circuit for the Buzzer to properly function which includes a transistor and a small resistor.

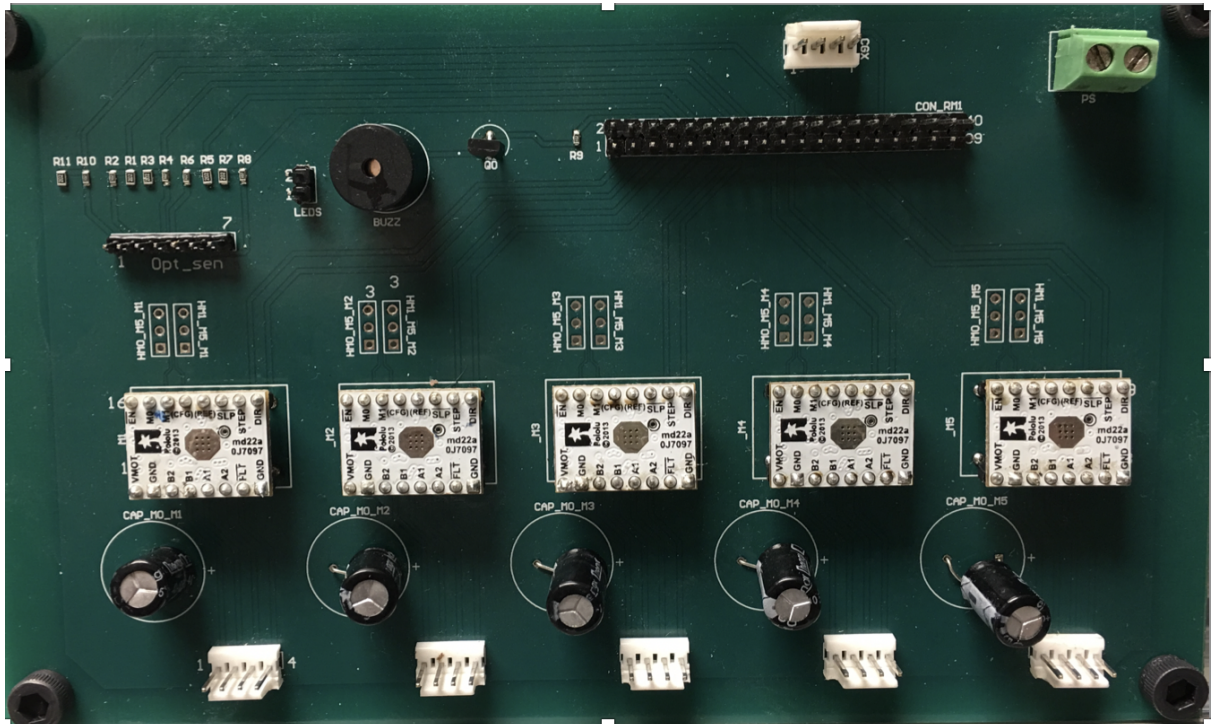


Figure 56: Main Motor and Power PCB

The design for the Optical Sensor PCB was done to properly read inputs through the 5 photodiodes and amplify the signal using the 5 op amp circuits. This is the first PCB for the Blood Verification PCB. We used an ATMEGA328PB-AU as our microcontroller and added 4 decoupling capacitors which can be seen to the left of the MCU. There is also 7 pin connectors which are wired to the main PCB board. The circuit also includes a 16 MHz clock oscillator Crystal with two 18pF capacitors that sets the external clock for the MCU. To the right of the PCBs are the 5 photodiodes aligned vertically with their individual op amp and circuits. Each circuit includes two capacitors (100 nF) and one resistor (1 MOhm).

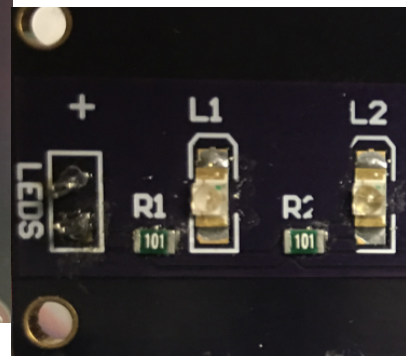
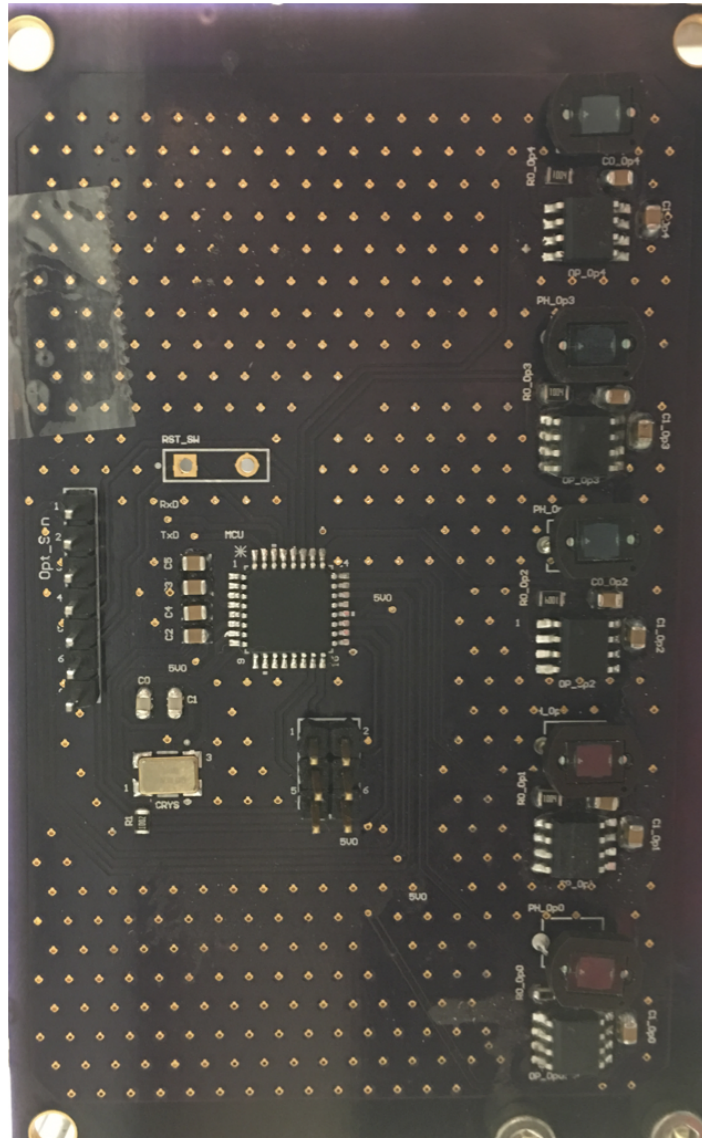


Figure 57: Optical Sensor PCB

This small PCB is the other part of the Blood Verification subsystem. It has 7 LED with lower power consumption and an ideal wavelength (470 nm) to match the photodiode chosen. It also has high luminous intensity with a beaming blue light that shines directly through the vial onto the photodiodes. Per each LED there is an 85 Ohm resistor. This board is connected to the main PCB through the bottom two pin connectors.

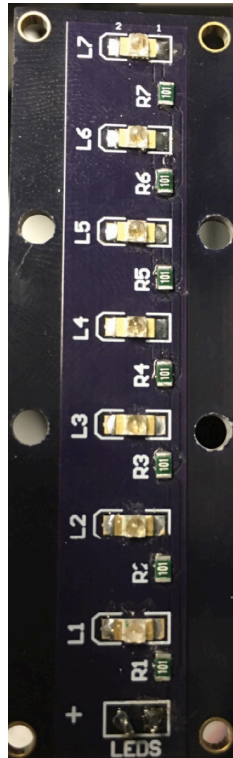


Figure 58: LED PCB

Table # 8 below outlines the system requirements that need to be met by each subsystem in order to achieve the project goal of supporting the phlebotomy process and reducing pre-analytical errors. Initial functionality testing showed that not all requirements were met by PhleAid. Table # lists the requirements that were met initially (Y) and the requirements that were failing (N).

Table #8: PhleAid SubSystem Requirements

| SubSystem | System Requirements | Performance Measures | Initially Met? |
|----------------------|--|---|----------------|
| Blood Vial Selection | Receive patient name as input | Graphical User Interface allows phlebotomist to type patient name | Y |
| | Extract Patient information and correlate tests needed to what vials should be dispensed | Program successfully extracts patient information and correlates tests need with 100% reliability | Y |
| | Determine appropriate dispensing order | Program activates the motor that draws out the required vials with 100% reliability | Y |
| | Assist in patient screening process before phlebotomy | Graphical User Interface alerts phlebotomist when patient does not pass screening process | Y |
| Blood Vial Handling | Store vials independently and dispense when needed. | Dispensers separate different types of vials. Hold up to 50 different vials | Y |
| | Move vial into position for labeling and blood collection | A ramp underneath the dispensers permits the vials to roll down to the first vial | N |

| | | | |
|-------------------------|--|--|---|
| | | inverter with 100% reliability | |
| | Hold vial steadily for blood collection | A motor holds the vial inverter and changes its position during the blood collection process | Y |
| | Invert vial appropriate amount of times after collection | A motor inverts the filled vial the appropriate amount of times after collection | Y |
| | Easily remove vials when procedure is complete | Pull out vial tray in effective manner | Y |
| Blood Vial Labeling | Scan and register barcode on blood vial | Repeated testing to confirm 100% scanning | Y |
| Blood Vial Verification | Measure blood volume collected | Record varied voltages when filling vial | Y |
| | Alert phlebotomist when blood vial is fully filled. | Sound Buzzer when photodiodes record enough blood in vial | Y |

The team initially observed functionality problems in the following areas:

- As vials were dispensed, they bounced when impacting the ramp. Such impact derailed the vials causing them to get stuck inside the vial ramp.
- Barcode scanner does not always scan barcode when vials are rolling.

These problems occurred occasionally. Therefore, the team evaluated factors that could be hindering PhleAid's functionality. A series of tests were performed to determine the best possible configuration to prevent such failures. The procedure and results for the tests performed are outlined in the next sections of this report.

5.2 Functionality Testing

Testing was performed to evaluate what factors could be causing the performance failures and how they could be prevented. The functions evaluated were divided into three tests. The general procedure for each test is outlined in this section of the report.

Test I: Vials are dispensed and roll into collection position

Test I evaluates how three factors influenced the success of dispensing and rolling vials. These factors were selected because how the vials are dispensed impacts the bounce it will have and therefore the possibility of getting stuck. The factors evaluated were: the direction in which the wheel rotates to dispense the vial, the speed of rotation and the angle of rotation of the wheel.

To test the direction of rotation: 22 vials were dispensed in each wheel using a clockwise and a counterclockwise rotation. To test the speed of rotation: 22 vials were dispensed in each wheel

using a speed of 74 [steps/ms] and 83 [steps/ms]¹. Finally, to test the angle of rotation: 22 vials were dispensed in each wheel using a speed of 120 and 90 [degrees].

The ultimate objective of this test is to determine a configuration of motor direction, speed and angle that could minimize the percentage of failure in the system.

Test II: Vial Ramp Re-design

The vial ramp was re-designed to improve the overall success of dispensing and rolling the vials. Figure # displays the design changes made to the ramp.

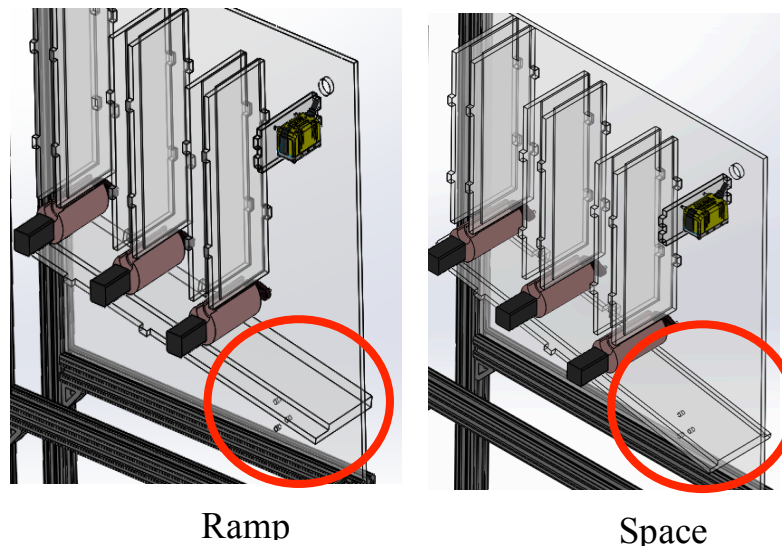


Figure #59: Ramp Re-Design

Test II evaluates how the ramp re-design impacts the subsystem's performance. 22 vials were dispensed from each wheel using the following settings:

Wheel Direction: CCW

Rotation Speed: 83 [steps/ms]

Angle of Rotation: 120 degrees

Test III: Barcodes are scanned

Test III evaluates how different camera heights impact the percentage of barcode that are successfully scanned. Two different heights were evaluated to determine the optimal camera position.

5.3 Test Results

Test I consisted of three different parts. To evaluate the events that could occur when the vial was dispensed and rolled down to the next part, the team characterized the results into pass and fail.

¹ Steps/ms is a unit of angular velocity given by the amount of steps a Stepper Motor takes per millisecond.

Failing vials could be characterized according to four failures modes. The section of the ramp where the vial was stuck or stopped rolling determined each failure mode. Each failure mode was designed with a unique identifier code. The four sections, respective codes and wheels are displayed in the Figure # below.

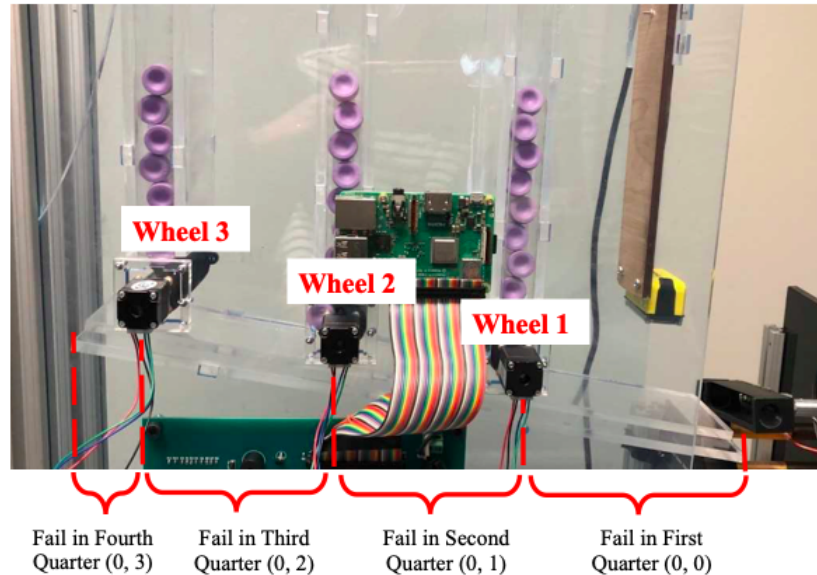


Figure #60: Failure Modes according to section of ramp

For the first part of Test I, the results show that spinning the wheels counterclockwise (CCW) obtains a higher percentage of vials that pass. Figure # shows that in all three wheels, the percent of vials that pass (show as in green) while spinning the wheels CCW is much higher that spinning the wheel clockwise (CW).

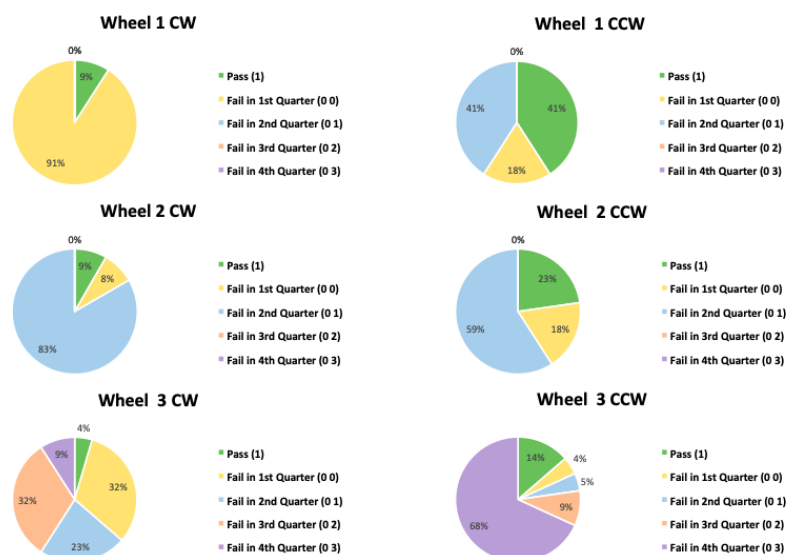


Figure #61: Percentage of Passing and Failures for CW and CCW in all wheels.

It is also important to note, that the percentage of vials passing is significantly larger in Wheel 1 than in Wheel 2 and 3. This can be explained by the fact that the vials have to roll down a longer

path in Wheels 2 and 3 than in Wheel 1. Therefore, there is a higher probability of failing in a longer ramp.

For the second part of Test I different angular velocities were tested. The results show that generally, 83 steps/ms produces a better passing outcome than 74 steps/ms. In both Wheel 1 and 3, the percentage of passing vials is almost double when using 83 steps/ms than using 74 steps/ms. However, Wheel 2 showed no percentage difference between both velocities.

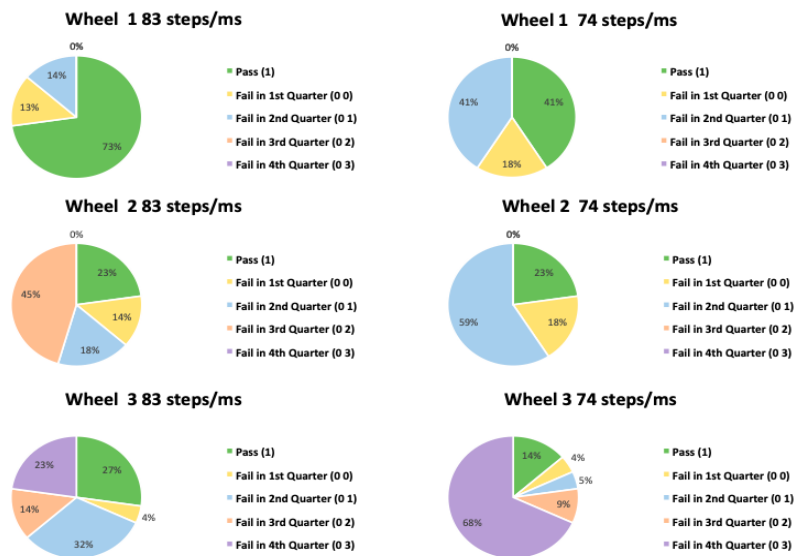


Figure #62: Percentage of Passing and Failures for 83 and 74 [steps/ms] in all wheels.

For the third part of Test I the team tested two degrees of rotation. The results show that 120 degrees of rotation produces a better passing outcome than 90 degrees in Wheels 1 and 2. However, Wheel 3 showed no percentage difference between both degrees.

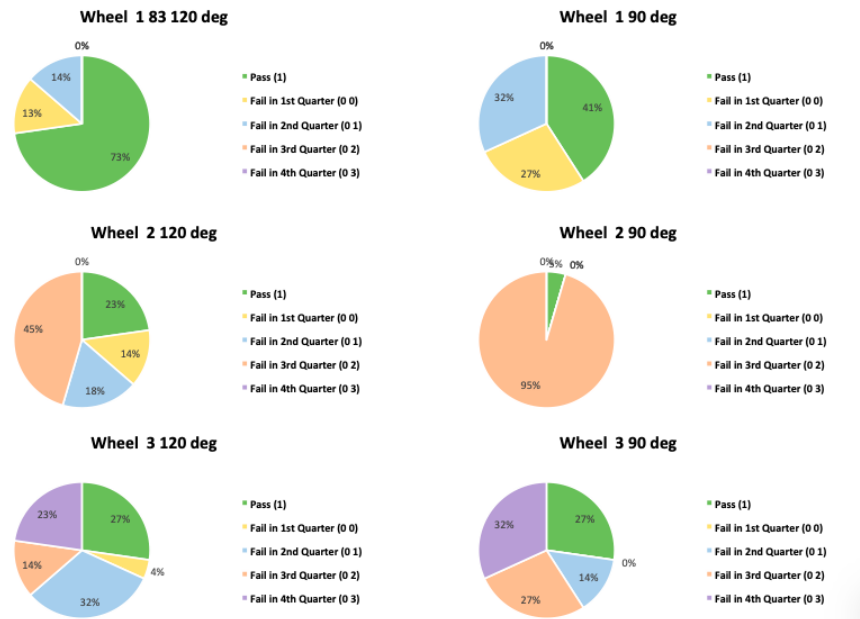


Figure #63: Percentage of Passing and Failures for 120 and 90 degrees of rotation in all wheels.

The raw data for Test I is included in the Appendix Section of this report. Overall, the configuration that improves the chances of the vials being dispensed and rolling into the next mechanism successfully is: Counterclockwise, 83 steps/ms and 120 deg. However, the success rate is not 100%. Which means that there is opportunity for re-designing and improving the dispensing mechanism of the Blood Vial Handling Subsystem.

The team decided to re-configure the ramp and evaluate if it improved the system's repeatability. Test II evaluated if the design changes significantly impacted the results. The figure below shows that the results for the new ramp design were significantly more successful than the old ramp. In all three wheels, the dispensing and rolling mechanism had a success rate of over 75%. The raw data for Test II is included in the Appendix Section.

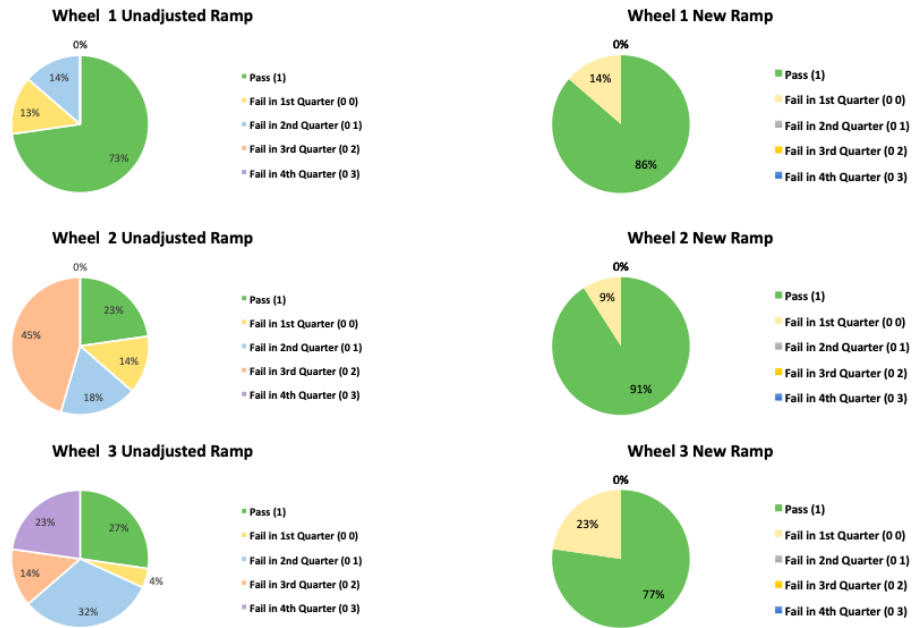


Figure #64: Percentage of Passing and Failures for Old and New Ramp in all wheels.

The results for Test III show that the height where the Cognex Camera is position, slightly affects the camera's ability to successfully read barcodes. Comparing the two heights studied, they both show promising repeatability results. However, at five inches the camera achieved 100% functionality over the samples tested. Therefore, this height was selected for the final design. The raw data for Test III is included in the Appendix Section of this report.

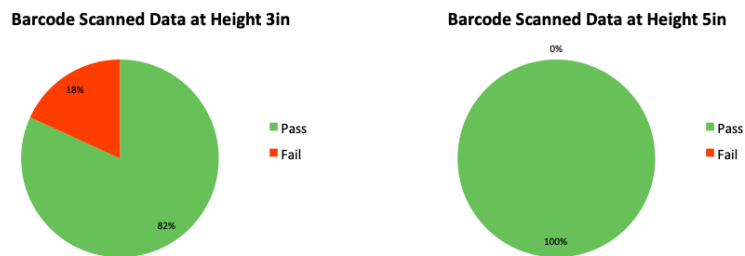


Figure #65: Percentage of Passing and Failures for Different Camera Heights.

Chapter 6

Design Validation

This chapter details the final performance and project impact of PhleAid™ with the integration of the four subsystems and if we met the set guidelines based on the literature review. Additionally, the limitation the faced with the design are explain and the necessary recommendation to improve the overall performance of PhleAid™.

6.1 PhleAid™ Final Performance

As stated in Chapter 3, the overall goal of our project is to develop a robot that simplifies and supports the phlebotomy process as well as minimizes pre-analytical laboratory errors. Therefore, the team created the four subsystems to reduce the following pre-analytical errors:

- Inappropriate vacutainer selection.
- Vacutainer improperly labelled or mislabeled.
- Insufficient sample volume.
- Inadequate sample due to clotting, hemolysis and lipemia.

The Design Requirements that were defined in Chapter 3 aim to minimize each of these errors specifically. To do so, four subsystems were created; each with their own system requirements. The table below outlines how the completion of each system requirements satisfies the design requirements and overall goal of the project.

Table 8: PhleAid Performance - Design and System Requirements

| SubSystem | Design Requirements | System Requirements | Initially Met? |
|--------------------------------|---|--|----------------|
| Blood Vial Selection | Select appropriate vials for indicated test | Receive patient name as input | Y |
| | | Extract Patient information and correlate tests needed to what vials should be dispensed | Y |
| | | Determine appropriate dispensing order | Y |
| | | Assist in patient screening process before phlebotomy | Y |
| Blood Vial Handling | Minimize user's contact with blood vial | Store vials independently and dispense when needed. | Y |
| | Invert blood vial after specimen collection | Move vial into position for labeling and blood collection | N |
| | | Hold vial steadily for blood collection | Y |
| | | Invert vial appropriate amount of times after collection | Y |
| | | Easily remove vials when procedure is complete | Y |
| Blood Vial Labeling | Links each blood vial with the patient's file/information | Scan and register barcode on blood vial | Y |
| Blood Vial Volume Verification | Verify Blood Volume | Measure blood volume collected | Y |
| | | Alert phlebotomist when blood vial is fully filled. | Y |

With the Blood Vial Selection Subsystem, the robot successfully selects the appropriate blood vial required for each test of the patient. The use of a GUI guarantees that the only mistake that can occur when selecting the vials is if the phlebotomist types in the wrong name or misspells the patient's name. Next, the use of the Cognex scanner ensures that the vials are always properly labeled. All the blood vials are pre-barcode; therefore, the scanner reads the barcode and the software matches that number to the patient's information. Based on the data from Test II, all vials that rolled down the ramp at five inches from the camera were scanned by the Cognex camera. For the actual

blood drawing phase, the Blood Vial Verification Subsystem guarantees that all samples contain the necessary amount of blood with the use of the photodiodes as a detection mechanism. Additionally, once the blood volume is reached, the phlebotomist is alerted with an alarm. Finally, since the blood vials are always inverted the correct amount of times, the Blood Vial Handling system should minimize clotting.

As mentioned in the chapter 2, there are multiple technologies that assist the labeling and the blood vial handling issues, but none of them are able to assist the whole phlebotomy process as PhleAid™ does. Comparing our device to previous art, including both the GTN5 and Protube Suite have a great system for the blood vial labeling and selection, but they are lacking a verification and handling system. Since the vials need to be manipulated, their handling system is not as effective as PhleAid's Blood Vial Handling Subsystem. Furthermore, the labeling technologies have more advanced techniques and processes, but these technologies are just used for blood vial labeling. The PillPick handling product has multiple sophisticated features to label and handle blood vials, however it does not have a verification and selection system and other limitations as explained in Chapter 2. PhleAid™ is capable of integrating all of these subsystems that successfully minimize pre-analytical laboratory errors; which makes this technology truly innovative.

6.2 Limitations

Every new technology has certain limitations that can affect the functionality of the product. Due to time and budget constraints, the team decided to list several limitations each PhleAid™ Subsystem has. These limitations should be addressed in order to assemble a more reliable PhleAid™. The limitations for each subsystem are the following:

- **Blood Vial Selection Subsystem**

Currently, the system does not have the capability to check the number of vials inside each dispenser. This eventually can lead into errors along the phlebotomy process. For example, if a patient requires three vials and one of the dispensers is empty, the system is going to wait until the vial is released. Therefore, the phlebotomy process is going to last more time.

- **Blood Vial Handling Subsystem**

This subsystem has limitations in regards with the dispensers, ramp, 2nd flipper mechanism and motors:

- The dispensers' main issue is the process of stocking them. The vials are dropped from the top part of the dispenser and land on the inside part of the wheel. If the vial is not dropped correctly, there is a possibility that the vials' rubber lid touches the inner walls of the dispenser and then gets stuck or changes position due to friction with the wall.
- The ramps main issue is that when the vials are dispensed. When the rubber lid lands on the ramp, it causes the blood vial to bounce and immediately gets stuck with the next wheel. This does not apply for the first wheel (Figure #) because the vials just simply roll into the first flipper mechanism. Additionally, this can affect the labeling subsystem because the vials need to roll down the ramp perfectly in order to be scan by the Cognex camera.
- With the current design, the 2nd flipper mechanism can only fit four vials at a time.
- The stepper motors are very usual for PhleAid because the number of steps and the direction of rotation can be programmed to our convenience. However, this motor still has issues that affect this subsystem. The motors have to be manually placed to the starting position (with the hole of the wheel pointing upward). Therefore, if the motors' motion is interfered, there is no way for the motor to return to its default position.

- **Blood Vial Labeling Subsystem**

The main issue with this subsystem is that the vials need to be pre-barcode by hand, so this process can be very tedious for phlebotomists. Moreover, if vial does not roll down perfectly down the ramp, the camera will not scan the vial.

- **Blood Vial Volume Verification Subsystem**

This system has two main limitations that affect its performance. Due to the way the PCB was designed, the maximum baud rate the serial communication between the ATmega328 microcontroller, and the Raspberry Pi has to 9600 bits per second. It affects how quickly the ATmega328 microcontroller sends the photodiode output voltages to the Raspberry Pi. The second issue is that the bottom two photodiodes are interfered with the 1st flipper mechanism base. However, since it is ideal that the vial is completely filled with blood, the top three photodiodes are going to be extended from the PCB. With this modification, the photodiode can reach the maximum volume of the vial.

6.3 Recommendations

Based on the limitations of each subsystem discussed in the previous section, the team decided on a set of recommendations to improve the overall performance of PhleAid™, so it can optimally minimize pre analytical errors. The recommendations for each subsystem are the following:

- **Blood Vial Selection Subsystem**

- Incorporate current lab management software and patient databases such as LabCollector LIMS [53] and ProLis [54], instead of using a mock patient database that is limited to five tests per blood vial.
- Incorporate a touch screen to PhleAid™ to display the GUI, instead of using monitor since the monitor is more complicated to carry and to move around. Additionally, there is a chance that phlebotomists do not have a monitor at their disposition, generating more problems for them.
- Incorporate a sensor in order to detect if there are vials inside the dispensers, so the system can alert the phlebotomist if the dispenser is empty.
- Change to GUI library to enhance the GUI functionality.

- **Blood Vial Handling Subsystem**

- Integrate an additional stepper motor and a conveyor belt to create a more reliable way to dispense the vials without them depending on rolling perfectly into the 1st flipping mechanism. Instead, the vials would be dispensed on the conveyer belt and it would drop them inside the 1st flipping mechanism.
- Redesign the dispensers, so it is easier to place vials, to hold more vials and to remove vials if they get stuck inside the dispenser.
- Include an additional sensor to create a starting default position for the stepper motors, so they can return to this position even if the vials interfere with the motion of the motors.
- Readjust the 1st flipping mechanism so all of the photodiodes can detect a change in voltage due to the blood vial being filled with blood.

- Redesign the main motor PCB (Figure #), so the Raspberry Pi header matches the correct pins of the Raspberry Pi. Some connections were routed to incorrect positions such as tracing the buzzer signal to pin 8 (Figure #), which it suppose to be the Tx/D UART serial pin. This was manually fixed by switching the cables of the rainbow cable to match the Raspberry Pi pins (see Appendix ...).
- **Blood Vial Labeling Subsystem**
 - Integrate an automatic labeling solution that can print and place the labels on the vials instead of doing the process by hand, so it is faster and more automated.
- **Blood Vial Verification Subsystem**
 - The optical sensor PCB board needs to be redesigned to increase the baud rate for the serial communications. Some changes that should be done are creating a ground and a power planes to eliminate unnecessary traces on the top and bottom layer and making the traces of the board more symmetric.
 - Adding some type of filter so the photodiodes do not detect the ambient light. This can significantly aid the output voltage change detection once blood vials are in the process of being filled.

6.4 Project Impact

Economic Impact

Currently, there is no other phlebotomy assistive device on the market that selects, handles, labels and verify patient's blood sample vials. As a prototype we can only calculate its value based on our bill of materials, it equals to \$1143.04. The detailed Bill of Materials is included in the Appendix Section. However, if introduced into production PhleAid™ would have a lower bill of material price.

On another note, PhleAid™ will potentially save money for hospitals, medical laboratories, and even patients. Since errors in the phlebotomy process call for repeated tests, an extra cost is created for all participants. Lawsuits can also be filed against institutions who misdiagnose patients due to incorrect laboratory results. This could cost institutions thousands of dollars. An automated process with minimal errors can positively impact the economic burden for all the parties involved. Another recurrent issue in medical laboratories are incomplete testing session that usually require revisits. This issue can also have an economic impact on the patients who have to pay out of pocket for a second transportation as well as for the laboratory who has to use a second set of materials for

the blood tests. In Conclusion by minimizing errors this device can also minimize costs for parties involved.

Environmental Impact

The team anticipates that PhleAid™ will not have a negative impact on the environment. This depends largely in the way the device is powered. PhleAid™ runs on a wall plug, therefore, there are no batteries that can be harmful to the environment when disposed. Many of the parts in our device can be reused and last up to various years. For the mechanical structure, the steel rods can be melted and reused. The acrylic can be transformed or cut into other pieces for different purposes. If the device were to be manufactured and sold, a large component would be to make sure this device were to last up to 20 years or more.

Societal Influence

Every year, 2,000,000 patients are negatively impacted by preanalytical errors[27]. Like many other automated solutions the world has created, this one, designed specifically for phlebotomy, aims to reduce errors throughout this procedure. A device like PhleAid™ allows laboratories around the world to cut costs, eliminate the possibility of lawsuits, and have better results. Our device can have a strong impact not only in the laboratory industry but also on society diminishing the amount of times a patient has to get blood drawn or is misdiagnosed. It can also alleviate the burden that phlebotomist face when dealing with difficult patients like children or elderly since the automation allows for them to focus completely on inserting the needle into the patient. The purpose of this device is to create an overall better experience for society when getting blood drawn.

Ethics

After conducting interviews with different phlebotomists the team realized there was the possibility close of a major ethical concern. Once we presented our device to phlebotomist at different laboratories, we realized that they felt undermined by our idea. Their belief was that our device would eliminate their jobs, just one more automated product that ended someone's career. However, after explaining the purpose of our device which was that it is not going to take over their job but rather be of great assistance, they felt more receptive to PhleAid™. The team realized it was important to present PhleAid™ as a robotic phlebotomist assistance that will help reduce human errors, but just like many other robots, a human is needed to be present and deal with the important medical aspect like needle puncturing. It is important to keep in mind that our robot was created to

help reduce errors in the preanalytical process, whereas a human phlebotomist is still needed to insert the needle into the patient.

Another ethical concern through the verification process of this project was testing with blood. Since we did not want to violate ethical values we decided to use fish blood which we obtained from a fresh catch at our local fish market. Some blood was used to make sure that our blood verification subsystem would function correctly with real blood. Our test were successful and we did not need to obtain human blood since fish blood is very similar.

Health and Safety Concerns

The purpose of this device is to reduce human error and assist phlebotomists. Furthermore, it has to be very precise in order to accomplish that goal. Since it involves human blood it is very important to address health and safety concerns. All vials should be ordered directly from a verified vacutainer supplier. Phlebotomists should begin the process using sterilized gloves. When puncturing the patient's vein, they should follow the proper guidelines for phlebotomy.

Our robot minimizes the contact with blood by allowing the phlebotomist to draw it, however, the phlebotomist needs to insert the other side of the butterfly needle into our device to begin filling the vial. For this part of the procedure it is very important to be cautious since having blood drop on the device would completely be unsanitary and affect final results. One solution to this could be to add disposable parts to be placed in the subsystem that holds the vial for filling. Another can be to be very careful when inserting the needle through the subsystem and cleaning the subsystem later with a disinfecting wipe. If this device were to be manufactured as a closed system, cleanability is an important aspect to consider since it can be a serious hazard. This is a major concern for the procedure but could be avoided with careful handling.

Manufacturability

PhleAid™ can be manufactured at large scale and sold by changing the material selection and sourcing new components to minimize production costs. The current selection of materials include mostly plastics, acrylic and PLA, held together by a network of aluminum extrusions. Acrylic was used for PhleAid's walls because it is a sturdy material and its transparency allowed the team to observe the motion of the vials during the testing phases of the project. However, the acrylic we used is expensive compared to other types of clear plastics in the market. A cheaper, less stiff type of transparent injection molded plastic would make PhleAid™ easier to manufacture because it brings the total cost down and the plastic would still be held together by the aluminum outer structure. Also, the acrylic walls could be substituted by adding more aluminum extrusions to hold the vial dispensers and motors in the robot.

Injection molded plastic could also potentially replace the 3D printed parts in PhleAid™. 3D printing takes a long time and fails often, making it an unreliable process during manufacturing. On

the other hand, plastic injection molding is a common procedure and many modern products that include plastic parts are made using this technique.

If this product was taken to market, the team would have to decide if keeping the Cognex camera or developing one would be the best option. The Cognex camera adds a higher costs to the overall price of the project but it is highly compatible and adequate for a top quality device like PhleAid™. If one were to be developed in the future, it would have to have the same capacities as the Cognex Dataman 50 camera.

Chapter 7

Conclusion

The objective of PhleAid is to assist phlebotomists by properly selecting, labeling, handling and verifying vials throughout the blood collection process. To do so, the team designed an automated device that achieves these objectives while reducing human error. During the design process, the device was divided into four main subsystems, each having their own series of mechanical and electrical components that assist the motion of the vials to the next mechanism.

PhleAid implements a combination of four subsystems: a vial selection system, a vial handling, a labeling system and a blood volume verification system. The vial selection system chooses the appropriate vial for each test through a graphical input and decision-making system that utilizes a microprocessor and test database. The vial handling minimizes user contact with the blood specimen by implementing our designed hardware and stepper motors. The labeling system consists of a barcode scanner that is used to identify each blood vial and system records the barcode value in the database. Finally, the blood volume system utilizes a series of photodiodes, LED lights and amplifiers to detect the level of blood inside the vial. This system ensures that the volume of blood obtained is sufficient for testing.

Overall, each subsystem met the design requirements and achieved the intended function. However, the Blood Vial Handling Subsystem showed problems with dispensing and rolling the vial for collection. A series of tests were performed to better understand the present issues and determine the most efficient way to improve the functionality problem. No test yielded a 100% success rate, but the team managed to make improvements to various parts of the device to increase the success rate. Due to time and budget constraints, the team could not address every problem PhleAid had, but suggested various solutions to these problems. The main recommendation was to assist the motion of the vials with electronic components to improve success rate, since the rubber lid produces interference with the vial motion. A more successful PhleAid should be a minimal error automated assistive device to support and simplify the phlebotomy process.

Appendix

Appendix A: PCB Schematics

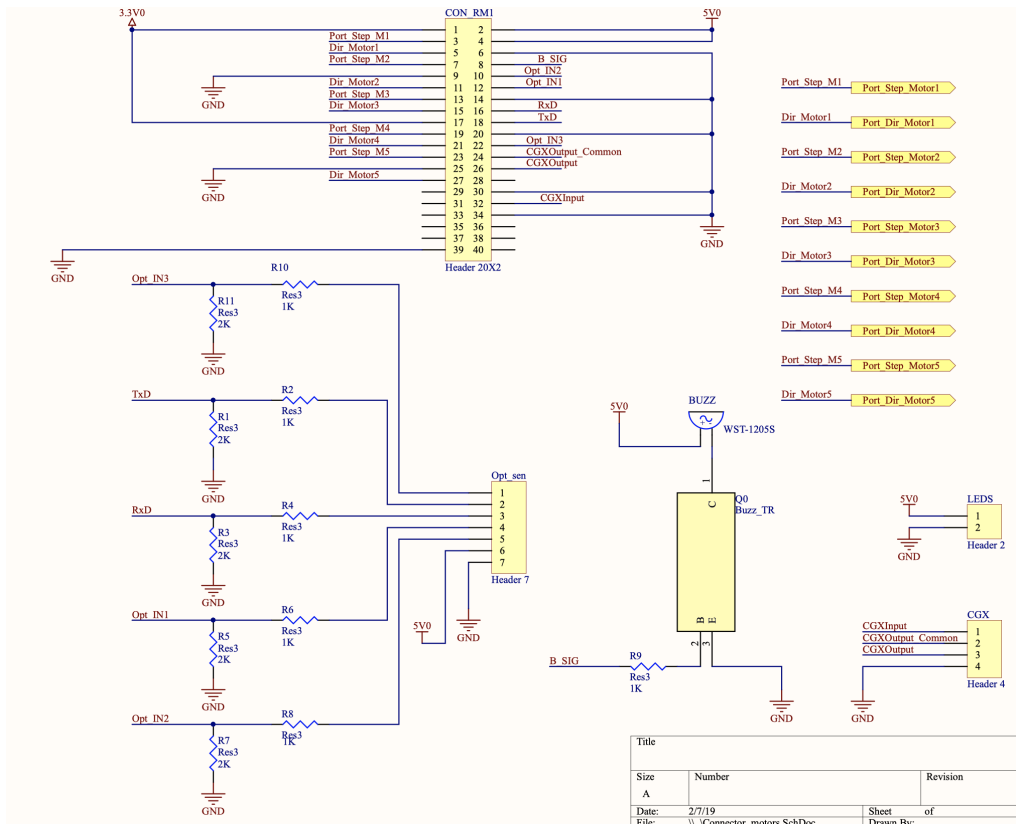


Figure 66: Main PCB Schematic

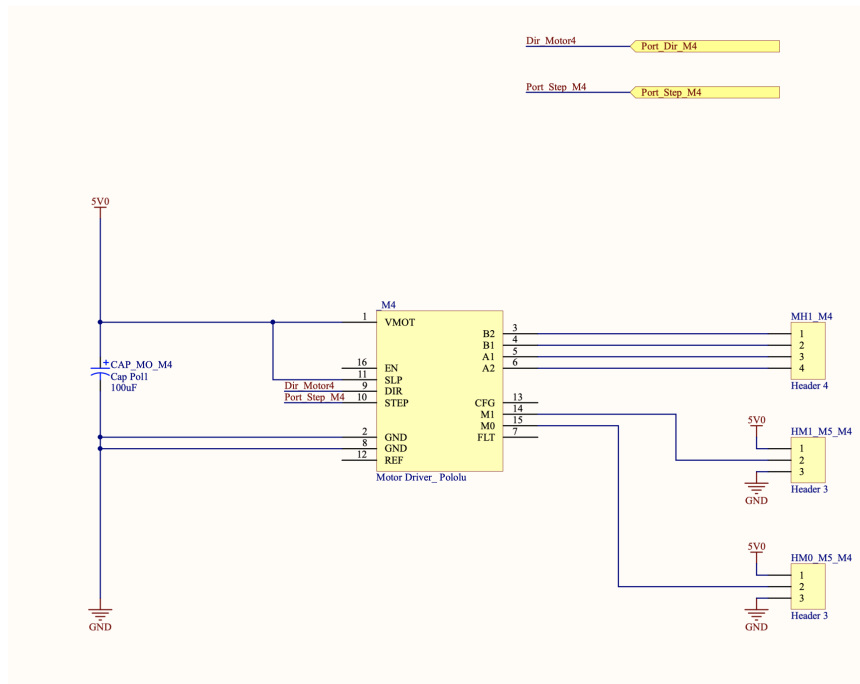


Figure 67: Stepper Motor Driver Schematic

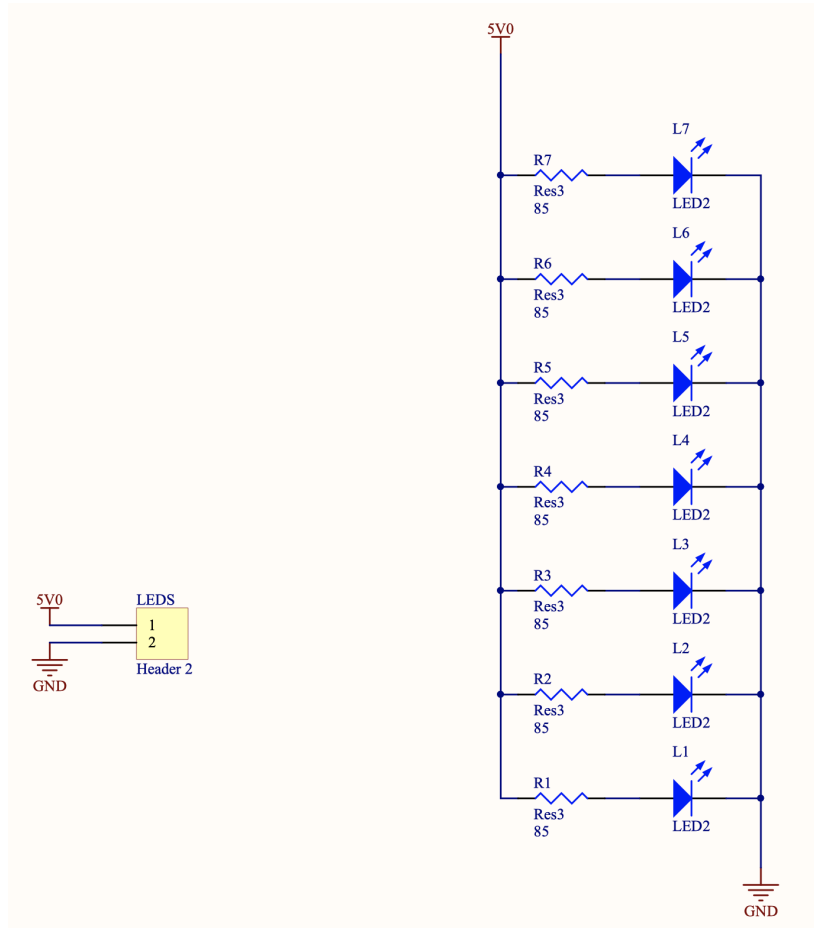


Figure 68: LED PCB Schematic

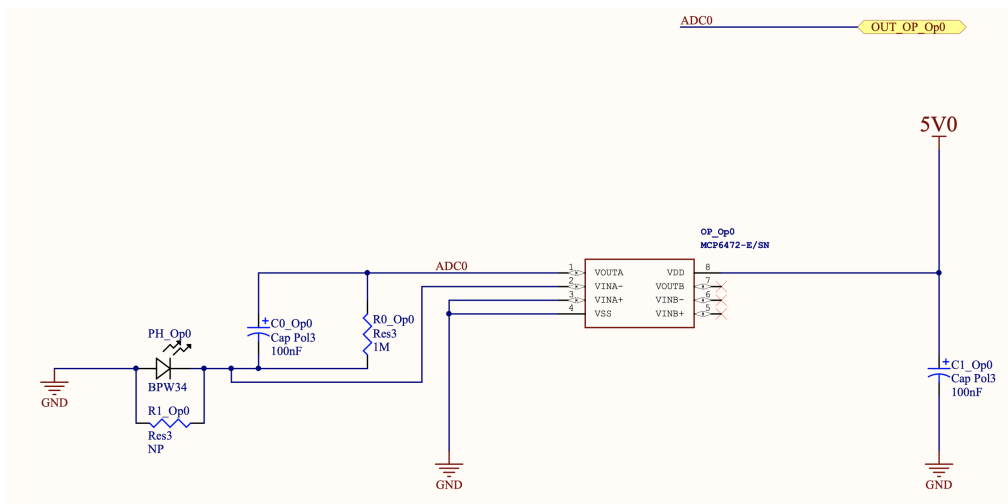


Figure 69: Photodiode Zero Biased Operational Amplifier Circuit PCB Schematic

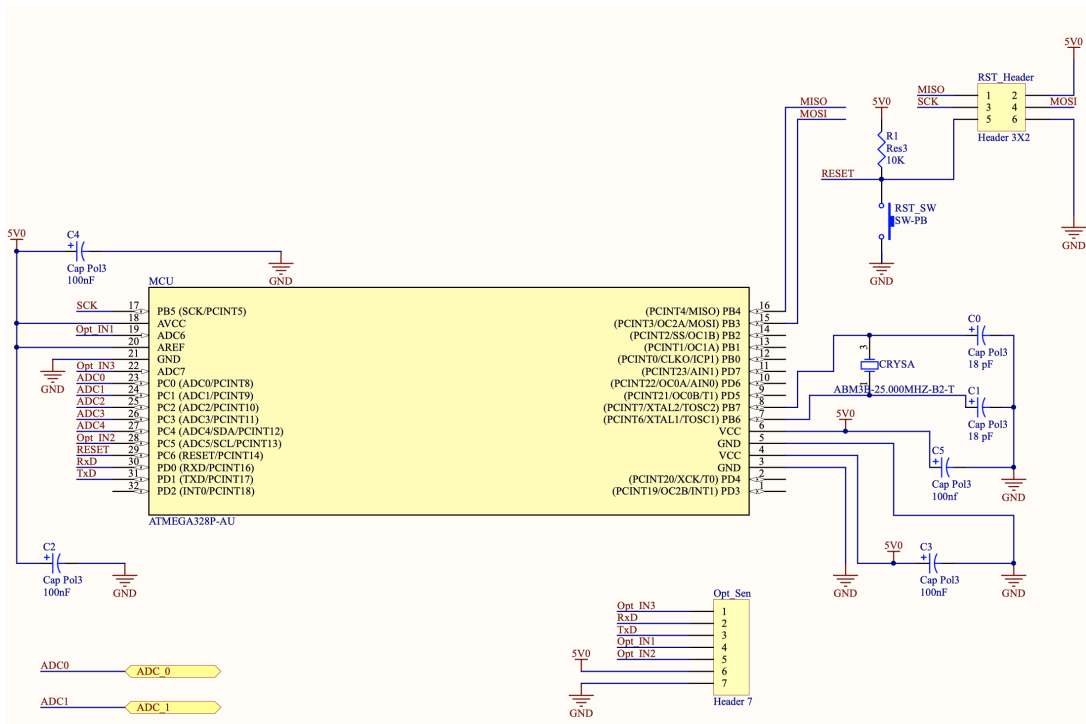


Figure 70: Microcontroller PCB Schematic

Appendix B: Testing Raw Data

Table #9: Results observed when dispensing three wheels ClockWise and CounterClockWise

| Sample | Wheel 1 | | Wheel 2 | | Wheel 3 | |
|--------|--------------|----------------|--------------|----------------|--------------|----------------|
| | Forward (CW) | Backward (CCW) | Forward (CW) | Backward (CCW) | Forward (CW) | Backward (CCW) |
| 1 | 0 (0) | 0 (1) | 0 (1) | 0 (2) | 0 (1) | 1 |
| 2 | 0 (0) | 1 | 0 (1) | 1 | 0 (0) | 0 (2) |
| 3 | 0 (0) | 0 (1) | 0 (0) | 0 (2) | 0 (3) | 0 (1) |
| 4 | 0 (0) | 0 (1) | 0(1) | 0 (2) | 0 (1) | 0 (3) |
| 5 | 1 | 1 | 0 (1) | 1 | 0 (0) | 1 |
| 6 | 0 (0) | 0 (1) | 0(1) | 0 (2) | 0 (2) | 0 (2) |
| 7 | 0 (0) | 0 (0) | 0 (1) | 0 (2) | 0 (1) | 0 (3) |
| 8 | 0 (0) | 0 (0) | 0 (1) | 1 | 0(2) | 0 (3) |
| 9 | 0 (0) | 1 | 0 (1) | 1 | 0 (0) | 0 (3) |
| 10 | 0 (0) | 0 (1) | 0 (1) | 0 (2) | 1 | 0 (3) |
| 11 | 0 (0) | 1 | 0 (0) | 0 (0) | 0 (2) | 0 (3) |
| 12 | 0 (0) | 1 | 1 | 0(2) | 0 (0) | 1 |
| 13 | 0 (0) | 1 | 0 (1) | 0(2) | 0 (3) | 0 (3) |
| 14 | 0 (0) | 0 (1) | 0 (1) | 0 (2) | 0 (0) | 0 (3) |
| 15 | 0 (0) | 0 (1) | 0 (1) | 0 (2) | 0 (1) | 0 (3) |
| 16 | 0 (0) | 1 | 0 (1) | 1 | 0 (1) | 0 (3) |
| 17 | 0 (0) | 0 (0) | 0 (1) | 0 (0) | 0 (0) | 0 (0) |
| 18 | 0 (0) | 1 | 0 (1) | 0(2) | 0 (0) | 0 (3) |
| 19 | 0 (0) | 0 (1) | 1 | 0(2) | 0 (2) | 0 (3) |
| 20 | 1 | 1 | 0 (1) | 0 (0) | 0 (2) | 0 (1) |
| 21 | 0 (0) | 0 (0) | 0 (1) | 0(2) | 0 (2) | 0 (3) |
| 22 | 0 (0) | 0 (1) | 0 (1) | 0 (0) | 0 (2) | 0 (3) |

Table #10: Results observed when dispensing three wheels 83 and 74 [steps/ms]

| Sample | Wheel 1 | | Wheel 2 | | Wheel 3 | |
|--------|-------------|-------------|-------------|-------------|-------------|-------------|
| | 74 steps/ms | 83 steps/ms | 74 steps/ms | 83 steps/ms | 74 steps/ms | 83 steps/ms |
| 1 | 0 (1) | 0 (0) | 0 (2) | 0 (2) | 1 | 0 (1) |
| 2 | 1 | 1 | 1 | 0 (0) | 0 (2) | 0 (2) |
| 3 | 0 (1) | 1 | 0 (2) | 0 (0) | 0 (1) | 0 (1) |
| 4 | 0 (1) | 1 | 0 (2) | 0 (2) | 0 (3) | 1 |
| 5 | 1 | 1 | 1 | 0 (0) | 1 | 0 (2) |
| 6 | 0 (1) | 1 | 0 (2) | 0 (1) | 0 (2) | 0 (0) |
| 7 | 0 (0) | 0 (1) | 0 (2) | 1 | 0 (3) | 0 (1) |
| 8 | 0 (0) | 1 | 1 | 0 (1) | 0 (3) | 0 (1) |
| 9 | 1 | 1 | 1 | 1 | 0 (3) | 0 (1) |
| 10 | 0 (1) | 0 (0) | 0 (2) | 1 | 0 (3) | 0 (3) |
| 11 | 1 | 1 | 0 (0) | 0 (2) | 0 (3) | 0 (2) |
| 12 | 1 | 1 | 0(2) | 0 (2) | 1 | 1 |
| 13 | 1 | 0 (0) | 0(2) | 0 (2) | 0 (3) | 0 (3) |
| 14 | 0 (1) | 0 (1) | 0 (2) | 0 (2) | 0 (3) | 0 (3) |
| 15 | 0 (1) | 1 | 0 (2) | 0 (2) | 0 (3) | 1 |
| 16 | 1 | 1 | 1 | 0 (2) | 0 (3) | 1 |
| 17 | 0 (0) | 1 | 0 (0) | 0 (1) | 0 (0) | 1 |
| 18 | 1 | 0 (1) | 0(2) | 1 | 0 (3) | 0 (1) |
| 19 | 0 (1) | 1 | 0(2) | 0 (2) | 0 (3) | 0 (3) |
| 20 | 1 | 1 | 0 (0) | 0 (2) | 0 (1) | 0 (3) |
| 21 | 0 (0) | 1 | 0(2) | 0 (1) | 0 (3) | 0 (1) |
| 22 | 0 (1) | 1 | 0 (0) | 1 | 0 (3) | 1 |

Table #11: Results observed when dispensing three wheels 120 and 90 degrees of rotation

| Sample | Wheel 1 | | Wheel 2 | | Wheel 3 | |
|--------|---------|--------|---------|--------|---------|--------|
| | 120 deg | 90 deg | 120 deg | 90 deg | 120 deg | 90 deg |
| 1 | 0 (0) | 0 (0) | 0 (2) | 0 (2) | 0 (1) | 1 |
| 2 | 1 | 1 | 0 (0) | 0 (2) | 0 (2) | 1 |
| 3 | 1 | 0 (1) | 0 (0) | 0 (2) | 0 (1) | 0 (1) |
| 4 | 1 | 0 (0) | 0 (2) | 0 (2) | 1 | 0 (2) |
| 5 | 1 | 1 | 0 (0) | 0 (2) | 0 (2) | 0 (1) |
| 6 | 1 | 0 (1) | 0 (1) | 0 (2) | 0 (0) | 1 |
| 7 | 0 (1) | 0 (1) | 1 | 0 (2) | 0 (1) | 0 (3) |
| 8 | 1 | 1 | 0 (1) | 0 (2) | 0 (1) | 0 (2) |
| 9 | 1 | 1 | 1 | 0 (2) | 0 (1) | 0 (2) |
| 10 | 0 (0) | 0 (0) | 1 | 0 (2) | 0 (3) | 0 (1) |
| 11 | 1 | 0 (0) | 0 (2) | 0 (2) | 0 (2) | 1 |
| 12 | 1 | 0 (1) | 0 (2) | 0 (2) | 1 | 0 (2) |
| 13 | 0 (0) | 0 (1) | 0 (2) | 0 (2) | 0 (3) | 0 (2) |
| 14 | 0 (1) | 0 (0) | 0 (2) | 0 (2) | 0 (3) | 0 (2) |
| 15 | 1 | 1 | 0 (2) | 0 (2) | 1 | 0 (3) |
| 16 | 1 | 1 | 0 (2) | 0 (2) | 1 | 1 |
| 17 | 1 | 1 | 0 (1) | 0 (2) | 1 | 0 (3) |
| 18 | 0 (1) | 0 (1) | 1 | 1 | 0 (1) | 0 (3) |
| 19 | 1 | 0 (1) | 0 (2) | 0 (2) | 0 (3) | 1 |
| 20 | 1 | 1 | 0 (2) | 0 (2) | 0 (3) | 0 (3) |
| 21 | 1 | 1 | 0 (1) | 0 (2) | 0 (1) | 0 (3) |
| 22 | 1 | 0 (0) | 1 | 0 (2) | 1 | 0 (3) |

Table #12: Results observed when dispensing the vials onto the old and new ramp design.

| Sample | Wheel 1 (Dir 15 Step 13) | | Wheel 2 (Dir 11 Step 7) | | Wheel 3 (Dir 5 Step 3) | |
|--------|--------------------------|----------|-------------------------|----------|------------------------|----------|
| | Unadjusted Ramp | New Ramp | Unadjusted Ramp | New Ramp | Unadjusted Ramp | New Ramp |
| 1 | 0 (0) | 1 | 0 (2) | 1 | 0 (1) | 1 |
| 2 | 1 | 1 | 0 (0) | 1 | 0 (2) | 1 |
| 3 | 1 | 1 | 0 (0) | 1 | 0 (1) | 1 |
| 4 | 1 | 1 | 0 (2) | 1 | 1 | 1 |
| 5 | 1 | 1 | 0 (0) | 1 | 0 (2) | 0 (0) |
| 6 | 1 | 1 | 0 (1) | 1 | 0 (0) | 1 |
| 7 | 0 (1) | 0 (0) | 1 | 1 | 0 (1) | 1 |
| 8 | 1 | 1 | 0 (1) | 1 | 0 (1) | 0 (0) |
| 9 | 1 | 1 | 1 | 1 | 0 (1) | 0 (0) |
| 10 | 0 (0) | 0 (0) | 1 | 1 | 0 (3) | 1 |
| 11 | 1 | 1 | 0 (2) | 1 | 0 (2) | 1 |
| 12 | 1 | 1 | 0 (2) | 0 (0) | 1 | 1 |
| 13 | 0 (0) | 1 | 0 (2) | 1 | 0 (3) | 1 |
| 14 | 0 (1) | 1 | 0 (2) | 1 | 0 (3) | 1 |
| 15 | 1 | 1 | 0 (2) | 1 | 1 | 1 |
| 16 | 1 | 0 (0) | 0 (2) | 1 | 1 | 1 |
| 17 | 1 | 1 | 0 (1) | 0 (0) | 1 | 1 |
| 18 | 0 (1) | 1 | 1 | 1 | 0 (1) | 1 |
| 19 | 1 | 1 | 0 (2) | 1 | 0 (3) | 1 |
| 20 | 1 | 1 | 0 (2) | 1 | 0 (3) | 0 (0) |
| 21 | 1 | 1 | 0 (1) | 1 | 0 (1) | 0 (0) |
| 22 | 1 | 1 | 1 | 1 | 1 | 1 |

Table #13: Percentage of Passing and Failures for Camera Height of 3in and 5in.

| Sample | Height 1 (3 in) | Height 2 (5 in) |
|--------|-----------------|-----------------|
| 1 | Y | Y |
| 2 | Y | Y |
| 3 | Y | Y |
| 4 | Y | Y |
| 5 | Y | Y |
| 6 | Y | Y |
| 7 | N | Y |
| 8 | Y | Y |
| 9 | Y | Y |
| 10 | Y | Y |
| 11 | Y | Y |
| 12 | Y | Y |
| 13 | N | Y |
| 14 | Y | Y |
| 15 | Y | Y |
| 16 | N | Y |
| 17 | Y | Y |
| 18 | Y | Y |
| 19 | Y | Y |
| 20 | N | Y |
| 21 | Y | Y |
| 22 | Y | Y |

Appendix C: Bill of Materials

Table #14: Mechanical Bill of Materials

| Mechanical Bill Of Materials | | | | | |
|------------------------------------|------------|--------------|----------|------------|------------------|
| Material | Unit Price | | Quantity | | Total Price |
| Vial Dispenser SubAssembly | | | | | |
| New Wall Motor Side | 0.0001126 | \$/mm^2 | 160,000 | mm^2 | 18.016 |
| New Wall Bearing Side | 0.0001126 | \$/mm^2 | 160,000 | mm^2 | 18.016 |
| Top of ramp | 0.0001126 | \$/mm^2 | 39280 | mm^2 | 4.422928 |
| Bottom of ramp | 0.0001126 | \$/mm^2 | 29040 | mm^2 | 3.269904 |
| Backboard (6) | 0.0001126 | \$/mm^2 | 117840 | mm^2 | 13.268784 |
| Short Acrylic (6) | 0.0001126 | \$/mm^2 | 88320 | mm^2 | 9.944832 |
| M2 screws | 0.2272 | \$/screw | 30 | screws | 6.816 |
| Nuts for M2 | 0.039 | \$/nut | 6 | nuts | 0.234 |
| Motor Mount (3) | 0.0001126 | \$/mm^2 | 1600 | mm^2 | 0.18016 |
| Wheel (3) | 0.01919 | \$/g | 27.87 | cm^3 | 0.668531625 |
| Wheel Shaft (3) | 0.001624 | \$/mm | 360 | mm | 0.584645669 |
| Adapter for shaft (3) | 10.27 | \$/ft | 45 | mm | 0.252706693 |
| 4/40 set screws (6) | 0.627 | \$/screw | 6 | screws | 3.762 |
| Flanged Bearing | 2.62 | \$/bearing | 3 | bearings | 7.86 |
| First Inverting SubAssembly | | | | | |
| 3.0 Side Wall | 0.0001126 | \$/mm^2 | 50662 | mm^2 | 5.7045412 |
| Vial Holding Arc | 0.01919 | \$/g | 14.63 | cm^3 | 0.359937125 |
| Large plastic spacers for arc | 0.1025 | \$/in | 6 | in | 0.615 |
| 8/32"x1" screw | 0.1602 | \$/screw | 6 | screws | 0.9612 |
| Inverting Hold | 0.01919 | \$/g | 3.01 | cm^3 | 0.0577619 |
| M2.5 Screws | 0.161 | \$/screw | 4 | screws | 0.644 |
| Support for big motor (2) | 0.0001126 | \$/mm^2 | 3136 | mm^2 | 0.3531136 |
| Big Motor base support | 0.0001126 | \$/mm^2 | 1097.6 | mm^2 | 0.12358976 |
| Adapter | 10.27 | \$/ft | 30 | mm | 0.168471129 |
| Aluminum Bar | 5.67 | \$/ft | 25 | mm | 0.077509843 |
| Motor shaft adapter | 0.0562 | \$/adapter | 1 | adapters | 0.0562 |
| 4/40 set screws | 0.627 | \$/screw | 3 | screws | 1.881 |
| M2 screws | 0.2272 | \$/screw | 3 | screws | 0.6816 |
| Heat inserts (3) | 0.1726 | \$/insert | 3 | inserts | 0.5178 |
| Camera Mount SubAssembly | | | | | |
| Camera Mount | 0.0001126 | \$/mm^2 | 3928 | mm^2 | 0.4422928 |
| M3-3.5 Screws | 1.88 | \$/screw | 2 | screws | 3.76 |
| Final Inverting SubAssembly | | | | | |
| M2.5 Screws | 0.161 | \$/screw | 4 | screws | 0.644 |
| Motor Holder | 0.0001126 | \$/mm^2 | 7750 | mm^2 | 0.87265 |
| Motor Holder Simple | 0.0001126 | \$/mm^2 | 7750 | mm^2 | 0.87265 |
| Support for big motor (2) | 0.0001126 | \$/mm^2 | 3136 | mm^2 | 0.3531136 |
| Motor Shaft Adapter | 0.0562 | \$/adapter | 1 | adapters | 0.0562 |
| M2 screws (3) | 0.2272 | \$/screw | 3 | screws | 0.6816 |
| Heat Inserts (3) | 0.1726 | \$/insert | 3 | inserts | 0.5178 |
| 4/40 set screw | 0.627 | \$/screw | 1 | screw | 0.627 |
| Lower Side Wall (2) | 0.0001126 | \$/mm^2 | 32410 | mm^2 | 3.649366 |
| Large Inv Hold | 0.01919 | \$/g | 25.7 | cm^3 | 0.61647875 |
| Large Inv Hold Drawer | 0.01919 | \$/g | 10.68 | cm^3 | 0.2561865 |
| Drawer Handle | 0.01919 | \$/g | 1.06 | cm^3 | 0.02542675 |
| Framing (1" by 1") | | | | | |
| 609.8mm / 2ft Al Ext (4) | 0.022 | \$/mm | 2439.2 | mm | 53.6624 |
| 400mm Al Ex (2) | 0.022 | \$/mm | 800 | mm | 17.6 |
| 450 mm / Al Ext (3) | 0.022 | \$/mm | 1350 | mm | 29.7 |
| 187.6 mm Al Ext (1) | 0.022 | \$/mm | 187.6 | mm | 4.1272 |
| 304.8 mm /1 ft Al Ext (4) | 0.022 | \$/mm | 1219.2 | mm | 26.8224 |
| Connectors (10) | 1.79 | \$/connector | 10 | connectors | 17.9 |
| 1/4" x 20" Screws | 0.1138 | \$/screw | 12 | screws | 1.3656 |
| Total\$! | | | | | 264.04158 |

Table #15: Electrical Bill of Materials

| Electrical Bill Of Materials | | | | | |
|------------------------------|----------------------|----------------|--------|---------------|-----------------|
| Part | Manufacturer Number | Description | Amount | Unit Price | Total Price |
| LED Sensor Board | | | | | \$20 |
| LEDS | XZFBB55W-3 | | 8 | \$0.75 | \$6.00 |
| Resistor | Y162485R0000F9R | 85 Ohms | 7 | \$5.90 | \$41.30 |
| header de 2 | B2B-EH-A(LF)(SN) | connector | 1 | \$0.14 | \$0.14 |
| | EHR-2 | housing | 1 | \$0.10 | \$0.10 |
| | ASXHSXH22K305 | crimp | 2 | \$0.77 | \$1.54 |
| Optical Sensor Board | | | | | \$20 |
| Photodiode | VTB8441BH | | 5 | \$6.73 | \$33.65 |
| R0_optical SMD | RC0805FR-071ML | 1 Mohm | 5 | \$0.10 | \$0.50 |
| C0_Optical SMD | CL21F104ZBCNNNC | 100nF | 5 | \$0.10 | \$0.50 |
| C1_Optical SMD | CL10C101JB8NNNC | 100nF | 5 | \$0.10 | \$0.50 |
| Op Amp | MCP6472-E/SN | | 5 | \$0.77 | \$3.85 |
| Reset Switch | 50-0015-00 | | 1 | \$1.49 | \$1.49 |
| Reset Switch 2 | 40-2385-01 | | 1 | \$1.52 | \$1.52 |
| Reset Header | 87666-5 | 2x3 | 1 | \$0.57 | \$0.57 |
| MCU | ATMEGA328PB-AU | ATMEGA328 | 1 | \$1.38 | \$1.38 |
| Opt Sensor header | 5-102202-4 | 1x7 | 1 | \$2.70 | \$2.70 |
| header recaptacle | 103975-6 | | 1 | \$5.80 | \$5.80 |
| crimp | 87523-6 | | 7 | \$0.28 | \$1.96 |
| header recaptacle w/o crimp | 102241-5 | | 1 | \$0.81 | \$0.81 |
| C0 SMD | CC0805JRNPO9BN180 | 18 pf | 1 | \$0.14 | \$0.14 |
| C1 SMD | CC0805JRNPO9BN180 | 18 pf | 1 | \$0.14 | \$0.14 |
| C2 SMD | CL21F104ZBCNNNC | 100 nf | 1 | \$0.10 | \$0.10 |
| C3 SMD | CL21F104ZBCNNNC | 100 nf | 1 | \$0.10 | \$0.10 |
| C4 SMD | CL21F104ZBCNNNC | 100 nf | 1 | \$0.10 | \$0.10 |
| C5 SMD | CL21F104ZBCNNNC | 100 nf | 1 | \$0.10 | \$0.10 |
| R1 SMD | RMCF0805FT10K0 | 10 kOhm | 1 | \$0.10 | \$0.10 |
| Crystal | ABM3B-25.000MHZ-B2-T | | 1 | \$0.67 | \$0.67 |
| Main Board | | | | | \$33 |
| Buzzer | wst-1205S | wst-1205S | 1 | \$1.41 | \$1.41 |
| Transistor | BC550CG | BC550CG | 1 | \$0.10 | \$0.10 |
| Resistors | RNCP0805FTD1K00 | 1 Kohm | 6 | \$0.10 | \$0.60 |
| Resistors | RG2012N-202-W-T1 | 2 Kohm | 5 | \$0.10 | \$0.50 |
| Capacitor Motors | FG20X5R0J107MRT06 | 100 uF | 5 | \$0.39 | \$1.96 |
| M1/M2 3 header | B3B-XH-A(LF)(SN) | Connector at | 10 | \$0.19 | \$1.90 |
| | XHP-3 | housing | 10 | \$0.10 | \$1.00 |
| | ASXHSXH22K305 | crimp | 30 | \$0.77 | \$23.10 |
| Cognex 4 header | B4B-XH-A(LF)(SN) | Connector | 6 | \$0.21 | \$1.26 |
| y Motor header | XHP-4 | housing | 6 | \$0.10 | \$0.60 |
| | ASXHSXH22K305 | crimp | 24 | \$0.77 | \$18.48 |
| LED | B2B-EH-A(LF)(SN) | connector | 1 | \$0.14 | \$0.14 |
| header de 2 | EHR-2 | housing | 1 | \$0.10 | \$0.10 |
| | ASXHSXH22K305 | crimp | 2 | \$0.77 | \$1.54 |
| Power Source | 282836-2 | terminal block | 1 | \$0.71 | \$0.71 |
| Motor Driver | DRV8834 | | 5 | \$5.95 | \$29.75 |
| Motor NEMA 8 | | | 3 | \$15.41 | \$46.23 |
| Motor NEMA 11 | | 4.5 V | 2 | \$19.95 | \$39.90 |
| Rasberry Pi | | | 1 | \$35.00 | \$35.00 |
| Vacutainer | | box of 100 | 1 | \$30.00 | \$30.00 |
| | | | | Total: | \$383.04 |

Table #16: Final Bill of Materials

| Components | Price [\$] |
|-------------------|----------------|
| Mechanical | 264.041581 |
| Electrical | 383.04 |
| COGNEX Camera | 760 |
| Total [\$] | 1143.04 |

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