Bedside Blood Clotting Test - Final Design Report

Brandon Brozich, Yilin Fang, Eleanor Frazee, Aaron Gunn, Thomas Vincent, Zachary Wanger

December 12, 2023

Abstract

Postpartum hemorrhage (PPH), or excessive bleeding after giving birth, is the leading cause of maternal death in Ghana. Coagulopathy, the impaired ability to clot blood, increases risks associated with PPH. Our task was to develop an improved method of testing for coagulopathy at bedside. The solution must be affordable and require minimal caregiver supervision compared to the current method of visually inspecting the blood clot formation time. This new method of testing prior to birth will aid hospitals in assessing treatment methods for patients.

Bedside Blood Clotting Test - Design Review Executive Summary

Problem Motivation

Postpartum hemorrhage (PPH), or excessive bleeding after giving birth, is the leading cause of maternal death in Ghana. Coagulopathy, the impaired ability to clot blood, increases risks associated with PPH. Our task was to develop an improved method of testing for coagulopathy at bedside. The solution must be affordable and require minimal caregiver supervision compared to the current method of visually inspecting the blood clot formation time. This new method of testing prior to birth will aid hospitals in assessing treatment methods for patients.

Ghana is a low-income nation with limited resources, and Ghanaian hospital practitioners operate on restricted schedules due to short staffing. The current test performed requires hands-on analysis from a medical practitioner for the duration of an 11 minute test and tends to be inaccurate. Other existing solutions do not meet our stakeholders' needs. Our primary stakeholders include patients and patient care staff in Ghana, both of whom would benefit from an ideal solution.

Requirements & Specifications

We determined our top three critical requirements and specifications based on research, contextual factors, and stakeholder input. The solution had to be low-cost to align with the low-resource needs in Ghana, with a target material cost under $300. The solution had to be easy to use to reduce the need for supervision from practitioners during the test. The target goal for this requirement was for users to be able to complete the test with under 3 minutes of hands-on input. Lastly, the solution had to be durable. To offset the high initial cost of the device, it had to minimally last 1 year or 3650 tests.

Selected Concept

After exploring many solutions and garnering stakeholder feedback, the selected concept automates the current test performed by Ghanaian practitioners, inverting a blood vial at a specified interval and filming blood flow. Practitioners can replay the video at their convenience to determine clot formation time, reducing hands-on input and human error. This concept was intended to be easy for Ghanaian practitioners to use, low cost, and durable.

Final Design

The final design builds upon the selected concept by incorporating a locally available phone to improve sustainability and ease of use. It enhances portability with smaller dimensions, added handles, and includes a battery pack to ensure functionality in Ghana's unstable power grid. The final design has been verified to meet all requirements, including cost, ease of use, durability, consistency, and more.

Manufacturing Plan & Cost

Two manufacturing strategies have been proposed: the first involves precise production via 3D printing outside of Ghana, offering ready-to-use devices but relying on non-local sources, posing accessibility and repair challenges for Ghanaian hospitals. The second pathway emphasizes local wood sourcing in Ghana, enhancing accessibility but requiring more complex assembly processes which involve hospital engineers. The material cost of our build design is $181.87. We suspect this reflects the material cost of the final design.

Critique and Conclusion

One of the main drawbacks of our design is that it builds upon a diagnostically inaccurate testing method. This was by design, to align with the current workflow of Ghanaian practitioners to improve user-friendliness. Also, the results are not automated, as it requires human interpretation of a video.

TABLE OF CONTENTS

INTRODUCTION & BACKGROUND

Over the course of 6 weeks at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana, and 2 weeks at Korle Bu Teaching Hospital in Accra, Ghana, Yilin Fang conducted a healthcare needs assessment in the hospital's obstetrics and gynecology (OB-GYN) department to identify current challenges to be addressed via engineering solutions. KATH is a high-traffic referral center, receiving many high-risk patients, with hospital caregivers often having to juggle multiple tasks at a time to keep up with patient influx. KATH is also a low-resource hospital compared to hospitals in high-income countries. Only 1.4% of Ghana's total GDP contributes to their domestic government healthcare sector, leaving little available funding for Ghana's national health insurance program (NHIS) [53]. This is significantly less than countries such as the U.S. and Canada, which stand at 18.3% and 12.2% respectively [53]. After identifying 59 distinct needs in conjunction with two colleagues over the assessment period, Yilin chose a specific need to pursue as a project in ME 450 under our sponsor, Dr. Dhanu Thiyag, an OB-GYN practitioner at Michigan Medicine. The specifics of this need are outlined below.

In 2020, the maternal mortality rate (MMR) in Ghana was 263 per 100,000 live births, over 12 times that of the United States in the same year [7]. Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the largest single contributor to maternal mortality in Ghana, contributing to 21.8% [13] of associated deaths. Coagulopathy, defined as an impaired blood clotting ability, is an umbrella term that encompasses a large number of specific diseases where certain clotting factors (biochemicals that assist in the formation of blood clots) are missing in the blood [66]. This leads to slow blood clotting times, or ineffective clot formation. People with severe forms of untreated coagulopathy are at higher risk of hypovolemic shock (too little blood circulating through the body, leading to organ failure) upon injury. Since PPH leads to excessive bleeding, and coagulopathy means that this bleeding may last longer than normal, a mother who has coagulopathy is at a severely increased risk of hypovolemic shock and thus death during or after childbirth [3]. We refer to this condition of having both PPH and coagulopathy as "coagulopathy-enhanced PPH".

At KATH, it is routine to perform a bedside "coagulation test" on pregnant patients at some point prior to childbirth, to determine if the patient is at risk for coagulopathy-enhanced PPH and if they will need any additional supportive treatments in the event of PPH. The current method of bedside blood clot testing in KATH is a simplified version of the Modified Lee-White blood clot test (detailed in benchmarking) [26][47], which measures the time to blood clot formation, and uses this to predict if a patient has an underlying coagulopathy. There are multiple flaws with this current method in use. Due to the large amount of user input to facilitate the test, it not only limits the caregivers' ability to effectively serve other patients but also creates room for user error. As KATH is a busy hospital, it is common for caregivers to be distracted, prompting them to miss the exact time at which the blood has clotted, reducing test accuracy [26]. Therefore, a hands-free, accurate blood clotting time test that can assess patients' likelihood of coagulopathy has the potential to minimize strain on hospital employees and eliminate user error in testing. As a result, caregivers can better prepare for potential coagulopathy-enhanced PPH patients and have additional time to locate treatment resources. Ideally, this will in turn reduce PPH-related deaths in Ghana.

PROBLEM SCOPE

While coagulopathy affects many patients outside of OB-GYN, we chose to frame the problem based on the assumption that our solution would be implemented in an OB-GYN environment since that is where the need was discovered. Under this assumption, solutions were constrained to work at the patient's bedside rather than in a lab setting, since a fast and portable test is needed to keep up with the high-traffic and time-sensitive aspects of childbirth at KATH. Additionally, pregnancy can cause certain forms of temporary coagulopathy. Preeclampsia, or high blood pressure as a result of pregnancy, is common and can lead to disseminated intravascular coagulation (DIC) in which the clotting factors in the bloodstream are activated to form a blood clot [17]. When DIC occurs, clotting factors are used up and are no longer available to form clots where needed, i.e. in vaginal or uterine lesions formed as a result of childbirth [67]. While a solution to this problem could be applied elsewhere (i.e. emergency surgery), it is important to keep in mind that a bedside test would not provide the same accuracy in diagnosis as a lab test, although a bedside test provides a much quicker result.

After interviewing our sponsor and hematologists Dr. Lauren Shevell (a hematology faculty member in Michigan Medicine), and Dr. Jennifer Girard (a specialist in hematology in Michigan Medicine), we discovered that there are two primary solution pathways to this problem. One pathway would be to create a device that measures blood clot time, similar to the one currently used at KATH, simply reducing the need for hands-on input from caregivers, and minimizing human error in the test. Dr. Shevell and Dr. Girard advocated that we implement a more expensive, advanced solution such as a thromboelastography machine (outlined below in benchmarking). This type of machine could measure more than just clotting time, capable of not only predicting whether or not a person has coagulopathy but also being able to diagnose which specific form of coagulopathy is present. This would be beneficial to practitioners, as it would provide insight into which specific treatment method to proceed with since not all forms of coagulopathy should be treated in the same way. However, after speaking with one of our primary stakeholders, Dr. Thomas O. Konney (a Consultant Gynaecological Oncologist at KATH) informed us that while additional functionality would be beneficial, we should prioritize low cost and ease of use since an accurate lab test already exists in KATH but is not commonly used due to cost and time to obtain results [27]. Thus, we decided to pursue a bedside test that focuses on measuring blood clotting time over additional measurements such as viscosity, as would be done on a traditional thromboelastography machine.

DESIGN CONTEXT

To best understand the contextual factors surrounding this design problem, we sought to identify key stakeholder power dynamics and roles, as well as socioeconomic, environmental, and ethical considerations and challenges we may face during our design process. Table 1 below on page 4 lists a few of the most important stakeholders with their contexts and need priorities ranked.

Table 1: Key stakeholder map, priority, and roles. Complete stakeholder map in Appendix A.

Priority	Stakeholder(s)	Role
Primary	Ghanaian patient care staff (doctors, nurses, midwives)	Beneficiary and resource provider
	Ghanaian patients	Beneficiary
Secondary	Ghanaian hospital waste management workers	Affected bystander
	Ghanaian hospital administration and system	Beneficiary of status quo and influential bystander
	Project sponsor	Ally and resource provider
Tertiary	Ghanaian local manufacturers	Influential bystander
	People who perpetuate the stigma against blood donations/contact	Opponent
	Michigan Medicine and Global Health Design Initiative	Ally and resource provider

The primary stakeholders are composed of Ghanaian patients and Ghanaian patient care staff, whose lives and work respectively are directly impacted by the development of an accurate blood clotting test product. Both patients and patient care staff are beneficiaries or customers of our product, while patient care staff are also resource providers as they have provided us with knowledge on the subject. A timely and accurate clotting time test result positively impacts any patients with existing coagulopathy by allowing adequate interventions to be done without delay, such as calling for plasma and platelets to be donated to the patient. The current cultural stigma and reluctance around donating blood due to "fear and worries around ineligibility" [25] make sourcing platelets and plasma donated by direct family and relatives to the patient early even more crucial, as finding a willing donor can be difficult and time consuming.

The hospital administrators and system are beneficiaries of the status quo as the current test will require the least amount of investment and administration change. The current testing method Ghanaian patient care staff use carries virtually no operation costs, as all components of the test come from reused materials. Ghanaian patient care staff rinses and reuses non-heparinized, empty medicine bottles for blood vials and blood flows directly into the vial from an IV. For our product, we focused on minimizing cost because the co-pay of these tests typically falls outside of the NHIS healthcare system, [27] and any out-of-pocket costs can burden low-income patients. Within the secondary stakeholder group, the Ghanaian hospital system and administrators prioritized a low-cost product because the initial installation of the product will decrease the budget allocated towards regular hospital expenses for the time duration. Adding a new device to the OB-GYN department in a Ghanaian hospital also required us to consider the implication of a department-wide procedural and protocol change, therefore we sought to minimize the disruption of the existing workflow in our design.

One stakeholder who could be impacted negatively by the development of the product is hospital waste management workers. A social cost to consider is that, according to an existing study [2], medical waste in Ghana, including plastic and glass wastes are often burned in a pit after being

transported which can release carcinogens into the air. To make matters worse, close to 60% of the Ghanaian waste management workers surveyed in the study said that they rarely wear a mask while burning. To minimize the damage to the environment and to the health of waste management workers, we planned to make the product reusable with minimal disposable consumables. To further improve reusability, it would be beneficial to make the design from locally accessible materials so that parts are repairable/replaceable in the event of failure. Furthermore, using recyclable and/or biodegradable materials reduces environmental costs of the design.

It is important to underscore that even though the medical patients and the waste management workers have the most at stake from the development of the product, they have the least amount of decision making power when it comes to making the product itself. When working on this project, we faced the ethical dilemma of prioritizing the patient care team and sponsor input over data or opinions collected from patients themselves. We tried to minimize the ethical concerns around this dilemma by gathering patient and waste management workers' input from secondary sources, such as online forums and research reports. Nonetheless, social impact was ranked as one of the most significant priorities for this project, as expediting access to correct intervention is of utmost importance for pregnant patients with coagulopathy, a potentially fatal condition. We are one of the first teams on the market to navigate the problem of diagnosing coagulopathy among pregnant patients seeking a low-resource specific solution. Within our team, we extended inclusivity and a balanced dynamic among ourselves by regularly checking in with each other and encouraging constructive criticism and positive feedback during discussions.

Other ethical issues we considered for concept generation and selection included concerns around gathering real blood samples for testing, and consent to use the clinician's phones as a part of the device. To obtain human blood for the purpose of testing, an Institutional Review Board (IRB) must be obtained. Therefore, for the scope of this class, we did not include testing or verification plans that would need to be tested with real blood. Instead, we tested with blood proxy when necessary. As a part of the design, we considered using the clinician's phone as a camera to reduce cost. However, after considering the possibility of theft with the phone being left unattended, and additionally the potential for clinicians to miss important notifications transmitted via phone, this idea was rejected.

In addition to ethical issues, the importance of public health and safety was also considered. To keep patients and hospital staff safe, the patients should not touch the device itself and blood must be contained at all times in the device to avoid contamination. It was also important to keep in mind while designing for the ease of use requirement that hospital staff may use the device while wearing gloves, which could affect touch screen responsiveness. Finally, when assessing the margin of error for the device, we raised the ethical issues of encountering either a false positive or a false negative for the test. After speaking to our sponsor, we determined that we must work to prevent false negatives because a false negative means potentially neglecting a high-risk patient from needed resources to be allocated towards them, while a false positive test result would not put a patient's life at risk. A false positive test result could falsely alarm the patient care team and thus allocate unnecessary resources, but those resources could be used later for other patients and minimize waste. However, a false positive test may also result in a patient receiving care that they don't need, which may create additional costs for the patient.

DESIGN PROCESS

Early in our coursework, our team was introduced to different design processes, the one most relevant to our project being the ME450 course design process shown in Figure 1 below.

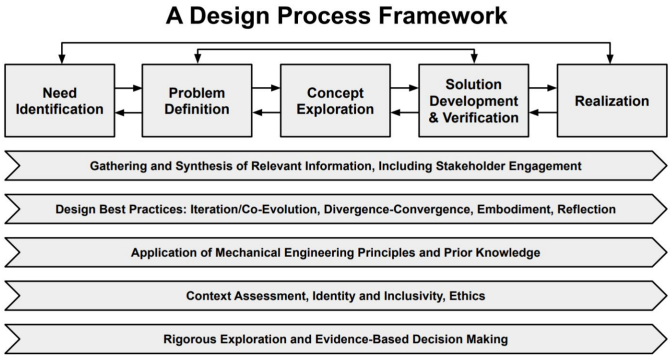


Figure 1: The model above shows the ME450 design process with the blocks above showing the key stages, and the ribbons beneath showing iterative steps that must be performed at each stage. The arrows between the stages show that each stage must be revisited throughout the design process

From a visual standpoint, our team decided that we would need a model that emphasizes how late design changes can result in a revaluation of earlier design stages. We also wanted to highlight the converging and diverging aspects of each stage of the process. The Double Diamond Model [55] and the French Model (1999) [54] shown below in Figures 2a and 2b respectively, possessed notable components that we wished to incorporate into the ME450 design process.

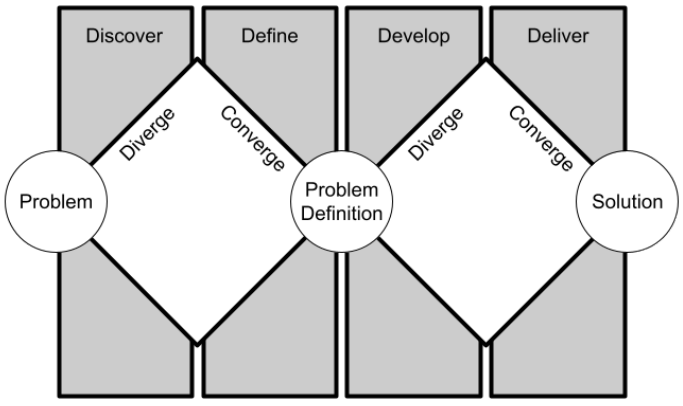


Figure 2a: Double Diamond Model [55]. The most notable components include the converging and diverging thought process, symbolized by the diamond's shape.

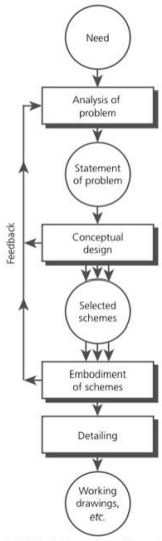


Figure 2b: French Model [54]. The most notable component of this model is the feedback arrow which results in iteration throughout the design process.

Using components from these three design processes, our team developed a new design process shown in Figure 3 below.

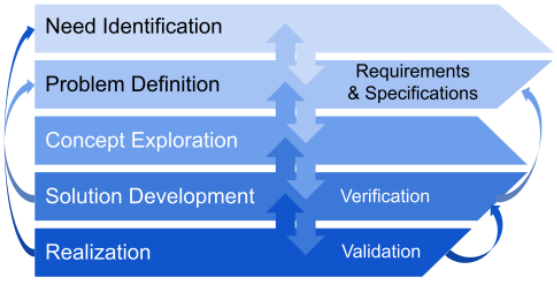


Figure 3: The model above is a vertical adaptation of the ME450 design process. The Requirements & Specifications, Verification, and Validation sections were integrated into the diagram to align with the course emphasis on these blocks in developing a solution. The large, centralized arrows and rightmost feedback loops are included to show constant iteration between steps and provide pathways for the design to be improved upon or reworked. The slopes on the right side of each design phase are meant to indicate divergence ("\") and convergence ("/") of the solution space.

Components of the French Model and the Double Diamond Model were also incorporated into the final design process. Starting with the original ME450 model, we transposed the structure and made feedback arrows to provide a similar structure to the French Model, and the angled corners on each design phase provide a similar flow structure to that of the Double Diamond Model. These differences visually emphasize the broadening/constricting nature of each design phase which eventually reduces to a single solution. We believed that visualizing iteration would play an important role in our design process.

Our modified model was valuable for this specific project because it covered our project topics while also showing how each block opens up and closes design potential. Our Need Identification block was completed during Yilin's 8-week experience in Ghana along with our team's information gathering and synthesis efforts. Identifying a problem and learning more about current solutions broadened the solution space. The Problem Definition block included meeting with stakeholders, drawing research-based conclusions, and determining requirements and specifications for a viable solution, which narrowed the solution space.

Following problem definition, concept exploration was undertaken in the form of team-wide divergent concept generation. Subsequently, logical convergence was performed through a combination of team/stakeholder discussion, assessing engineering feasibility, referencing the previously defined requirements and specifications, and benchmarking proposed designs against current solutions. From this convergence, an initial alpha design was determined which was then iterated via engineering analysis and further stakeholder discussion into a build design. Following our conceptual design process, this build design was then manufactured and rigorously verified against our requirements and specifications through a variety of analytical and empirical tests. Using results from build design verification, alterations were made to the build design to arrive at a final design. Realization and Validation of the final design are outside of the scope of this course, however, plans for validation have been outlined in the Design Validation Plan section.

BENCHMARKING

To gain a further understanding of blood clot test methods, benchmarking was conducted to compare KATH's blood clotting time test to other tests currently practiced. We split the methods into two tables, including the blood clot time approach in Table 2, and the detailed diagnosis approach in Table 3. Note that this analysis only contains bedside solutions for blood clot testing.

Table 2: Current low-resource bedside blood clot time tests that can assess coagulopathy as compared to KATH's method. The process of each test is outlined below the table. "Sensitivity" represents the percentage of patients who are affected with coagulopathy which the test reports as positive.

Test Type	Modified Lee-White (MLW) [47]	20 Minute Whole Blood Clot Test (20WBCT) [47]	KATH Practice
Result Time	30 minutes	20 minutes	10-11 minutes
Caregiver Input	Caregiver must check blood for clotting every minute following 5 minutes from the start of test	Caregiver must check blood for clotting at 20 minutes from start	Caregiver inspects blood every 2-3 minutes for clots for the duration of test
Sensitivity (%)	85	55	-
Consumables / Extra Equipment Required	Blood Vials (3), Syringe	Blood Vial, Syringe	Blood Vial, Syringe

All of the above blood clot tests rely on visual inspection of blood in a vial at certain time intervals in order to detect clotting. Additionally, the only costs associated with these tests come from vials and syringes. An example of clotted and unclotted samples are shown below in Figures 4a and 4b for reference.

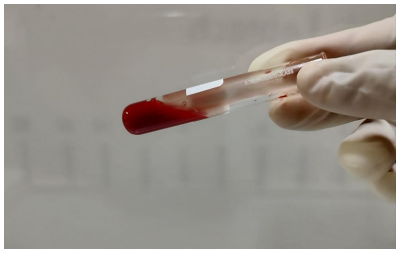


Figure 4a: Above is an example of unclotted blood in a vial. As can be seen, the blood is fluid and changes shape as the vial is tilted. [47]

Figure 4b: Above is an example of clotted blood in a vial. This clotted sample is not fluid and maintains its adherence to the bottom of the vial when tilted. [47]

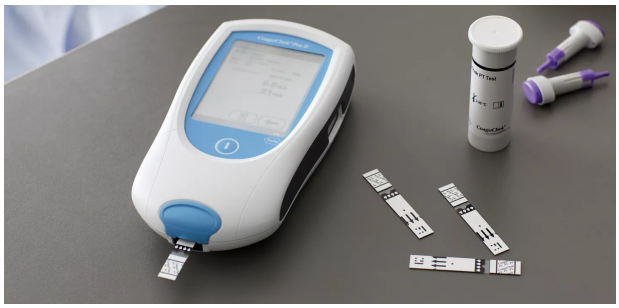
The Modified Lee-White (MLW) test is conducted by splitting 6 mL of freshly drawn blood equally into three separate labeled test tubes (2 mL per tube) at room temperature. The last tube filled will have the highest level of tissue clotting factor, as it harbors the initially drawn blood, then the second and third respectively will have decreasing amounts of tissue factor. These vials are left undisturbed for 5 minutes, upon which the highest tissue factor vial is checked for clot formation at one-minute intervals. Upon the first vial clotting, the second (next highest tissue factor content) is tested every subsequent minute, then the third. Once all three vials are clotted, the "clot time" is recorded. The test is considered positive for coagulopathy if 20 minutes is reached and all tubes have not clotted [47].

The 20-minute whole blood clot test (20WBCT) involves placing 2 mL of freshly drawn blood in a vial and allowing it to rest for 20 minutes before inspecting for clotting. If no clot has formed after the 20-minute interval, the test is positive for coagulopathy [47]. This test has notably low sensitivity in detecting coagulopathy, likely due to the longer resting interval between sample collection and observation compared to MLW. Shortening the resting period post-blood draw is thought to improve sensitivity by identifying more unclotted samples, as longer intervals following blood collection statistically increase the chance of clot formation or solidification [74]. Thus, the 20WBCT's extended resting interval likely leads to an increased number of samples identified as clotted, irrespective of the presence of coagulopathy, resulting in reduced test sensitivity.

The current method of bedside blood clot testing at use in KATH is comparable to the Modified Lee-White blood clot test [27]. This test is conducted by placing 2 mL of blood into a vial and monitoring the sample for 10 minutes, tilting the vial periodically to check for clotting. The time interval between checking for clotting is not standardized but is on average conducted every 2-3 minutes [27]. Caregivers hold the test specimen in their hands to simulate body temperature but often need to put the vials down to complete other tasks. The time at which the clot is formed is recorded. If clotting is not achieved in 10-11 minutes, the test is considered positive for coagulopathy.

Our hematologist stakeholders recommended that we consider a solution pathway that can not only detect whether or not a patient has coagulopathy but can also give insight into the cause of coagulopathy. Table 3 below on page 10 shows these bedside blood clotting tests that are typically applied in high-resource settings.

Table 3: Current high-resource bedside blood clot tests that can assess coagulopathy.



Test Type	Thromboelastography (TEG) [48], [49]	Activated Partial Thromboplastin Time (aPTT) [10]	Prothrombin / International Normalized Ratio (PT/INR) [10]
Result Time	30 - 60 minutes	5 minutes	1 minute
Dimensions (cm)	29 x 22 x 18	18.7 x 9.7 x 4.3	18.7 x 9.7 x 4.3
Mass (g)	5400	280	280
Initial Cost	$2000	$800 - $1000	$800 - $1000
Cost Per Test	$160	$38	$38
Test Metrics	Clotting time, Clotting factors, Platelet function	Thromboplastin	Prothrombin
Consumables / Extra Equipment Required	Syringe, Dedicated computer to process test information, disposable test cup, catalyst & pin	Syringe, Vial, Disposable test strips	Syringe, Vial, Disposable test strips

Thromboelastography (TEG) is a test which places a volume of blood into a cup, the blood is then rotated over the course of 20-30 minutes, and the viscous resistance of the blood is measured by a pin attached to a force transducer. The viscous resistance is then plotted against time. Many causes of coagulopathy can be diagnosed from values provided by a TEG graph. A sample TEG graph is shown below in Figure 5.

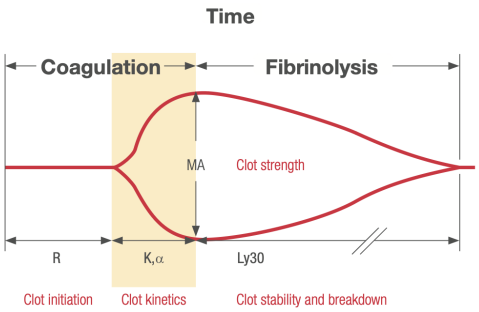


Figure 5: Above is a sample TEG graph [48], analyzing variables produced from the graph allows caregivers to not only diagnose if a patient will have coagulopathy but also give some light on the root cause.

Although TEG is a very powerful tool for bedside coagulation testing, due to the initial and per-test costs as well as the extensive amount of extra equipment and consumable materials required to operate, this test is not a practical solution for KATH.

A Prothrombin (PT/INR) test measures prothrombin content (one of the 12 clotting factors) which is used to predict blood clotting time. The results are represented in the form of the International Normalized Ratio (INR), where a higher INR indicates a longer time to clot. This test is often taken with an activated Partial Thromboplastin Time test (aPTT), which measures the blood's ability to clot with regard to thromboplastin content (another clotting factor). The bedside solution benchmarked for PT/INR and aPTT is capable of conducting both tests within one unit, which is common in devices that detect these respective factors. The high cost, interdependency between the two tests, and need for proprietary test strips make the PT/INR and aPTT tests impractical for practice in KATH.

Given the emphasis on a low-cost, easy to use solution provided by our key stakeholders, we have elected to proceed with the blood clotting time approach (benchmarked in Table 2 above) as our solution pathway. Additionally, our primary stakeholder, Dr. Konney emphasized that a solution that can diagnose the specific cause of coagulopathy may not be useful at KATH due to the lack of specific blood resources necessary for targeted treatments [27].

INTELLECTUAL PROPERTY

A nonexclusive license has been granted to the University of Michigan Global Health Design Initiative, permitting the University of Michigan legal access to the production, distribution, and sublicensing of the resulting design in pursuit of advancing global health. This nonexclusive agreement allows our team to retain all ownership rights of the resulting product.

INFORMATION SOURCES

Throughout the course, we used a variety of primary and secondary sources to obtain information that enhanced our understanding of the problem, helped to define requirements and specifications, and drove design decisions.

Several primary information sources provided direct insight into the foundation of the problem, aiding in the progression of this project. Yilin Fang's need assessment at KATH and Korle Bu was a foundational primary source of information as it served as the initial framework of our project, identifying the core demand for a solution. Additionally, our sponsor Dr. Thiyag met with our team weekly to discuss problem context and project progression, providing valuable insight and suggestions to improve our design. Other important stakeholders who served as primary sources of information included Dr. Augustine Tawiah, an OB/GYN practitioner at KATH, and Dr. Konney. Dr. Tawiah and Dr. Konney were especially important sources given their experience working in Ghanaian hospitals as OB/GYN practitioners, and their opinions on requirements and specifications as well as design attributes were weighed heavily in design decisions. Dr. Girard and Dr. Shevell were also crucial primary sources, providing insight into current practices in high-resource settings to detect coagulopathy.

Secondary sources contributed to much of the technical/engineering information paramount to the success of the design. The National Institutes of Health (NIH) had many detailed articles on current blood clot tests (in both bedside and lab applications). Furthermore, the NIH had a plethora of reports on the mechanical properties of blood. The understanding of these properties allowed the team to create informed designs in the concept generation stage. Engineering textbooks such as *Engineering Materials and their Properties* [84], and *Fundamentals of Heat and Mass Transfer* [64] were another integral secondary source, providing important relations and equations for the engineering analysis and verification of our build design.

Our team also met with Sarah Barbrow from the Engineering Library to further develop our research skills. At times throughout the project, some difficulties arose in communicating promptly with Ghanaian stakeholders to obtain input on progress made and respective next steps. To address this information gap, we leaned on our sponsor Dr. Thiyag, who has extensive experience in global health for further guidance.

REQUIREMENTS & SPECIFICATIONS

To determine the target stakeholder requirements, we conducted research and held interviews with our stakeholders. Prominent contributors included Dr. Thomas Konney, Dr. Lauren Shevell, Dr. Jennifer Girard, Dr. Dhanu Thiyag, Dr. Augustine Tawiah, and Dr. Julia Kramer (an assistant professor at the University of Michigan College of Engineering). As a primary stakeholder, Dr. Konney's extensive experience with Ghanaian PPH patients and clot testing procedures led us to choose his requirements as the highest priority. Similarly, we were in contact with Dr. Tawiah later in our design process and his input was heavily valued due to his OB-GYN experience at KATH. He played a crucial role in the revision of our requirements and specifications.

From our initial interview with Dr. Konney, the requirements specified for our device include being easy to use for Ghanaian caregivers, being affordable, and possessing an optimal 5-year lifespan [27]. Dr. Thiyag and Dr. Kramer also showed support for these targets. In our team's interview with Dr. Shevell and Dr. Girard, the importance of test accuracy was discussed, and a solution similar to that of a TEG or ROTEM test was advised. After these interviews, our team was then able to formulate the following initial top requirements: low cost, easy to use, durable, and consistent. It is important to note that although accuracy is an important aspect of a solution, primary stakeholder input emphasizes ease of use and low cost. Therefore, our team chose the word consistent as opposed to accurate to encompass more stakeholder needs without limiting design possibilities.

After careful consideration, our team chose to prioritize the low cost and easy to use requirements. This unfortunately limited test accuracy and diagnosing capabilities. Our focus was on a point-of-care solution that can streamline the current KATH coagulation test by reducing caregiver input and standardizing a repeatable test. From research and with Dr. Konney's approval, our team proceeded with our four top requirements and began considering more requirements. The justifications of rank for each requirement are listed in Table 4 below.

Table 4: Requirements, ranked from highest to lowest priority with justifications for each rank.

Priority	Requirement	Justification
High	Low Cost	KATH is a low resource hospital. A solution that is too expensive to implement and use is not financially sustainable and thus unusable [27].
	Easy to Use	Current testing is difficult for caregivers to perform. To be an improvement, a solution must reduce caregiver supervision and require minimal training [26].
	Durable	Coagulopathy testing occurs ~15 times per day within the OB-GYN department. Damage to the machine will be difficult to repair and will render the solution useless. [27].
	Consistent	Current testing is inaccurate and unstandardized. To justify costs and retraining staff, the solution must provide notable improvements to accuracy and standardization [26].
Medium	Portable	KATH is a high-traffic hospital. A solution should be able to quickly move between patients to maximize its utility [26].
	Safe	Testing may involve blood and sharp, brittle materials. Caregivers should not be in any danger while using the device [6].
	Locally Maintained	A solution will be more sustainable if it can be maintained with regionally sourced parts and tools [26].
Low	Control Blood Temperature	Being able to control blood temperature during testing improves test accuracy, although common coagulopathy test techniques do not always follow this requirement [26].

There was a supporting correlation between low cost and easy to use, portable, and locally maintained. If we limited our solution to inexpensive materials, we limited device complexity-thereby making the device simple to operate, light, and regionally serviceable. There were also competing requirements that complicated the design process. In modern medical equipment, certain components can be expensive. For instance, the minimum price of the blood clot test equipment in Table 3 was $800. Since this is a global health focused project, and Ghana is a low income country, requirements such as durability, safety, consistency, and controlled blood temperature were limited by cost as the most advanced solutions were out of our price range. This was beneficial for our project considering that low cost is a high priority requirement.

The next step was to quantify our requirements with specifications. Specifications were based on standards, previous medical studies, primary sources, and informed team decisions. Our team sought to create a device that attempts to follow standards from the FDA and CDC. Examples of this include a quick turnaround time [15], sterilization durability [39], and handling ergonomic requirements [18]. However, Ghanaian practices and tests can deviate greatly from American standards due to resource shortages. Our team acknowledged that there may be aspects of the design that do not fulfill American device standards. Reasons for deviation from American standards included stakeholder requirements, a lack of resources on the configuration of a device like this, and project constraints (such as class timeline, budget, and scope). Minimal specifications were considered the lower bound to achieve our requirements, whereas optimal specifications were the team's aspirations. Nevertheless, achieving these specifications was outside the scope of the class, with some of the optimal specifications set by standards or stakeholders not being feasible with our resources and time frame. A greater effort was allocated to the high priority requirements, and low priority requirements were not a large point of focus

but were considered. Further testing of the specifications is outlined in the verification plan section of the report. Table 5 contains all stakeholder requirements and engineering specifications.

Table 5: User requirements, ranked from highest to lowest, alongside minimal and optimal specifications. All specifications with or without sources were requested or approved by Dr. Konney respectively [26]. "Sensitivity" refers to the percentage of patients with coagulopathy whose tests are positive.

Requirements	Minimal Specification	Optimal Specification
Low Cost	< $300 (USD) in material costs	
	<$0.14 per test	
Easy to Use	The device uses whole blood without reagents or inhibitors	
	Blood container is removable	Blood container removable in < 10 sec
	< 1 minute setup time	
	Alert each minute after the 3 minute mark	Alert given when a test result is ready
	< 3min caretaker supervision per test	< 1min caretaker supervision per test
Durable	Withstands > 3650 uses (1 year) [24]	Withstands > 18,250 uses (5 years)
	Withstand trials in 10 & 44°C [57]	
	Withstand trials in 10 & 99% humidity [57]	
	Must withstand hospital sterilization, i.e. 3-6% hypochlorite bleach, 70% alcohol [99]	
Consistent	30s time resolution error	
	Continuously operate for 11 mins	
	Can operate without grid power for 8 hrs	
Portable	< 11.6 kg [18]	< 3.76 kg [10]
	< 46 cm in all dimensions	< 25 cm in all dimensions [10]
Safe	Blood containers are fixed to device during testing	
	Blood container must not break under under standard testing conditions	
	Only pinch point at blood container fixture	No pinch points
	The device must not expose practitioner to blood	
Locally Maintained	Consumable components are locally available (≤5 imported components)	
	≤2 consumable components	
Control Blood Temperature	Blood is kept at body temperature (35.5°C-38.3°C)	

All requirements have complimentary engineering specifications which have been approved by Dr. Konney and have gone through multiple research-based reviews. Minimal specifications were primarily determined from Dr. Konney's suggestions, while optimal specifications were determined on team research and industry standards. These specifications were later reviewed and approved by Dr. Tawiah.

Low Cost:
To discuss the specifications in greater detail, the Low Cost specification was determined in the following manner: first, the average salary of a Ghanaian nurse was determined to be $2500/year [91]. Then, the number of hours worked was determined to be 40 hours per week for 50 weeks in a year [92]. From these metrics, we can generate a rough estimate of how much a nurse's labor is worth to a hospital in Ghana: $1.25/hour, or about $0.02/minute. From the specifications listed above, with the current coagulation test requiring about 11 minutes of time and our device requiring a maximum of 4 minutes of hands-on labor to complete a test (sum of minimal setup and hands-on time), we observe that our device saves roughly 7 minutes of nurse labor which can be directed elsewhere. This 7 minutes multiplied by the cost of labor per minute, $0.02, equates to a device that is worth $0.14 per test it performs. With our device being required to complete 3650 tests without failure, its estimated worth is $511.00. To ensure this value encompasses all contributions to cost, such as materials, manufacturing, shipping, tax, etc, we decided to apply a safety factor of 1.5 and round down to $300 for the materials budget. This safety factor additionally aims to minimize the fact that the cost for a novel device such as the one we propose later in this report is very subjective and people will have varying perceptions of its value. We understand this method of quantifying cost generates much uncertainty, however, there was no better way to determine a cost specification without time-intensive market research.

Easy to Use:
The ease of use specifications were determined mostly based on feedback from sponsors, including Dr. Konney and Dr. Dhanu. One of their highest concerns was with staff training and implementation. One way in which our team facilitated ease of use is to make the device easy to set up (< 1 min) to ensure that the blood does not start coagulating prior to testing which could be as soon as 2 min [28]. We also wanted to provide alerts at the 3 minute mark when tests typically coagulate [86]. It is important that the device requires less than 3 minutes of caregiver attention [26], and that the blood container is easily removable [26]. These specifications are justified by ensuring a close resemblance to the current practices in Ghana while minimizing the time of caregiver input.

Durable:
Durability encompasses the first two minimal and optimal specifications from Dr. Konney, while the remaining durability requirements adhere to American standards which can account for Ghana's potentially harsh environmental conditions. This included high and low temperature testing between 10°C and 44°C following similar procedures set forth by IEC 60601-1-11:2015, Section 8 [56]. Likewise, a high and low humidity test was to be performed between 10-99% humidity with similar procedures set forth by IEC 60601-1-11:2015, Section 4 [56]. Lastly, durability against sanitation with 3-6% hypochlorite bleach and 70% alcohol guarantees that our device is resilient to chemical wear.

Consistent:
The consistent specifications were based on Dr. Konney's request for running the test for 11 minutes and having a 30 second resolution error. Dr. Konney also requested a backup power supply [26]. The operation without grid power for 8 hours was determined by observing power outages during Yilin's needs assessment in Ghana. It was observed that the longest periodic outages that KATH or Korle Bu experienced were no longer than 8 hours.

Portable:
The size and weight of our device conform with the designs of similar portable blood testing devices outlined in benchmarking, used in the United States.

Safe:
Safety specifications incorporated per Dr. Konney's recommendations included fixing the container to the device, minimizing pinch points, and not exposing caregivers to open blood [26]. Ensuring the blood container will not break is crucial for the caregiver's safety as a broken container could result in exposure to blood and broken glass.

Locally Maintained:
Dr. Konney specified the importance of locally sourced materials and approved the quantity of consumable and imported parts. Having a device with minimal imported components enables quick replacement and repair compared to a device with many internationally-sourced components. This prolongs device lifespan while minimizing downtime.

Controlled Blood Temperature:
The controllable blood temperature optimal specification was based on the average human blood temperature [42]. This was measured directly using a thermometer.

Throughout our semester we have gone through revisions and iterations of our requirements and specifications. Compared to our requirements and specifications from DR1 (shown in Appendix AD) we have decided to change the purchase cost of the final design to the material costs of prototyping to better align with our project outcome. We omitted the <$100 purchase unit optimal specification as we determined that it was not feasible within the material costs required for the project. We changed the < 5 minute setup time specification to <1 minute as 5 minutes for setup alone was determined to be an insufficient reduction in time input vs. the current test (which has a total input of 11 minutes). We removed the sanitation time specifications because they were unnecessary, considering that our device (outlined in the Final Design section) does not come in contact with the blood under standard use. This renders it unnecessary to fully sanitize after every use. The patients per day specification was omitted because it is included in the number of uses specification. We added temperature and humidity durability specifications to ensure the product could withstand the extremes of Ghanaian temperatures. The alcohol percentage was changed to be more inclusive of typical products used in Ghana. The original time resolution optimal specification of 1 second was omitted following stakeholder feedback, as an unnecessarily low resolution error means inverting the vial too frequently, which disrupts coagulation processes, creating test inaccuracies [86]. The 12 min test specification was reduced to 11 min to align more with the methods used currently in Ghana [86]. The test sensitivity specification was omitted due to the lack of feasibility within this course, as this would entail testing with real human blood to obtain accurate data points, which would require an IRB. The initial pressure applied to the blood vial specification was omitted as it was resolved into the specification regarding the blood container not breaking during testing. The minimum blood temperature control specification was omitted because it was not necessary as maintaining blood at room temperature doesn't require anything from the device.

CONCEPT GENERATION & SELECTION

We accomplished initial concept divergence through the use of an idea map. We then decomposed the ideas on the map and determined common functions used to satisfy requirements. These subfunctions were sorted into a morphological chart, along with the components of each concept used to meet those subfunctions. The morphological chart was then used in the second stage of concept generation to produce detailed designs. Our process of concept selection was to first eliminate ideas that were unable to meet high priority requirements since these are strictly necessary for a successful project. We then further refined our list of concepts using our medium and low priority requirements. By looking at each concept in the remaining set, our team attempted to determine which ideas underperformed among these requirements when compared to the others. Lastly, we eliminated ideas that were not feasible to produce, i.e. concepts that would need more than a semester's worth of research and testing to validate, and had no literature to support them. This led to our top 5 concepts, which we compared using a decision matrix against our requirements, stakeholder feedback, and feasibility.

CONCEPT GENERATION

Concept generation began with each team member individually formulating 40 concepts in response to the list of requirements that were determined. Each member then iterated upon these 40 concepts individually, combining their ideas while taking into account each idea's strengths and weaknesses. This individual concept generation was followed by a rapid, collective brainstorming session, where each team member presented all of their ideas, and similar or duplicated ideas among the team were merged when recording the idea map in Figure 6. During this session, we recorded every unique idea that was mentioned to ensure judgment was deferred. The resulting idea map was loosely categorized to spark new concepts from those listed and to identify patterns in promising solutions. This idea map can be seen in Figure 6 below.

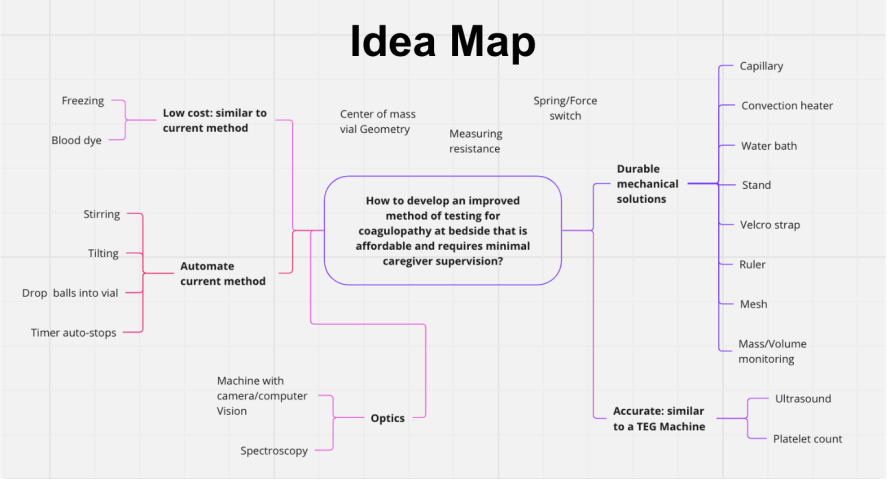


Figure 6: Idea map generated from our group brainstorming session.

After the brainstorming session, we revisited the benchmarked solutions and notes from the meeting with Dr. Konney [26][27], then came up with 7 essential components listed in the leftmost column of Table 6 below by using the functional breakdown method. Functional breakdown entails the hierarchical decomposition of a device into its elemental parts. Across all clotting test solutions, both clot time tests and lab test machines, a clot detection component and

a result presentation method must be included to check and visualize the result. In addition, all solutions used a blood container and we determined that our solutions should too. Looking specifically at the KATH modified Lee and White method that we've chosen to pursue, a blood agitation component was required as a part of the test procedure, a heating component was required to maintain body temperature, and a support component to assemble the body of the device. Due to the bedside and emergency nature of the test, a notification component was also required so that the test result could be reviewed in a timely manner. We concluded that for our design to be successful, it must contain all 7 essential components.

In the next phase of concept divergence, we re-diverged and brainstormed potential solutions or methods for each of the 7 essential components. We then populate the morphological chart with concepts generated from the idea map and during the re-divergence phase. In total, there were 172,800 possible ideas represented by this morphological chart.

Table 6: Morphological chart, with essential components in the left column, and potential matters of addressing those components in the columns to the right. New concepts can be formed by selecting one of the potential subcomponents in each row. The essential components listed along with their variants originate from a combination of elements identified from benchmarking, as well as elements identified via concept ideation.

Essential Components	1	2	3	4	5	6	7	8
Blood Agitation Component	No Stirring	Magnetic Stir Bar	Vibration	Rotating Container	Mechanical Blood Agitation	Bubbler		
Clot Detection	Doctor Observes Clot	Doctor Views Images/ Video	Computer Vision	Blood Diffusion Length	Dye Diffusion Length	Electrical Resistance	Mesh Catch	Force Transducer
Blood Container	None/ Uncontained	KATH Container	Direct IV Connection	Custom Container				
Support	Unsupported	Arm/Waist Band	Tape	Stand	Solid Body			
Result Presentation	Paused Timer (Autonomous)	Paused Timer (Manual)	Graph	Physically Indicated	Mass			
Notification Type	No Notification	Sound	Vibration	Text Doctor	Paging System	Light		
Temp Regulation	Unregulated Temperature	Current Through Conductor	Body Heat	Microwave	Fire	Convection		

CONCEPT SELECTION

With a completed morphological chart, we had comprehensively explored the solution space. The next step was to begin converging on an alpha design using a process that would methodically eliminate concepts and leave us with the most complete solution. We began this process by selecting 24 unique ideas from our morph chart to pursue with detailed designs. The

choice to pursue only 24 ideas was based on the time limitations of the course since each of our 6 group members had enough time to explore 4 unique concepts.

This initial selection process highlighted a weakness in our idea generation process – exhaustively comparing all 172,800 ideas to find the 24 best options was infeasible. We remediated this by filtering the subcomponents which we believed to be impractical based on the time frame of the course and engineering difficulty. Subcomponents that could be completed during the time frame of the course and minimized complexity were preferred. Additionally, we leaned on the 40 individual concepts each group member had initially ideated to identify subcomponents that group members intuitively preferred. Subcomponents that were common to many of our initial ideas were considered best as they were deemed natural choices by our group members. Ideally, we would have improved this part of our idea generation process by pre-filtering subcomponents on our morph chart to shrink our solution space to ~1000 ideas such that every permutation could be objectively assessed, rather than subjectively selecting 24 concepts. Additionally, we could have refined our subcomponent list by removing ideas that were not supported by research and literature. An example of a selected idea can be seen in Table 7 below.

Table 7: Seen below is the functional implementation of Idea #4 – one of our 24 ideas built from the morphological chart. The left column shows the functional components that all 24 designs contain, and the right column shows the specific implementation of each functional component for Idea #4 taken from different columns in the morphological chart. The viscous force transducer was common to many of our initial solution ideas, so it was used as the starting point for this idea and the other 6 subcomponents were filled in to maximize function and minimize complexity.

Functional Components	**Idea #4: Capillary Pump**
Stirring Component	No Stirring
Reader	Viscous Force Transducer
Blood Container	Custom Container
Support	Solid Body
Result Presentation	Paused Timer (Autonomous)
Notification Type	Sound & Light
Temp Regulation	Current Through Conductor

To draft our 24 ideas, we focused on satisfying our design requirements and maintaining “engineering feasibility”. We defined “engineering feasibility” as a design quality that is intuitively functional and manufacturable based on our experience with mechanical engineering principles. On the other hand, we were less focused on the level of detail in our designs nor the mechanical interactions of components. With this approach, we rewarded creativity in our designs while maintaining important stakeholder values and requirements such as low cost and ease of use. For each of the 24 ideas, a detailed drawing was created to outline general mechanical characteristics and functions. An example of one of these drawings can be seen in Figure 7 below.

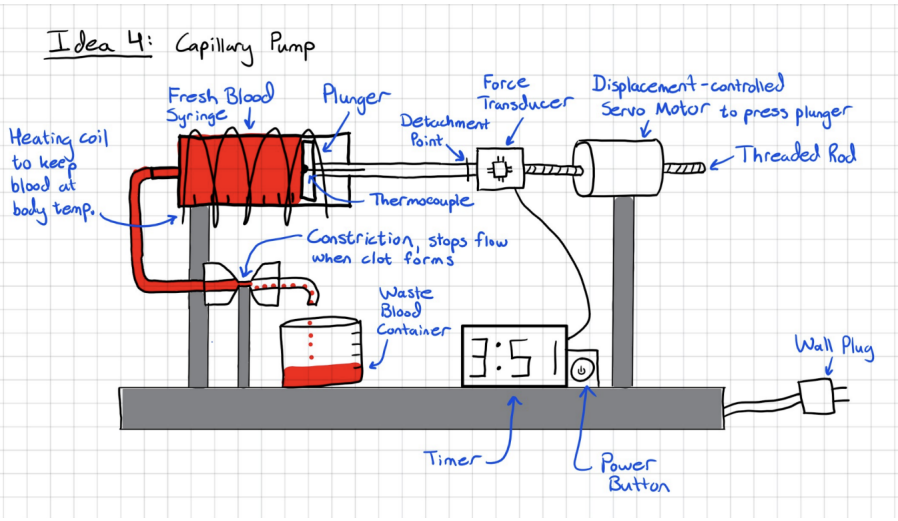


Figure 7: This image shows the full design drawing for idea #4 corresponding to the morph chart elements in Table 7. This design drawing describes a "capillary pump", an approach that would force blood through a small constriction that would get obstructed if blood clots are present, indicating clotting time. Following our process, this diagram contains some mechanical components including a force transducer, and displays the general blood testing technique but does not go into substantial detail about mechanical interactions.

All 24 completed design drawings can be viewed in Appendix B-Y. The next step in convergence was to assess our 24 ideas to select the top 5. We developed a set of criteria to filter out ideas that were impractical or less functional than alternatives. As we had considered design requirements and engineering feasibility in drafting our designs, we used these as our main criteria for assessing them. These three criteria are listed in Table 8 below with justifications for why they can be used to remove ideas.

Table 8: Contains the three elimination criteria used to reduce our solution space from 24 ideas down to 5 ideas. Each criterion is accompanied by a justification for why it was used in particular.

Design Elimination Criteria	Justification
Misalignment with High Priority Requirements Low Cost, Easy to Use, Durable, and Consistent	These concepts were **fundamentally misaligned with our project goals** such that they couldn't be reworked.
Underperforming in Low/Medium Priority Requirements Portable, Safe, Locally Maintained, Temp. Controlled	These concepts **underperformed** in comparison with other concepts when it came to low and medium priority requirements.
Engineering Feasibility	These concepts were **unsupported** by engineering principles, were **not manufacturable,** or were **mechanically flawed**.

Applying these criteria, and allowing for the combination of similar ideas, we were able to reduce our 24 concepts down to only 5. Ideally, we would have used the criteria in Table 8 to iterate and improve upon our 24 concepts before down-selection. For instance, ideas that underperformed in low/medium priority requirements but were feasible and aligned with high priority requirements could have been reworked and made more competitive with other ideas. We elected not to perform this stage of iteration due to the time constraints of the course. Instead, we made note of the strengths of eliminated ideas for the iteration of other ideas, as seen in Table 9 below. Figure 8 on the next page summarizes the convergence of our solution space with the application of each criterion in Table 8 above.

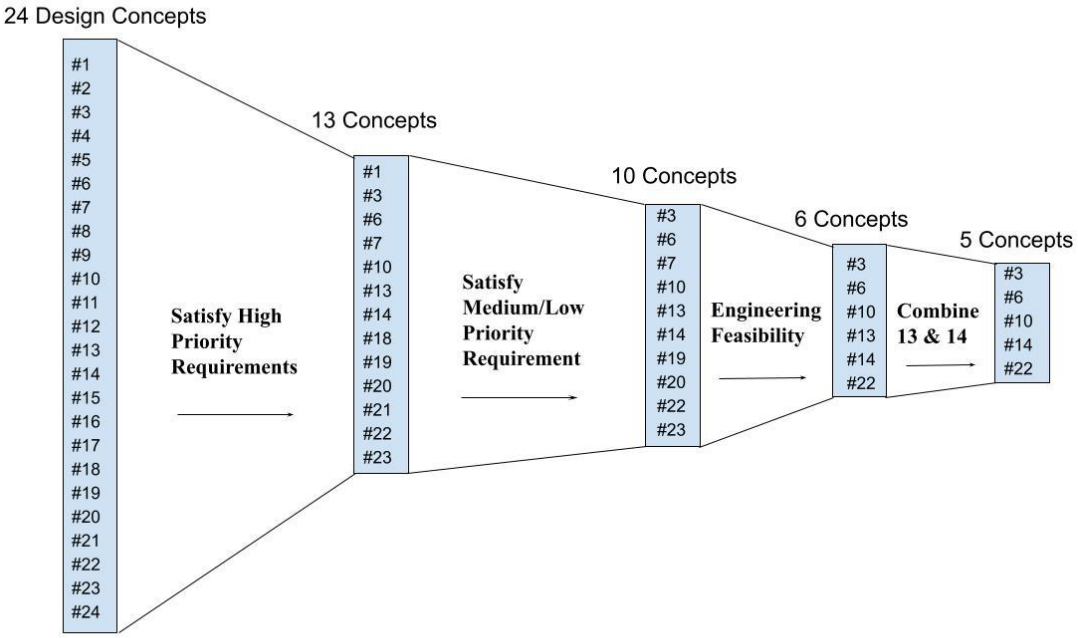
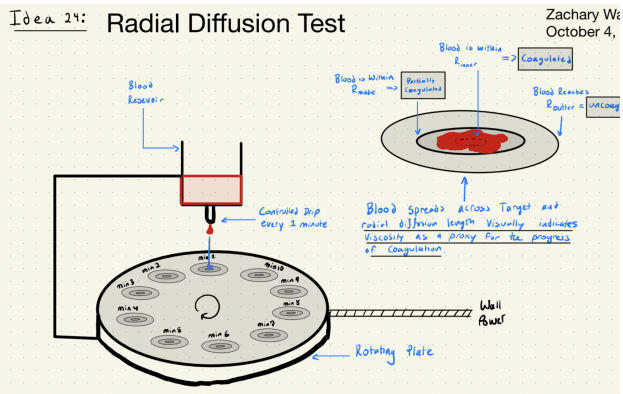
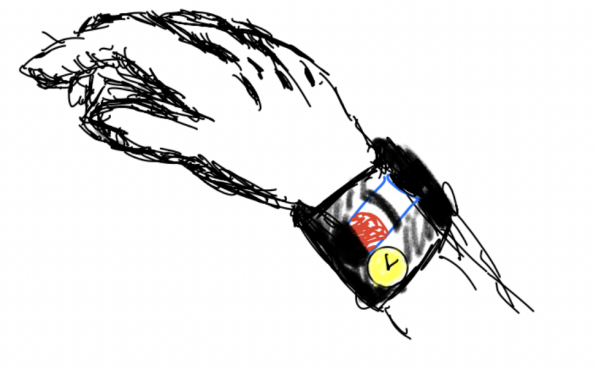
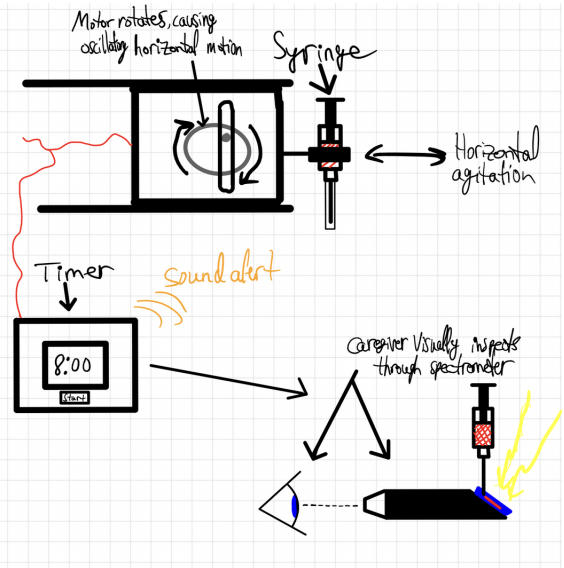


Figure 8: Each number in the blue columns represents a unique idea, and moving from left to right, the intermediate spaces show the application of our 3 selection criteria. Applying our high-priority requirement criterion, we converged from 24 concepts to 13 concepts. Applying our medium/low requirement criterion, we converged from 13 concepts to 10 concepts. Applying our engineering feasibility criterion, we converged from 10 to 6 concepts. Lastly, we combined ideas 13 and 14, which were similar, to come up with our top 5 concepts.

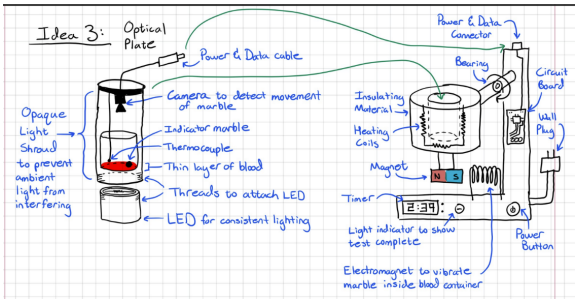
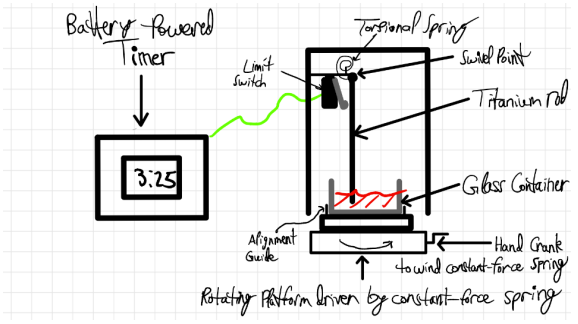
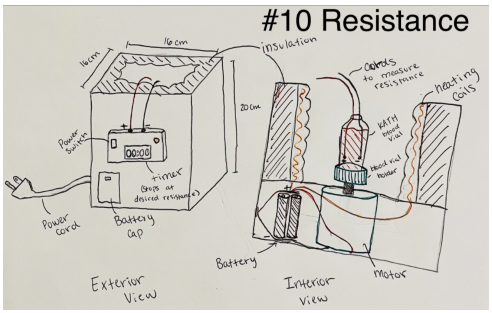
Concept elimination can result in the loss of valuable design qualities, so throughout this process, we noted the strengths of each design to consider reincorporating into other concepts during iteration. Table 9 below demonstrates the application of our selection criteria as well as the design qualities that we noted for reincorporation later.

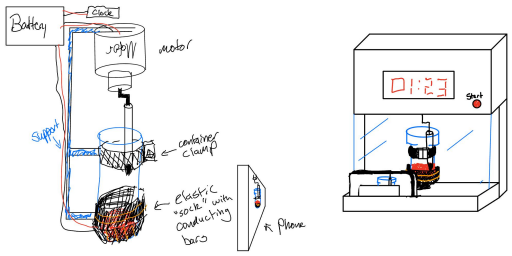
Table 9: Examples of three design concepts that were eliminated, along with the criteria used to eliminate that design, and the strengths that we considered reincorporating in other designs or our alpha design.

Concept	Application of Criteria
	**Design:** #24. Drop blood onto 10 flat blood "targets" to test blood viscosity based on radial blood diffusion. Viscosity is considered to be an indicator of coagulation. [58] **Elimination:** Fails to satisfy high priority requirements (Easy to Use). Blood drop nozzle risks clogging – requires supervision. **Strengths to Reincorporate:** Our final design must be spatially compact.
	**Design:** #16. Caregiver wears the blood vial on a wristband to note the time of coagulation visually. **Elimination:** Incompatible with Medium Priority Requirement (Safe). Falling might expose caregivers to blood and broken glass. Wearable devices Inhibit the mobility of caregivers. **Strengths to Reincorporate:** Concepts can successfully tap into natural heat reservoirs and free up the caregiver's hands.
	**Design:** #7. Blood is oscillated to uniformly mix contents. A drop of blood is placed onto a spectrometer and a light diffraction spectrum is used to visualize coagulation. **Elimination:** Engineering Feasibility. We found no literature that supports the idea that blood diffracts light differently as it coagulates. **Strengths to Reincorporate:** Rear motor for mixing allows for high visibility of blood. Visual methods fit well into Ghanaian Hospital workflows.

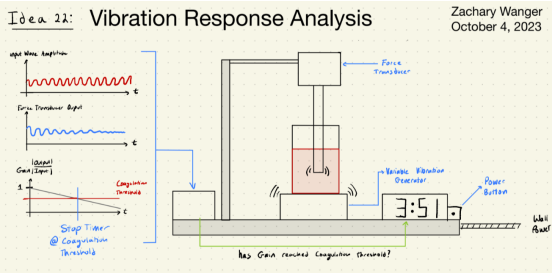
While our criteria were strict, it was understood that no idea was perfectly feasible and adhered to every engineering requirement. There was no way to completely remove subjectivity in the idea selection process, despite our best practice. This was partially rectified by retaining the best qualities from removed ideas moving forward – we hoped that every eliminated concept would improve our understanding of the problem and potential design iterations. These strengths also refine our understanding of the project requirements and specifications. For instance, the use of smartphones was a strength of several eliminated concepts that resurfaced in our final design to remove buttons that better satisfy the easy to use requirement. Ideally, we would have conducted an additional round of iterations on our 24 concepts to get an improved set of design options, but we are limited by the pace of the ME450 class schedule. The final 5 concepts that we selected are summarized in Table 10 below.

Table 10: Our top 5 design concepts derived from our 24 primary concepts. Each design concept is accompanied by a brief description of its functionality.

Top 5 Concepts	Description
	**Design: #3.** A marble is placed in a cup with a thin layer of the patient's blood. The cup is tilted such that the marble freely moves in the blood. A camera observes the marble and a computer vision algorithm uses the movement patterns of the marble to identify coagulation. This will autonomously stop a timer to indicate clot time.
	**Design: #6.** A long rod is suspended vertically in a container of the patient's blood. The blood is rotated such that the rod is angularly displaced by the blood (like a paddle in current). As coagulation occurs, blood viscosity increases and the rod will be displaced more at the same rotation speed [58]. A limit switch will be placed at an angle indicating the blood viscosity at coagulation. This will stop a timer to indicate clot time.
	**Design: #10.** Blood is exposed to a free voltage and the resulting current will be measured to approximate the blood's resistivity. The timer will stop when the blood resistivity indicates coagulation. Preliminary data indicates that the conductivity of blood varies with coagulation [59].



Design: #14. The blood is mixed and heated in a clear blood vial. A phone or external camera is placed with a direct view of the vial. Reviewing the video will allow doctors to identify the time of coagulation by visually identifying a formed clot.



Design: #22. The blood is given an input vibration – a constant amplitude sinusoidal input, for example. A force transducer is suspended in the blood and measures the output wave response from the blood. As blood viscosity increases during coagulation, the output amplitude should change and the signal gain value will be used to indicate coagulation.

With our 5 top concepts, we reached out to Dr. Dhanu Thiyag and Dr. Thomas Konney, our project sponsor and primary stakeholder respectively, for their input. Our stakeholders have a unique understanding of the problem, so we considered their feedback in the next steps of convergence. However, we also contextualized this feedback with the other research we've conducted. Dr. Thiyag provided several important points of feedback that we have used to continue concept convergence and iteration.

Regarding concepts #10 and #22 shown in Table 10 above, Dr. Thiyag expressed concern with the blood property models fundamental to their function. Idea #10 relies on the conductivity of blood which is only lightly documented in academic literature [59]. Similarly, idea #22 uses the unique dampening characteristics of blood for our unique test setup. Dr. Thiyag pointed out that refining these models from scratch and proving them to be effective would take more time than we have in the course. This testing would require a large amount of time and access to human blood. We had not yet considered the time it would take to refine our models, and this led us to reassess these ideas as infeasible. Dr. Thiyag suggested we do not pursue these concepts further.

Regarding concept #3, Dr. Thiyag disliked the complexity of the blood tilting mechanism as well as the minimal visibility of the blood during testing. As a global health fellow for the University of Michigan, Dr. Thiyag has worked directly with our stakeholder hospitals and suggested that the system might not integrate well into the current testing workflow. This was because it uses a dedicated blood container that requires special cleaning and lacks visibility of the blood that would allow caregivers to quickly verify results. This meant that the solution risks being unsustained and unused by caregivers. We kept solution sustainment in mind throughout our design process, so this weighs poorly on concept #3.

Regarding concepts #6 and #14, Dr. Thiyag applauded their simplicity. She believed that both ideas would likely integrate well into the workflow at KATH. An additional benefit of concept #14 that was mentioned was its similarity to the current test procedure in place. Since it operates under a similar mechanism and allows for visibility of the blood during testing, it required less training and would have been more familiar at Ghanaian Hospitals.

For concept #6, Dr. Thiyag's suggestions led to two iterations. The first was to remove the torsional spring from the design since it was functionally replaced by the viscosity of the blood. She also suggested the use of a disposable sleeve for the suspended rod to preserve sterilization and reduce downtime for cleaning.

For concept #14, Dr. Thiyag's suggestions led to two design iterations. The first was to rotate the vial instead of stirring it. Rotation is the method used in the current testing protocol since it allows for the flow of blood to be visualized best. Next, she suggested considering an integrated camera that runs a computer vision algorithm to automate results.

The stakeholder feedback we received gave us confidence that our concepts were solving the correct problems and maintaining our project requirements. With this, we were ready to converge to a single solution, our alpha concept. We chose to use a Pugh chart to select between the 5 remaining concepts. We populated the Pugh chart with the 9 criteria described in Table 11 below.

Table 11: The left column outlines the 9 criteria we used to select our alpha concept, the central column outlines the weight given to each criterion, and the right column outlines a justification for each criterion.

Selection Criteria	Weight	Justification
Low Cost	**5**	We elected to compare each design against requirements, rather than specifications, since we cannot test all specifications without a prototype. Our requirements, however, can be quickly assessed using preliminary engineering analysis and intuition. Weights were selected by requirement priority level and the priority expressed by our primary stakeholders.
Easy to Use	**5**	
Durable	**4**	
Consistent	**3**	
Portable	**2**	
Safe	**2**	
Locally Maintained	**1**	
Temperature Controlled	**1**	
Stakeholder Feedback	**4**	Our stakeholders (sponsor) best understand the problem context and can pinpoint design flaws that we might miss. Thus, we have given a high weight of 4 for this selection criteria.
Engineering Feasibility	**4**	Ideas that are not supported by engineering analysis or exceed the timeframe of the course can not be completed. Thus, we have weighed this like a high priority requirement.

Stakeholder feedback was a selection criterion that might seem over-weighted, but we valued the hands-on experience our stakeholders had with the problem that allowed them to contextualize our solutions effectively. We have maintained a strong trust in the advice of our stakeholders for this reason, and weigh their feedback equally to a high priority design requirement.

Combining our criteria into a Pugh chart, we created Table 12.

Table 12: Each column of the Pugh chart represents one of our top 5 design concepts, relative to the existing test which scored a baseline 0. A score of 1, 0, -1 represents a concept's adherence to the design criterion. Each value 1, 0, or -1 is multiplied by the weight of its respective criterion, and the sum of these products is added to create a total in the bottom row. The highest scoring column is idea 14, which qualifies it as our alpha concept.

Criteria	**Weight**	**Existing Test** (Baseline)	**Idea 3:** Computer Vision w/ Marble	**Idea 6:** Lever Arm Viscometer	**Idea 10:** Blood Conductivity	**Idea 14:** Filming the Coagulation	**Idea 22:** Vibration Response Analysis
Easy to Use	5	0	1	0	0	1	1
Low Cost	5	0	-1	1	1	0	0
Consistent	4	0	1	0	1	1	0
Durable	3	0	0	0	1	1	1
Portable	2	0	0	0	0	0	0
Safe	2	0	1	1	0	1	1
Locally Maintained	1	0	-1	0	0	-1	-1
Temperature Control	1	0	1	1	1	1	1
Stakeholder Feedback	4	0	0	1	0	1	0
Engineering Feasibility	4	0	0	0	-1	1	0
Total:		**0**	**6**	**12**	**9**	**22**	**10**

Had we not included stakeholder feedback and engineering feasibility as criteria, idea #14 would still have been the idea that best adheres to our design requirements. It excelled in all criteria except for a moderate score in low cost, portability, and a low score in local maintainability. We discuss these failure points and potential remedies in the Alpha Design section below. Additionally, many other advantages of this concept were not reflected within the Pugh chart. The concept is very similar to the current testing protocol at KATH in Ghana, which meant it would likely fit into the workflow of caregivers. It was a very adaptable design, potentially accommodating a cell phone for filming in addition to an external camera. It was compact and simple to use. It had the potential to be equipped with computer vision software in upcoming iterations to automate the test.

Even with these advantages in mind, idea #6 was most competitive with our alpha concept – we ultimately selected idea #14 based on several key points of failure that could occur with idea #6, to ensure the Pugh chart was not our only selection criteria.

The first point of failure with idea #6 was regarding the uniformity of blood clots. Concept #6 assumed blood has a uniform viscosity that would apply a constant moment on the rod. However, from our conversation with hematologist Dr. Shevell, we learned that blood does not clot uniformly, but in small clumps. With this in mind, we were concerned that the rod might push clots out of the way which would provide an inconsistent viscous shear force. If the vertical rod clears a path in the clots, then it fails to measure the shear force component imparted on the rod from the clots, rendering this concept unable to determine when the clot forms.

The second point of failure with idea #6 was that blood viscosity varies between patients. Blood viscosity normally ranges from 3.5 and 5.5 cP, but can vary beyond this range depending on blood characteristics such as plasma viscosity [60]. Additionally, underlying health conditions, such as hypergammaglobulinemia, can result in blood viscosities outside of the normal range [61]. Idea #6 operates with a limit switch placed at a static displacement angle, however, we haven't considered that differences in blood viscosity will require different displacement angles. This could be rectified by making the limit switch position adjustable, but this would require extensive preliminary testing of each patient's baseline blood viscosity, creating additional user input requirements.

Idea #14 improves upon the existing test procedure, the Modified Lee and White test, so we are confident in its functionality. Idea #6 has several points of failure that discredit its functionality, so we ultimately pursued idea #14 in agreement with our Pugh chart.

The final step to take with our alpha concept was iterating based on stakeholder feedback and prior designs. We changed our vial stirring system to vial rotation, incorporated an integrated camera, designed a video replay UI, compacted the mechanism (like eliminated concept #7), and encased the mechanism to ensure operator safety. The final design concept can be seen in Figure 9 below.

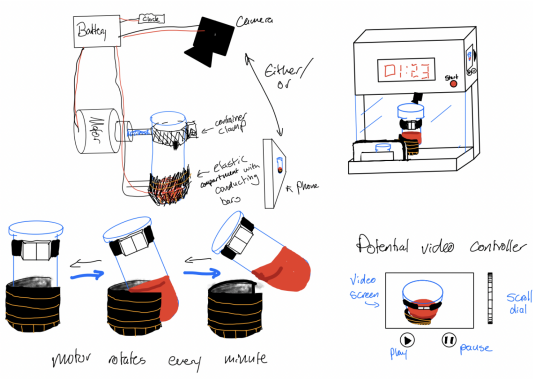


Figure 9: The top right image in Figure 9 shows the compact form of the device, which was inspired by the design of eliminated ideas (#7, #10, #11, #12, & #13). The new rotation motion is outlined in the left two diagrams. The vial will be heated by a black thermal sleeve and will rotate every minute to be in the frame of a phone/external camera and check for clotting. Lastly, as suggested by Dr. Thiyag, we incorporated an integrated video controller with button controls as seen in the bottom right image.

ALPHA DESIGN

From this alpha concept, our team constructed a CAD model. CAD images of the alpha design are shown below. Figures 10a-f show our alpha design from different angles, each angle includes two pictures. The top one has a solid frame, while the bottom picture's frame is transparent.

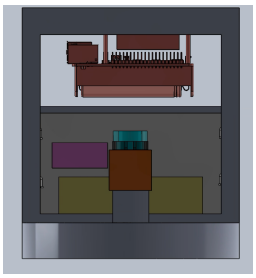
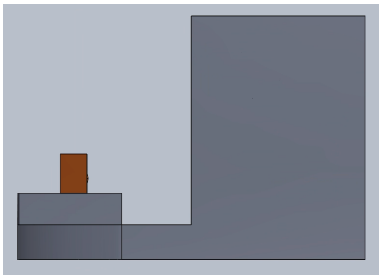


Figure 10.a: A depiction of the front view of the alpha design. Key components from this view are the orange camera enclosure, the yellow heat pads, and the pink 4-bit time display.



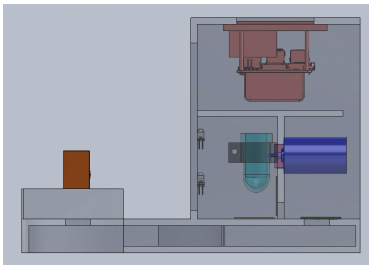
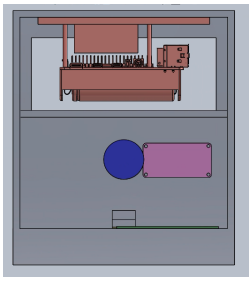


Figure 10.b: A depiction of the right view of the alpha design. Key components include the blue motor which rotates the light blue blood vial and the spacing relationship between the camera and the test.



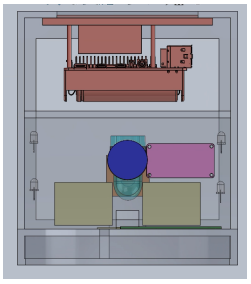
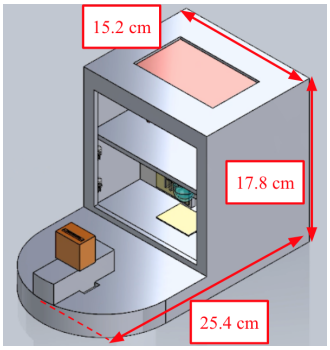
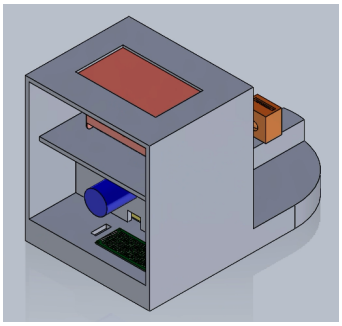
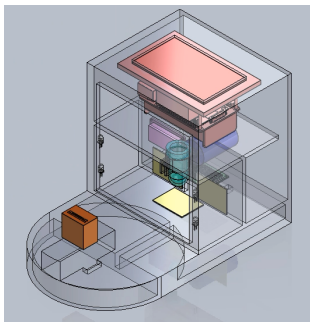
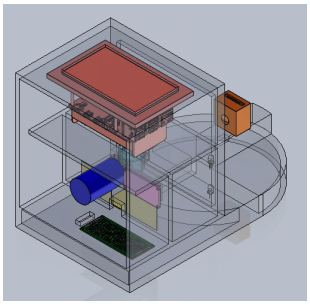


Figure 10.c: A depiction of the back view of the alpha design. Key components include the red subsystem consisting of a touch screen, microcontroller, power supply, and batteries.









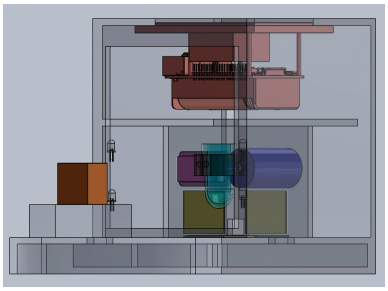


Figure 10.d: A depiction of the front isometric view of the alpha design. A key component is the clear LED lights that connect to the frame in front of the blood vial.

Figure 10.e: A depiction of the back isometric view of the alpha design. A key component from this view is the green breadboard on the back deck of the frame.

Figure 10.f: A depiction of the front dimetric view of the alpha design.

There was design iteration between the drawing of the alpha design and the CAD model of the alpha design. Significant changes include the design of the frame, the initial decision to use a camera and not the caregiver's phone (which was being considered in the original concept as a method to reduce cost), the placement of the screen relative to the frame, and the removal of the dials/buttons. The design of the frame was modified to better incorporate all components in the system, this included the semi-circular platform for the camera, the clock display changed to the left of the blood container, the position of the screen, and the elimination of a protective screen. The removal of the caregiver's phone was based on a lack of knowledge of caregiver dependency on their phone. When we were given an opportunity to speak with Dr. Konney again, this was a primary point of discussion to determine if we should switch directions and reduce costs by using the caregiver's phone. The screen was changed from the side to the top, as when the device is on a table, the caregiver will be looking down at it and will have the best view if the screen is on the top of the device. The decision to remove the dials/buttons stemmed from the screen's ability to execute similar functions, which reduces overall cost. With these design changes, the next step was to determine the components, their cost, and the supplier. Each one of the components was carefully considered to minimize cost and satisfy as many specifications as possible, considering priority. A bill of materials was developed to assess cost and is shown in Table 13 below.

Table 13: Bill of materials for the alpha design, colors in CAD complement the colors shown in Figure 10. All components are sourced from Amazon, the links of which are found in Appendix Z.

Component	Part Number	Color in CAD	Quantity	Cost / Unit
Miuzei LCD Screen (includes case, fan, and stylus)	MC21-4	Red	1	$33.99
Raspberry Pi 4 Model B	SC15184	Red	1	$68.99
AUTOTOOLHOME Motor	00933	Royal Blue	1	$6.89
DORHEA 4 Bit Clock Display	TM1637	Pink	1	$1.80
Icstation Square Heating Elements	9884	Yellow	3	$4.00
Solderable Breadboard	ECPB_H_B_5P+1	Green	1	$1.99
Arducam 5MP Camera	B0033	Orange	1	$9.99
Chanzo LED Lights	120DF5T-YT-WH -6SE-12V	Clear	4	$0.11
MakerHawk Power Supply	UPS HAT 18 650	Red	1	$33.99
18650 Lithium Ion Batteries	25R-2500mAh	Red	2	$6.97
Wiring	Fermerry-30	N/A	1	$2.17
3D Filament	OVPLA175	(Grey, Orange, Black)	1	$14.99
Tax, Shipping, and Handling				$18.23
Total				$219.41

With the key components chosen for the alpha design, our team performed an analysis on how our design should operate and how each component could be potentially improved. Firstly, a 3D-printed frame was chosen for prototyping to test the placement of all components and cheaply determine any design changes that may be needed. A potential design flaw with the frame was the difficulty of inserting the blood container into the device. With this version of the design, the caregiver may have difficulty accessing the vial with their hand. To address this, further iteration of the design included more open access to the vial and clamp.

The camera component of this design is fulfilled by a Raspberry Pi-compatible camera module. We chose this part due to its feasibility with prototyping microcontrollers and its low cost. The camera module in our alpha design is encapsulated by a 3D printed cover. The prototype frame supports the camera by keeping it centered while still allowing for adjustable camera positions. This was to accommodate adjustments we may make to the placement of the camera. Figure 11 on the following page shows the positioning between the camera and the vial/clock.

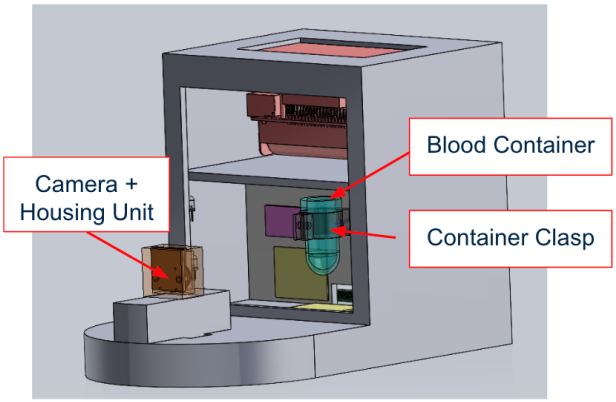


Figure 11: A labeled diagram of our alpha design. The camera enclosure is transparent so that the camera module can be seen within the enclosure. The blood container will be centered in the video with the 4-bit clock positioned to the left of it. When the container rotates during the test, the camera will maintain its position and the tilted blood container will still be visible in the video.

The lower portion of the back of the frame consists of a motor, a 4-bit clock display mounted to the wall, and a breadboard mounted to the deck of the frame. The motor powers the rotation of the blood container. The 4-bit clock displays the time of the test next to the blood vial. A rear view of the alpha design with relevant components can be seen in Figure 12 below.

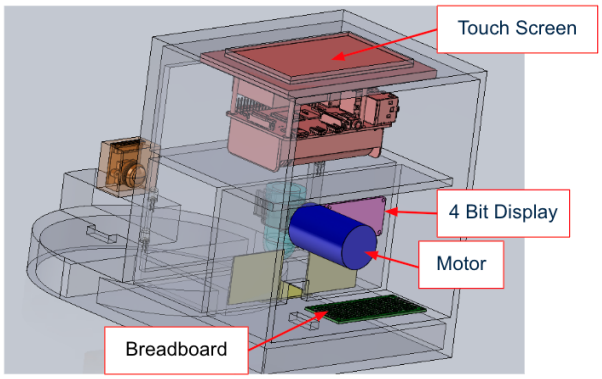


Figure 12: Back view of alpha design. The motor and 4 bit display are both mounted to the middle wall panel and will be connected to the breadboard.

In front of the wall that the clock is mounted to, are the heating pads, blood vial clasp, and LEDs. Further testing and research were required to determine how tightly secured the vial should be while not obstructing the view of the camera. The heating pads shown act as placeholder for the eventual heating system in the build and final designs, which will be mounted to the clamp, and come into direct contact with the vial. Details of heating power requirements can be found in the Engineering Analysis section. The LEDs will be used to ensure optimal video clarity. These components can be seen in Figure 13 below.

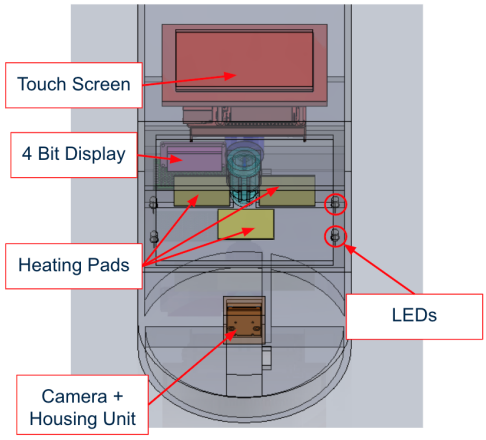


Figure 13: Front/top view of the alpha design. The clasp and blood container are labeled and clearly shown in Figure 11. Note that as of now the heating pads are not shown in their final positions. They are displayed on the sides as a placeholder, but the next iteration of the design will include the heating pads attached to the clamp.

The upper compartment of the frame consists of a touch screen, microcontroller, power supply, and two 18650 lithium-ion batteries shown in Figure 14. Starting from top to bottom, the screen was chosen because it is compatible with standard medical gloves and will not require the practitioner to take off their gloves to use the device. All electronic components are connected to the breadboard and controlled via the Raspberry Pi 4B. Additionally, it is equipped with a fan to combat overheating in the hot Ghanaian climate, touch compatibility for easy interaction, and a housing unit for simple device implementation. However, we anticipated that this component may be too expensive, non-interchangeable, and unnecessary for our design. Possible replacement microcontrollers were considered. For our alpha design, the microcontroller is a Raspberry Pi 4B with 2 GB of storage. We initially believed that this is the best microcontroller for our device due to its incorporation of storage for videos, ample resources, and potential for operating all of our design components. There was also a possibility that it could be locally sourced given electronic stores in Accra, Ghana [69]. The downside of this component was that it costs nearly $60. The power supply of the device consists of a housing unit and lithium-ion batteries. These batteries will power all subcomponents of our device, are rechargeable, and the power supply can be plugged into a standard wall outlet. This is shown in Figure 14 below.

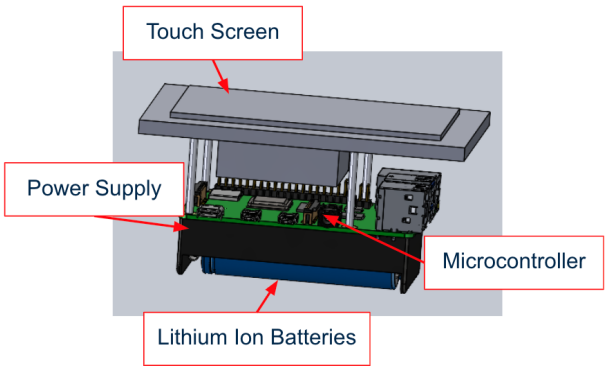


Figure 14: A breakdown of the red subcomponent in the previous depictions of the alpha design.

From this alpha design, further research and iteration needed to occur to create a final design. This included all the suggested improvements above along with a complete circuit schematic incorporating all electrical components, interchanging various parts for locally sourced components, and developing code to seamlessly integrate all components of the system. After completing the alpha design and presenting it in class, our team learned that we needed to spend additional time focusing on how to lower the cost of our device and also looking more extensively into locally sourced materials. Further team research and stakeholder meetings were conducted to ensure the feasibility of a final design. Once all subcomponents were finalized, shipping costs and consumer assembly were points of contention. We learned that the final design needs to be easily assemblable in Ghana and should have locally sourced replacement parts in case of malfunction.

ENGINEERING ANALYSIS

To confirm the components of our alpha design are fully functional and serve to meet the requirements and engineering specifications outlined, a preliminary engineering analysis was conducted. Camera viewing distance was calculated to determine the dimensional requirements of the blood clotting test's frame. The blood vial heater's power requirement was also calculated to determine the power supply requirements. The motor torque requirement to rotate the blood vial was calculated to designate the motor size and power supply required for the motor. Finally, Design Failure Mode and Effect Analysis (DFMEA) was conducted to gain a preliminary understanding of the potential failure modes of the alpha design.

Firstly, to promote the ease of use requirement by ensuring user input is minimized, the selected camera module's field-of-view must cover the full blood vial as well as the timer for the duration of the test. Trigonometric calculations of the camera's horizontal (HFOV) and vertical fields-of-view (VFOV) were performed to validate the camera's minimal viewing distance with the vial placed at the focal center of the camera. The vertical and horizontal calculations were conducted independently, and the largest distance between the calculations was taken to be the minimum viewing distance. These calculations can be seen in Figure 15 below. We ensured the camera we chose in the final design had a minimum focal distance below the determined viewing distance so that the vial and timer were in focus and the image was clear. The FOV angles were selected from our camera module.

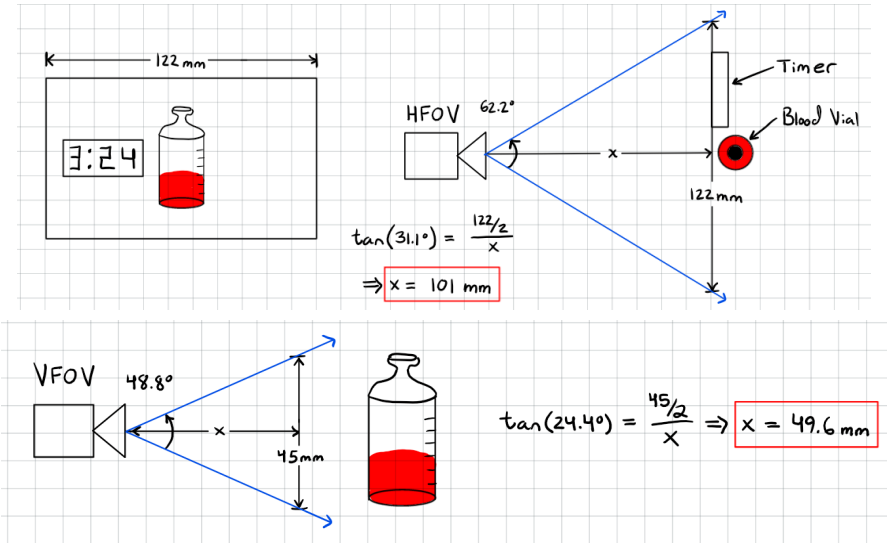


Figure 15: Above are the calculations for camera viewing distance. Note that the blood vial dimensions are from an ISO 8362-10R standard vial, which is comparable to the blood test vials currently used at KATH and Korle Bu. Note that the HFOV is the limiting factor for the viewing distance, caused by the clock being offset from the center.

From these calculations, it was determined that the camera must be placed 10.1 cm from the blood vial and timer to capture the entirety of the timer and vial in the image.

To ensure the optimal blood temperature control specification is met, a calculation of the power required to maintain blood at body temperature (37°C) [42] was performed. This was done via a thermal resistance circuit. The calculation and assumptions are outlined in Figures 16a and 16b below.

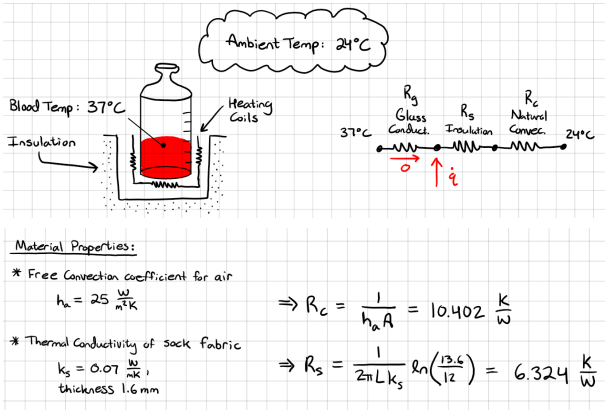


Figure 16a: Above is the thermal circuit, which includes the conduction resistances of borosilicate glass, thermal insulator, as well as convection resistance. Note that energy input is taken to be in between the insulation and borosilicate glass. [62], [63]

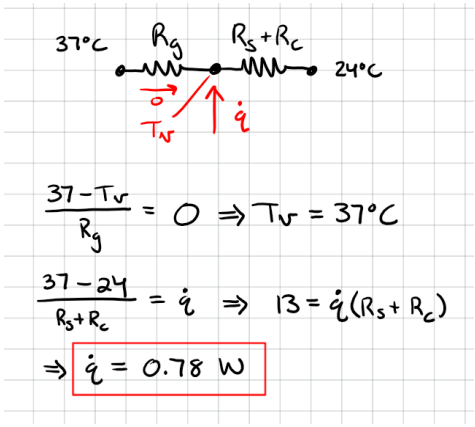


Figure 16b: From solving for the thermal circuit, the energy input found to be required is 0.78 watts. All formulae and relations for these calculations were obtained from *Fundamentals of Heat and Mass Transfer, Eighth Edition*. [64]

From these calculations, it was determined that the blood vial heater must supply 0.78 watts of energy to the vial to maintain the blood at body temperature. In the final design, a higher power heater was selected, and a duty cycle was applied for added flexibility.

Finally, to ensure the consistent requirement was satisfied concerning the continuous operation specification, the required torque to fully rotate a blood vial was calculated via a moment balance calculation. If the motor does not have sufficient torque, then the blood vial may not turn enough so that the user has more difficulty discerning if the blood has clotted, which can result in inaccuracies. The assumptions and results from this calculation are shown below in Figure 17.

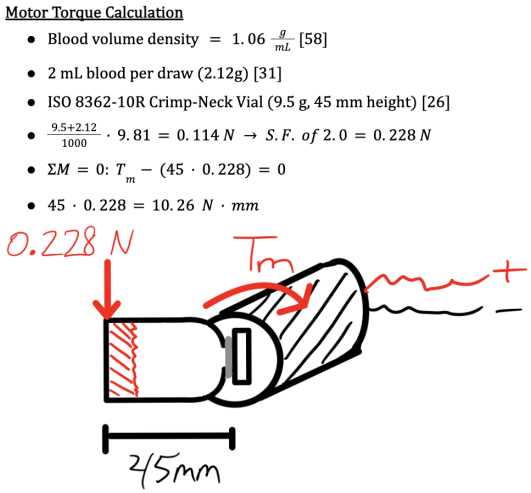


Figure 17: Seen left are the assumptions and calculations to determine the torque required to fully rotate a blood vial. Note that for the static calculation, all mass of the blood and vial are taken to be concentrated at the end of the length of the vial, and an additional safety factor of 2 is implemented. All formulae were obtained from *Engineering Mechanics: Statics 12th Edition* [65].

From these calculations, it was determined that the motor must provide 10.26 N · mm of torque to rotate the blood vial.

Multiple potential failure modes in the alpha design were identified. These failure modes are outlined in the design failure modes and effect analysis (DFMEA) seen in Table 14 below, which explored potential failure modes, their respective severities, potential causes, and preventative measures for the respective failure modes. The severity of failure modes was rated on a 1 to 5 scale, with 1 being minor malfunctions that only affect the convenience of operation, and 5 being catastrophic failure including but not limited to user harm or a false-negative reading.

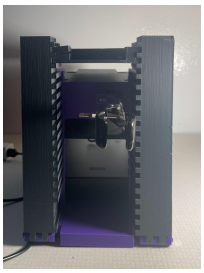
Table 14: The following DFMEA report summarizes potential failure modes that have been identified, providing the severity of risk from 1 to 5, effects on the design, and effect mitigation routes.

Potential Failure Mode	Effects of Failure Mode	Severity	Potential Causes	Preventive Measures
Vial breaks during operation	Users may be exposed to a biohazard	5	Improper clamping force, defective blood vial, vial heater failure (overheating)	Ensure adequate padding on clamp, inspect vial before use, select proper fuse for vial heater
Device does not power on	User cannot use device	3	Dead batteries, unplugged power cord, loose internal wiring	Ensure proper soldering of electronic components, provide battery level warning to the user, check power cord
Images are of poor quality	User cannot determine if blood is clotted	3	Contaminants on camera lens, item obstructing camera view, inappropriate lighting, damaged camera, error in auto focus	Clean the camera lens daily, place device in well lit room during operation, user checks camera view before running test, require user to verify vial is in focus
Motor does not tilt vial to correct angle	User may find it more difficult to determine if blood is clotted	1	Wear on motor transmission components, dysfunctional encoder	Inspect motor for backlash

From Table 14, important preventative procedures in both manufacturing and in device operation were identified. The preventative procedures in operation should be outlined in any future user manual. Furthermore, plans for engineering analysis were devised and conducted with the build design via the DFMEA. To mitigate the risk of vials breaking during operation, we performed verification tests outlined in the Specification Verification section under the safe requirement, which ensured the vial would not break during the clamping process. To facilitate quality images, a minimum camera resolution specification was set in the Component Selection section. To make sure the motor can consistently invert the blood vial at the correct angle, we made sure to select a quality motor to rotate the blood vial, which has been verified against durability under the durable test in the Specification Verification section.

BUILD DESIGN

After conducting preliminary analysis and incorporating stakeholder input on the alpha design, a prototype build design was modeled in CAD. This was subsequently constructed to assess remaining uncertainties and verify that the design is capable of meeting the requirements and specifications. The build design not only addressed certain shortcomings of the alpha design but also introduced some enhancements. Figure 18 below and on the following page displays six different views of the build design including the CAD and physical prototype.



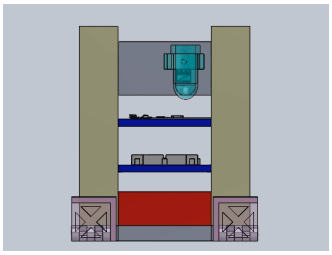
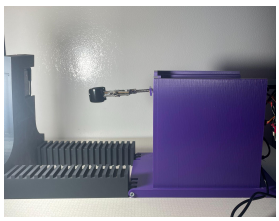


Figure 18.a: A depiction of the front view of the build design. Key components from this view are the green phone enclosure in line with the blue blood container.



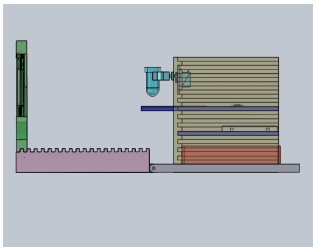


Figure 18.b: A depiction of the right view of the build design. Key components from this view include the pink arms which allow adjustability for the phone-to-container distance.

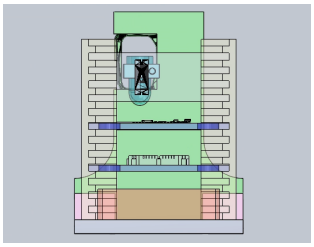
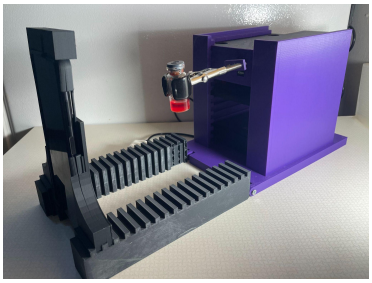


Figure 18.c: A depiction of the back view of the build design. Key components include the gray motor mount plate, a Raspberry Pi Pico atop a blue shelf, a breadboard atop another blue shelf, and a red power supply.



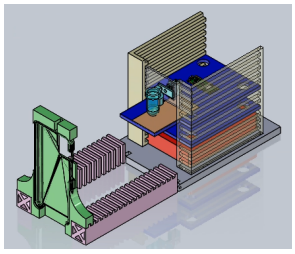


Figure 18.d: A depiction of the front isometric view of the build design. A key component seen from this angle is an orange heating pad.

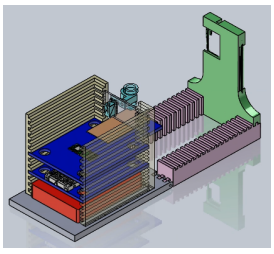
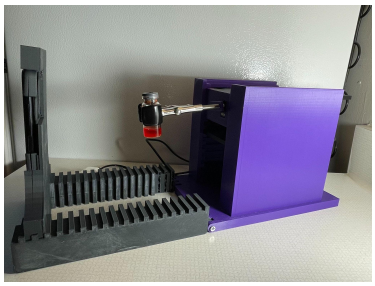


Figure 18.e: A depiction of the back isometric view of the build design.



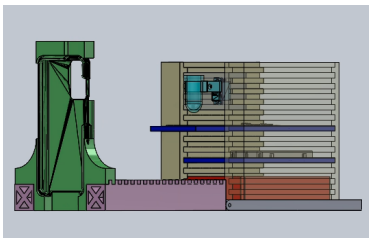


Figure 18.f: A depiction of the front dimetric view of the build design.

The key features present in the build design that did not appear in the alpha design include the addition of a phone, adjustability features, easier access to the vial clamping mechanism, and a folding feature to compactify the device during storage. The phone was selected as a cost-efficient replacement for the individual camera, touch screen, LEDs, and 4-bit display components present in the alpha design. Concerns with the clinician's use of medical gloves potentially impairing the usability of the device were addressed in the build design. Dr. Tawiah informed us that some other devices at KATH, such as a colposcope showcased during the interview, incorporate touchscreen technology. From this, our team inferred that there should be no issues with medical gloves [86]. Figure 19 below provides a side-by-side comparison between the alpha and build designs and highlights the key components of each.

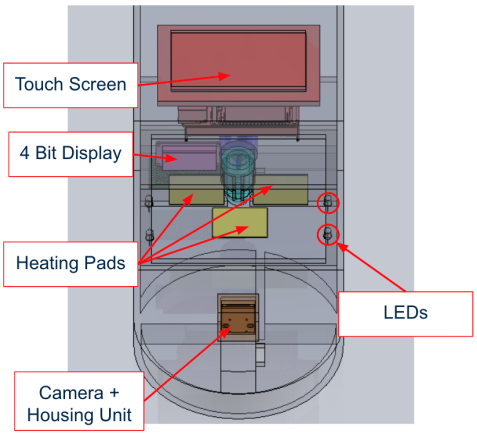


Figure 19.a: A front view of the alpha design with the notable components labeled.

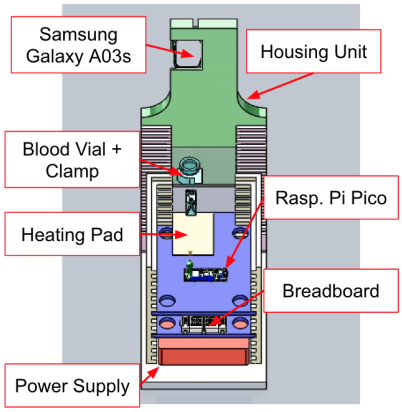


Figure 19.b: A back view of the build design with the notable component changes labeled.

Additional adjustability was achieved through the incorporation of ridges on the arms extending to the phone housing and on the inside walls of the power supply housing, as depicted in Figure 19 above. These ridges enabled flexibility in the placement of the phone camera with respect to the vial, allowing for adjustability as needed. This adjustability played a crucial role in testing as it enabled verification of distance calculations and the flexibility to refine distances if they were not favorable in the playback video. The adjustability features are not present in the final production design, as the ideal placement of the camera and vial is known and fixed. The ideal placement is defined as the closest point at which the camera can maintain the entire blood vial in the field of view at any orientation while maintaining focus.

The build design also addressed the concern with the alpha design of impaired access to the blood container. The alpha design placed the vial in a 5-sided enclosure which could have obstructed the user from accessing the container easily. The build design fixed this problem by positioning the blood container in such a way that it is accessible and no longer enclosed.

The build design added a folding feature to the design that reduces the size of the device by a factor of ~2. This allows for compact storage and improved portability. It also allows for easy viewing of the test video without having to remove the phone from the device. The device's folding feature is shown in Figure 20 below.

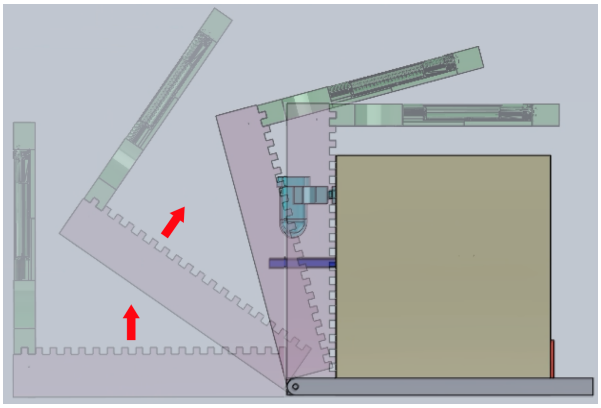


Figure 20.a: A stop-motion diagram of how the device folds. The design allows for the phone to stand upright on a flat surface, and then easily lifted to fold on top of the yellow frame. The hinges are attached by M5 X 35 mm self-tapping screws.

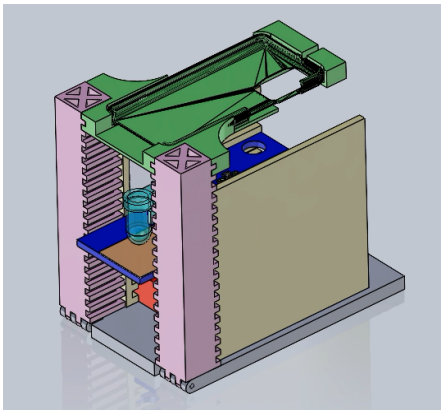


Figure 20.b: The build design folded up. Once folded up, the caregiver can easily stand over the device and assess the test.

The dimensions of the build design are within the outlined minimal dimensions of the specifications. When folded, the device fits within the optimal 25 cm dimension specification. This is shown below in Figure 21.

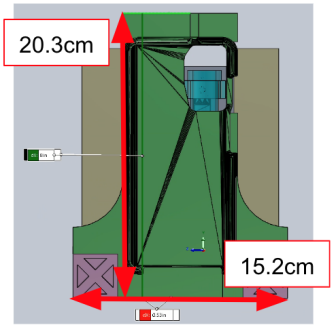


Figure 21.a: An unfolded front view of the build design with max height and width shown to be less than the optimal dimension of 25 cm

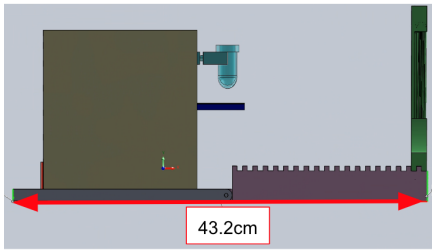


Figure 21.b: An unfolded left view of the build design with max length being less than the minimal dimension of 46 cm.

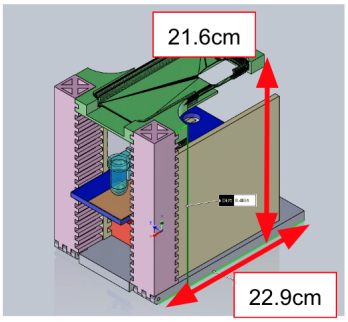


Figure 21.c: A folded isometric view of the build design with all dimensions less than 25 cm. Width shown in Figure 21.a

To analyze the effect on cost that the changes from the alpha design to the build design introduce, as well as ensure that the materials budget of $300 is satisfied, a bill of materials for the build design was generated, shown below in Table 15.

Table 15: Bill of materials for the build design, colors in CAD correspond to the colors shown figures above. The cost column represents the unit cost of each component multiplied by quantity. All components except for fasteners are sourced from Amazon, links to build design components except for fasteners can be found in Appendix AA.

Component	Part Number	Color in CAD	Quantity	Cost / Unit
Shanqiu Power Supply	FX 5-12	Red	1	$79.99
Raspberry Pi Pico	RP2040	Green	1	$6.62
Lewansoul Motor	LFD-01M	Light Blue	1	$8.99
Vial Clamp	CH0688A	Light Blue	1	$9.89
Icstation Circular Heating Element	9885	Orange	1	$3.50
Solderless Breadboard	EL-CP-003	White	1	$3.33
Samsung Galaxy A03s Phone	TVSAS134DCP	N/A	1	$49.88
3D Filament	OVPLA175	Dark Green, Yellow, Pink, Grey, Royal Blue	1	$14.99
Wiring	Fermerry-30	N/A	1	$2.17
Power MOSFET	IRLB8721	N/A	1	$1.00
M5 X 35 mm self-tapping screws	N/A	N/A	2	$0.39
M2 X 10 mm self-tapping screws	N/A	N/A	2	$0.29
Tax, Shipping, and Handling				$8.92
Total				$190.64

As shown in the bill of materials above, the build design was within the $300 materials cost specification. Furthermore, the build design was found to cost approximately $29 less than the alpha design.

In addition to the structural embodiment of the build design laid out above, a system connection diagram was developed to document the electrical connections between components. This diagram is shown on the next page in Figure 22, and includes the peak power requirements of each device used in the calculation of total power consumption and verification of the power supply component.

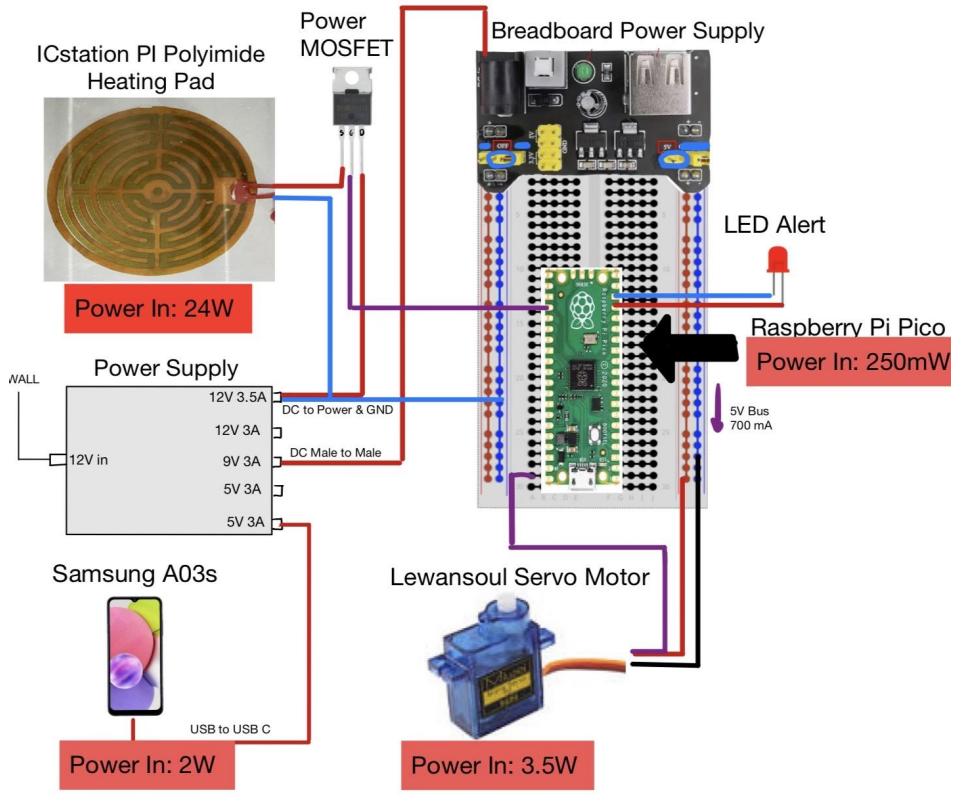


Figure 22: Shows the layout and connections of electrical components in our build design. Maximum instantaneous power consumption is also labeled to quantify the electrical costs and battery life of the device.

As shown in Figure 22 above, all components received their desired operating power in this configuration. The main power sinks include the heating pad, phone, servo, and Raspberry Pi. The instantaneous power consumptions of each component are shown, however, these are not representative of the average power consumptions over a test cycle. For example, the motor may consume 3.5 W while active, however, it is only active for ~1 minute during the 11 minute test. Thus, in calculating the average power consumption for one test, the motor's power input was divided by 11. Summing the listed power metrics, this resulted in an average power consumption of 27 W for the device throughout the 11 minute test, or 5 Wh of energy for one test.

Furthermore, an accompanying concept phone application was developed. The proof of concept design visualizes the two necessary components: testing and video library. The application wireframe made in Figma is outlined below in Figures 23 and 24.

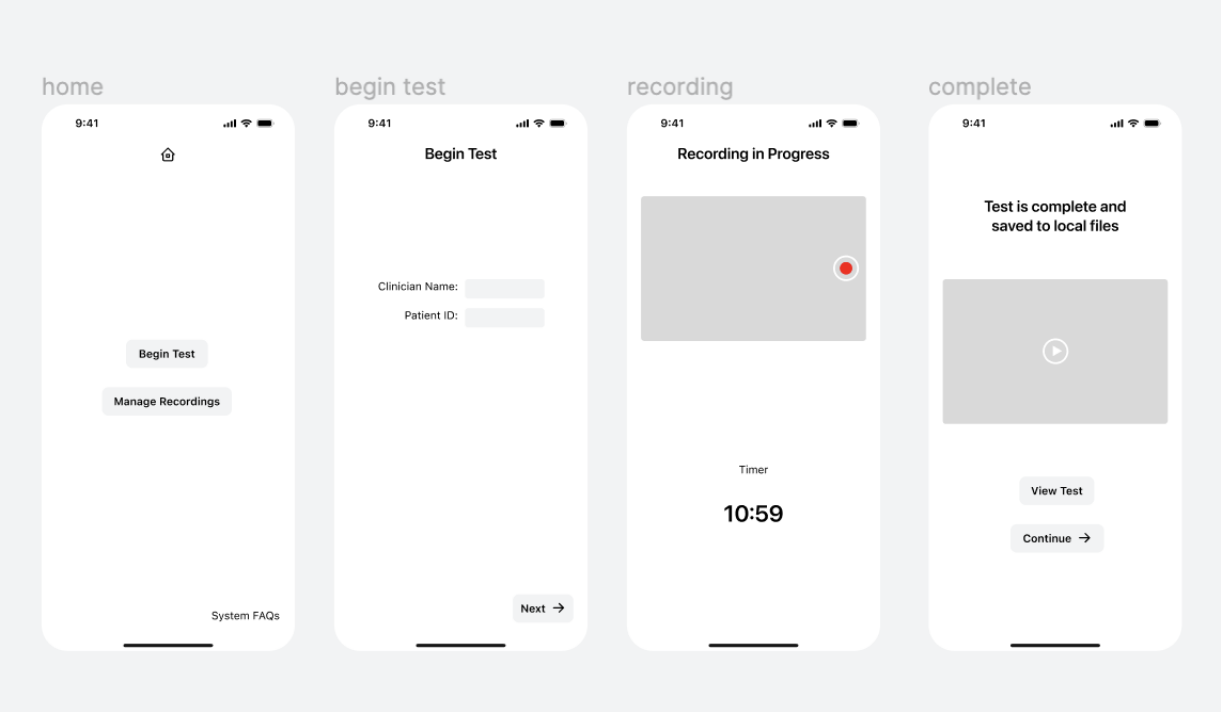


Figure 23: Phone Application - Testing Feature

Figure 24: Phone Application - Video Library Feature

In addition to visualizing time and recording for the test, the application also encourages caregivers to input patient and caregiver information for identification purposes. After the test has been recorded, the caregiver can choose to view the test and log the clotting time immediately, or review the test later from the library. The library labels the recorded tests by the status of the clotting time: under 11 minutes (green check mark), above 11 minutes (red cross), and undetermined (gray).

This is an example application that we recommend to be implemented in the final design. The testing feature functionality of the application can be coded with Macros on this phone with MacroAndroid. Macros are sequencing of tasks on digital devices that automate a process, and the test can be automated by simultaneously starting a timer for 11 minutes and a video camera recorder. After the timer, the alarm can be the alert system and the video will be saved to the photo album after the test is done. In the future, a computer vision algorithm may be implemented (without any additional physical components) to autonomously determine the clotting time, but currently, that is outside of the scope of the class.

MANUFACTURING PROCESS

As mentioned in the Bill of Materials in the previous section, almost all components of the build device were sourced via Amazon, except for fasteners which were sourced from Carpenter Brothers in Ann Arbor, MI. All frame components, the vial link, and the Galaxy A03s phone case were 3D-printed using PLA. This build design was completely assembled at the University of Michigan in Ann Arbor, MI. A detailed assembly guide for the build design can be seen in Appendix AE.

COMPONENT SELECTION

To ensure our build design satisfies the engineering requirements and specifications outlined, a formal critical component selection process was conducted. This involved preliminary analytical calculations to designate component specifications, interpreting the calculation results to make data-driven component selections, and empirically verifying the selected components (note that component specifications differ from design specifications, as they provide the design with the fundamental ability to fulfill tasks which satisfy the design's engineering specifications). Critical components which have been analyzed, selected, and verified are outlined below.

Firstly, to inspect if the blood has clotted while minimizing user input for the easy to use requirement, a motor must rotate the blood vial 180° once every minute for the duration of the test. Note that the minimum torque requirement for the motor is unchanged from the Alpha Design Engineering Analysis section. This calculation can be seen in Figure 17 and requires 10.26 N · mm of torque to fully rotate the blood vial. This specification along with the durability requirement in consideration led us to choose the Lewansoul 9g Micro servo motor. This motor has 180° of positional control with a stall torque of 147 N · mm, and an MSRP of $8.99 [76]. An image of the selected servo can be seen below in Figure 25.

Figure 25: Seen left is the Lewansoul 9g servo motor for reference [76].

A noteworthy feature of the Lewansoul servo motor is the metal internal gearbox which provides a durability advantage over other servo motors of comparable power ratings and price which generally have plastic internal gearboxes. Empirical testing of the Lewansoul servo motor was

conducted using a load of 10.26 N·mm on the motor at a 1 Hz frequency for 15 minutes to verify that the motor could consistently rotate the determined load requirement. The test setup for verifying the motor's capability to rotate this load is shown below in Figure 26.

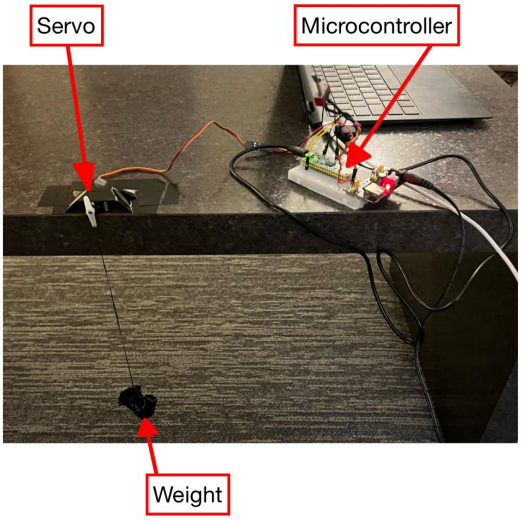


Figure 26: Displays the test setup for verifying the motor torque output capability. The servo motor was tested at 10.26 N · mm of load at a frequency of 1 Hz. for 15 minutes.

The Lewansoul servo motor successfully completed this test sequence, verifying that the quoted capability of the motor satisfies the task of rotating the blood 180°.

Next, analysis and selection of the device's phone camera was performed. A camera that can record a clear video of the whole blood vial at high quality for the duration of the test is crucial to minimizing caregiver input and in turn, promoting the easy to use requirement. To ensure the video recordings are clear, the minimum recording quality is chosen to be 1080p at 30 frames per second. This was found to be sufficient for the build design application, as it not only provides clear image quality for the user but is also efficient from both a cost and memory standpoint vs. higher-resolution sensors such as 4K [81]. Furthermore, a camera's field of view is important as it contributes to the minimum viewing distance of the blood vial while maintaining the whole vial in the image, and consequently affects the dimensional footprint of the build design. A shorter minimum viewing distance enables a smaller dimensional footprint to be utilized, contributing to the portable requirement. To satisfy the dimensional specification (< 46 cm in all dimensions) while leaving room for electronic components, a minimum viewing distance of < 23 cm was identified. This minimum viewing distance was determined by subtracting the largest dimension of our largest electrical component, the power supply [79], with a safety factor of 1.5, from the minimum dimensional specification. Using trigonometric calculations with the dimensions of the blood vial, the < 23 cm minimum viewing distance necessitates a minimum horizontal / vertical field of view of 24.6° / 24.6°. Details of calculations regarding the field of view are included in Appendix AB. With these specifications in mind and stakeholder discussion with Dr. Tawiah, the selected phone for the build design is the Samsung Galaxy A03s, which is capable of 1080p video quality at 30 frames per second, and a horizontal / vertical field of view of 48.6° / 62.1° [82]. Video quality and field of view of the device are implicitly verified from the phone's specifications. Note that the MSRP of the Galaxy A03s is $49.88 [85], and the unit is readily available in Ghana [86], which serves to promote the low cost and locally maintained requirements. To empirically confirm the A03s can focus on the vial at a distance of < 23 cm throughout a 180° rotation while maintaining the full vial in frame, the phone was placed in the

build device starting at the maximum distance of 16 cm from the vial on video setting, checking the phone's frame and focus for an entire rotation. This test was repeated in decreasing distances of 1.5 cm per interval. The setup of this test with the Galaxy A03s can be seen in Figure 27 below.

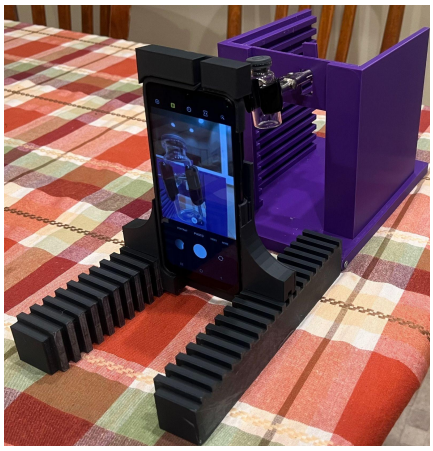
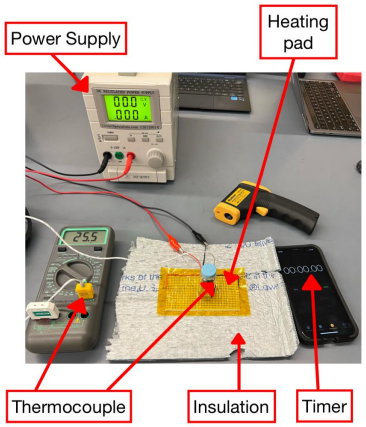


Figure 27: Shows the setup for the Samsung Galaxy A03s camera verification test. The vial was rotated a full 180° while monitoring the camera's frame and ability to focus on the vial.

Upon testing, it was found the minimum distance at which the camera could maintain the entire vial within the frame was 11.5 cm. At this distance, the camera was still able to maintain focus. It is concluded that the Galaxy A03s fully satisfies component specifications and operates as expected. Note that we were able to move the phone to < 10 cm distance from the blood vial before beginning to observe issues with focus.

To achieve the blood temperature control requirement, the blood must be maintained at body temperature (37°C) for the duration of the test. A heating pad that provides sufficient power to maintain this temperature is necessary to satisfy this specification. From preliminary engineering analysis of the heating system in the alpha design, seen in Figure 16, it was estimated that the heating pad must provide roughly 0.78 W of power directly to the vial to achieve the desired blood temperature. From this, we chose to select heating components within the 5-20 W range to ensure unavoidable heat losses would be accounted for. This led to the selection of two potential heating pads, including the Adafruit 1481 with an MSRP of $5.95, and a peak power output of 12 W, as well as the Icstation PI Polyimide Heater, with an MSRP of $3.50 and a peak power output of 13 W. Due to time constraints, only the Adafruit 1481 was tested. To verify this component was able to meet the minimum power requirements, a blood vial filled with 2 mL of water (which has comparable specific heat to human blood [80]) was placed on top of the Adafruit 1481 and the pad was powered using a DC power supply. The test setup to verify this power output along with the resulting plot of blood temperature vs. time can be seen below in Figure 28.



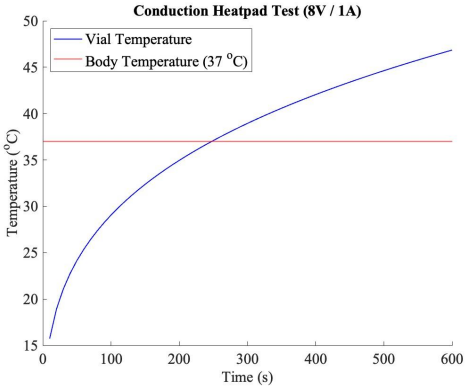


Figure 28a: Shown above is the test setup to verify required energy to heat blood to body temperature.

Figure 28b: Shown above is the plot of vial temperature vs. time.

The purpose of this test was to verify that the heating pad meets the minimum power requirements, and is able to achieve a temperature at or above the desired 37°C. If the temperature exceeds 37°C, then it is possible to implement a basic control system that reduces the power output of the heating pad to maintain the desired temperature. This control system would require no additional components and adds negligible cost. As shown in the graph above, the Adafruit 1481 was able to surpass the desired temperature of blood at a power output of 8 W, conforming to the set specifications. Additionally, we can confidently state that the Icstation PI heater will also conform to these specifications, as it has a sufficient power output (13 W peak compared to the 8 W tested with the Adafruit pad), and outputs this power over a smaller surface area [77], [78], reducing the heat lost to the environment and increasing direct power to the vial. This improves the power efficiency of the heating system, and thus we plan to move forward with the Icstation pad. This heater pad and its position in the blood container receptacle of the build design is depicted below in Figure 29:

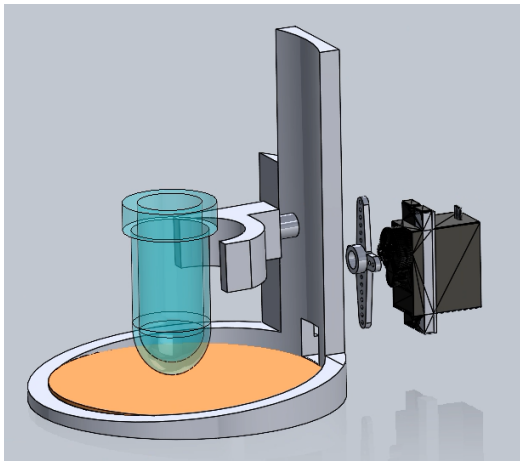


Figure 29: Blood container receptacle assembly. From left to right there is a blood container, clamp, heating pad bracket, servo-motor arm, and the servo. The blood vial sits on the heating pad (orange) and is heated primarily via conduction.

With this configuration, the vial receptacle can support a range of vial sizes, with the clamp being able to grip vial diameters between 15 and 45 mm.

Finally, the selection process for the power supply was carried out. The device's ability to continuously operate in the absence of grid power for 8 hours contributes to the consistent requirement. Note that 8 hours of use without grid power is equivalent to 3.3 tests when expressing the 8 hour time frame as a fraction of the uses per year specification (3,650), however, we chose to analyze the power requirement based on operating 5 tests without grid power to implement a safety factor on the calculation to account for potential spikes in testing volume. To determine the required Watt hours (Wh) capacity of the power supply, the energy consumption of one 11-minute test (5 Wh as calculated previously in the build design section) was multiplied by 5 tests. With a safety factor of 2, this leads to a minimum power storage requirement of 50 Wh. Using this data, the power supply chosen for the build design is the Shanqiu Mini UPS Battery Backup, which has an energy capacity of 72 Wh [79]. The Shanqiu power reserve is shown below in Figure 30.

Figure 30: Above is the Shanqiu Mini UPS Battery Backup [79].

Note that the MSRP of the backup battery is $79.99, making it the largest material cost of our build design. It is understood that this power supply has energy storage slightly beyond what is minimally necessary, and we recommend future teams look to reduce cost by selecting a smaller power supply for the final production design. Empirical verification of the power supply was conducted to verify the device's ability to conduct 5 tests without grid power. This process is discussed later in the verification plan for the consistent requirement.

SPECIFICATION VERIFICATION

To verify that the design will meet the necessary specifications laid out in Table 5, verification plans for each minimum specification have been constructed. Most of the verification plans involve empirical testing of the prototype build design, however, some involve analytical calculations or a combination of both. Table 16 below summarizes these verification plans and the specifications they address. The verification plans focus on the minimum specifications, as the optimum specifications are targets of future iterations of the design.

Table 16: Verification Matrix

Requirement	Specification(s)	Verification Plan	Date / Compliance
Low Cost	< $300 Material Cost	Cost Analysis	11/19, Compliant
	< $0.14 Per Test	Cost Analysis	11/19, Compliant
Easy to Use	The device uses whole blood without reagents or inhibitors	Verified by design	Compliant
	Blood container is removable	Usability testing	12/5, Compliant
	< 1 minute setup time	Usability testing	12/5, Compliant
	Alert each minute after the 3 minute mark	Verified by design	Compliant
	< 3 minute caretaker supervision per test	Usability testing	12/5, Compliant
Durable	Withstands > 3650 uses (1 year) [24]	Subsystem testing of all working components	11/7, Compliant
	Withstand trials in 10 & 44°C [57]	Test at various temperatures and humidities	12/5, Compliant
	Withstand trials in 10 & 99% humidity [57]	Test at various temperatures and humidities	12/5, Compliant
	Must withstand hospital sterilization (3-6% hypochlorite bleach, 70% alcohol) [39]	Research on material compatibility	11/29, Recommended Design Changes
Consistent	30s time resolution error	Verified by design	Compliant
	Continuous operation for 11 minutes	5 consecutive tests on power reserve	12/4, Compliant
	Able to operate for 8 hours without grid power	5 consecutive tests on power reserve	12/4, Compliant
Portable	< 11.6 kg [18]	Weight Test	Compliant
	< 46 cm in all dimensions	Verified by design	Compliant
Safe	Blood containers are fixed to device during testing	Clamp and rotate test	11/13, Compliant
Safe (cont.)	Blood container must not break under standard testing conditions	Clamp and rotate test	11/13, Compliant

	Only pinch point at blood container fixture	Verified by design	Compliant
	The device must not expose practitioner to blood	Verified by design	Compliant
Locally maintained	Consumable components are locally available (≤5 imported components)	Verified by design	Compliant
	≤2 consumable components	Verified by design	Compliant
Controlled Blood Temperature	Blood is kept at body temperature (35.5°C-38.3°C)	Blood proxy heat test	12/5, Compliant

Low Cost:
To meet the low cost requirement, two specifications must be satisfied: < $300 material cost, and < $0.14 cost per test. To verify that the design is under $300 in materials, the bill of materials (Table 16 above) was used. To verify that the design meets the $0.14 cost per test, the per-test cost was estimated using the following formula:

$$C = E + M/3650$$

In this equation, C is the cost per test, E is the electricity cost per test, and M is the total material cost from the bill of materials. The number 3,650 comes from the minimum number of uses from the durability specification. Electricity cost was calculated from the average cost of electricity per kilowatt-hour in Ghana [93], $0.063/kWh, as well as the total power consumption of all components in the device as determined in the build design introduction above (~27 W), and the time length of one test (11 minutes). Multiplying these figures together, we obtain the result that one test will cost about four-hundredths of a penny in electricity costs. In other words, the electricity costs of this device are negligible compared to material costs. With the bill of materials of our prototype adding up to $180.43, the material cost term results in a cost per test of ~$0.05, well within the $0.14 per test specification.

We are confident that this device meets the specifications listed in the low cost requirement, given the analysis above. Assuming no pivotal design changes are made in the transition between the build design and the final production design, the final product will also satisfy the low cost requirement. This is additionally supported by the fact that, at larger production volumes, manufacturing costs are reduced, meaning the upfront material costs of the final design have the potential to be even lower than the determined material cost of the build design. It is important to note, however, that some additional costs have been neglected in the formula used to calculate the per-test cost. These neglected costs include consumable costs (of which there are none as this design uses no consumables), and additional upfront costs involved in purchasing, such as shipping/import tariffs, taxes, etc. These additional costs would need to be greater than $328.50 to invalidate the cost per test specification of $0.14, since all of these costs are divided by 3,650. We estimate through brief market research that these additional costs would be roughly $100 for a device of this size and value, far below the $328.50 metric.

This is the best methodology for verifying cost as it is quick and provides a metric that is at a comparable level of rigor to our cost specification. Since our cost specification is difficult to

calculate and there is uncertainty with the accuracy of the number as described in the requirements and specifications, there is no need to perform a rigorous cost analysis using software such as CES.

Easy to Use:
There are three ease of use specifications to verify: 1. Blood container removable within 10 seconds, 2. Less than 1 minute set up time for the device, 3. Less than 3 minutes of caregiver hands on time per test. Specifically, set up time refers to the amount of time a caregiver spends preparing a test before starting the timer, and the caregiver's hands-on time refers to the amount of time a clinician spends reviewing a recording and determining the clotting time. To verify these specifications, we have conducted usability testing with a control group including our team members and 9 additional participants [97] and verified that the results are within the specified time limits. Even though our testing cannot replace a full scope usability test or clinical trial in Ghana, we believe that conducting usability testing among our team and other participants provides a sufficient baseline, as full scope usability testing at the field site cannot be done without an IRB. All tests were conducted with a water, corn-starch solution that replicated different blood coagulation viscosities. In the future, we encourage future groups to further verify these specifications with the Easy to Use IRB detailed in the Build Design Validation Plan section. The results of our verification can be seen below in Table 17.

Table 17: Summarizes the test setup and verification results for our 3 unverified Easy to Use specifications. Error margins were calculated as 2 standard deviations above the mean to guarantee a 95% verification pass rate.

Specification	Test Setup	Verification Result	Status
Less than 1 minute set up time for the device	The prototype is placed in the open position and a vial is pre prepared with a blood proxy. Participants are instructed to secure the vial in the clamp, begin the test sequence, and start recording. Each participant conducts this 5 times and the test administrator records the time to complete.	3.3 ± 2.4 seconds	Compliant
Blood container is removable within 10 seconds	The prototype is placed in the open position and loaded with a vial containing a blood proxy. Participants are instructed to remove the vial from the clamp and stop the recording. Each participant conducts this 5 times and the test administrator records the time to complete.	5.6 ± 3.0 seconds	Compliant
Less than 3 minutes of caregiver hands on time per test	The prototype and a vial containing a blood proxy are used to record 3 unique test recordings on the Samsung A03s. Each recording is conducted to achieve different coagulation times. Participants are instructed to review each recording on the Samsung A03s and a test administrator records the time to correctly identify the time of coagulation for each test.	49.0 ± 30.5 seconds	Compliant

We are confident in the verification results for these three specifications since our test accounts for the same procedure as the onsite experience would. The blood proxy that we used performed well and achieved good coagulation behavior. Future plans for validation will encompass this specification and clarify any remaining uncertainties.

Durable:
To satisfy the durability requirement for this device, the first specification we must satisfy is that our device minimally withstands 1 year of use, corresponding to 3,650 uses. To verify this specification we split the design into 3 subsystems that experience loading and are likely to fatigue: the vial tilting subsystem (servo, clamp, and loaded vial), the heating pad, and the phone subsystem (Samsung Galaxy A03s).

To verify the lifespan of the vial tilting subsystem we empirically tested the Lewansoul 9g Servo Motor to one year's worth of loaded cycles and monitored the servo to ensure that performance didn't degrade. The servo was secured to a surface and weights were attached to apply 10.26 N·mm of torque, which simulated the load of a filled vial (with a safety factor of 2) according to the calculations seen in Figure 17. Assuming 5 turns per test and 3,650 tests per year, the servo was run for 18,250 total cycles to simulate a full year of turns. The test setup can be seen in Figure 31 below:

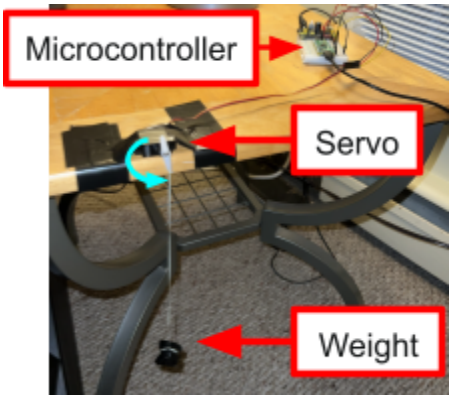


Figure 31: Shows the test setup used to verify the 1 year lifespan of the vial tilting subsystem.

The passing condition for this test was that the servo maintained regular function after a year's worth of cycles. No change in rotational speed, angular precision, responsiveness, or weight bearing capacity was observed after completing this test on 11/6/23. We consider this subsystem to be compliant with our specifications. We are confident in this testing approach as we have directly proven the lifespan of the servo to be beyond one year of use.

To verify the lifespan of the heating pad subsystem, we used analytical methods to estimate the number of cycles the heating pad could undergo before failing. Since the heating pad would be turned on and off once per test, the passing condition for this testing was a number of failure cycles exceeding 1 year of usage or 3650 cycles. To set up the fatigue analysis for the heating pad, we assessed the most likely failure mode of the pad. The two materials that make up the heating pad are Polyimide plastic and ASME 304 Stainless Steel, as seen in Figure 32 below.

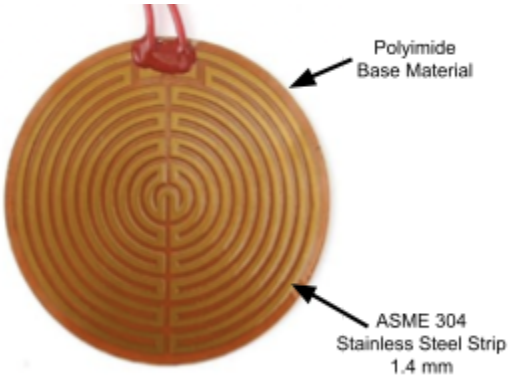


Figure 32: Shows the two materials making up the heating pad. The dark orange background material is a thin polyimide adhesive backing that provides insulation and protection. The shiny gold material is ASME 304 stainless steel which provides resistive heating when exposed to an input voltage.

Research into polyamide plastics revealed that the material has impressive thermal resistance properties and a very low coefficient of thermal expansion [75], which indicates that ASME 304 stainless steel is more likely to cause failure. Since the steel film is thin and very wide, we expect that failure due to fatigue under thermal expansion and contraction is likely. Additionally, since the heating pad is bendable we expect that some degree of internal cracking already exists in the film. Using these insights, the Paris equation of crack growth [84] was used assuming that a crack spanning ¼ the film width exists and that thermal loading from 0°C to 80°C occurred continuously. The crack growth equation and crack scenario can be seen in Figures 33a and 33b below:

$$N_{\mathrm{f}} = \int_0^{N_{\mathrm{f}}} \mathrm{d}N = \int_{a_0}^{a_{\mathrm{f}}} \frac{\mathrm{d}a}{A(\Delta K)^m}$$

Figure 33a: Shows the Paris equation for crack growth [84]. In this equation, Δk represents stress due to heat cycling, a represents crack size, A and m are material properties [83], and N_f represents the number of cycles to failure.

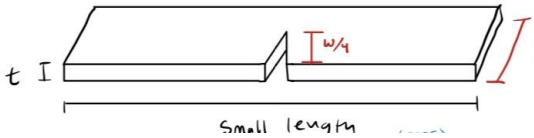


Figure 33b: Shows the crack growth scenario which was used based on our insights into common failure modes of the heat pad.

Inspection of the heating pad revealed that no visible cracking initially existed, so assuming an initial crack size of ¼ the film width is an overestimation and serves as a safety factor. Additionally, testing with the Adafruit 1481, as seen in Figure 28b indicated that the temperature range will likely be from 25°C to 70°C in practice, so we also have a safety factor in temperature exposure. To add another safety factor, we assumed that all stress due to thermal expansion was perpendicular to the crack and that the polyimide material never expands with heating. Using these assumptions and the Paris Equation for crack growth, we estimate that our heating pad will minimally withstand 11,494 cycles before the crack separates the ASME 302 stainless steel film. The work behind this result can be seen in Appendix AD. This result exceeds the 3,650 failure cycles needed to satisfy this specification, so we feel confident that the lifespan of our heating pad is within the durability standards of the project. Additionally, the use of such heavy safety factors in our calculations means that it is reasonable to expect the heating pad to withstand many more than 11,494 cycles before failing. We chose to perform analysis rather than empirical testing since empirical thermal cycling would take a very large amount of time and may create a fire hazard in the case of a premature failure.

To verify the lifespan of the phone subsystem we reviewed literature on the most common failure points of smartphones. Of the functional failures that occur with smartphones, 66% of non-destructive failures occur in the battery and software of phones [87]. Since the Samsung A03s will only be running the testing software, we are confident that software issues will not cause a failure in our case. Instead, battery failure is significantly more likely to occur. Data shows that the average modern smartphone battery withstands 26 months of usage [88], which is compliant with our durability standards. Regarding destructive failures, dropping and water exposure account for 78% of these cases [87]. To avoid these points of failure, we have designed our device to secure the Samsung A03s such that the phone cannot fall out during usage and will not be exposed to large amounts of moisture. If these failures occur, we can lean on the 12 month Samsung warranty which will completely cover battery, software, and destructive failures from typical usage [89]. We are confident that the lifespan of the Samsung A03s will exceed one year of usage and will use the warranty as a contingency plan in the case of an early failure. We elected to verify this specification using literature since durability analysis is technically challenging for smartphones and empirical testing would require us to use the Samsung A03s for an entire year without extrapolation.

The design also met the specification that it must withstand trials at 10 & 44°C [57] and at 10 & 99% humidity [57] for the durability requirement. To verify these specifications, we completed three tests with the prototype at three different operating temperatures and humidities. The operating conditions we tested were approximately 10°C and 50% humidity, approximately 22°C and 40% humidity, and approximately 35°C and 99% humidity. We were unable to simulate a higher temperature with our available resources, but since the annual mean maximum temperature is 34°C in Ghana [57], this test was sufficient. The first test was completed by running the tests outside in Ann Arbor, MI. The temperature was 3°C at the time of the test, which is well below the specification. The test setup is shown in Figure 34.

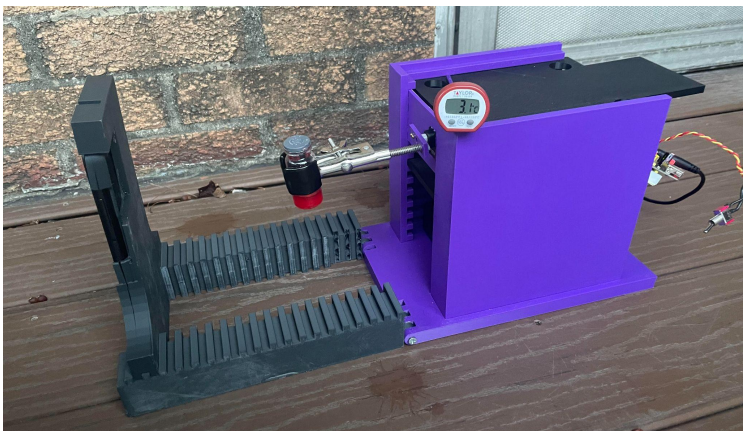


Figure 34: Shows the test setup used to verify the low end of the temperature and humidity specification.

The second was run inside at room temperature and humidity. The final test was tested in a closed bathroom with the shower on hot and a space heater running, which allowed the temperature to reach 36°C and the humidity to reach 99%. The final test setup is shown in Figure 35 on the following page.

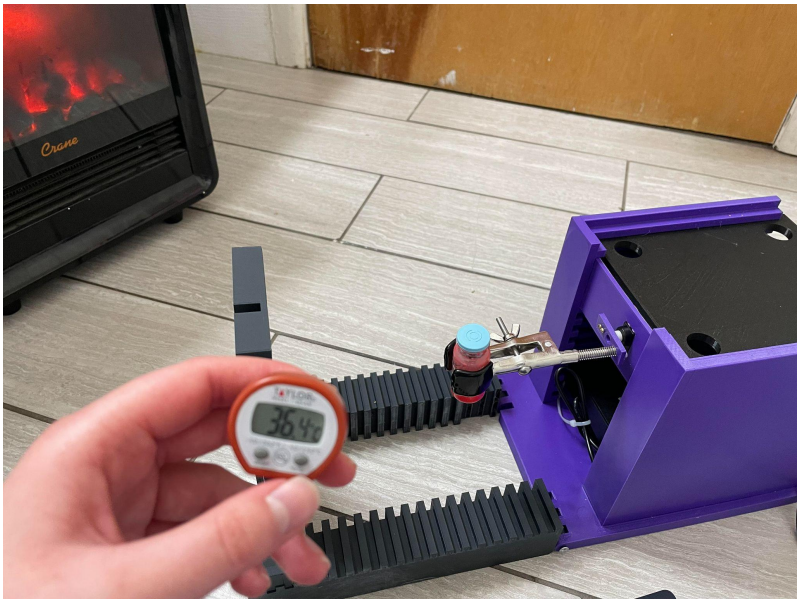


Figure 35: Shows the test setup used to verify the upper end of the temperature and humidity specification.

The device completed three successful 11-minute tests at each condition to verify these two specifications. While this verification plan does not assess the entire range of operating conditions, the tests did assess the extreme conditions that we expect the device to run in. This provides a much quicker and cost-efficient method to test the environmental response of the design, as opposed to a different method such as long-term humidity and temperature cycling. We are confident that these results reflect the final design's ability to function in the necessary operating conditions, given the extremes to which we are testing and the fact that the final design uses identical electronic components.

The last durability specification we must meet is that the device must withstand hospital sterilization using 3-6% hypochlorite bleach or 70% alcohol. To verify this specification, we researched the resistance of several plastic filaments and wood coating material against isopropyl alcohol and sodium hypochlorite bleach. Common materials and their respective compatibility with sterilization chemicals can be seen below in Table 18.

Table 18: Chemical Resistance of potential materials for manufacturing.

Material Choice	Isopropyl Alcohol	Sodium Hypochlorite Bleach
ABS	Compatible [103]	Compatible [103]
PLA	Compatible [106]	Incompatible [107]
Nylon	Compatible [105]	Compatible [105]
Wood Epoxy	Compatible [104]	Compatible [104]

We determined that if we continue with 3D printing the final design, we would use ABS or nylon rather than PLA. Another material we are considering for our frame is wood. This would also need an epoxy coating to protect against alcohol and bleach, and to enable easy sterilization. All of these materials would be compliant with this specification. From this research, we determined the need for a design change to meet the specification. We are choosing this verification method as there is extensive research on these materials, which ensures all potential materials can withstand common sanitation methods.

Consistent:
To satisfy the device's consistent requirement, the build design must meet the following three specifications: a 30 second time resolution error, continuously operating for 11 minutes, and operating without grid power for 8 hours. Firstly, the 30 second time resolution error specification is immediately verified by the design, as the motor will rotate the blood vial to inspect for blood clotting once every minute. The verification plan for the latter specifications will be conducted in one comprehensive empirical test upon fully integrating the heater, phone, Pico, and motor with the power supply. This test involves fully charging both the phone and reserve power supply, then subsequently disconnecting the power supply, leaving the device unplugged for 8 hours to simulate the idle time/consumption for the duration of a potential power outage. After 8 hours, 5 consecutive, 11-minute tests will be performed using the reserve power supply. If the device can complete 5 consecutive tests on the power reserve without recharging, the grid power specification will be met. As mentioned in the Component Selection and Verification section, 8 hours of use is conducive to 3.3 tests, however, we chose to verify with 5 consecutive tests for a safety factor to account for potential spikes in testing volume.

Furthermore, the ability to run 5 consecutive tests without grid power implies that the specification for 11 minutes of continuous operation has been met. This ensures that the higher-priority specification of operating for 8 hours without grid power in the consistency requirement can be met. We believe this test was the optimal verification method as it was practical and feasible within the scope of our project timeline, and directly proves the device's ability to meet the specifications in question. After completing this testing procedure, the power supply still had some power left over, and therefore the device meets these specifications.

Portable:
To meet the portability requirement, our build design must have a maximum dimension of < 46 cm in any direction, and an overall mass of less than 11.6 kg. The dimensional portability specification is met and verified by inspection as shown in Figure 21 of the build Build Design section, and thus does not require a verification plan. To verify the mass requirement of the device (< 11.6 kg), the entire build design will be weighed on a scale with < 0.5 kg resolution error once completely assembled. If the measured mass of the device meets the minimum requirement while accounting for resolution error, the portable requirement is fully verified. If the device fails to meet mass requirements, structural optimization will be conducted on the frame, and a cost tradeoff assessment of lighter frame materials will be considered to reduce mass. We are confident that this is the simplest possible rigorous verification method, as both specifications can be directly analyzed by inspection from the build design without complex analysis. Additionally, we expect no significant changes in mass from build to final design, as the

final design's frame will be made of 3D-printed plastic of comparable density, or wood which has a density comparable to common 3D-printed plastics [108], [109].

Safe:
The specifications that the blood containers are fixed to the device during testing and the blood container must not break under standard operating conditions must be verified to meet the safe requirement. To verify these specifications we completed a test with the vial and clamp. Using proper PPE, we used the maximum force from our hands to tighten the clamp around the vial. We had three group members perform this task, checking for cracks after each trial. After the vial was clamped, we marked the top and bottom of the clamp on the vial with a marker. Then, we quickly turned the clamp-vial assembly upside down and back rapidly. This was done 24 times to simulate a standard test that turns 8 times with a safety factor of 3. After the test was performed, we inspected the vial to see if it moved or loosened in the clamp. Since the vial did not break from the clamping force or move in the clamp, the test was successful. We are confident that this test properly verifies the specifications, as we do not expect a clinician to tighten the clamp with as much force as was applied, and the vial will be shaken less vigorously on the device than in this test. This test method was chosen over other methods as it is simple, quick, and provides direct verification of our concerns with the vial breaking due to over tightening the clamp.

The last two specifications for the safe requirement are only a pinch point at the blood container fixture and the device must not expose the practitioner to blood. Both of these specifications are verified by our design, and thus do not require a verification plan.

Locally Maintained:
All locally maintained specifications were verified by our design and bill of materials, and thus do not require a verification plan. We do not consider blood vials to be a part of our design. Instead, we designed the device to be compatible with the wide variety of blood vial sizes that are currently used for coagulopathy testing. The design uses no consumable components as the blood vial is not a part of our design. To account for this, we designed our device to accommodate the various blood vial sizes used at KATH.

Controlled Blood Temperature:
To verify our blood temperature control requirement, we must satisfy our specification that the blood should be kept at body temperature (35.5°C-38.3°C). Additionally, since environmental conditions affect steady state blood temperature, we must verify this specification for all possible environmental conditions in Ghana, or a temperature range of 10°C to 44°C [57]. Humidity was not considered for this testing, as it has a negligible effect on the convective properties of air in this temperature range [102]. Additionally, we cannot cool blood, so we will ignore environmental temperatures exceeding 38.3°C. Therefore, the passing condition for this verification test is proof that a control system can maintain blood temperature from 35.5°C to 38.3°C in an environment ranging from 10°C to 38.3°C. Due to an issue with heat pad power regulation which we discussed in the Recommendations section of this report, we were unable to develop a control system during the course. So, we tailored this verification testing to prove that any properly implemented control system can satisfy our passing condition. To conduct this testing, we placed our heat pad subsystem in an environment colder than 10°C and heated a vial of blood proxy to demonstrate that our heating pad subsystem can achieve blood temperatures

exceeding 38.3°C. This test scenario demonstrates that our heating pad can provide enough heat to combat the most demanding environmental conditions. Since a properly implemented control system can reduce or prevent heating to the blood vial, any control system has sufficient power to control blood temperature from 35.5°C-38.3°C in any environmental condition. We used cow's milk as the blood proxy since it has similar thermal properties to blood [90]. The results from this testing can be seen in Figures 36a and 36b below.

Figure 36a: This test was conducted outdoors at an environmental temperature of 2.8°C. This is well below 10°C, the minimum observed temperature in Ghana.

Figure 36b: Using our heat pad subsystem, the blood proxy was able to reach a temperature of 48.7°C. This exceeds the maximum required temperature of 38.3°C as we hoped.

Our testing results are compliant with our passing condition, so we feel confident that a control system can maintain blood temperature to satisfy our specifications.

FINAL DESIGN

Following prototype evaluation where optimal geometry for image quality was identified, and other necessary modifications were discovered, the final design shown in Figure 37 on the following page was developed. There is a back panel intended to be attached to the rear of the final design which is not depicted in the CAD model to enhance the visibility of the internal components.

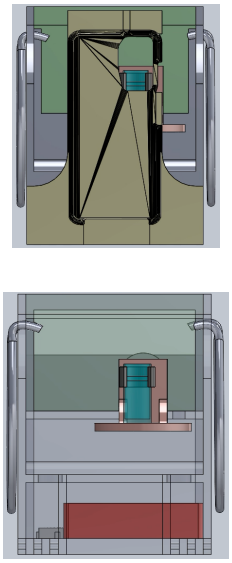


Figure 37a: A depiction of the front view of the final design. Key components from this view are the yellow phone enclosure which is in line with the blue blood container.

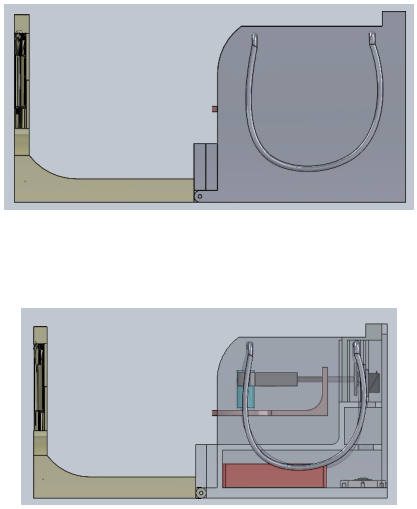


Figure 37b: A depiction of the right view of the final design. Key components from this view include the nylon carrying handle, the enclosure around the test, and the phone-to-container distance.

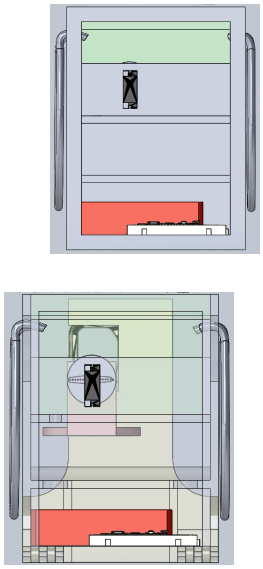
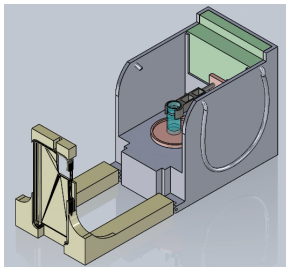


Figure 37c: A depiction of the back view of the final design. Key components include the gray servo motor, the Raspberry Pi Pico atop the breadboard, and the red power supply.



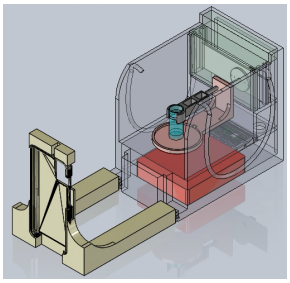
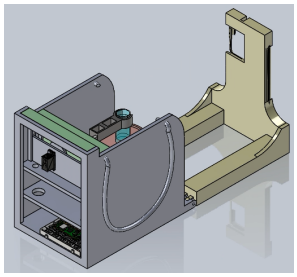


Figure 37d: A depiction of the front isometric view of the final design. A key component seen from this angle is an orange heating pad bracket.



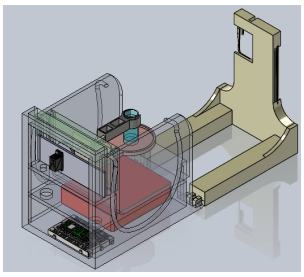
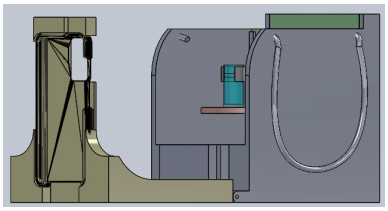


Figure 37e: A depiction of the back isometric view of the final design.



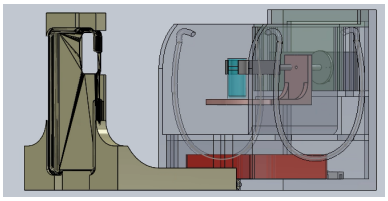


Figure 37f: A depiction of the front dimetric view of the final design.

Several improvements were made from the build to the final design. In Figure 38 below, there are three immediately visible iterations from the build to the final designs: the elimination of adjustability ridges, changes to the motor/blood container assembly, and the addition of handles.

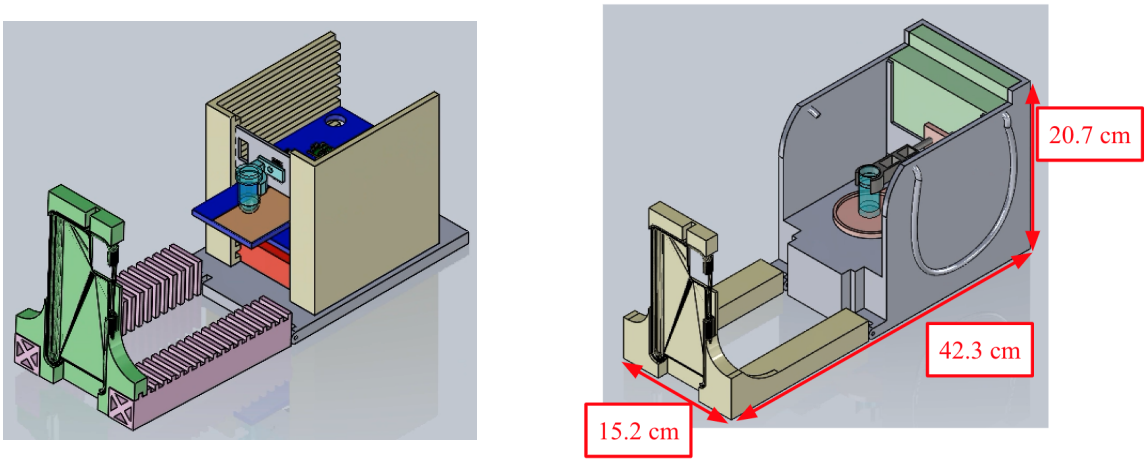


Figure 38: The build design side by side with the final design. Some key differences between the two include the removal of adjustability, the addition of the green plate in the final design that acts as a bushing, the complete enclosure of all the electronic components, the recession of the motor assembly in the frame, the addition of handles, and addition of the red heat pad bracket. There has also been a 0.9 cm reduction in both the height and unfolded length of the device.

It was discovered in the build design that the large mass of the vial/heat pad bracket was being supported by the motor gearbox – potentially leading to long-term durability issues. To address this issue, the final design adds a wall with a bushing clearance hole to support this mass, as depicted by the green box in Figure 39a below. This is also highlighted in green in Figure 39.b. More detail on how this subsystem is assembled is listed in Appendix AF.

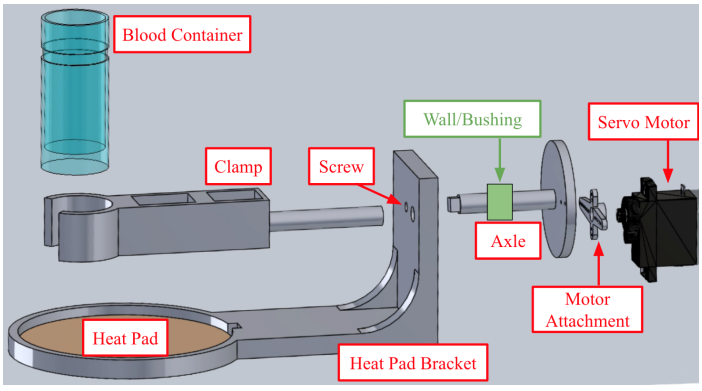


Figure 39a: A diagram that separates all the components of the motor assembly. The green box is representative of a larger component and can be better seen in Figure 39.b

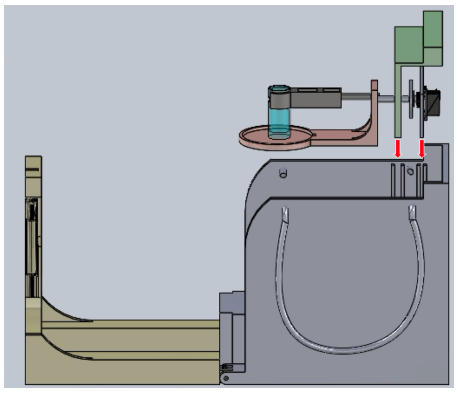


Figure 39b: A visual of how the motor assembly is placed into the frame.

Additional minor improvements were made. Figure 40 below shows how the design will be transported. Nylon straps were added to improve portability while minimizing additional cost. The extra material on top of the yellow phone case and the green plate at the top surface of the device lay flush with each other. This allows the addition of a latch if extra stability is desired, although this is not currently included in the final design BOM as it may not be necessary. Other changes include the complete enclosure of electrical components to prevent physical interference with delicate components, and the recession of the vial receptacle assembly into the device to account for the length of the clamp.

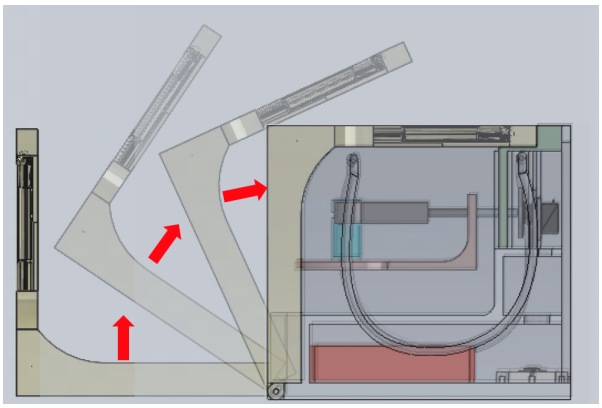


Figure 40a: An overlaying visual representing what the folding of the device would look like. Once folded, the arms of the phone case align flush with the frame of the device

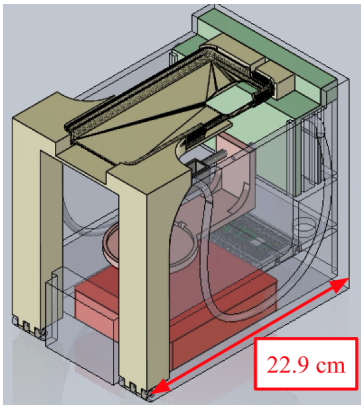


Figure 40b: The isometric view of the device when folded. The device should only be transported in this configuration to decrease the possibility of damage.

The BOM for the final design is listed in Table 19 below on page 61.

Table 19: Bill of materials for the final design, colors in CAD correspond to the colors shown in Figure 37.

Component	Part Number	Color in CAD	Quantity	Cost / Unit
Shanqiu Power Supply	FX 5-12	Red	1	$79.99
Raspberry Pi Pico	RP2040	Green	1	$6.62
Lewansoul Motor	LFD-01M	Black	1	$8.99
Vial Clamp	CH0688A	Dark Gray	1	$9.89
Icstation Circular Heating Element	9885	Orange	1	$3.50
Solderless Breadboard	EL-CP-003	White	1	$3.33
Samsung Galaxy A03s Phone	TVSAS134DCP	N/A	1	$49.88
3D Filament	OVPLA175	Green, Yellow, Pink, Gray	1	$14.99
Wiring	Fermerry-30	N/A	1	$2.17
Power MOSFET	IRLB8721	N/A	1	$1.00
M5 X 35 mm self-tapping screws	N/A	N/A	2	$0.39
M2 X 10 mm self-tapping screws	N/A	N/A	2	$0.29
M4 X 14 mm self-tapping screw	FW03600001	N/A	1	$0.10
¼” Nylon Rope Handles	N/A	Gray	2	$0.32
Tax, Shipping, and Handling				$8.92
Total				$191.38

MANUFACTURING PLAN

Two distinct manufacturing pathways have been identified for the final design, each with its own advantages and considerations.

The first approach involves external manufacturing, leveraging accurate production methods such as 3D printing in countries like China. This method allows for the production of plastic components, made from a material that meets the sterilization criteria, listed in Table 5. Additionally, most 3D printing filaments are recyclable. The remaining components in the bill of materials can be obtained and assembled to the device at the external facility before shipping the finalized product to Ghanaian hospitals. While this offers precise manufacturing and ready-to-use devices, reliance on non-local sourcing is a drawback that makes the device more difficult to obtain and repair for Ghanaian hospitals.

Alternatively, the second pathway focuses on local sourcing by utilizing Ghana's wood production strengths [50]. The current structural components can be made from wood, which can be acquired locally and is biodegradable. Suitable wood finishes to withstand sterilization are detailed in Table 5. Necessary hardware components can either be sourced locally or shipped in for assembly by hospital engineers. Potential local hardware suppliers include OkuElectronics [69] and Fastener First [71], both located in Accra, Ghana. Assembly instructions can be modified for the use of basic tools like a screwdriver and may include the integration of keyed wiring harnesses for easy electrical connections. While this method improves local sourcing, it also introduces a more difficult assembly process, requiring involvement from hospital engineers.

Both pathways present unique benefits: the first prioritizes efficient production and ready-to-use devices, while the second improves local sourcing, albeit with a more involved assembly process requiring hospital staff participation.

DESIGN VALIDATION

While the process for completing validation on our build design is outside the scope of the class, if we were to continue with the project these plans would outline the steps we would need to take. These plans work towards validating our hypotheses and assumptions. The questions we wish to address are: can someone with little experience with our product quickly learn to operate the device and fulfill the ease of use specifications? Are there any safety concerns with the device? Is the caretaker supervision time less than the current test? Does the device aid in diagnosing coagulopathy to help providers assess treatment methods?

The first two questions on ease of use and safety will be addressed using the verification plan that involves usability testing at the field site with at least 30 participants, as a sample size of 30 or more is large enough for the normal approximation to be adequate [101]. The test cannot be conducted without approval from the IRB. Once the IRB has been approved, we would teach a control group how to use the device, then record participant performance/feedback regarding the ease of use specifications as well as their safety feedback. This feedback would be compared to the feedback on the gold standard. The gold standard is the test currently used in Ghana, the modified Lee and White test. We are confident that this test will successfully validate those questions, as we are getting real feedback from care providers working in similar conditions. If this test is unsuccessful, the contingency plan is to make design adjustments based on participant feedback and complete the process again. For the test to be successful, all ease of use specifications must be met with positive feedback, and there should be no safety concerns mentioned.

The last two questions on caretaker supervision time and assessing treatment methods would be verified with a 30-day clinical trial in Ghana. Once the IRB is completed, we would send the build design to Ghana to conduct a quasi-experimental design to test the device. We would spend two weeks observing the doctors in Ghana before introducing the device. This would allow us to observe how often the gold standard is used. The current testing method in Ghana is our gold standard. After those two weeks, we would train caregivers on how to use the build design. We would spend the next month collecting data on the frequency of each testing method, and analyze the data to determine why one device was chosen over the other. If the probability of using our

test method is greater than the probability of using the gold standard at a 5% significance level, the test would be considered successful [101]. This would answer the question of whether our device will be used more frequently than the gold standard. We would also collect data on the hands-on time it takes caregivers to use our device and compare it to that of the gold standard. At the end of the 30 days, we would interview the caregivers and have them share their opinions on design improvements and their use of the device. We are confident that this trial will produce viable results, as 30 days allows for ample time to learn how to use the device and become comfortable with it. If the device were to fail this test, we would make design changes based on user feedback and redo the trial at a different hospital in Ghana.

To ensure that the clotting time is accurate and aids in assessing treatment methods, we would complete a comparison trial. To do this, we would need to test clotting time using our device and the gold standard. We would test two vials of blood from the same patient at the same time and compare the results of each test to the results of a TEG machine. Whichever testing method has a blood clot time closer to the TEG machine would be considered the more accurate method. If our testing method is found to be more accurate, we can conclude that it aids in assessing treatment methods. This trial will produce viable results as the device will be compared to an already accurate testing method.

CLOSING REMARKS

In this section, we want to discuss the strengths and weaknesses of our design process, the challenges we faced during design and manufacturing, the lessons we learned, and potential recommendations for improvements for future teams who may work on this project.

DISCUSSION

While we are proud of the work we have completed throughout this project, there is room for improvement throughout every design process. If we had more time and resources, we would have approached the project differently.

To better define the problem, we would have preferred to have spoken with more Ghanaian doctors, especially Ghanaian hematologists. This would have allowed us to better understand how the current test is performed. We had developed an understanding from conversations with doctors in Ghana, but it would have been helpful to see exactly how this test is performed via a video recording. We also would have interviewed more Ghanaian doctors at other hospitals to present our ideas and receive feedback if time had permitted. We would have utilized our and Dr. Thiyag's contacts to arrange these interviews.

While completing concept selection, we would have explored further how blood viscosity relates to blood clotting time. Many of our generated concepts were discarded due to lack of knowledge on the specifics of blood coagulation. If we had more time and resources, we would have used human blood to test these concepts with prototype designs.

Despite those challenges, our final design has many strengths. The final product was designed with a global health focus that allowed us to produce a product that was inexpensive and similar to the current test performed. This makes it affordable for the hospital to implement and easy for

the doctors to operate with minimal training. The design is also simple with minimal components which makes it easy to repair and assemble.

While we passed the verification tests, there are a few considerations in the final design to keep in mind. Mainly, the device reflects an outdated testing method. Blood clot time is not used to diagnose coagulopathy in high income countries as it tends to be inaccurate and does not reveal information on the source of the problem or treatment method. While this is not necessarily a design flaw, it is important to note that the test procedure that this device performs should not be used as an alternative to a lab test, as it does not provide the same level of detail and accuracy. The testing device is also not fully automated as it currently requires a doctor to play back the video to assess clot time.

Throughout the design process, we encountered a few challenges that affected our design. From the verification process, we realized it is more difficult than expected to determine the clot time from a video. The background is dark, which makes the blood more difficult to visualize, and it takes 49.0 ± 30.5 seconds to scroll through the video and identify clot time. The final design should use white plastic to act as a light background.

We also encountered challenges with our heating pad. Since the mount was 3D printed, the heat pad started to melt the PLA during the testing process. To address this, we added an insulator between the heater and the mount, which we also addressed in the final design. If the heating pad malfunctions and overheats, there is a potential that the insulation is insufficient and the PLA could soften. This would also cause the blood to overheat, voiding the accuracy of the test.

We encountered risks in the final design manufacturing. While we initially considered injection molding components in Accra, Ghana, small molds cost over $1000 [100] and there are multiple parts in our build design that require separate molds. For the low production rates of this product, it is not economically feasible to manufacture the device in this fashion. An alternative is 3D printing parts of the final design outside of Ghana and importing them, or having these components made from wood which can be manufactured locally in Ghana.

Other risks we faced included the delay of part delivery. We encountered supply chain issues that put our project behind schedule. To address this, we adjusted our schedule to delay the verification of our build design. Through this process, we learned the importance of selecting and ordering parts early. We also consolidated our orders to reduce shipping fees.

We also faced the challenge of a lack of access to real human blood, which made it more difficult to test our device. To address this, we modified verification plans to use blood proxy for testing.

Other lessons learned include rigorously reviewing our design after each CAD change. During the assembly process, we encountered challenges mounting the clamp-vial-heating pad assembly. This is due to a design mistake that could have been prevented with a formal design review. For the final design, we thoroughly reviewed the CAD to prevent this issue moving forward.

RECOMMENDATIONS

As we approach the end of the course, we hope to facilitate a productive handoff of this project to our project sponsor and future teams. Our discussion section highlighted the major design flaws we have identified and noted any risks to our stakeholders that our final design might present. Future teams must address these risks to increase the efficacy of our final design and maximize the benefit to our stakeholders. We have provided a comprehensive list of system-level and detailed-level recommendations to guide the next steps for product improvement.

During the verification of our Easy to Use specifications, we noted that recording and reviewing testing videos on the Samsung A03s screen presented several difficulties to end-users. First, recording the video requires users to simultaneously activate the Raspberry Pi Pico script and start a video recording which is tedious. In reviewing the video, we found that the quality of lighting was variable between recordings which made coagulation hard to see. Additionally, since the test recording was 12 minutes in length, it was difficult to precisely locate the exact moment of coagulation by hand. Our verification showed that identifying coagulation took participants 48 seconds, on average, which we believe can be reduced considerably. These difficulties make it harder for practitioners to properly conduct the coagulopathy test, and lead to inaccurate results which will risk the wellbeing of our patient stakeholders.

To improve the recording process, we recommend integrating step-by-step test instructions into the application seen in Figure 23 above. These instructions will include images and informative text which will instruct a caregiver how to properly set up the device, begin the test with the Raspberry Pi, and start the recording. Additionally, if future groups have the technical ability, it would be ideal to initiate the Raspberry Pi testing sequence directly from the Samsung A03s application, unifying all user interfacing with the Samsung A03s. We were unable to complete a prototype application during the timeline of this course, so we recommend future groups reference our Build Design section for guidance on how to design and implement this.

To improve the video reviewing process, we recommend trimming the coagulation testing video on the testing application so that practitioners only review moments when the vial is turning over. Since the flipping sequence is when coagulation can be identified, any stationary moments should be removed; this will reduce the overall recording lengths from 12 minutes to 4 minutes. To address lighting problems, we found that the Samsung A03s camera flashlight must be activated during the recording process. Additionally, integrating a white material behind the vial will increase contrast to make identifying coagulation easier. Lastly, we recommend implementing a computer vision algorithm on the Samsung A03s testing application to automatically provide a coagulation time and remove the video review process entirely.

Another important risk to our end-users that must be addressed for our final design is identifying a manufacturing process for the frame of our device. As mentioned in our Discussion section, the initial idea of injection molding our device would require us to purchase several $1000+ custom injection molds [100]. Based on our conversations with Dr. Thiyag and Dr. Konney, we anticipate that no more than 100 devices will need to be manufactured to satisfy the regional needs. Thus, the cost of custom injection molding at this scale is significant.

We first recommend conducting market research in Ghana to assess the number of hospitals that might benefit from the use of our device and the total number of units that these hospitals would require. Using this information as a basis, we recommend referencing the Manufacturing Plan in the Final Design section. We have identified two potential pathways of manufacturing for the final design that eliminate the tooling cost that comes with injection molding. These include creating 3D printed parts outside of Ghana and importing them, or alternatively producing the structural components from wood in Ghana to improve local maintainability. Both manufacturing methods will be of sufficient quality for end-users, and future groups should select the lowest overall cost per unit between these methods. Additionally, to lower unit cost, we recommend replacing the most expensive component, the 72 Wh Shanqiu Power Supply, with a 50 Wh alternative. As discussed in the Component Selection section, a 50 Wh Power Supply maintains a safety factor of 2 on power capacity and is considerably cheaper.

Lastly, there are several detail-level issues in the final design that still need to be addressed to improve the mechanical functionality of our design. These flaws lower the reliability of our final design and risk a premature failure. Early device failure means a lack of reliable testing for our patient stakeholders and a financial loss for our hospital stakeholders. The first detail-level issue is poor heat insulation in our heat pad subsystem. When conducting our Durability verification, we noticed that the heating pad warped the adjacent PLA plastic. This directly threatens the structural integrity of the heating pad subsystem. The next issue with our final design is the lack of power regulation for our heating pad. We initially selected a power MOSFET to regulate power to our heating pad, but this component had the incorrect threshold voltage and couldn't maintain sufficient wattage. A power MOSFET allows us to control the blood temperature using our Raspberry Pi Pico, so without a working MOSFET we cannot guarantee the accuracy of our test.

To improve the heat regulation issues in our heat pad subsystem, we recommend placing a layer of insulation in between the polyimide heating pad and the PLA heating pad holder. A good thermal insulator will prevent heat from reaching any plastic component and will decrease heat losses for our heating pad. Additionally, research needs to be done to identify the best control system to maintain blood temperature according to our specifications. We have already verified that our heating pad is capable of providing sufficient heat output, so we recommend that future groups experiment with open and closed loop control systems.

To address the lack of power regulation to our polyimide heating pad, we recommend future groups conduct market research to identify a power MOSFET that can regulate a 12V 3.5A input to an output range of 5W to 24W. Additional code should also be added to the Raspberry Pi Pico to control the power MOSFET through the gate pin.

REFLECTION

Reflecting on this project, a number of topics were considered throughout the development of the solution. These topics include contextual factors, team diversity, inclusion and equity, and ethics. The following section provides a discussion of these topics throughout solution development, and how they influenced the project.

Contextual factors such as public health, safety, and welfare are directly related to this project, given that the solution is a device that is to be implemented in a hospital setting, where it can impact the decisions of healthcare workers. This means the device has a direct impact on the health, safety, and welfare of both hospital workers and patients. Safety of those interacting with the device was thoroughly considered via the "Safe" requirement. Additionally, patient safety was considered through the "Consistent" requirement, ensuring the device behaves in a predictable manner that provides consistent and accurate results. This device was designed with very niche requirements in mind in order to meet the needs of the Ghanaian healthcare system (for example, automating the exact workflow already performed by Ghanaian practitioners), and therefore the solution is much less useful in a global context. Taking into account that much less than ~100 of these devices will ever be produced (given the number of hospitals in Ghana and the number of devices we expect each hospital would incorporate), the cost of each individual device, the materials used in production, and the lack of consumable components, the social and economic impacts associated with manufacturing, use, and disposal of these devices are negligible in comparison to other industries that generate much larger production volumes.

Differences among team members and our sponsor were also considered throughout the design process. Cultural, privilege, identity, and stylistic similarities did not appear to play a significant role in influencing the design process throughout the project. Instead, team members were assigned tasks based on their strengths, and the team collectively agreed to make decisions based on logical justifications that incorporated thoughts from every member. Our sponsor, Dr. Dhanu Thiyag, on the other hand, had much power over the decisions made by the team due to their experience in the healthcare industry, and the team's lack thereof. Our sponsor was a primary resource for project context information, before secondary research.

To include and balance diverse viewpoints, we actively reached out to various stakeholders, from both Ghana and the U.S. throughout the design process. As a result, we did receive conflicting viewpoints from stakeholders. From meeting with U.S. medical stakeholders, we learned that the current Ghanaian bedside testing is not very accurate and that they would prioritize accuracy in design. However, after meeting with various Ghanaian stakeholders, price and local maintainability are prioritized. To balance the viewpoints, we consulted other perspectives from other stakeholders, existing solutions, and price points, and we decided to prioritize the low cost requirement more.

As detailed in the design context, an ethical dilemma we faced was the lack of patient input during the context gathering process, and we resolved this by rigorous secondary research and asking our Ghanaian stakeholders patient related questions. Another major ethical challenge we face is innovating a pioneering product that has not been implemented in the past. In order to resolve this challenge, we first try to understand the existing ecosystem by conducting extensive benchmarking and market analysis. Lastly, due to our IP agreement, we as a team represent the University of Michigan and we uphold the same ethical standards as the University. However, in the future, if another organization decides to take this project further, they may choose what ethical standards to align to based on their own discretion.

CONCLUSION

To address the high levels of PPH among pregnant patients in Ghana, patient care staff perform a modified version of the Lee and White Method blood clotting test to assess patient blood clotting time. This test requires constant hands-on supervision to be performed correctly. Due to the low resource nature of the Ghanaian hospitals evaluated in the needs assessment by the UM Global Health Design Initiative, the patient care staff often does not have the time to give their undivided attention to a blood test for over 10 minutes. We were tasked with designing a new bedside device to test blood clotting time that addresses these issues and meets our stakeholder's needs.

Our key stakeholders included the patients and patient care staff in Ghana, both of whom are beneficiaries and primary stakeholders. From our research and interviews with various stakeholders, we identified the requirements of the project and prioritized our stakeholders' needs. We determined that our top three requirements of the design are a hands-off test, that is low cost and is durable. This translates to the top three specifications, requiring less than 3 minutes of hands-on practitioner time, material cost under $300, and a minimum 1 year lifespan.

Various concept generation techniques were used, including brainstorming and a morphological chart. Through concept selection, our top five designs were determined and iterated on. These designs were then sent to our stakeholders for review. Based on their feedback and a Pugh chart, a device that films the blood clotting and plays it back for the doctor was selected as our Alpha design.

The Alpha design underwent further iterations based on stakeholder feedback and research to develop our build design. The build design includes a phone, adjustability features, easier access to the vial clamping mechanism, and a folding feature to compactify the device during storage. This differs from the final design which no longer has the ribs for adjustability, has an improved clamp assembly, a locking mechanism, and a strap for portability.

Analytical calculations were used in our component selection process. Further verification plans were performed to ensure that all of our specifications were met. We also created a validation plan to determine that the device does indeed solve the original problem outlined. However, this plan is outside the scope of this class.

We provided several recommendations for future teams working on this project. The main recommendations included increasing the automation of the device, recommendations for final design manufacturing, and including power regulation.

ACKNOWLEDGEMENTS

We are grateful to Dr. Dhanu Thiyag, our sponsor, for her continual support throughout this project. We would like to thank Dr. Julia Kramer for her ongoing advice and expertise. We give special thanks to Dr. Konney and Dr. Tawiah from KATH for their generous feedback and Dr. Girard and Dr. Shevell from UM Hematology for their unique insights. We thank Sarah Barbrow, the Engineering Librarian, for providing research assistance.

REFERENCES

[1] Adu, Joseph, Shree Mulay, and Mark Fordjour Owusu. "Reducing Maternal and Child Mortality in Rural Ghana." *The Pan African Medical Journal* 39 (August 24, 2021): 263. https://doi.org/10.11604/pamj.2021.39.263.30593.

[2] Afesi-Dei, Clement, Miriam Appiah-Brempong, and Esi Awuah. "Health-Care Waste Management Practices: The Case of Ho Teaching Hospital in Ghana." *Heliyon* 9, no. 4 (April 18, 2023). https://doi.org/10.1016/j.heliyon.2023.e15514.

[3] Bell, Sarah F. et al. "Managing the Coagulopathy of Postpartum Hemorrhage: An Evolving Role for Viscoelastic Hemostatic Assays," March 25, 2023. https://www.sciencedirect.com/science/article/abs/pii/S1538783623002623.

[4] Blood safety and availability. "Blood Safety and Availability." ..Int, June 2, 2023. https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability.

[5] Brito Sousa, Jose Diego de, Jacqueline Almeida Gonçalves Sachett, Sâmella Silva de Oliveira, Iran Mendonça-da-Silva, Hedylamar Oliveira Marques, Marcus Vinicius Guimarães de Lacerda, Hui Wen Fan, and Wuelton Marcelo Monteiro. "Accuracy of the Lee–White Clotting Time Performed in the Hospital Routine to Detect Coagulopathy in Bothrops Atrox Envenomation." *The American Journal of Tropical Medicine and Hygiene* 98, no. 5 (May 2018): 1547–51. https://doi.org/10.4269/ajtmh.17-0992.

[6] "Chemical Sterilization and High-Level Disinfection in Health Care Facilities." *ANSI/AAMI ST58:2013; Chemical Sterilization and High-Level Disinfection in Health Care Facilities*, Default Book Series, May 24, 2022. https://doi.org/10.2345/9781570205057.ch1.

[7] CIA. "Maternal Mortality Ratio." Accessed September 20, 2023. https://www.cia.gov/the-world-factbook/field/maternal-mortality-ratio/country-comparison/.

[8] Ciobanu, Anca Marina, Simona Colibaba, Brandusa Cimpoca, Gheorghe Peltecu, and Anca Maria Panaitescu. "Thrombocytopenia in Pregnancy." *Mædica* 11, no. 1 (March 2016): 55–60.

[9] CLIA Regulations, 42 USC 263a CLIA Regulations § 42 CFR Part 93 (1990). https://www.ecfr.gov/current/title-42/part-493.

[10] CoaguChek® Pro II. "Roche CoaguChek® Pro II," n.d. https://diagnostics.roche.com/global/en/products/instruments/coaguchek-pro-ii-ins-6011.html.

[11] Community, Biotechnology and Bioengineering. “Blood Coagulation Testing Using Smartphones.” Biotechnology and Bioengineering Community, February 14, 2022. http://bioengineeringcommunity.nature.com/posts/blood-coagulation-testing-using-smartphones.

[12] “Compass.” Accessed September 14, 2023. https://compass.astm.org/document/?contentCode=ASTM%7CE3173-18%7Cen-US.

[13] Der, E. M., C. Moyer, R. K. Gyasi, A. B. Akosa, Y. Tettey, P. K. Akakpo, A. Blankson, and J. T. Anim. “Pregnancy Related Causes of Deaths in Ghana: A 5-Year Retrospective Study.” *Ghana Medical Journal* 47, no. 4 (December 2013): 158–63.

[14] Diagnostics. “Cobas® Liat® Analyzer.” Accessed September 28, 2023. https://diagnostics.roche.com/us/en/products/instruments/cobas-liat-ins-6050.html.

[15] “Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC,” May 24, 2019. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html.

[16] “Environmental Health & Safety | Lifting and Material Handling Guidelines.” Accessed September 10, 2023. https://www.ehs.wvu.edu/general-safety/ergonomics/lifting-and-material-handling-guidelines.

[17] Erez, Offer et al. “DIC in Pregnancy – Pathophysiology, Clinical Characteristics, Diagnostic Scores, and Treatments.” NIH, January 6, 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8747805/.

[18] *Ergonomic Guidelines for Manual Material Handling*. Cal/OSHA Consultation Service, 2007.

[19] Federal Register. “Standards for Accessible Medical Diagnostic Equipment,” January 9, 2017. https://www.federalregister.gov/documents/2017/01/09/2016-31186/standards-for-accessible-medical-diagnostic-equipment.

[20] GDP per capita (current US$). “GDP per Capita (Current US$).” Accessed September 23, 2023. https://genderdata.worldbank.org/indicators/ny-gdp-pcap-cd/.

[21] Gust, Jeff C., Robert M. Graham, and Michael A. Lombardi. *Stopwatch and Timer Calibrations*. 9th ed. National Institute of Standards and Technology, 2009.

[22] Haldeman-Englert, Chad et al. “Activated Partial Thromboplastin Clotting Time.” In *Activated Partial Thromboplastin Clotting Time*. University of Rochester Medical Center. Accessed September 16, 2023.

https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=167&contentid=aptt.

[23] Hu, Bingjie, Guochen Bao, Xiaoxue Xu, and Kai Yang. “Topical Hemostatic Materials for Coagulopathy.” *Journal of Materials Chemistry B* 10, no. 12 (March 23, 2022): 1946–59. https://doi.org/10.1039/D1TB02523F.

[24] Kirby, Rebecca, and Kara Palamountain. *Target Product Profile*. 1st ed. UNICEF, 2020.

[25] Klinkenberg, Elisabeth, Elisabeth Huis in ’t Veld, Puck de Wit, Wim de Kort, and Mirjam Fransen. “Barriers and Motivators of Ghanaian and African‐Surinamese Migrants to Donate Blood.” *Health Soc Care Community* 27, no. 3 (May 2019): 748–56. https://doi.org/10.1111/hsc.12692.

[26] Konney, Thomas, September 20, 2023.

[27] Konney, Thomas, July 13, 2023.

[28] Lamb, Thomas, Michael Abouyannis, Sâmella Silva de Oliveira, Rachana Shenoy K., Tulasi Geevar, Anand Zachariah, Sanjib Kumar Sharma, et al. “The 20-Minute Whole Blood Clotting Test (20WBCT) for Snakebite Coagulopathy—A Systematic Review and Meta-Analysis of Diagnostic Test Accuracy.” *PLoS Neglected Tropical Diseases* 15, no. 8 (August 10, 2021): e0009657. https://doi.org/10.1371/journal.pntd.0009657.

[29] Lamb, Thomas et al. “The 20-Minute Whole Blood Clotting Test (20WBCT) for Snakebite Coagulopathy—A Systematic Review and Meta-Analysis of Diagnostic Test Accuracy.” NIH, August 10, 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8405032/.

[30] “Likert Scale - Google Search.” Accessed September 20, 2023. https://www.google.com/search?channel=fen&client=firefox-b-1-d&q=Likert+Scale#vhid=YK8LGhETBZd-MM&vssid=l.

[31] Louka, Marinos, and Efstathios Kaliviotis. “Development of an Optical Method for the Evaluation of Whole Blood Coagulation.” *Biosensors* 11, no. 4 (April 9, 2021): 113. https://doi.org/10.3390/bios11040113.

[32] Meredith, Christopher S, and Jeffrey J Swab. *Compression Strength of Borosilicate and Soda-Lime Silicate Glasses Using a DumbbellShaped Specimen*. DEVCOM Army Research Laboratory, 2020.

[33] Mohammadi Aria, Mohammad, Ahmet Erten, and Ozlem Yalcin. “Technology Advancements in Blood Coagulation Measurements for Point-of-Care Diagnostic Testing.” *Frontiers in Bioengineering and Biotechnology* 7 (December 11, 2019): 395. https://doi.org/10.3389/fbioe.2019.00395.

[34] “Technology Advancements in Blood Coagulation Measurements for Point-of-Care Diagnostic Testing.” *Frontiers in Bioengineering and Biotechnology* 7 (December 11, 2019): 395. https://doi.org/10.3389/fbioe.2019.00395.

[35] Offences and penalties in the NBS Act 2020 (Act 1042). “Ghana NBS Act.” ..Gov.gh, June 29, 2022. https://nbs.gov.gh/offences-and-penalties-in-the-nbs-act-2020-act-1042/.

[36] “Postpartum Haemorrhage.” Accessed September 10, 2023. https://www.who.int/teams/sexual-and-reproductive-health-and-research-(srh)/areas-of-work/maternal-and-perinatal-health/postpartum-haemorrhage.

[37] Prothrombin Time (PT) Test. “Prothrombin Time (PT) Test.” ..Org, March 14, 2022. https://my.clevelandclinic.org/health/diagnostics/17691-prothrombin-time-pt-test#:~:text=A%20prothrombin%20time%20(PT)%20test,to%20investigate%20potential%20blood%20disorders.

[38] Raber, Martin N. “Coagulation Tests.” In *Clinical Methods: The History, Physical, and Laboratory Examinations*, edited by H. Kenneth Walker, W. Dallas Hall, and J. Willis Hurst, 3rd ed. Boston: Butterworths, 1990. http://www.ncbi.nlm.nih.gov/books/NBK265/.

[39] *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*. U.S. Food and Drug Administration, 2015.

[40] Sahli, Sebastian D., Julian Rössler, David W. Tscholl, Jan-Dirk Studt, Donat R. Spahn, and Alexander Kaserer. “Point-of-Care Diagnostics in Coagulation Management.” *Sensors (Basel, Switzerland)* 20, no. 15 (July 30, 2020): 4254. https://doi.org/10.3390/s20154254.

[41] “Point-of-Care Diagnostics in Coagulation Management.” *Sensors (Basel, Switzerland)* 20, no. 15 (July 30, 2020): 4254. https://doi.org/10.3390/s20154254.

[42] Shevell, Lauren, and Jennifer Girard, September 15, 2023.

[43] Sousa et al., Jose Diego de Brito. “Accuracy of the Lee–White Clotting Time Performed in the Hospital Routine to Detect Coagulopathy in Bothrops Atrox Envenomation.” National Library of Medicine, April 2, 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5953394/.

[44] SSA, ORDP. “Physical Exertion Requirements.” Accessed September 10, 2023. https://www.ssa.gov/OP_Home/cfr20/404/404-1567.htm.

[45] Statista. “Ghana: Governmental Health Spending as a Share of GDP.” Accessed September 28, 2023. https://www.statista.com/statistics/1124307/ghana-domestic-general-government-health-expenditure-as-share-of-gdp/.

[46] “Statistical Analysis in Method Comparison Studies Part One.” Accessed September 20, 2023. https://acutecaretesting.org/en/articles/statistical-analysis-in-method-comparison-studies-part-one.

[47] Suseel, Appu, Siju V. Abraham, Sarah Paul, Maglin Monica Lisa Tomy, and Aboobacker Mohamed Rafi. “Comparing Modified Lee and White Method against 20-Minute Whole Blood Clotting Test as Bedside Coagulation Screening Test in Snake Envenomation Victims.” *The Journal of Venomous Animals and Toxins Including Tropical Diseases* 29 (n.d.): e20220088. https://doi.org/10.1590/1678-9199-JVATITD-2022-0088.

[48] TEG 5000. “TEG 5000.” Accessed September 24, 2023. https://hospital.haemonetics.com/hemostasis-management/teg-5000.

[49] TEG 5000 Hemostasis Analyzer System. “Transfusionguidelines.Org: TEG 5000 Hemostasis Analyzer System.” Brochure, 2010. https://www.transfusionguidelines.org/document-library/documents/teg-5000-hemostasis-analyser-system-supported-by-haemonetics/download-file/rtc-nw_2014_05_P_TE_haemonetics.pdf.

[50] Thiyagarajan, Dhanu, n.d.

[51] “Thromboelastometry.” Accessed September 18, 2023. https://practical-haemostasis.com/Miscellaneous/Global%20Assays/teg_rotem.html.

[52] Whiting, P et al. “Viscoelastic Point-of-Care Testing to Assist with the Diagnosis, Management and Monitoring of Haemostasis: A Systematic Review and Cost-Effectiveness Analysis.” Health Technology Assessment, July 2015. https://www.ncbi.nlm.nih.gov/books/NBK305702/.

[53] “World Development Indicators | DataBank.” Accessed September 28, 2023. https://databank.worldbank.org/reports.aspx?source=2&series=SH.XPD.GHED.GD.ZS&country=GHA.

[54] French MJ (1999), Conceptual design for engineers. Springer

[55] Béla H. Bánáthy (1996), Double Diamond, Design Process Model

[56] IEC 60601-1-11:2015, Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, 2015 https://www.iso.org/standard/65529.html

[57] "Ghana Meteorological Agency. 'Climatology.' Ghana Meteorological Agency,” www.meteo.gov.gh/gmet/climatology/.

[58] Ranucci, Marco et al. “Blood viscosity during coagulation at different shear rates.” July 2014. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4187573/. Accessed October 9, 2023.

[59] Gelfan, S., and J. P. Quigley. “Conductivity of blood during coagulation.” *American Journal of Physiology-Legacy Content*, vol. 94, no. 3, 1930, pp. 531–534, https://doi.org/10.1152/ajplegacy.1930.94.3.531.

[60] Nader E, Skinner S, Romana M, Fort R, Lemonne N, Guillot N, Gauthier A, Antoine-Jonville S, Renoux C, Hardy-Dessources MD, Stauffer E, Joly P, Bertrand Y, Connes P. Blood Rheology: Key Parameters, Impact on Blood Flow, Role in Sickle Cell Disease and Effects of Exercise. Front Physiol. 2019 Oct 17;10:1329. doi: 10.3389/fphys.2019.01329. PMID: 31749708; PMCID: PMC6842957.

[61]Perez Rogers A, Estes M. Hyperviscosity Syndrome. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK518963/

[62] “Convection Heat Coefficient - 2012 - SOLIDWORKS Help.” Accessed October 8, 2023. https://help.solidworks.com/2012/english/solidworks/cworks/convection_heat_coefficient.htm.

[63] Wang, Wen, Kwok Hui, Chi Kan, Krailerck Visesphan, Saowanee Areechongchareon, Somporn Tiyasri, and Rattanaphol Mongkholrattanasit. “A Study of Thermal Conductivity Property of Socks.” Materials Science Forum 1007 (August 1, 2020): 118–24. https://doi.org/10.4028/www.scientific.net/MSF.1007.118.

[64] Bergman, T., & Lavine, A. (2017). *Fundamentals of Heat and Mass Transfer (8th edition)* (8th ed.). John Wiley & Sons, inc.

[65] Hibbeler, R. C. (2008). *Engineering Mechanics: Statics (12th Edition)* (12th ed.). Pearson.

[66] *Coagulopathy - an overview | ScienceDirect Topics*. (n.d.). Retrieved October 13, 2023, from https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/coagulopathy

[67] *Blood Clotting Disorders - Disseminated Intravascular Coagulation (DIC) | NHLBI, NIH*. (2022, March 24). https://www.nhlbi.nih.gov/health/disseminated-intravascular-coagulation

[68] “Kumasi Metropolitan.” Accessed October 19, 2023. https://mofa.gov.gh/site/directorates/district-directorates/ashanti-region/165-kumasi-metropolitan.

[69] “Oku Electronics | Make It Possible!” Accessed October 19, 2023. https://www.okuelectronics.com/.

[70] “Qualiplast Ghana - Contacts & Business Details.” Accessed October 19, 2023. https://yellowpagesghana.com/listing/qualiplast-ghana/.

[71] GhanaYello. “Fastener First Ghana Ltd.” Accessed October 19, 2023. https://www.ghanayello.com/company/39267/Fastener_First_Ghana_Ltd.

[72] weather-and-climate.com. (n.d.). *Average monthly humidity in Kumasi (ashanti region), Ghana*. World Weather & Climate Information. https://weather-and-climate.com/average-monthly-Humidity-perc,Kumasi,Ghana

[73] “Shipping to Ghana from the US.” *ShipBob*, Accessed October 16, 2022, www.shipbob.com/shipping-from-us/to-ghana/.

[74] Windberger, Ursula, and Jörg Läuger. “Blood Clot Phenotyping by Rheometry: Platelets and Fibrinogen Chemistry Affect Stress-Softening and -Stiffening at Large Oscillation Amplitude.” *Molecules* 25, no. 17 (January 2020): 3890. https://doi.org/10.3390/molecules25173890.

[75] “Polyimide.” *Polyimide - an Overview | ScienceDirect Topics*, www.sciencedirect.com/topics/materials-science/polyimide. Accessed 20 Nov. 2023.

[76] Amazon. “Lewansoul Servo Photo & Specs.” Accessed October 25, 2023.

[77] Amazon. “Polyimide Heating Pad.” Accessed November 3, 2023. https://www.amazon.com/dp/B07P1H8N8H/ref=emc_b_5_t?th=1.

[78] Electric Heating Pad - 10cm x 5cm. “Adafruit 1481 Heating Pad.” Accessed November 1, 2023. https://www.adafruit.com/product/1481.

[79] Shanqiu Mini UPS Battery Backup Uninterruptible Power Supply. “Power Supply.” Accessed November 4, 2023. https://www.amazon.com/Battery-Backup-20000mAH-Uninterruptible-Security/dp/B089SQFCBW?th=1.

[80] Nahirnyak, Volodymyr M. “Acousto-Mechanical and Thermal Properties of Clotted Blood.” NIH, October 7, 2001.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1995812/#:~:text=Density%2C%20specific%20heat%2C%20and%20thermal,Lehmann%20and%20DeLateur%2C%201982.

[81] Yeager, Charles. "1080p vs. 4K," January 12, 2021. https://www.premiumbeat.com/blog/shooting-in-1080-vs-4k/.

[82] gsmarena. "Samsung Galaxy A03s Specs." Accessed November 9, 2023. https://www.gsmarena.com/samsung_galaxy_a03s-review-2355p5.php.

[83]F. Ancona, D. Palumbo, R. De Finis, G.P. Demelio, U. Galietti, Automatic procedure for evaluating the Paris Law of martensitic and austenitic stainless steels by means of thermal methods, Engineering Fracture Mechanics, Volume 163

[84] Jones, David R.H., and Michael F. Ashby. "Engineering materials and their properties." Engineering Materials 1, 2019, pp. 1–12, https://doi.org/10.1016/b978-0-08-102051-7.00001-4.

[85] Amazon. "Galaxy A03s Amazon." Accessed November 2, 2023. https://www.amazon.com/Simple-Mobile-Samsung-Galaxy-Black/dp/B0BBXD7S5R/ref=asc_df_B0BBXD7S5R/?tag=hyprod-20&linkCode=df0&hvadid=633050500208&hvpos=&hvnetw=g&hvrand=3856955903442770002&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016852&hvtargid=pla-1879109325276&psc=1&mcid=db8dcc5d0d853a9f8e588dd09b56190e&gclid=Cj0KCQiApOyqBhDlARIsAGfnyMr9H1SJz0Sc90hYGk8wtW6iWLh-X-udD7RUNDpeZFrdmCM9boS5tOEaAsGeEALw_wcB.

[86] Tawiah, Augustine, October 26, 2023.

[87] Mauro Cordella a 1, et al. "Durability of Smartphones: A Technical Analysis of Reliability and Repairability Aspects." *Journal of Cleaner Production*, Elsevier, 4 Dec. 2020, www.sciencedirect.com/science/article/pii/S0959652620354342?via%3Dihub#bib9.

[88] *Environmental Evaluation of Current and Future Design Rules - Prompt*, prompt-project.eu/wp-content/uploads/2020/07/PROMPT_20200429_Environmental-Evaluation-of-Current-and-Future-Design-Rules.pdf. Accessed 14

[89] "What Is Covered under the Samsung Warranty for Mobile Devices." *Samsung Ph*, 18 Sept. 2023, www.samsung.com/ph/support/mobile-devices/what-is-covered-under-the-samsung-warranty/.

[90] *The Thermal Conductivities of Some Biological Fluids - Researchgate*, www.researchgate.net/publication/231088777_The_Thermal_Conductivities_of_some_Biological_Fluids. Accessed 22 Nov. 2023.

[91] Glassdoor. "Ghana Health Service Salaries in Ghana." Accessed November 22, 2023.

https://www.glassdoor.com/Salary/Ghana-Health-Service-Salaries-E532960.htm.

[92] Papaya Global. “Payroll and Benefits Guide, Ghana,” May 9, 2023. https://www.papayaglobal.com/countrypedia/country/ghana/.

[93] Statista. “Ghana: Average Electricity End-User Tariff.” Accessed November 14, 2023. https://www.statista.com/statistics/1293953/average-electricity-end-user-tariff-in-ghana/.

[94] At a Glance: Disinfectant Tables - Public Health Ontario, www.publichealthontario.ca/-/media/documents/a/2018/at-a-glance-ipac-pss-disinfectant-tables.pdf?la=en. Accessed 22 Nov. 2023.

[95]Access Real-Time AQI Data or the AQI Forecast at - Rochester, NY, www.urmc.rochester.edu/MediaLibraries/URMCMedia/environmental-health-sciences-center/COEC/documents/The-Air-Quality-Index-Guide_8-2-18.pdf. Accessed 22 Nov. 2023.

[96] *Use of Disinfectants: Alcohol and Bleach - Infection Prevention And ...*, www.ncbi.nlm.nih.gov/books/NBK214356/. Accessed 22 Nov. 2023.

[97] Esteve, S., Forkey, D., & Clark, S. (2021). Human factors testing sample size requirements: Is it time to reevaluate? Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care, 10(1), 243–246. https://doi.org/10.1177/2327857921101178

[98]“Polypropylene Chemical Compatibility.” *Polypropylene Chemical Compatibility Chart*, www.calpaclab.com/polypropylene-chemical-compatibility-chart/. Accessed 21 Nov. 2023.

[99] Key, A. P. (n.d.). *What to know about rubbing alcohol*. WebMD. https://www.webmd.com/first-aid/ss/rubbing-alcohol-uses

[100] Cooper, Daniel (2023). *ME 481 Manufacturing Processes Lecture #13&14 Polymer Processing*. [Powerpoint slides] College of Engineering, University of Michigan.

[101] Navidi, William. *Statistics For Engineers and Scientists*. Fifth. McGraw-Hill Education, 2020.

[102] *Estimating the Effect of Moist Air - Qats.Com*, www.qats.com/Qpedia-Article/Qpedia_Nov08_Estimating_the_Effect_of_Moist_Air_on_Natural_Convection_Heat_Transfer. Accessed 10 Dec. 2023.

[103] Abs Chemical Resistance Chart and guide. (n.d.). http://k-mac-plastics.com/data-sheets/abs_chemical_resistance.htm

[104] *Epoxy - chemical resistance*. Engineering ToolBox. (n.d.). https://www.engineeringtoolbox.com/chemical-resistance-epoxy-d_786.html

[105] *Nylon Chemical Resistance Chart*. Blue Nylon Sheet. (n.d.). https://kmac-plastics.net/data/chemical/nylon-chemical-.htm

[106] Pearce, J. M., Dhankani, K., Su, C. K., Carvalho, M. C., Zhang, C., Tanikella, N. G., Zander, N. E., Wittbrodt, B., Wittbrodt, B. T., Symes, M. D., Kitson, P. J., Erkal, J. L., Morgan, A. J., Bhattacharjee, N., Costa, E. T. D., Dragone, V., Sells, E., Jones, R., Bowyer, A., … Damase, T. R. (2018, July 30). *Chemical compatibility of fused filament fabrication-based 3-D printed components with solutions commonly used in semiconductor wet processing*. Additive Manufacturing. https://www.sciencedirect.com/science/article/pii/S2214860418303476

[107] Vaňková, E., Kašparová, P., Khun, J., Machková, A., Julák, J., Sláma, M., Hodek, J., Ulrychová, L., Weber, J., Obrová, K., Kosulin, K., Lion, T., & Scholtz, V. (2020, October 29). *Polylactic acid as a suitable material for 3D printing of protective masks in times of covid-19 pandemic*. PeerJ. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7603793/

[108] Filament Properties Table. “Filament Properties Table.” Accessed October 12, 2023. https://www.simplify3d.com/resources/materials-guide/properties-table/.

[109] Wood Species - Densities. “Wood Species - Densities.” Accessed December 10, 2023. https://www.engineeringtoolbox.com/wood-density-d_40.htmlhttps://www.engineeringtoolbox.com/wood-density-d_40.html.

TEAM BIOS

Brandon Brozich

Brandon is a senior mechanical engineering student, with a minor in electrical engineering. Brandon grew up in the small town of Byron, MI, where he became intrigued by mechanical systems and often spent his time repairing farm equipment and vehicles at his house. This led him to pursue study in mechanical engineering at the University of Michigan. Brandon also has applicable work experience in automotive sensory equipment, optics, and computer programming. While at university, Brandon discovered his passion for biomedical engineering, leading him to take classes in human biology and organic chemistry, in preparation for his plans to study biomaterials and regenerative medicine as a Ph.D. student. In his free time, Brandon enjoys building breadboard circuits, playing guitar, and motocross.

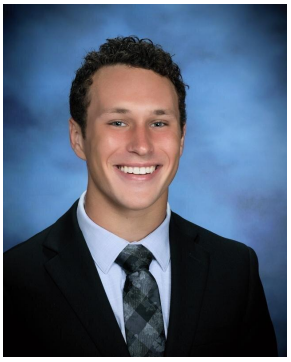
Yilin Fang

Yilin is a senior dual degree student studying Computer Science and Information at the University of Michigan. Yilin was born in Nanjing, China and grew up in both China and Toronto, Ontario. She became interested in global health design after learning about the GHDI program at the University of Michigan. She is really passionate about discovering unmet needs at low resource settings and developing task shifting solutions. In her free time, she enjoys writing, traveling and working out.

Eleanor Frazee

Eleanor is a senior studying Mechanical Engineering, with an International Minor for Engineers. Eleanor was originally from Rochester Hills, Michigan, prior to moving to Ann Arbor to attend the University of Michigan. She was drawn to mechanical engineering as she enjoys repairing things around the house and taking things apart to see how they work. Eleanor also enjoys problem-solving and puzzles. Outside of the classroom, Eleanor is the Chief Engineer of the University of Michigan Supermileage Team, where she works to design, build, and test highly efficient vehicles. She has completed internships in project management and powertrain manufacturing and also spent a summer studying abroad in Rome, Italy. On the weekends, she enjoys cooking, camping, and watching UofM football with her friends. Eleanor intends to graduate with her Bachelor's degree in May 2024. She plans to pursue a career in manufacturing for an automotive or medical device company. Eleanor eventually wants to return to school to pursue a Master’s degree in Business Administration or Engineering Management.

Aaron Gunn



Aaron grew up in Huntington Woods, MI. Living right next to Woodward Avenue, Aaron grew up going to the Dream Cruise with his family and was always interested in the automotive industry. Currently, he is a senior in mechanical engineering at the University of Michigan - Ann Arbor. With two and a half years worth of research experience at the UMTRI, Aaron's research experience has consisted mostly of working with scenario generation softwares (CarSim and Unity) as well as data processing. He is currently employed at Mcity, working on induction charging pads for electric vehicles. Aaron plans on getting a masters in mechanical engineering and pursuing a career in the electric vehicle industry. In his free time, Aaron enjoys hiking, football, and cooking.

Thomas Vincent

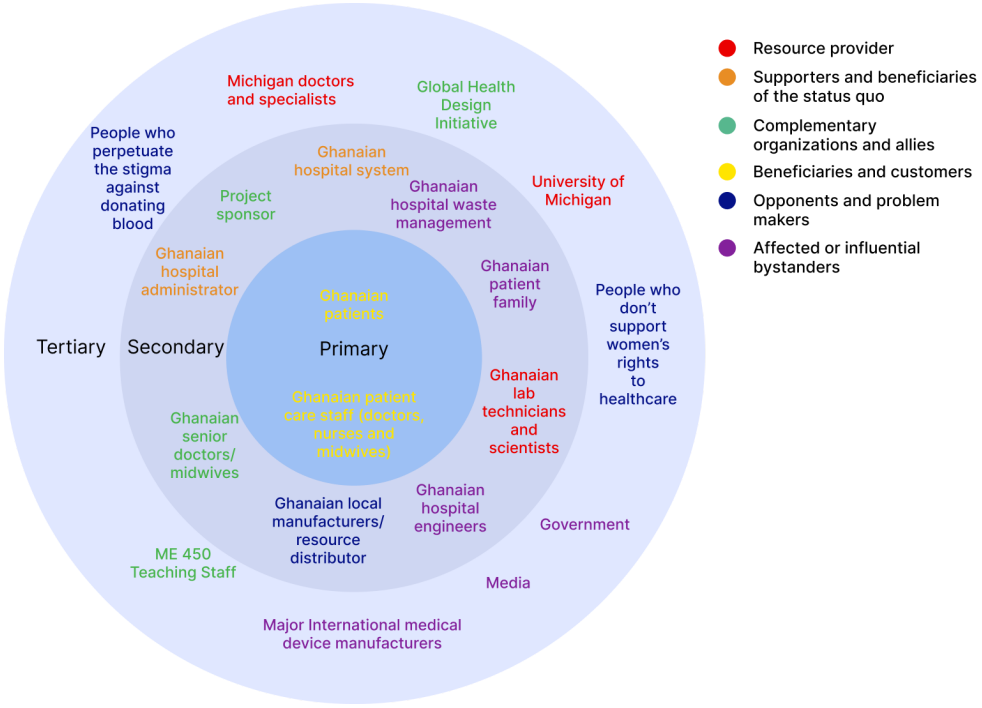
Thomas is a senior Mechanical Engineering student at University of Michigan - Ann Arbor. Thomas was born and raised in Jackson, Michigan until the end of his secondary education, in which he moved to Ann Arbor to study at university. Growing up in a family of both hobby and professional mechanics, Thomas was constantly exposed to the repair of broken machinery, learning over the years how to repair (on and off-road) vehicles. This exposure fostered a fascination which translated into his college education, ultimately causing him to pursue Mechanical Engineering as a major. In his free time, Thomas enjoys spending time outdoors, with family, water skiing, and making espresso drinks (americanos are the preferred option). He is also a member of the University of Michigan Supermileage team on the Mechanical Systems subteam at the Wilson Student Project Center. Thomas has held multiple internships in the automotive industry, focused on cost reduction and quality improvement. Thomas will graduate in May 2024 with a BSE, and plans to continue his education to obtain a MSE in Mechanical Engineering with a focus on controls through the SUGS program.

Zachary Wanger

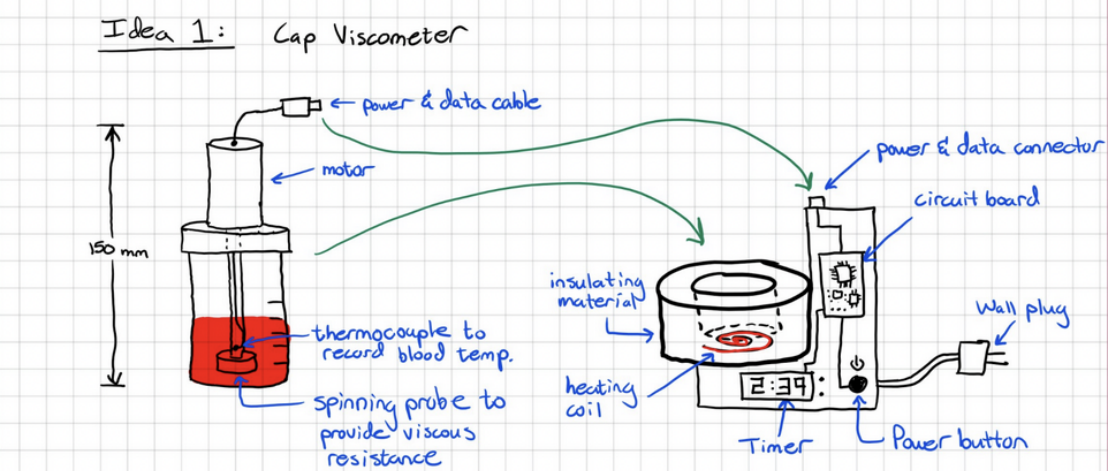
Zachary Wanger is a senior Mechanical Engineering student at The University of Michigan, with a minor in Computer Science. Zachary was born and raised in Chicago, Illinois, attending the Latin School of Chicago (K-12) and completing his junior year of high school abroad in Viterbo, Italy with the School Year Abroad program. Arriving at university, Zachary initially pursued an education in Civil Engineering but was drawn to Mechanical Engineering as he became interested in the interaction between machines and computers. Since joining the department, Zachary has completed coursework covering most major topics in engineering including Fluid Mechanics, Statics, Circuitry, and Material Science. In his free time, Zachary plays on the University of Michigan Club Ultimate Frisbee team, currently ranked as the #15th best collegiate team in the

nation. Zachary will graduate in May 2024 with a BSE, with plans to work in the aerospace or financial technology industry after graduation.

Appendix A

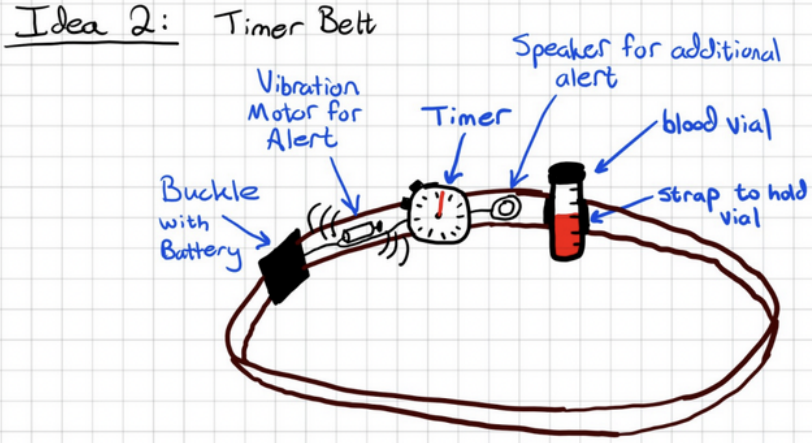


Appendix B (Concept #1/24)



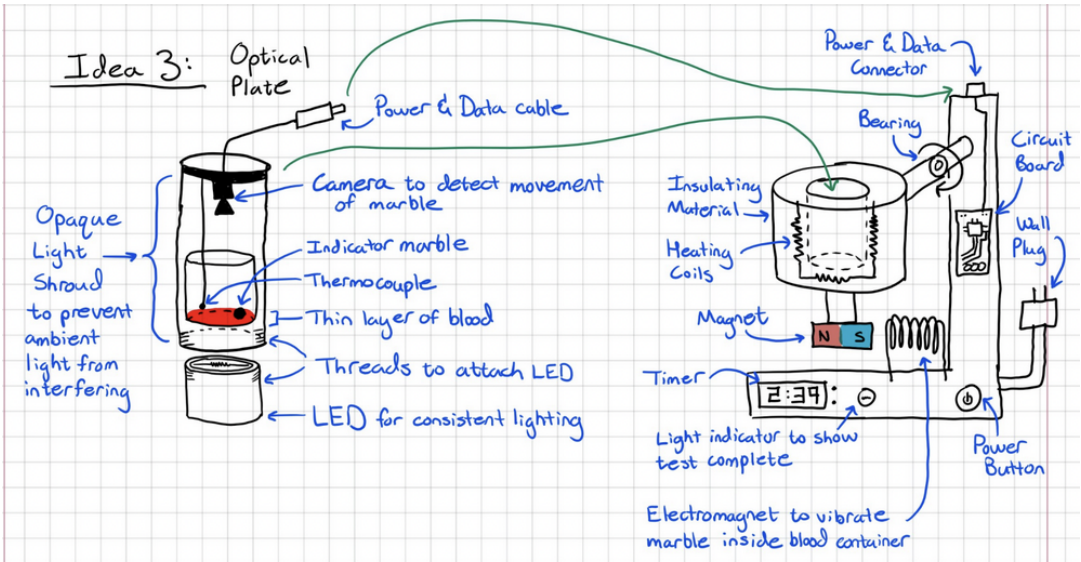
Idea 1 Operating Principle: Blood is drawn into the container. The cap with motor is placed on the container. The container is then placed onto the base, and the power and data cable is connected to the power and data connector. Once turned on, the motor begins to turn, and the heating coil keeps the blood at body temperature using feedback from the thermocouple placed on the spinning probe inside the blood container. As blood viscosity increases due to clot formation, the current through the motor also increases. This current is measured by the circuit board, which pauses the timer and turns off the machine once a current limit is reached. The time on the timer is taken to be the time at which the clot formed.

Appendix C (Concept #2/24)



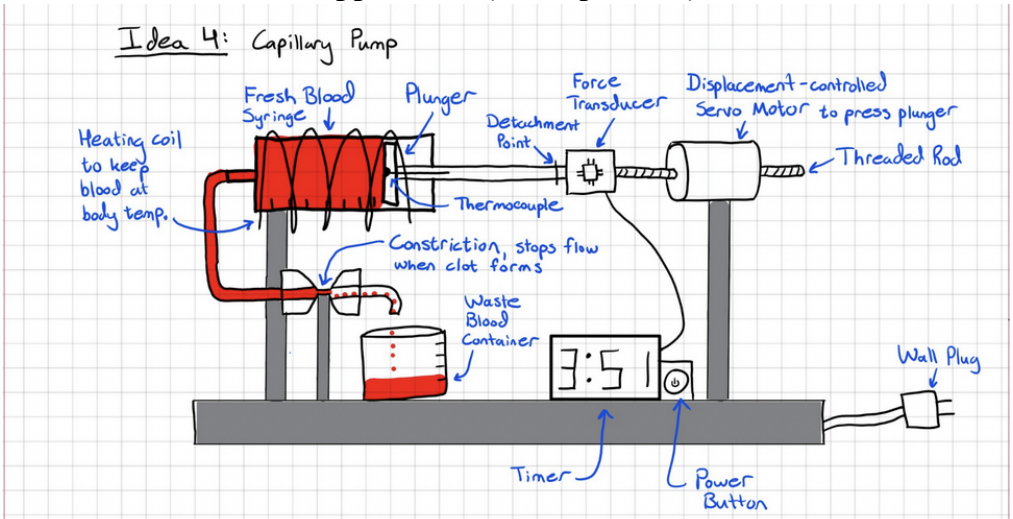
Idea 2 Operating Principle: Belt is worn by the user -- patient care staff. Freshly drawn blood is placed in a capped vial, which is secured to the belt via a strap. The vial is placed proximally to the outside of the belt, allowing the user's body heat to keep the vial warm. The belt buckle contains a battery, which powers the system. User presses start on the timer during blood collection. The timer sends a signal to the vibration motor and the speaker every minute after pressing start, prompting the user to check the blood vial for clotting. If a clot has formed, the user pauses the timer, and the time on the timer is taken to be the clot formation time.

Appendix D (Concept #3/24)



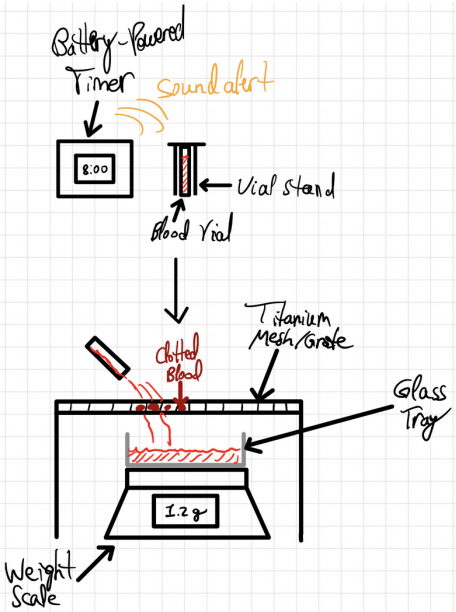
Idea 3 Operating Principle: The left side shows the optical housing containing the blood sample. A thin layer of blood is placed in a container, along with a marble. The container is then placed inside of the opaque shroud, and the LED is screwed into the shroud creating a closed system, blocking ambient light. The camera at the top of the shroud measures the position of the marble, assisted by light from the LED. This assembly on the left is placed into the heating mechanism on the right, which maintains the blood at body temperature. The heating mechanism is "rocked" back and forth via a permanent magnet interacting with an electromagnet as pictured, to promote the marble to move around. When the blood clots, the marble can no longer move, the camera detects no motion in the marble, and the circuit board reads the info from the camera to send a signal to stop the timer and shut the mechanism off. The time at which the timer was stopped is taken to be the clotting time.

Appendix E (Concept #4/24)



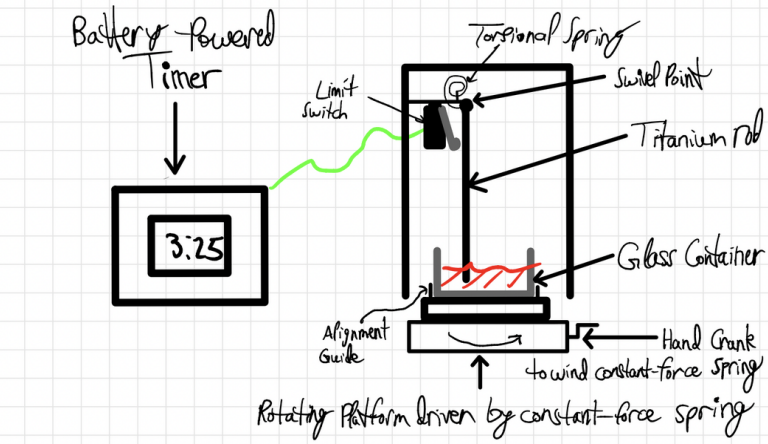
Idea 4 Operating Principle: User removes syringe from base, fills with patient blood, and purges any air bubbles. The filled syringe is then placed back on the base, and the servo motor is driven until the force transducer contacts the detachment point on the plunger. A heating coil in combination with a thermocouple on the plunger of the syringe keeps the blood at body temperature during the test. Pressing the power button starts the timer and the servo motor begins pressing the plunger into the syringe body at a constant velocity. Un-clotted blood passes through the constriction freely, but clotted blood increases the viscous resistance on the system, which then causes an increased reading on the force transducer. When a specified force threshold is met, the force transducer signals the timer to pause. The time on the timer is taken to be the time at which the blood clot formed. Blood that passes through the constriction lands in the waste blood container.

Appendix F (Concept #5/24)



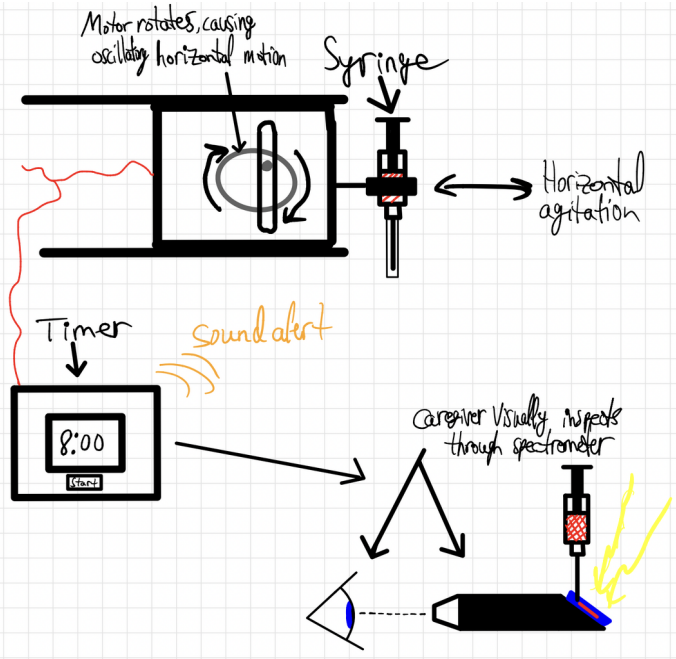
Idea 5 - Mesh: A predetermined volume (mass) of blood is drawn from a patient into a vial. User places drawn blood onto stand at room temperature for 8 minutes. Timer notifies user to pour volume of blood over a titanium grate into a glass container. Mass of blood making it through mesh into container is unclotted mass. Clotted blood will be caught by mesh. Ratio of unclotted blood mass to original mass can be used to determine whether a patient has coagulopathy.

Appendix G (Concept #6/24)



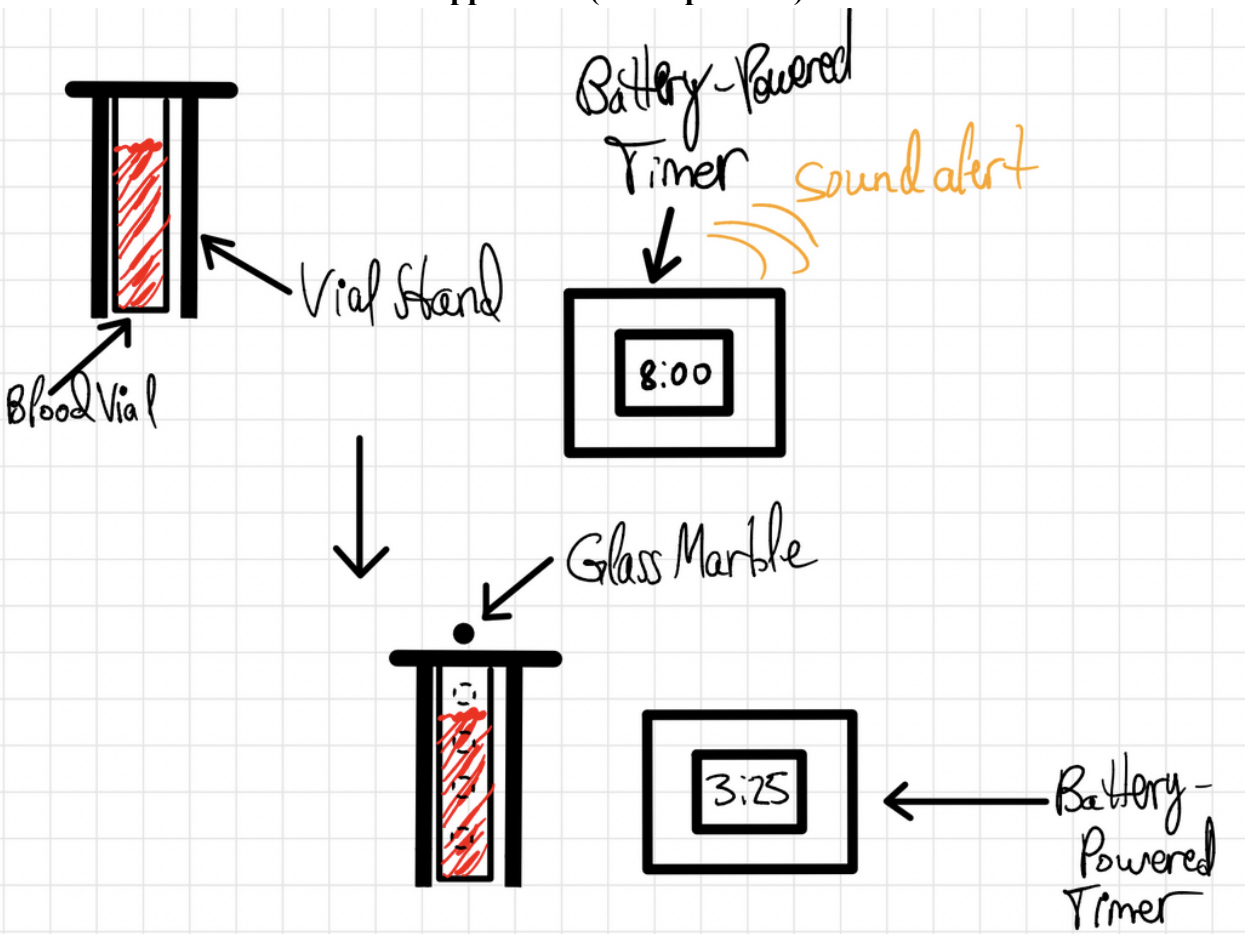
Idea 6 - Torsional Spring: A specified volume of blood is placed into a glass container. This container is then situated onto a rotating platform driven by a constant-force spring. This spring will in turn rotate the platform, imposing viscous force on a titanium rod that is submerged partially in the blood. A timer is started the instant that rotation is started. Upon a certain level of clotting, the viscous force applied will overcome the torsional spring attached to the titanium rod. The rod will then deflect to trigger a limit switch which stops the timer, recording the “clot time”.

Appendix H (Concept #7/24)



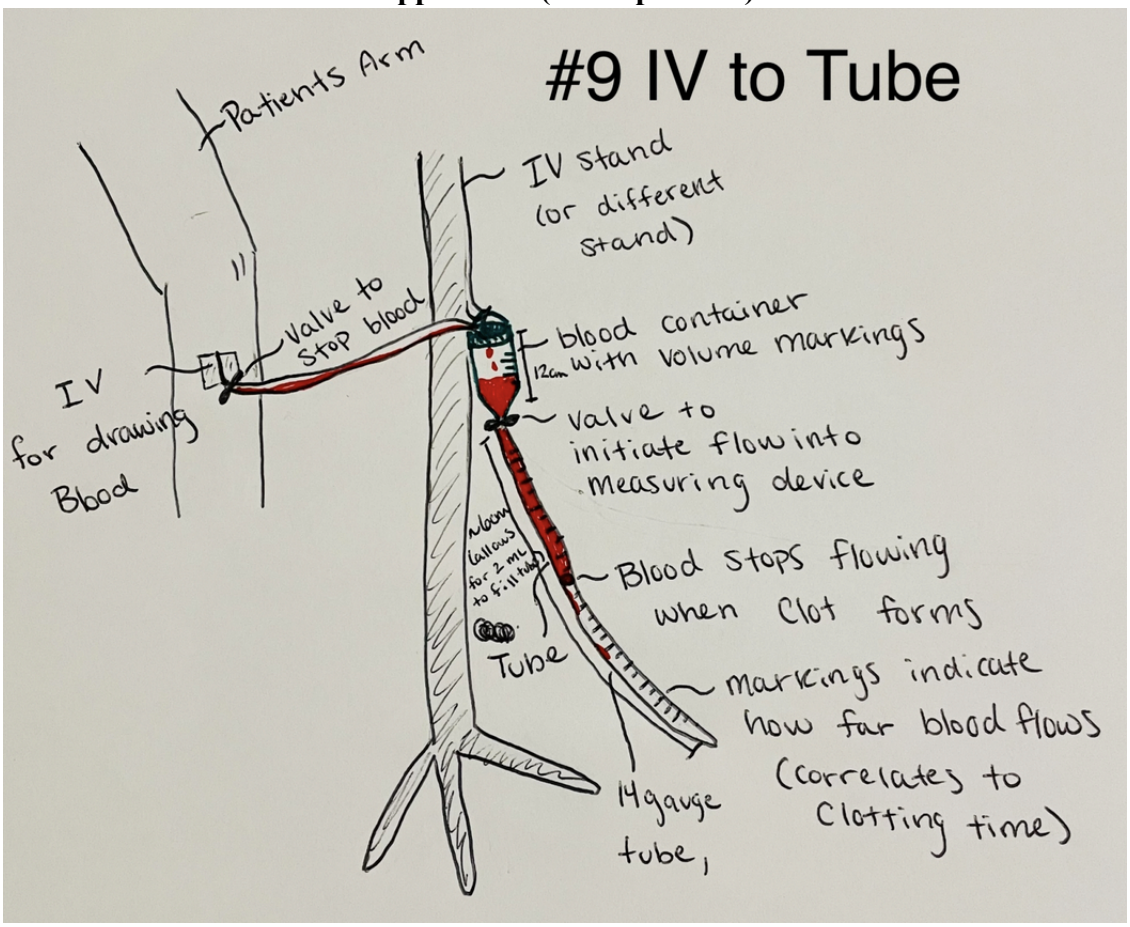
Idea 7 - Spectrometer: Blood syringe is placed on machine which incites horizontal oscillatory motion. Pressing start begins timer and actuation of syringe agitator for 8 minutes upon which the caregiver is notified via alarm and the agitation stops. Blood is transferred to a handheld spectrometer upon which the caregiver inspects frequency of light permitted to determine whether blood is clotted.

Appendix I (Concept #8/24)

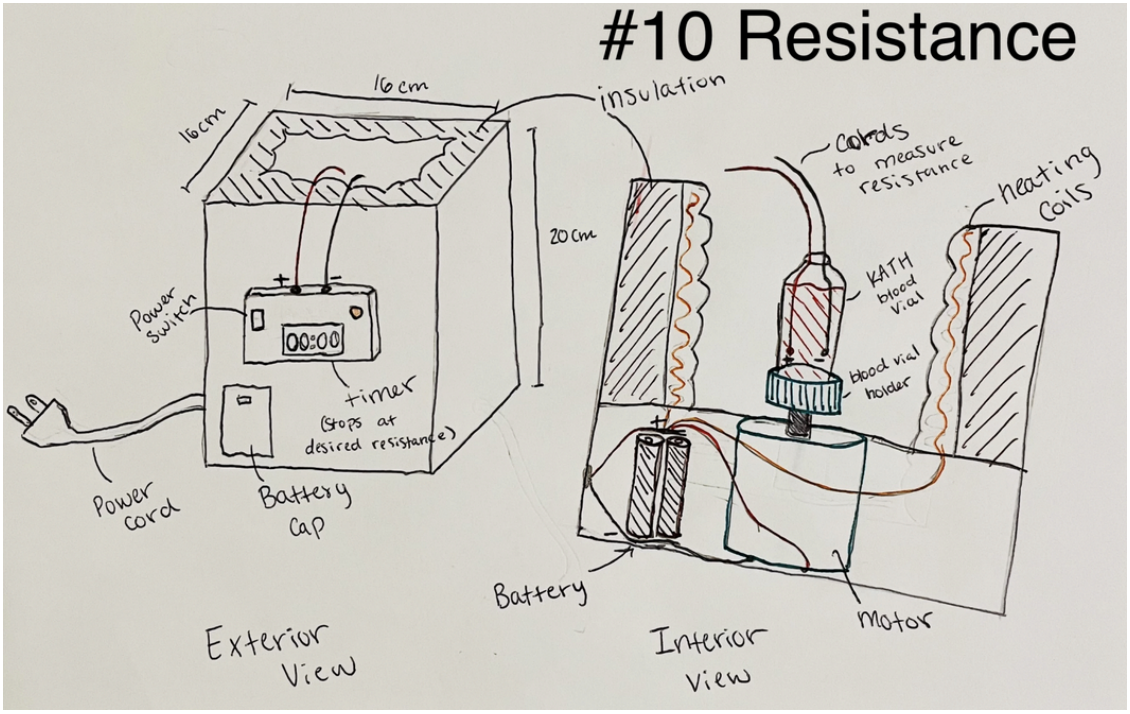


Idea 8 - Ball Drop: Blood is rested on a stand at room temperature for 8 minutes. Upon 8 minutes, an alarm will notify the caregiver to drop a glass marble into the blood vial to see if the marble falls to the bottom of the vial, and if it does, how long it takes for the marble to hit the bottom of the vial. This will give an indication on if the blood has clotted, as well as the quality of the clot given the viscous resistance observed on the marble.

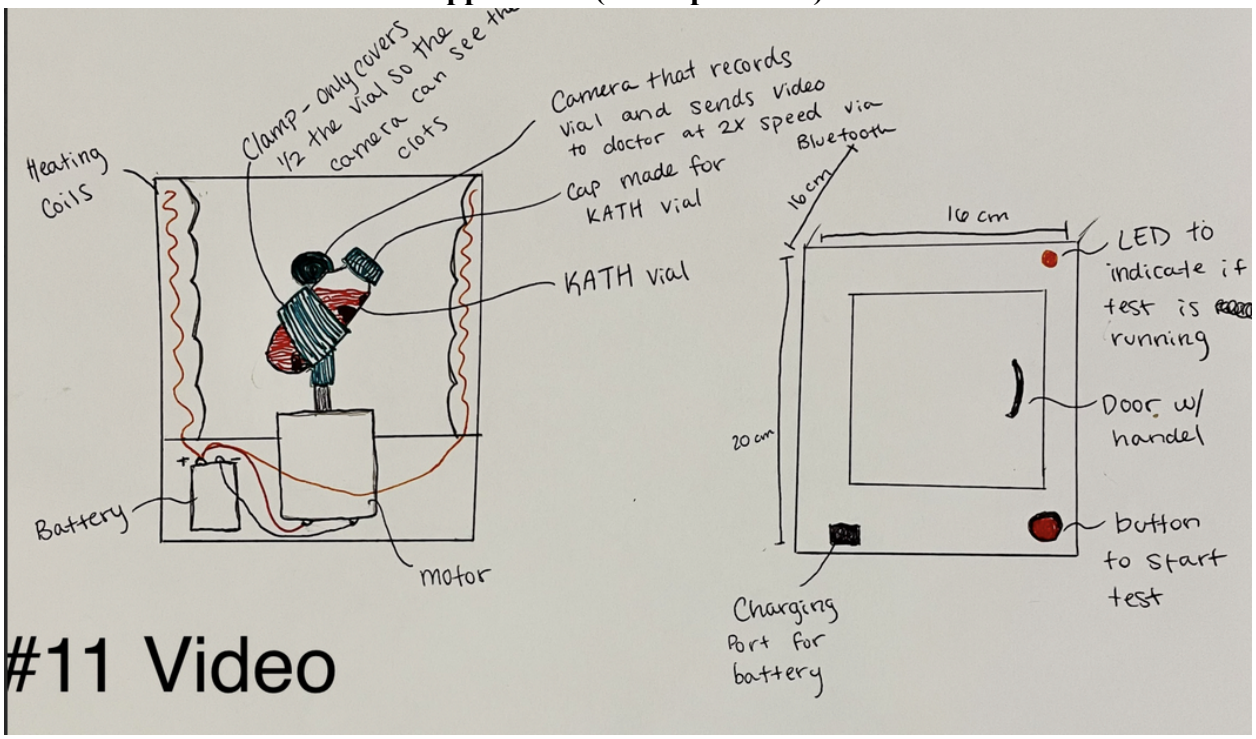
Appendix J (Concept #9/24)



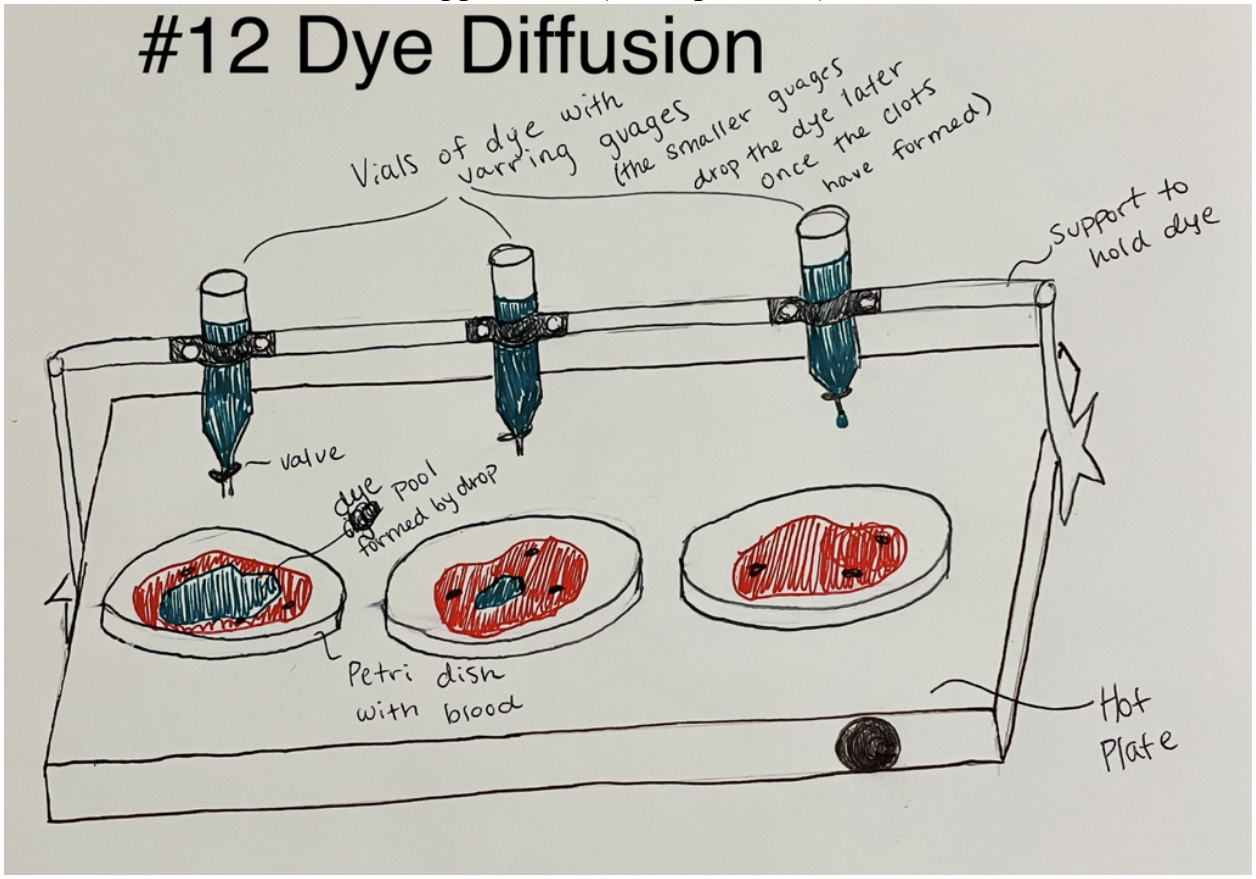
Appendix K (Concept #10/24)



Appendix L (Concept #11/24)

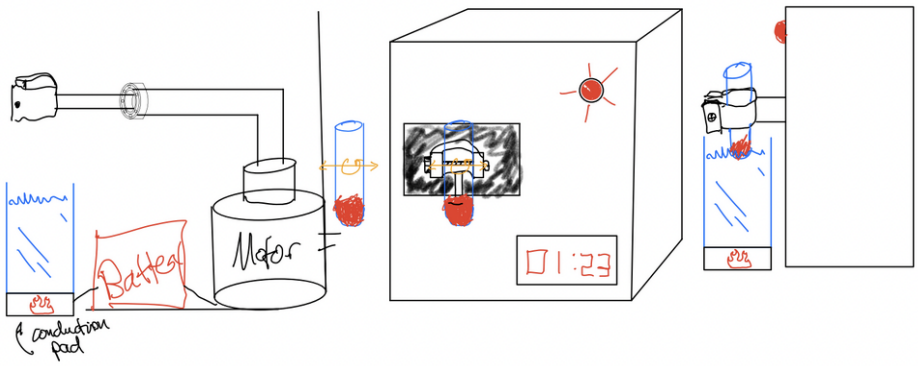


Appendix M (Concept #12/24)



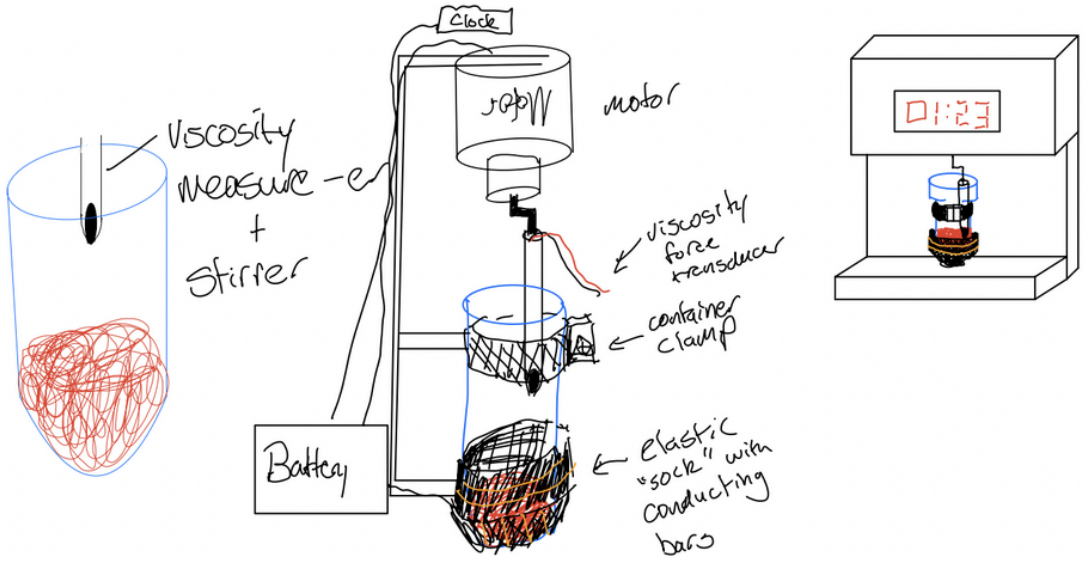
Appendix N (Concept #13/24)

The device works by clamping the blood container via strap, bolt, and wing nut. Once in position, the device is turned on via the button. The clock begins to count up, the motor rotates back and forth about the Z axis, and the bearing in the middle of the shaft allows the momentum of the container to twist around the Y axis. The container is partially submerged and the water is heated via hot pad. A light turns on every minute and the doctors phone records the whole process.

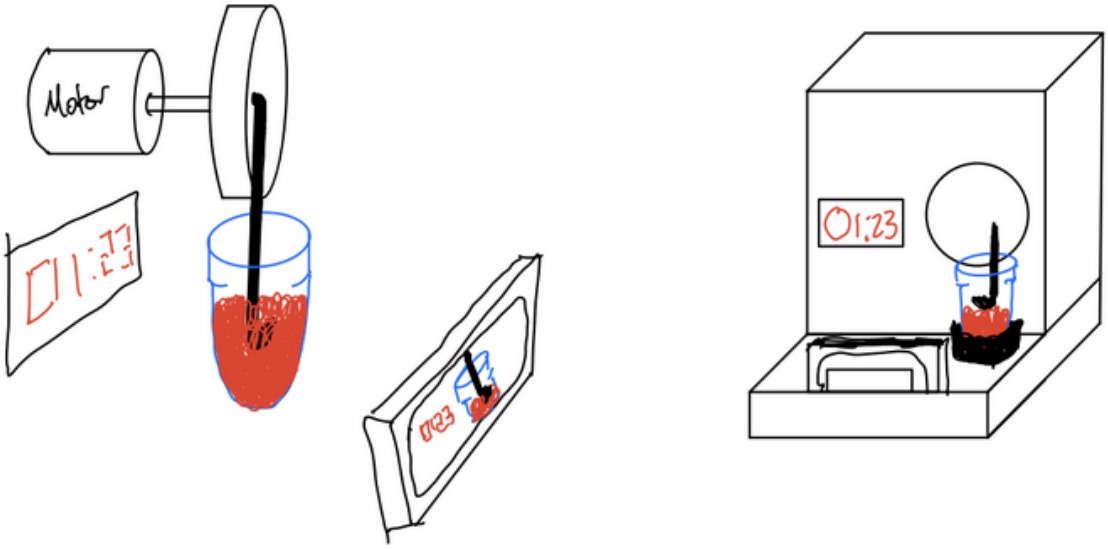


Appendix O (Concept #14/24)

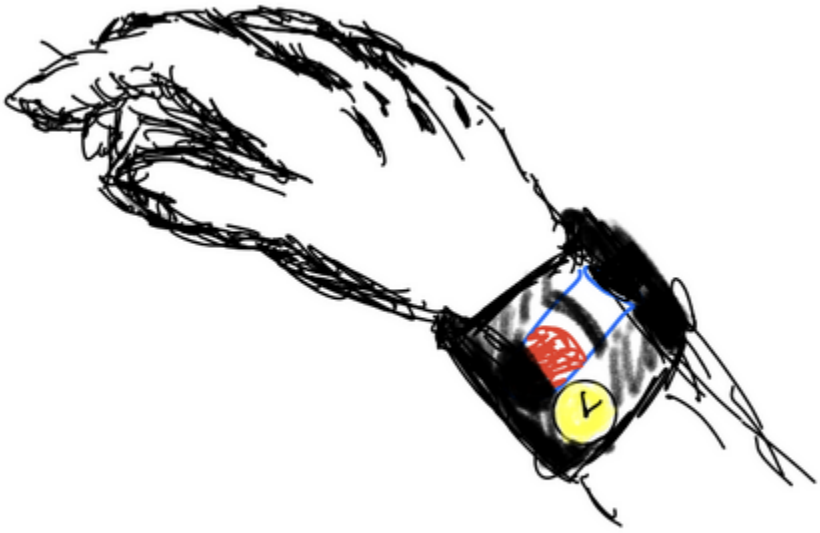
The blood container is the machine such that the stirrer is in the container and in an elastic basket that has conduction wires in it. The container is then put in the clamp system and the start button is pressed. The stirrer is equipped with a viscosity force transducer which stops the test when the viscosity of the blood reaches a specific value. When the test is over, the time stops and a constant alarm will alert the caregiver.



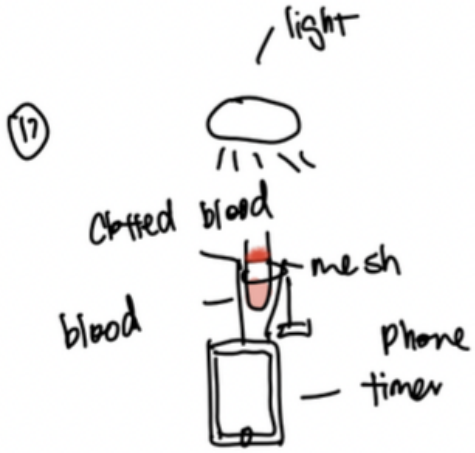
Appendix P (Concept #15/24)



Appendix Q (Concept #16/24)



Appendix R (Concept #17/24)



- picture every 10 seconds
- above mesh retains clot
- mesh not necessary

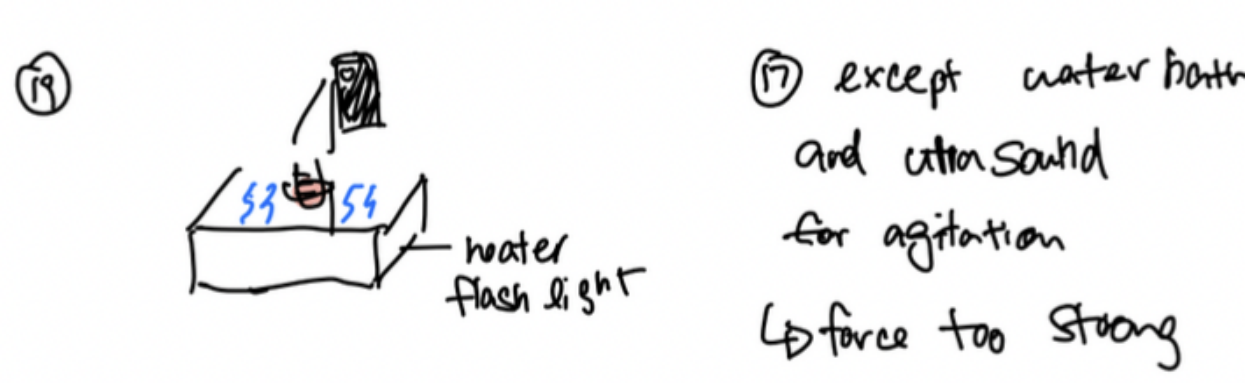
Appendix S (Concept #18/24)

Alternatively: use a phone camera to analyze stopping point

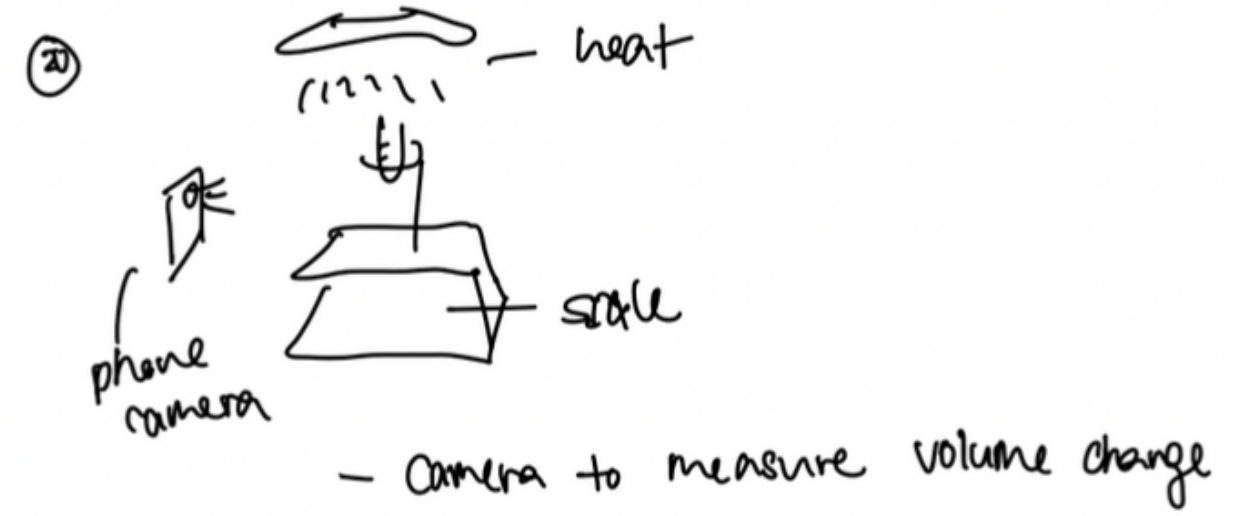
- very thin tube, flowing enough blood that would clot in the tube within 2 min

Con: additional disposable component

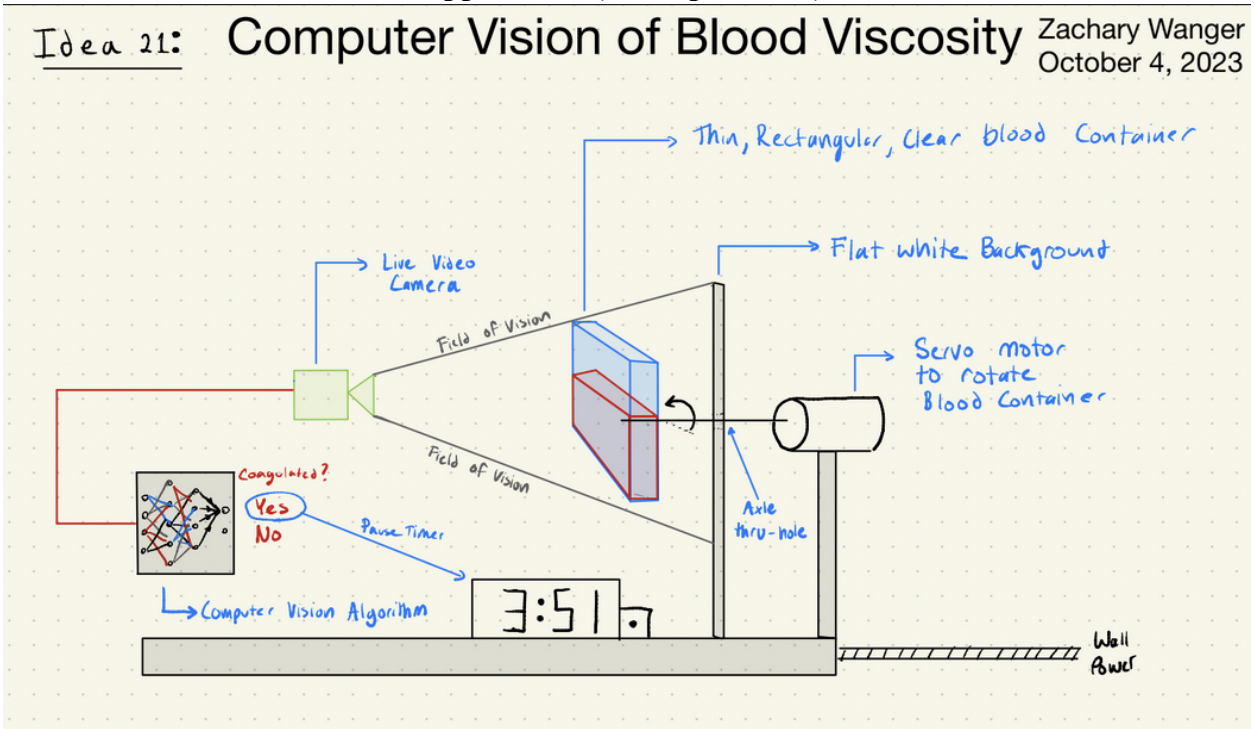
Appendix T (Concept #19/24)



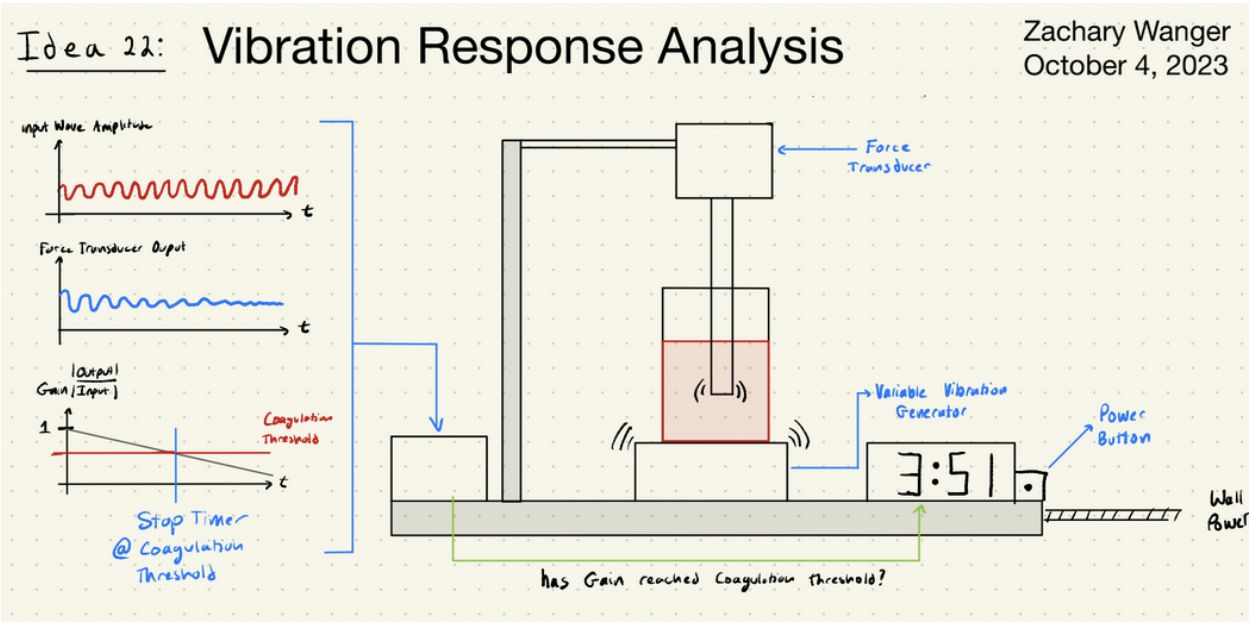
Appendix U (Concept #20/24)



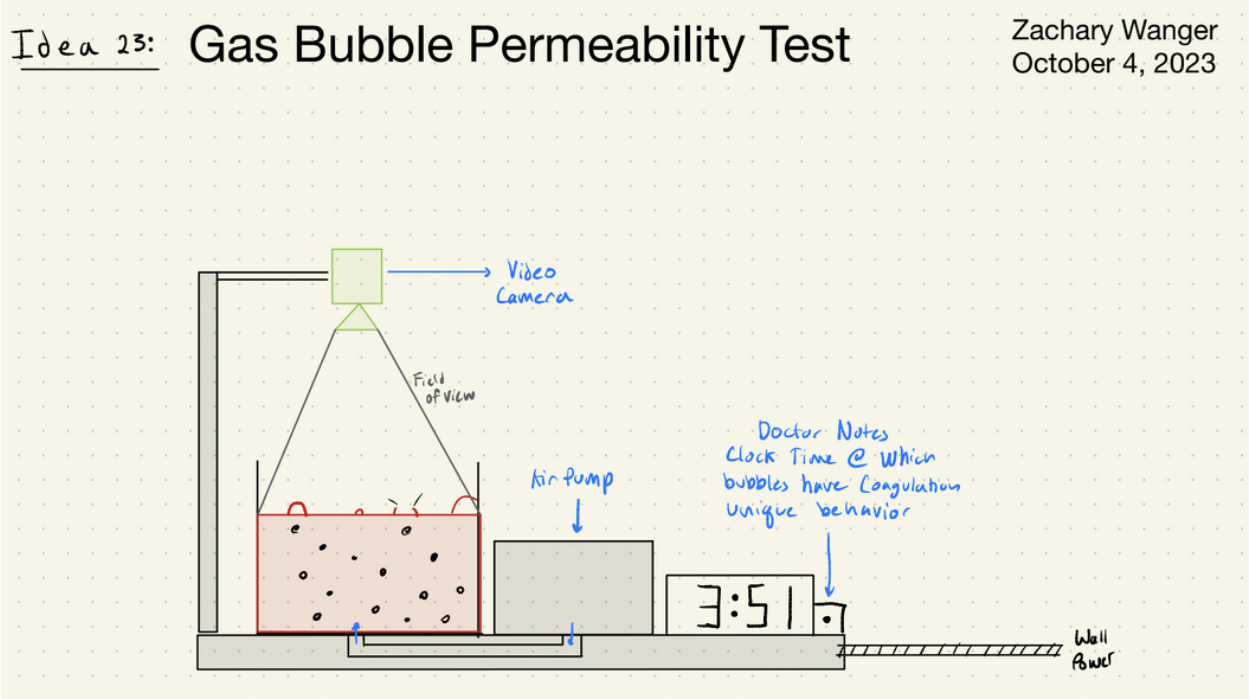
Appendix V (Concept #21/24)



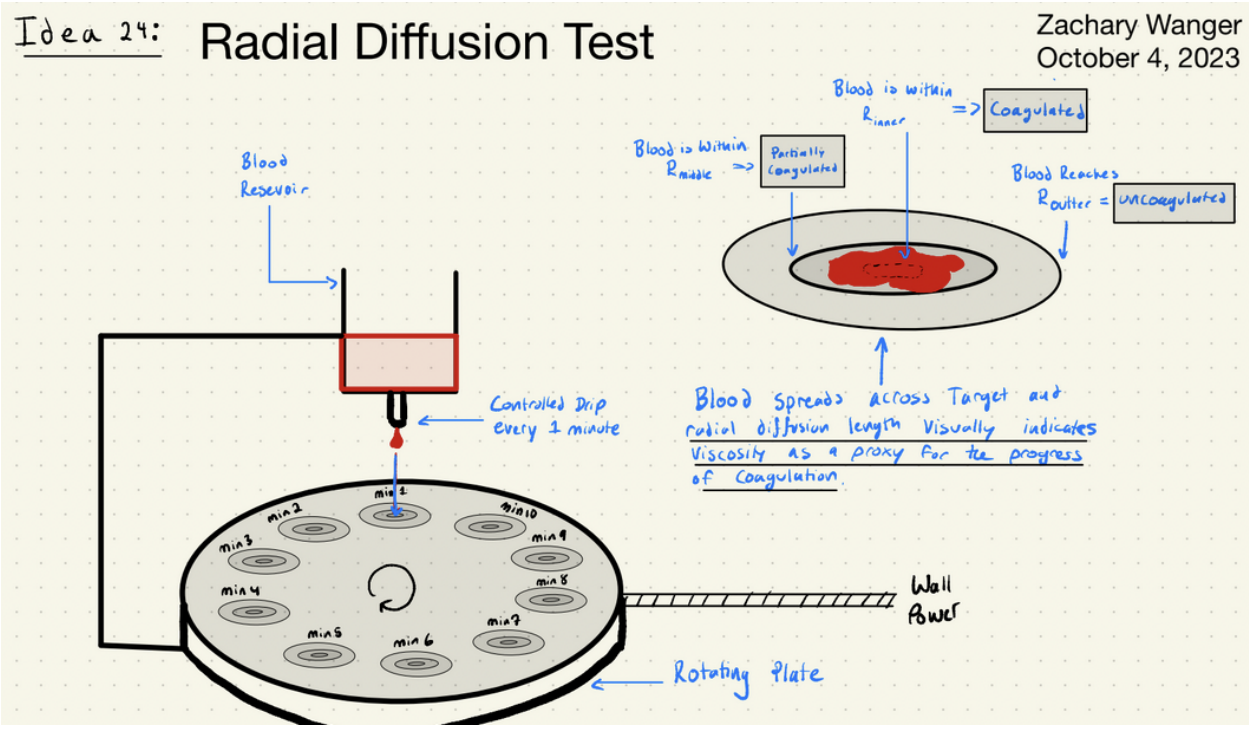
Appendix W (Concept #22/24)



Appendix X (Concept #23/24)



Appendix Y (Concept #24/24)



Appendix Z (Link for BOM Parts of Alpha Design)

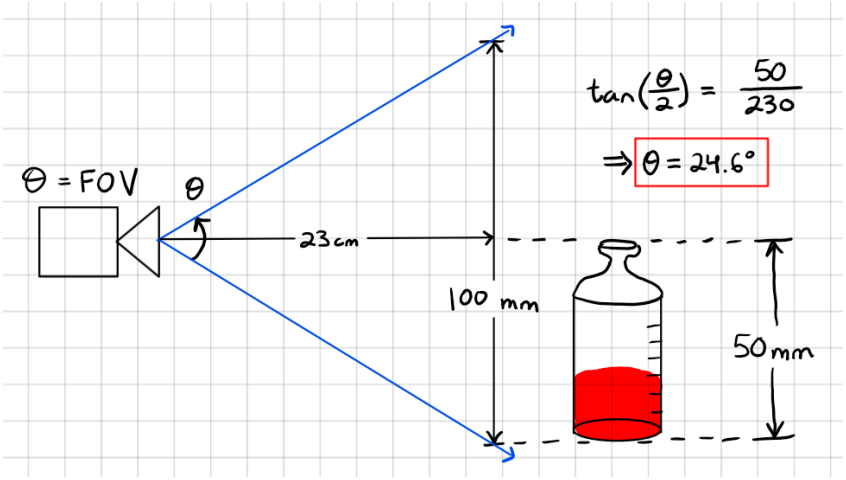
Part	Link
Miuzei LCD Screen (includes case, fan, and stylus)	https://www.amazon.com/Miuzei-Raspberry-Full-Angle-Heatsinks-Raspbian/dp/B07XBVF1C9/ref=sr_1_3?crid=2E8VJVO7KXKW2&keywords=miuzei+raspberry+pi+4+case+touchscreen&qid=1696907952&sprefix=miuzei+raspberry+pi+4+case+touchscreen%2Caps%2C76&sr=8-3
Raspberry Pi 4 Model B	https://www.amazon.com/Raspberry-Model-2019-Quad-Bluetooth/dp/B07TD42S27/ref=pd_rhf_d_dp_s_ci_mcx_mr_hp_d_sccl_2_2/146-8750364-8261303?pd_rd_w=gg8mQ&content-id=amzn1.sym.0a853d15-c5a9-4695-90cd-fdc0b630b803%3Aamzn1.symc.4d67cb82-b560-48ed-9497-a0a2a821f019&pf_rd_p=0a853d15-c5a9-4695-90cd-fdc0b630b803&pf_rd_r=HQDBATC31PQPYSYRCKE1&pd_rd_wg=XOF9y&pd_rd_r=bc382355-bed7-46c1-ae24-e95e0c31bf65&pd_rd_i=B07TC2BK1X&th=1
AUTOTOOLHOME Motor	https://www.amazon.com/AUTOTOOLHOME-Torque-Traxxas-Wheels-Electric/dp/B01M58POHF/ref=d_m_crc_dp_lf_d_t1_sccl_3_1/146-8750364-8261303?pd_rd_w=oVUN9&content-id=amzn1.sym.8b100b51-f90f-4d46-9d63-bbea9e08c9df&pf_rd_p=8b100b51-f90f-4d46-9d63-bbea9e08c9df&pf_rd_r=3TEP0QZXNGQ8V84X91AC&pd_rd_wg=oZOev&pd_rd_r=89f543ab-ecea-43b0-9af6-4fc7ebda780b&pd_rd_i=B01M58POHF&psc=1
DORHEA 4 Bit Clock Display	https://www.amazon.com/Dorhea-Digital-Display-Arduino-Raspberry/dp/B08X4H19FC/ref=sr_1_3?crid=WIF8J0S8LZQG&keywords=digital%2Bclock%2Bboard%2Braspberry%2Bpi&qid=1696909437&sprefix=digital%2Bclock%2Bboard%2Braspberry%2Bpi%2Caps%2C73&sr=8-3&th=1
Icstation Square Heating Elements	https://www.amazon.com/5V-Flexible-Polyimide-Heater-Plate/dp/B0727X2DGC/ref=asc_df_B0727X2DGC/?tag=hyprod-20&linkCode=df0&hvadid=642165314396&hvpos=&hvnetw=g&hvrand=3373229098332857831&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016855&hvtargid=pla-1634645228313&gclid=CjwKCAjwyY6pBhA9EiwAMzmfwZbEiDl78Wos7FWdJ6eAJIfpGSZ8yLWonzktwnsCcHfHP_8OnjXlORoC1QYQAvD_BwE&th=1
Solderable Breadboard	https://www.amazon.com/ElectroCookie-Solderable-Breadboard-Electronics-Gold-Plated/dp/B07ZV8FWM4/ref=sr_1_3?crid=7ZX1ZZ7881RL&keywords=solderable%2Bbreadboard&qid=1696911744&s=industrial&sprefix=solderable%2Bbreadboard%2Cindustrial%2C65&sr=1-3&th=1
Arducam 5MP Camera	https://www.amazon.com/Arducam-Megapixels-Sensor-OV5647-Raspberry/dp/B012V1HEP4/ref=sr_1_13?crid=IHSDM23TV1QF&keywords=raspberry%2Bpi%2B4%2Bcamera%2B4k&qid=1696915151&s=electronics&sprefix=raspberry%2Bpi%2B4%2Bcamera%2B4k%2Celectronics%2C73&sr=1-13&th=1
Chanzon LED Lights	https://www.amazon.com/Assorted-Transparent-Warm-White-Emitting-Assortment/dp/B08G4X23BR/ref=sxin_16_pa_sp_search_thematic_sspa?content-id=amzn1.sym.e0e55f1a-1cd9-448d-9cd8-1206bec97ce2%3Aamzn1.sym.e0e55f1a-1cd9-448d-9cd8-1206bec97ce2&crid=38VJKLLLDZB4H&cv_ct_cx=red%2Band%2Bwhite%2Bdiode%2Blights&keywords=red%2Band%2Bwhite%2Bdiode%2Blights&pd_rd_i=B08G4X23BR&pd_rd_r=d4373f16-aede-4288-afff-7a9c3d4417c6&pd_rd_w=payKC&pd_rd_wg=5lV3q&pf_rd_p=e0e55f1a-1cd9-448d-9cd8-1206bec97ce2&pf_rd_r=A473X9YRYGTA5D4QSK1Q&qid=1696916524&s=hi&sbo=RZvfv%2F%2FHxDF%2BO5021pAnSA%3D%3D&sprefix=red%2Band%2Bwhite%2Bdiode%2Blights%2Ctools%2C87&sr=1-2-2b34d040-5c83-4b7f-ba01-15975dfb8828-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9zZWFyY2hfdGhlbWF0aWM&th=1
MakerHawk Power Supply	https://www.amazon.com/MakerHawk-Raspberry-Uninterruptible-Management-Expansion/dp/B082CVWH3R/ref=asc_df_B082CVWH3R/?tag=hyprod-20&linkCode=df0&hvadid=416926807659&hvpos=&hvnetw=g&hvrand=15474221737465938208&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016855&hvtargid=pla-872104789898&psc=1&tag=&ref=&adgrpid=92859401246&hvpone=&hvptwo=&hvadid=416926807659&hvpos=&hvnetw=g&hvrand=15474221737465938208&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016855&hvtargid=pla-872104789898
18650 Lithium Ion Batteries	https://www.amazon.com/SOOCOOL-Authentic-Samsung25R-Rechargeable-Battery/dp/B09CQFCKLZ/ref=asc_df_B09CQFCKLZ/?tag=hyprod-20&linkCode=df0&hvadid=647197566468&hvpos=&hvnetw=g&hvrand=10263419800912034480&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9060451&hvtargid=pla-1956792620610&psc=1&gclid=Cj0KCQjw4bipBhCyARIsAFsieCxCC_AItAvuk-gZF1TfcI01-bjF9UrVQSXuTLifYw-PeTFREAw0TcoaAmJ5EALw_wcB
Electrical Wiring	https://www.amazon.com/Fermerry-Stranded-Silicone-Flexible-Electrical/dp/B089D29FHC/ref=asc_df_B089D29FHC/?tag=hyprod-20&linkCode=df0&hvadid=459579282194&hvpos=&hvnetw=g&hvrand=11899337367486777744&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016849&hvtargid=pla-943841638288&mcid=4ce575cbb60e3da980341b59a8e2a7ff&gclid=CjwKCAjAvdCrBhBREiwAX6-6Unhu7UdSzG9sW3E0SiGjG86_FeWJ9B0mjMlWHFoWrZkSP1YFBWvZfRoC1MkQAvD_BwE&th=1

3D Printer Filament	https://www.amazon.com/OVERTURE-Filament-Consumables-Dimensional-Accuracy/dp/B07PGZNM34/ref=sr_1_4?c=ts&keywords=3D%2BPrinting%2BFilament&qid=1697592179&s=industrial&sr=1-4&ts_id=6066129011&th=1

Appendix AA (Link for BOM Parts for Build Design)

Part Name	**Link**
Shanqiu Power Supply	https://www.amazon.com/dp/B089SQFCBW?ref=ppx_yo2ov_dt_b_product_details&th=1
Vial Clamp	https://www.amazon.com/dp/B00AWS3RGY?psc=1&ref=ppx_yo2ov_dt_b_product_details
Lewansoul Motor	https://www.amazon.com/dp/B081T2G4PN?psc=1&ref=ppx_yo2ov_dt_b_product_details
Vials	https://www.amazon.com/dp/B0BRHLC836?ref=ppx_yo2ov_dt_b_product_details&th=1
Adafruit Heating Element	https://www.amazon.com/dp/B00SK6M0AO?psc=1&ref=ppx_yo2ov_dt_b_product_details
Icstation Circular Heating Element	https://www.amazon.com/dp/B07P1H8N8H?psc=1&ref=ppx_yo2ov_dt_b_product_details
Samsung Galaxy A03s Phone	https://www.amazon.com/dp/B0BBY6DHJ8?psc=1&ref=ppx_yo2ov_dt_b_product_details
3D filament	https://www.amazon.com/dp/B07PGZNM34?ref=ppx_yo2ov_dt_b_product_details&th=1
Raspberry Pi Pico	https://www.amazon.com/Raspberry-Pi-Pico-RP2040-microcontroller/dp/B092S2KCV2/ref=sr_1_3?crid=3AZBKS4T4ZMXB&keywords=raspberry%2Bpi%2Bpico%2B2%2Bpack&qid=1700525827&sprefix=raspberry%2Bpi%2Bpico%2B2%2Bpack%2Caps%2C109&sr=8-3&th=1
Solderless Breadboard	https://www.amazon.com/EL-CP-003-Breadboard-Solderless-Distribution-Connecting/dp/B01EV6LJ7G/ref=sr_1_10?crid=25S1OXA79YBP9&keywords=solderless+breadboard&qid=1700525915&s=industrial&sprefix=solderless+%2Cindustrial%2C102&sr=1-10
Wiring	https://www.amazon.com/Fermerry-Stranded-Silicone-Flexible-Electrical/dp/B089D29FHC/ref=asc_df_B089D29FHC/?tag=hyprod-20&linkCode=df0&hvadid=459579282194&hvpos=&hvnetw=g&hvrand=11899337367486777744&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9016849&hvtargid=pla-943841638288&mcid=4ce575cbb60e3da980341b59a8e2a7ff&gclid=CjwKCAiAvdCrBhBREiwAX6-6Unhu7UdSzG9sW3E0SiGjG86_FeWJ9B0mjMlWHFoWrZkSP1YFBWvZfRoC1MkQAvD_BwE&th=1

Appendix AB (Field of View Calculation)



Appendix AC (Failure Cycles of Heat Pad Calculations)

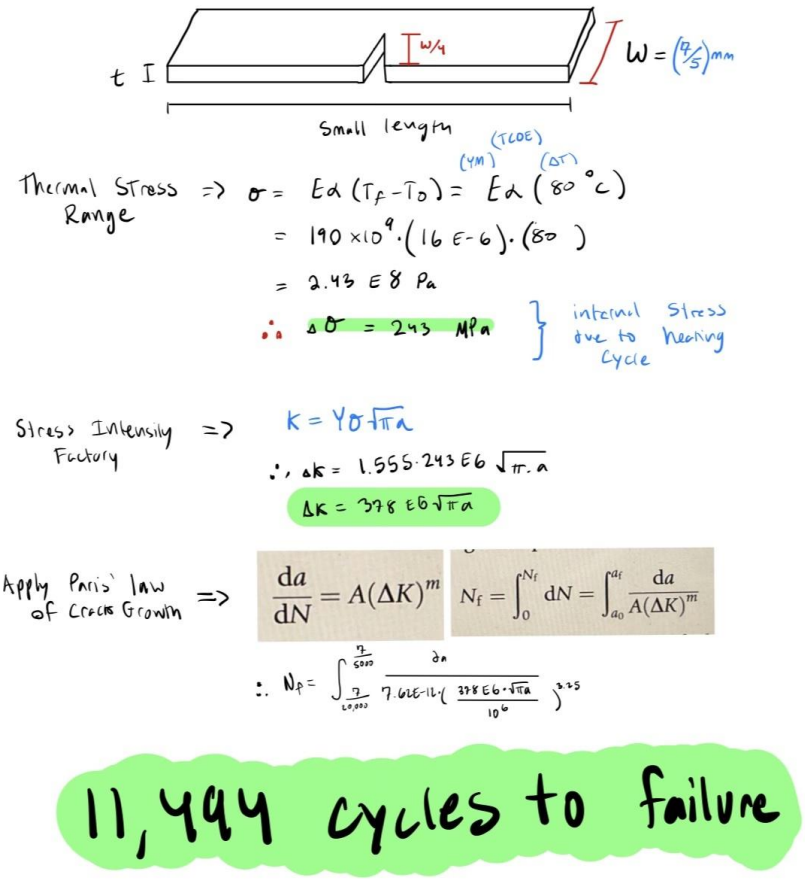
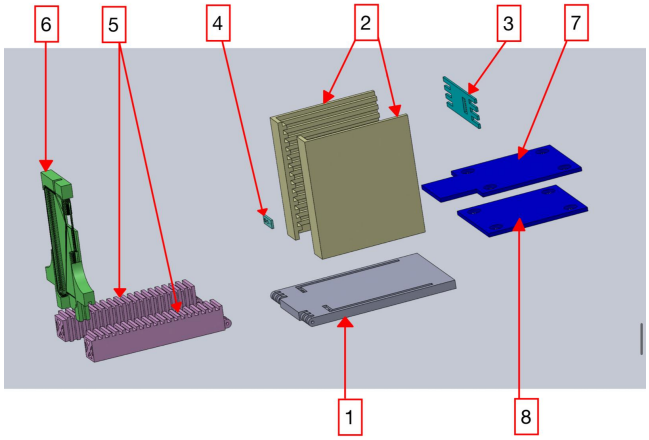
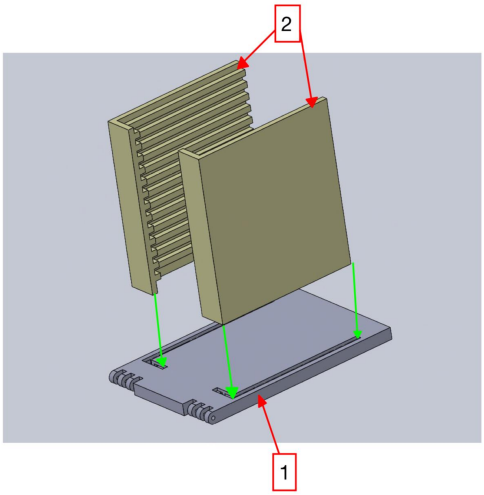
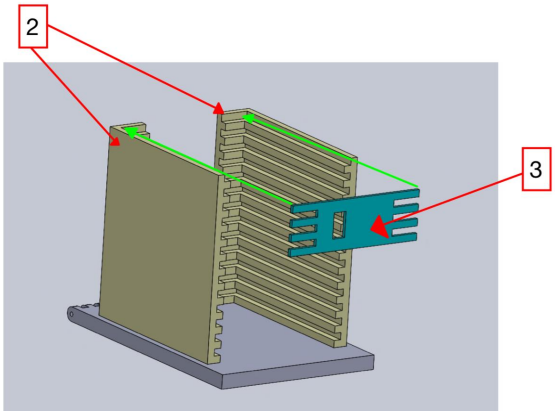


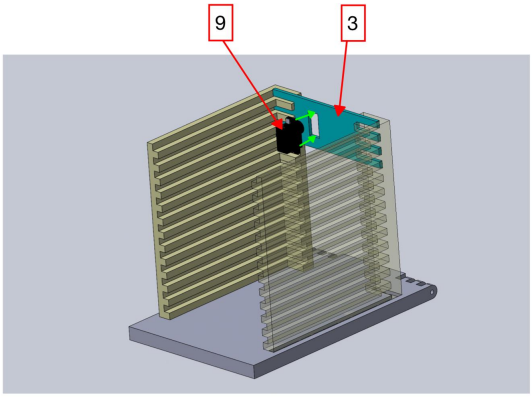
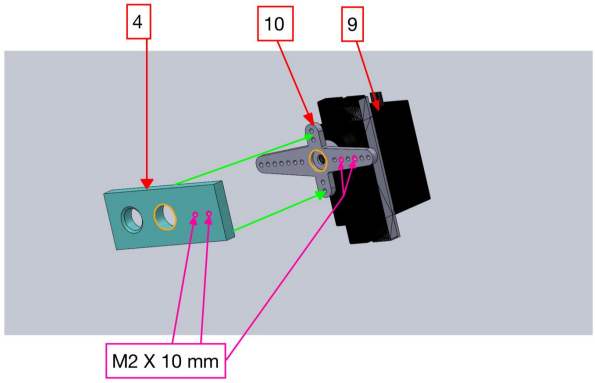
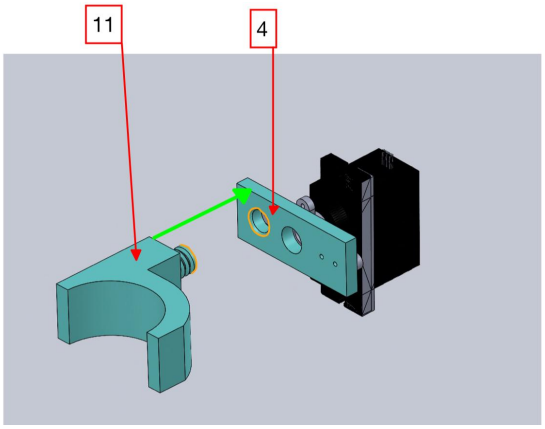
Figure above: Shows the application of the Paris Equation of crack growth using material properties and coefficients from literature [83][84]

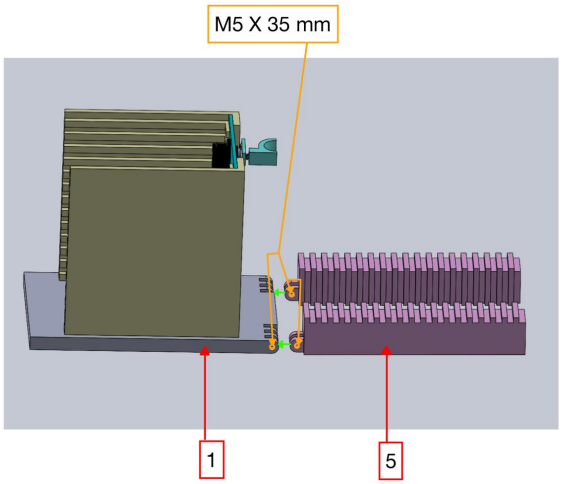
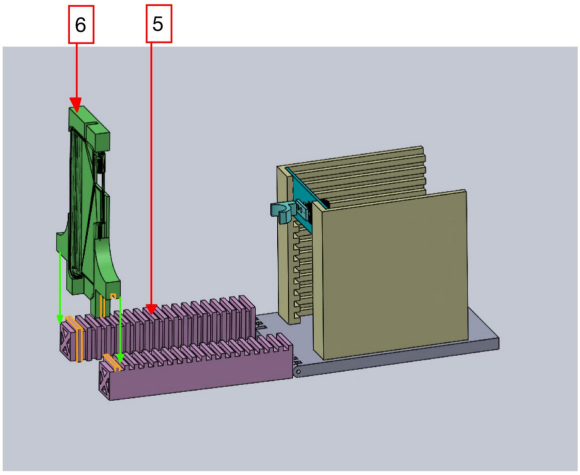
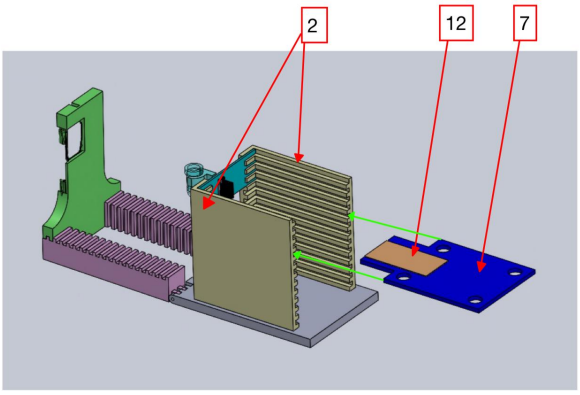
Appendix AD

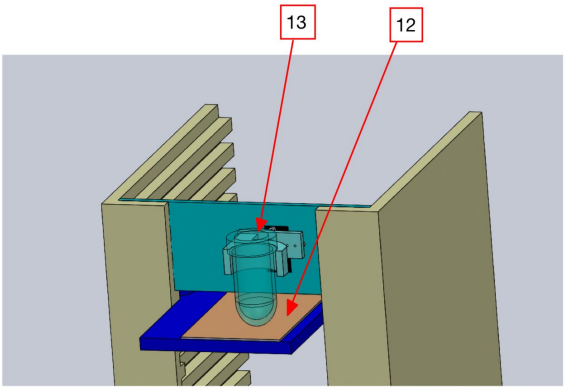
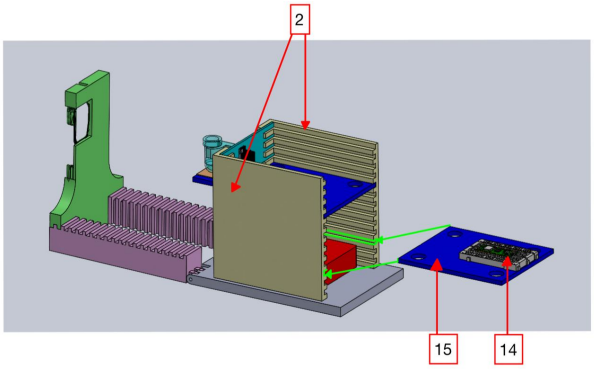
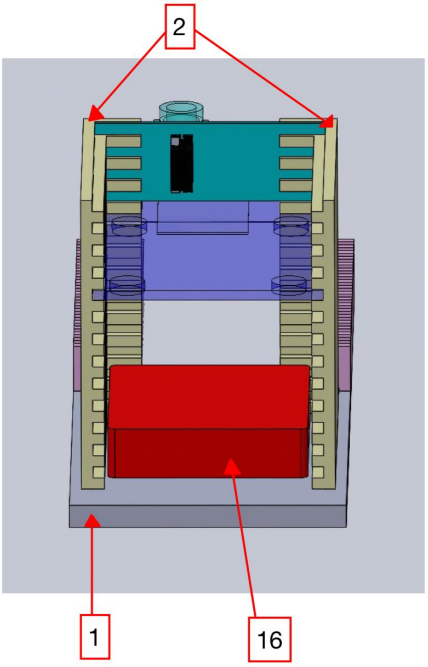
Requirements	Minimal Specification	Optimal Specification
Low cost	< $300 (USD) to purchase unit	< $100 (USD) to purchase unit
Easy to use	The device uses whole blood without reagents or inhibitors	
	Blood container is removable	Blood container removable in < 10 sec
	< 5 minutes setup time	
	Sanitation time < 10 min [15]	Sanitation time < 5 min
	Alert each minute after the 3 minute mark	Alert given when a test result is ready
	< 3min caretaker supervision per test	< 1min caretaker supervision per test
Durable	Withstands > 3650 uses (1 year) [24]	Withstands > 18250 uses (5 years)
	> 10 patients per day	> 15 patients per day
	Must withstand hospital sterilization, i.e. 3-6% hypochlorite bleach, 99% alcohol [39]	
Consistent	30s time resolution error	0.5s time resolution error [21]
	Continuously operate for 12 mins	Continuously operate for 20 mins [29]
	55% sensitivity [47]	Reaches experimental sensitivity of MLW (85%) [47]
	Can operate without grid power for 8 hrs	
Portable	< 11.6 kg [18]	< 3.76 kg [10]
	< 46 cm in all dimensions	< 25 cm in all dimensions [10]
	Pending Portability likert scale > 4.0/5.0	
Safe	Blood containers are fixed to device during testing	
	< 500MPa pressure applied to blood containers [32]	
	Only pinch point at blood container fixture	No pinch points
	The device must not expose practitioner to blood	
Locally maintained	Consumable components are locally available (≤5 imported components)	
	≤2 consumable components	
Control Blood Temperature	Blood is kept at room temperature (20°C-22°C)	Blood is kept at body temperature (35.5°C-38.3°C)

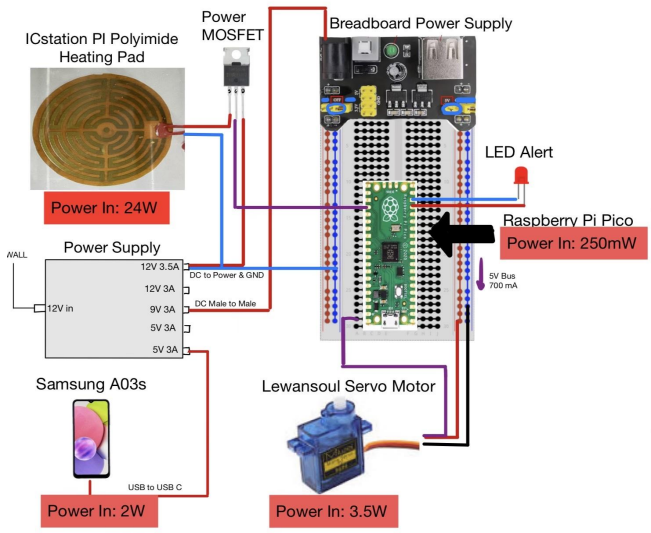
Appendix AE (Build Design Assembly Plan)

Steps	Reference Images
1. 3D-print all frame components, including the base plate (1), vertical grooved walls (2), motor plate (3), vial link (4), hinges (5), Galaxy A03s phone case (6), upper shelf (7), and lower shelf (8).	
2. Snap vertical grooved walls (2) into base plate (1).	
3. Attach the motor plate (3) to the vertical grooved walls (2) at desired height by sliding the plate through the grooves until fully seated.	

4. Snap Lewansoul LFD-01M servo motor (9) into press fit motor plate mounting hole (3) with motor shaft oriented upwards.	
5. Attach the vial link (4) to the motor wing (10) via two M2 X 10 mm self-tapping screws, then attach motor wing to motor via motor's center screw.	
6. Attach the CH0688A blood vial clamp (11) to vial link (4) by threading rear stud into the beveled hole of blood vial link	

7. Attach the hinges connecting the baseplate (1) and folding arms (5). Insert two M5 X 35 mm self-tapping screws to fasten hinges to baseplate.	
8. Snap Galaxy A03s into phone case, attach case with phone to folding arms at desired distance.	
9. Attach the Icstation 9885 heating pad (12) to the upper shelf (7) via the heating pad's integrated adhesive. Slide the upper shelf into the vertical grooved walls (2) at the respective height which contacts the heating pad to the blood vial (13) during testing.	

	
10. Attach the solderless breadboard and Raspberry Pi RP2040 (14) to the lower shelf (15) using the breadboard's integrated adhesive. Slide the lower shelf into the vertical grooved walls (2) at the third height setting from the bottom.	
11. Attach the Shanqiu FX 5-12 power supply (16) to the base plate (1) between the vertical grooved walls (2).	

12. Wire Lewansoul servo motor and Raspberry Pi Pico/Pico power supply to the solderless breadboard as seen in Figure 22, reproduced on the right. Note that wiring is not shown in assembly CAD, and the holes in the shelves are implemented for convenient wire routing.	
13. Wire Raspberry Pi Pico power supply, heating pad, and phone to Shanqiu power supply as seen in Figure 22, reproduced on the right. Note that wiring is not shown in assembly CAD, and the holes in the shelves are implemented for convenient wire routing.	

Appendix AF (Differences Final Design Assembly Plan)

Between the build and final design, most of the manufacturing process is the same. The main difference lies in the construction of the frame, eliminating the need for assembly on account of being one piece.

The motor assembly has changed slightly since the build design. To assemble begin by mounting the motor in the hole of the plate above the rightmost red arrow of Figure 39.b. Subsequently, then attach the motor attachment and the axle to the motor. Next, thread the axle through the hole of the green plate positioned above the leftmost arrow of Figure 39.b. Press the square end of the axle into the square recession of the heat pad bracket and secure it with a M4x14mm screw. Affix the heating pad to the bracket, feeding its wires through the adjacent narrow channel. The clamp should then be screwed into the heat pad bracket. Once these steps are completed, the assembly can be slid down the two groves of the frame as shown in Figure 39.b. Once in the correct position, a blood container can be safely loaded onto the device. The bottom of the blood container should be touching the heating pad and secured firmly with the clamp.

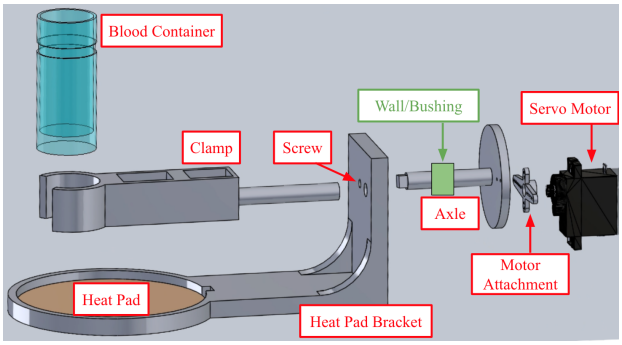


Figure 39a: A diagram that separates all the components of the motor assembly. The green box is representative of a larger component and can be better seen in Figure 39.b

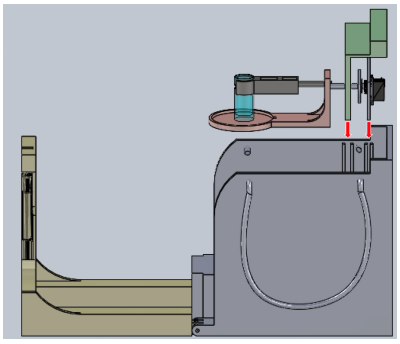


Figure 39b: A visual of how the motor assembly is placed into the frame.