Autologous Blood Transfusion Device for Use in Resource Limited Settings

Final Report

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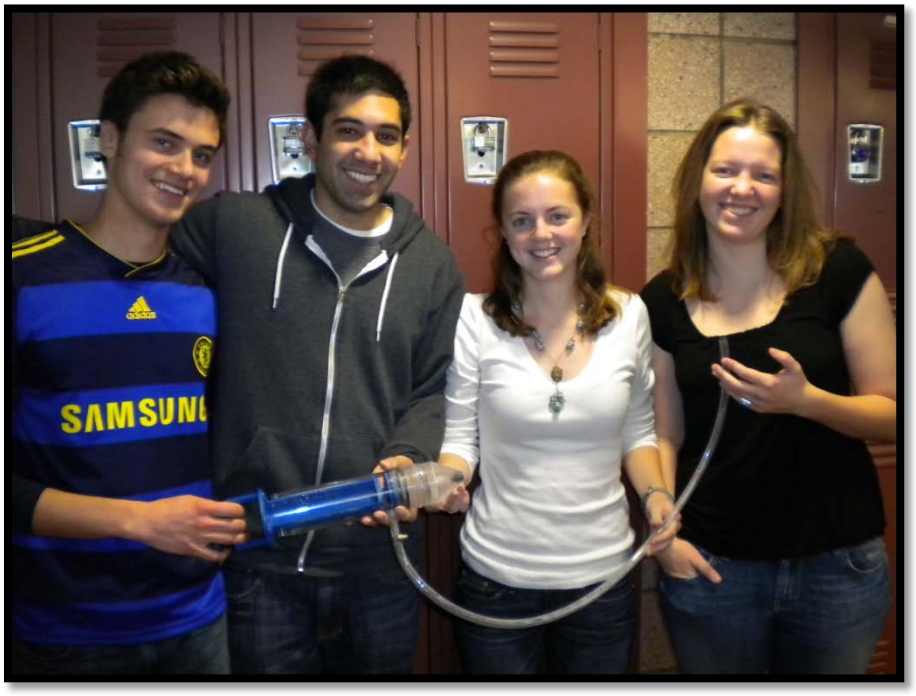

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1 Executive Summary

Our team spent one month performing observations in the Department of Obstetrics & Gynecology at Komfo Anokye Teaching Hospital (KATH), a main referral hospital located in Kumasi, Ghana. During this time, we observed a deficit in the supply of donor blood available at the blood bank. As a result, the hospital had developed a manual autologous transfusion method for use in ruptured ectopic pregnancies, which minimizes or eliminates the need for donor blood in these cases. This procedure requires many labor- and material-intensive steps and can cause further harm to the patient due to poor quality control of the blood. Therefore, our team identified the opportunity to create a blood salvage device that can be operated by a health care provider to collect, filter and transfuse blood in the event of severe blood loss that occurs during ruptured ectopic pregnancies and other hemoperitoneum hemorrhage procedures.

After identifying this opportunity, we spent one week gathering user requirements and engineering specifications through a series of stakeholder interviews. Quantification into engineering specifications was completed through expert interviews and review of the literature. After multiple brainstorming sessions, we emerged with five distinct system designs. Following a rigorous analysis with use of a Pugh chart, weighting system based on the ability of the concept to meet the user requirements, and creation of pro and con lists, we chose the “giant syringe” as the alpha design.

Our final design is the result of multiple iterations on the alpha design. The “giant syringe” is a self-contained, mechanically powered system composed essentially of a large-scale syringe with an internal filter. Three check valves direct flow of blood into the reservoir of the syringe and then subsequently into an attached blood bag through an outlet valve. An o-ring provides an air tight seal between the plunger and the reservoir housing, and a hollow, tapered tip provides storage for larger clots which are caught by a coarse internal filter before blood passes through an additional fine internal filter. Some of the benefits of the system include the lack of an expensive pump and the ease of maintenance due to a small number of parts and a simple design. However, the design also requires very high tolerances in manufacturing in order to create the necessary vacuum pressure to draw blood into the reservoir and is prone to clogging from blood clots.

Following the manufacturing and assembly of the prototype, we were able to conduct initial functional and human factors validation testing. Functional testing revealed mean flow rates of 1.6±1.0 L/min and 2.0±0.8 L/min for novice and experienced users, respectively, without any formal training. Additionally, the device was shown to be capable of processing 2L of liquid, can be operated by a single user, and requires less than 30 minutes of training time. Additionally, because the device is disposable, it would be presented to users fully assembled, so the only steps involved in readying it for use would be to connect it to the blood bag.

Human factors testing revealed that while users were comfortable with the overall function of the device, there is room to improve in the design. Specifically, further analysis and redesign of the handle is recommended, as well as the addition of a grip or handle of some sort on the reservoir barrel, which will provide greater comfort for the user during operation of the device.

2 Abstract

Our team spent one month performing observations in Komfo Anokye Teaching Hospital (KATH), a main referral hospital in Kumasi, Ghana. During this time, we observed a deficit in the available blood supply at the blood bank, as a result of which a manual autologous transfusion method was used in cases of ruptured ectopic pregnancies. We identified an opportunity for the development of a blood salvage device that can be operated by a health care provider to collect blood from a hemorrhaging patient (as occurs during ruptured ectopic pregnancy), filter it, and transfuse it back into the patient. We hope to help address the issue of minimal donated blood and reduce the likelihood of infections and other complications that could occur due to current blood salvaging procedures.

3 Problem Definition

3.1 Ethnographic Research

This past August a multi-disciplinary group of students from the University of Michigan traveled to Kumasi, Ghana as the first cohort in the College of Engineering's Global Heath Design Specialization. This group of students performed in-depth observations, brainstorming, and interviews in efforts to partner with the committed medical staff at Komfo Anokye Teaching Hospital (KATH). During this time, it was observed that a major challenge for the hospital was that of a blood bank with a severely limited blood supply. The worldwide total deficit of blood units available for transfusion was 40 million units per year in 2008. In addition, Africa has the lowest quantity of blood donated for transfusion per person in the world (Bates, 2008).

Ectopic pregnancy ruptures occur daily at KATH in part due to various barriers that prevent early detection by doctors in the antenatal clinic, which is similar to many situations throughout Africa and specifically within Ghana. Even in the developed world, ectopic pregnancy can be difficult to detect because 50% of patients are asymptomatic before rupture occurs (Tulandi, 2010). The rupture itself is caused by the implantation of the pregnancy outside of the uterus, usually in the fallopian tube, and leads to 300-1000 mL of blood loss contained within the abdominal cavity. In many cases, this blood can be salvaged and transfused back into the patient in what can often be a life-threatening procedure (Priuli, 2009). Ruptured ectopic pregnancy has recorded case-fatality rates of 1-3% in developing countries, which is ten times higher than the rates recorded in developed countries (Mignini, 2007).

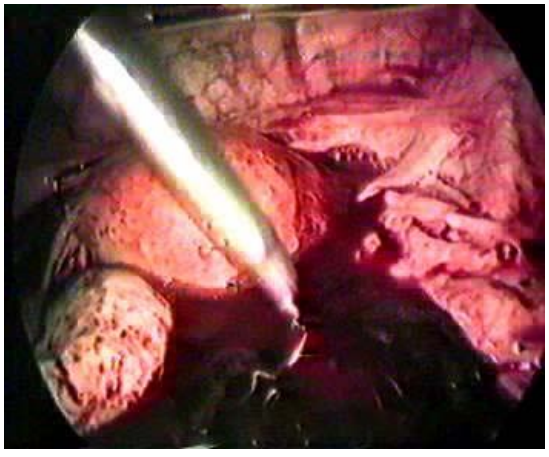


Figure 1: Ruptured Ectopic Pregnancy (Laparoscopic management of ectopic pregnancy)

Currently, the hospital implements a very labor- and material-intensive blood salvage method during certain surgical procedures. The head of the OB/GYN department at KATH, Dr. A.T. Odoi, along with other medical staff and mentors such as Dr. Kofi Amoah and Kwame Akwaboah, helped us to understand the complications that arise from this procedure. These include various infections and the possibility of causing cancerous growths by transfusion placental tissue. These discussions focused on ectopic pregnancy rupture (Figure 1), which is the leading cause of maternal mortality in the first trimester of pregnancy (UN Millennium Project).

3.2 Needs Statement

Based on these observations, we identified that there is a need for a blood salvage device that can be operated by a health care provider to collect blood from a hemorrhaging patient, filter this blood and transfuse it back into the patient. This would help to address the lack of available donated blood and improve the prognosis for the patient.

3.3 Scope of Application

Within obstetrics and gynecology, the term hemorrhage is used to refer to several different types of situations; therefore, it is important to specifically identify the intended scope of our design. As shown in Figure 2 below, major obstetric hemorrhage cases can be roughly divided into postpartum and hemoperitoneum (blood in the abdominal cavity) hemorrhage. Hemoperitoneum hemorrhage can be further divided into contaminated and uncontaminated cases; contaminated refers to cases in which the blood has been mixed with other bodily substances, such as placental tissue or fecal matter. In contaminated cases, the impurities must be removed before the blood is re-transfused. We are, therefore, narrowing our focus to include only uncontaminated abdominal surgeries. In obstetrics, the most applicable instance of this is in ruptured ectopic pregnancies. This procedure will serve as a case study, allowing us to validate our design with close cooperation between our team and the medical staff at KATH. This device may also have the potential to address other obstetric and emergency hemoperitoneum and hemothorax procedures. The ultimate goal would be to expand the scope of the device to address the much more pressing need of blood salvage in the case of post-partum hemorrhage.

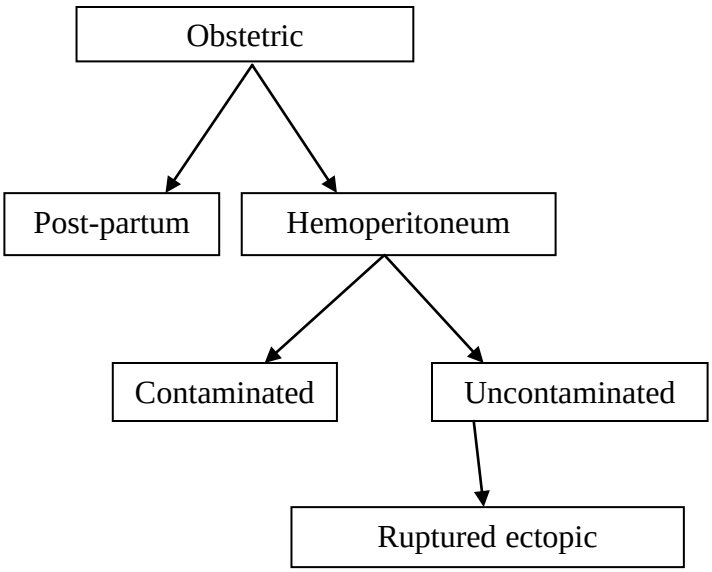


Figure 2: Flowchart describing scope of application

The current aim of this project is to develop a coarse prototype for field testing at KATH next February to confirm that the device has accurately addressed the end users' needs. The current user requirements will have to be re-evaluated to address similar challenges in health care settings that are smaller and more rural than KATH, most particularly in district hospitals. KATH is unique in Ghana in that it is a major referral hospital with more extensive resources than most tertiary facilities. Rural hospitals will have a modified set of requirements due to additional limitations on energy and resources, but it is evident that the need for a device such as this is greatest in a rural setting, since these locations lack even the limited blood bank available at KATH.

4 Information Sources

4.1 Background on Autologous Blood Transfusion

The general lack of blood for transfusion in developing countries has been well established by public health researchers and documented in academic literature. Autologous transfusion, in which the patient's own blood is collected, filtered, and returned to them, has been considered as one of the viable options to help alleviate the current shortage of donated blood. Autologous transfusion also eliminates many of the risks associated with allogenic blood transfusion (the transfusion of donor blood). Assuming no clerical errors, the risk of contracting diseases, including HIV/AIDS and Creutzfeldt-Jakob disease, among others, is completely removed. Additionally, crossmatching and iso-immunization to foreign proteins is unnecessary when using autologous blood (Adias, 2006).

Clinical studies have been performed to compare allogenic and autologous transfusion during ruptured ectopic pregnancy repair surgeries. No difference in complications (postoperative fever, postoperative wound infection, or prolonged hospital stay) was observed between the two groups. Patients in the autologous group were 6 times more likely to receive more than 1000 milliliters of blood and to have a higher postoperative hematocrit level than those in the allogenic group. The authors hypothesized that this was due to the fact that allogenic blood transfusions are given as sparingly as possible, resulting in patients receiving the minimum amount of blood necessary to survive (Selo-Ojeme D. O.-W., 2007).

There are three main types of autologous blood transfusions performed in the clinical setting. Preoperative autologous donation (PAD) is used for planned surgeries with large expected blood losses. Blood is collected from the patient several weeks before the surgery and transfused after hemorrhage has stopped during the surgery. This method is very effective in reducing the need for allogenic blood and eliminates the risks of hemolytic, febrile or allergic reactions. Time is an important factor in performing PAD, as sufficient time must be allowed for the patient to replace some of the lost blood prior to surgery. PAD is normally more expensive than allogenic transfusions due to the added costs of increased administrative management of the blood units (Adias, 2006; Silvergleid, Intraoperative and postoperative blood salvage, 2009)

Acute normovolaemic hemodilution (ANH), also termed intraopertive hemodilution, is another preoperative autologous transfusion method, wherein blood is collected from the patient immediately before surgery and the lost volume replaced with a colloid or crystalloid. The

collected blood can be transfused back into the patient once the patient is hemostable. This serves to minimize the blood volume lost during the surgery. The amount of blood that can be removed is limited and varies with the size of the patient. ANH cannot be used if the patient has already lost a large amount of blood, and is therefore not applicable in emergent situations involving heavy bleeding. Unlike PAD, ANH is more cost effective than allogenic transfusion. The main reasons for this are that the costs of testing, crossmatching and storing the blood are eliminated (Adias, 2006; Silvergleid, 2008).

The final type of autologous transfusion is intraoperative blood salvage (IBS), which can also be termed intraopertive autologous transfusion. In this method, blood is collected during surgery, processed, and returned to the patient. Processing methods vary, and can involve simple filtration or centrifugation and washing. Simple filtration transfuses whole blood back into the patient, while centrifugation and washing transfuses only packed red blood cells. The main advantage of this method over the previous two is the capacity to provide large quantities of autologous blood very rapidly. As the vast majority of ruptured ectopic pregnancy surgeries are performed in emergent situations, intraoperative salvage is the most suitable type of autologous transfusion for these patients (Adias, 2006; Silvergleid, 2009).

The addition of an anticoagulant is a vital step in all the methods of autologous transfusion. Adding an anticoagulant prevents new clots from forming in the collected blood, though it has no effect on existing clots. The most common anticoagulant used is citrate-phosphate-dextrose-adenine (CPDA-1). This anticoagulant comes prepackaged in most blood transfusion kits, and can prolong the shelf life of the blood unit by several weeks (Forson, 2010). Other anticoagulants, such as heparin, can be used at the surgeon's discretion.

4.2 Associated Risks of Autologous Transfusion

4.2.1 Hemolysis and Coagulopathy

The main risks associated with autologous transfusion are coagulopathy (clotting disorders), hemolysis (rupture of red blood cells) and infection. Hemolysis can occur and cause subsequent coagulopathy if the blood is subjected to excess mechanical stress or if the blood is contaminated with bacteria. To avoid this, autologous transfusion should not exceed 4000 milliliters and should be done within four hours of removal (Ansaloni, 1996; Selo-Ojeme D. O.-W., 2007). Using the correct amount of anticoagulant can further reduce this risk. Coagulopathy can also occur due to the presence of thromboplastic substances (proteins necessary for clotting) and other coagulation system components present in whole blood, which has led to the belief that transfusing whole blood is riskier than transfusing packed red blood cells (Silvergleid, 2009). However, interviews with expert physicians have indicated that transfusing whole blood is preferable in many cases due to the fact that whole blood contains many other substances (clotting factors, platelets, plasma, shown in Figure 3) that can positively influence a patient's prognosis.

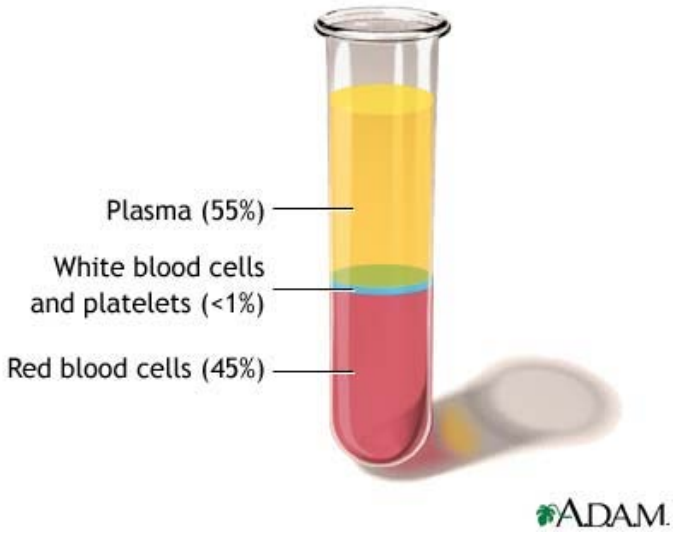


Figure 3: Components of Whole Blood (Robinson, 2010)

Further research in this area is needed to confirm which approach is most effective (Johnson, 2010). Additionally, infections can occur if any part of the device is exposed to the environment. Prophylactic antibiotics are commonly used to prevent infection (Odoi, 2010).

4.2.2 Air and Fat Embolisms

Air embolisms (air bubbles entering the veins) as shown in Figure 4 can occur during any transfusion procedure (allogenic or autologous) if proper protocols are not followed or devices are misused. Severe air embolisms can be catastrophic for the patient and cause complications in any organ system. Modern autologous transfusion devices have in-line air detectors which are used to prevent air embolisms. Most blood transfusion kits also have a mechanism to prevent air from entering the bloodstream during transfusion. Any new device must account for air embolisms as a potential side effect when considering design variables. Fat embolisms, while less likely to occur than air embolisms, can also cause complications during transfusion. Fat embolisms can be prevented by removing microaggregates from the blood (Silvergleid, 2009).

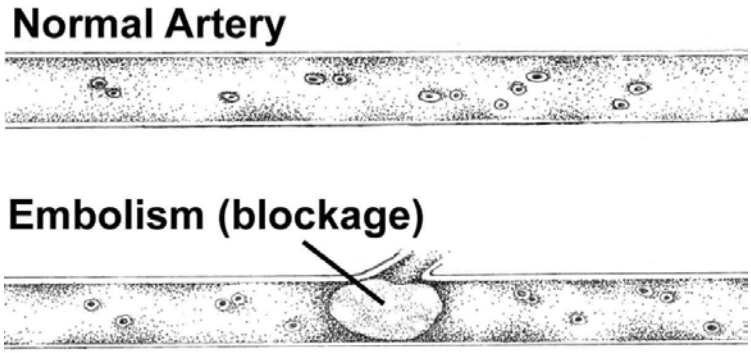


Figure 4: Embolism in an artery (Memory Loss & the Brain, 2010)

4.2.3 Salvaged Blood Syndrome

Salvaged blood syndrome has been reported primarily in cases of transfusing packed red blood cells, though the theoretical risk exists for whole blood as well. The mechanism for the

development of this syndrome is not well understood, but activation of platelets and white blood cells appears to be the cause. In this syndrome, the patient develops disseminated intravascular coagulation (DIC) and/or increased capillary permeability in the lungs (Silvergleid, 2009). DIC causes hemorrhage and thrombosis (blood clots), producing an array of complications that must be treated by transfusing platelets and clotting factors (Leung, 2009). Increased capillary permeability can cause pulmonary edema and shortness of breath. These symptoms are difficult to treat and often only treatment of the underlying disease will result in cessation of symptoms (Givertz, 2009).This syndrome can be prevented by using citrate as the anticoagulant as well as avoiding aspirating blood that has been heavily diluted by surgical fluids (Silvergleid, Intraoperative and postoperative blood salvage, 2009).

4.2.4 Hypotension

The rare but serious risk of severe hypotension has been reported in isolated cases. When receiving autologous blood, some patients have experienced a life-threatening drop in blood pressure that returned to safe levels only when the transfusion was halted. No antibodies or other abnormal features were found in the blood that could have been responsible for the drop in blood pressure. This phenomenon remains unexplained, through it is hypothesized that the bedside leukocyte filter used during many autologous transfusions passes the blood through a pressurized tube, which could result in the excretion of vasodilating agents. The FDA reported in 1999 that severe hypotensive events occur in approximately 80 out of 20 million (0.004%) transfusion cases (Kessack, 2010).

4.3 Maternal Mortality and MDG5

In 2000, the UN created the Millenium Development Goals (MDGs), which provide a framework to tackle the many issues contributing to extreme poverty around the world. MDG 5 is focused on improving maternal health, with specific targets of reducing the maternal mortality ratio between 1990 and 2015 by 75% and achieving universal access to reproductive health care by 2015 (UN Millennium Project). According to The Millennium Development Goals Report produced by the UN in 2010, as of 2008 only 46% of births in sub-Saharan Africa included a trained health care attendant (compared to 99% of births in developed regions of the world, and an average of 63% in the developing regions) (The Millenium Development Goals Report, 2010). Of the 350,000 women who die every year from complications during pregnancy or childbirth, 99% of these deaths occur in the developing world, and most are preventable (UN Millennium Project).

Currently, progress on MDG5 is lagging behind the schedule needed to achieve a 75% reduction in maternal mortality. At the UN Summit in late September 2010, Secretary-General Ban Ki-moon announced the creation of a “Global Strategy for Women’s and Children’s Health,” part of a massive effort to improve performance in the area of MDG5, including the commitment of $40 billion from various governments, private corporations, and UN agencies, among other groups, to achieve results on MDG5 (Deen, 2010).

4.4 Current Autotransfusion Technology

Intraoperative blood salvage first became widely used in the mid-1970s with the introduction of two different systems: the centrifuge-based cell salvage system and the passive canister collection system. A centrifuge-based cell salvage system was first marketed by Haemonetics in 1974. The company’s “Cell Saver” brand has become so widely accepted that centrifuge-based

cell salvage systems are commonly referred to as cell savers. Sorin, Fesenius Kabi, Davol, Medtronic, and many other companies produce their own versions of a cell-saver. These devices are widely used throughout the United States, Western Europe, and other developed nations (Haemonetics: products and programs - Cell Saver 5 system; Silvergleid, Intraoperative and postoperative blood salvage, 2009).

4.4.1 Cell Saver

Cell saver devices are used in a variety of different surgeries, but all operate in a similar manner. The Haemonetics Cell Saver 5 is shown, as an example, in Figure 5. First, the surgeon aspirates blood with a suction wand. The wand is attached to a double-channel of tubing, which allows an anticoagulant to be mixed with the blood as it passes through the channel. The blood is collected in a reservoir until the volume reaches a level that is large enough to process (a minimum of 70 mL), and is then pumped into a centrifuge bowl. The centrifuge separates the blood components into layers, and the layer of concentrated red blood cells is saved and washed in saline. Typically, the hematocrit level of this suspension is greater than 50%. The washed red blood cells are then transferred to an infusion bag and connected to the patient via an IV drip (Haemonetics: products and programs - Cell Saver 5 system).

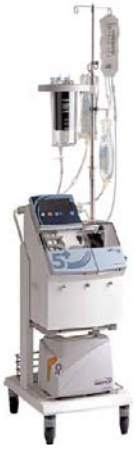


Figure 5: Haemonetics Cell Saver 5 (Haemonetics: products and programs - Cell Saver 5 system)

Current cell savers are extremely efficient, capable of washing 225 milliliters of blood in about three minutes, the equivalent of 12 units of blood per hour. The major limitation of these devices is cost, as cell savers retail for over $30,000 (Silvergleid, Intraoperative and postoperative blood salvage, 2009). The complex components of these devices also present a challenge to the hospital maintenance departments of developing countries, which are ill-prepared to service these machines.

4.4.2 Boehringer Autovac

Very few autotransfusion devices are currently available that transfuse whole blood products. Boehringer Laboratories manufactures an autologous blood transfusion system called Autovacc (Figure 6) that has the potential to be used in developing countries. The cost of blood collection with this device can be less than half the cost of using a cell saver. The system transfuses whole blood back into the patient, costs $200, and can be attached to a standard vacuum aspirator. While this device shows promise in addressing blood salvage in a cost-efficient manner, it requires a separate vacuum aspirator and has a maximum capacity of only 1 L of blood (Boehringer Labs, 2009).

Figure 6: Boehringer Autovac (Boehringer Labs, 2009)

4.4.3 EAT-SET

The Emergency Auto Transfusion Set (EAT-SET) device was developed in Nigeria by Brigadier General Dr. Ovadje to address the issue of blood shortages in developing countries. EAT-SET is a simple device consisting of a hand pump, filters, a single reservoir, tubing, and a blood bag (Figure 7). The hand pump is used to create a vacuum, removing blood from a hemorrhaging patient, which then passes through a gravity driven filter and into a blood bag. The hand pump can also be replaced by a vacuum aspirator in places where electricity is not reliably available. The device is designed for use in emergency autotransfusion cases with severe internal bleeding (EAT-SET). EAT-SET appears to address the need we had identified (although without a technical data sheet we have no way of determining if it meets all of our user requirements and engineering specifications); however, our team was unable to find any U.S. patent for the device, and the most recent reference was dated 2006. Additionally, Dr. Odoi was unaware of the existence of the device. We therefore concluded that it had stalled in the implementation stage.

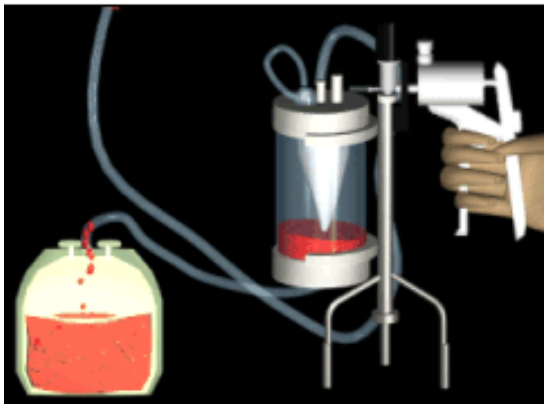


Figure 7: EAT-SET device with hand pump (EAT-SET)

4.4.4 Funnel/Soup Ladle Autotransfusion

Most surgeons in developing countries currently use a variation of the “soup ladle” method of autologous transfusion specifically for ruptured ectopic pregnancies. This procedure generally begins with a laparotomy, which gives the surgeon access to the abdominal cavity. The largest visible clots are removed by hand, and the remaining blood is scooped out using a soup ladle, large spoon, or cup held with forceps. This blood is poured over a nurse’s hands to perform initial filtering of large clots, and is then collected in a bowl. An anticoagulant is added, and the

blood is transferred into a pitcher through a funnel lined with several layers of sterile gauze. It is then poured into a blood bag and connected to the patient via an IV drip (Ansaloni, 1996).

This method is problematic for several reasons. First, excessive handling of the blood and exposure to the environment results in a high risk of contamination and subsequent infection. All patients receiving this type of transfusion must be given prophylactic antibiotics to stave off potential infections. Secondly, filtering through gauze does not remove all clots and other particulates, and small threads of the gauze can be mixed in with the blood. This increases the risk of coagulopathy, as well as the potential for an adverse immune response (Odoi, 2010). Finally, this method is labor-intensive, requiring a scrub nurse to filter the blood. Most developing countries have severe human resource shortages, especially in the area of health care, and eliminating the need for additional staff would be very advantageous (Chen, 2004).

5 User Requirements and Engineering Specifications

5.1 Process to Obtain User Requirements

The project requirements were determined during the course of the month-long observations at KATH. Interviews were conducted with doctors, nurses, and technicians. Based on the results of these interviews, we developed a preliminary list of user requirements. We then distributed surveys (Appendix 21.13) to these same personnel asking them to rank the user requirements. With the 17 returned surveys, it was possible to rank the user requirements in order of descending importance.

5.2 Ranking System

The survey responders were asked to rank the identified user requirements by their perceived importance: a rank of 1 was the highest priority, a rank of 3 was medium priority, and a rank of 9 was lowest priority. These rankings were then summed, with the lowest numbers representing the most important requirements. Due to a limited number of responses, we were unable to weight the results in a way that would provide both significant and accurate results, and therefore used a straight average of stakeholder responses.

One common problem we encountered was the tendency of users to rank every requirement as "high priority." To circumvent this issue, we also asked them to choose the five most important and five least important requirements. In summing the survey results, a point was deducted from a requirement's total for each "most important" ranking, and a point was added for each "least important" ranking. The results are a clearly delineated ranking system, shown in Table 1.

Table 1: Ranked user requirements

User Requirement	Raw Score
Removes particulates and blood clots	7
Minimizes contamination from environment	14
Minimizes risk of cross contamination between patients	17
Can be used in any clean abdominal surgery	20
Prevents air embolisms	24
Device is low maintenance	27
Alerts user when malfunctioning	27
Durable and long lasting	28
Easy to operate by any staff in surgical setting	29

Device is low cost	31
Connects to existing blood transfusion kit	32
Can contain large amounts of blood loss	33
Measures amount transfused to patient	35
Quick transition to backup power	36
Main power source is electrical	43
Device can be operated quickly	43
Device is portable	48
Device is small	50
Can change transfusion rate	50
Measures amount of blood lost by patient	52
Backup power source is mechanical	56
Device is quiet	57

5.3 Translating to Engineering Specifications

These user requirements were then translated into engineering specifications, either through direct literature research or through interviews which were then verified with the literature whenever possible. Table 2 below shows a modified list of user requirements matched to engineering specifications. The preliminary user requirement list was modified based on new findings from literature research and subsequent interviews with various stakeholders. The exact process for obtaining each engineering specification is described in Section 5.4.

One major problem we encountered was the implicit assumption that the device would function appropriately. Because this user requirement was not explicitly stated outside of requirements such as “removes particulates and blood clots” and “can contain large amounts of blood loss,” this idea was not adequately represented in the user requirements listed on the survey. To address this, we added several user requirements based on literature research. Additionally, after further conversations with a number of clinicians, including both Dr. Odoi and Dr. Johnson, we reworded and reordered several of the existing user requirements. The current list of user requirements reflects our team’s efforts to accurately represent the needs expressed by our end users (Johnson, 2010; Odoi, 2010). We are in contact with a number of clinicians in Ghana, who have reviewed the results of our first two design reviews. Because of logistical challenges, we have been unable to have an in-depth conversation with Dr. Odoi, but through email contact, he and two other health care providers have confirmed that our list of user requirements (as of Design Review 2) is satisfactory.

Our current engineering specifications are shown in Table 2 below. The double line in the table separates critical requirements from those which are considered non-critical, based primarily on the results of the customer survey distributed in Ghana, as well as additional literature research. All of the requirements above the line must be addressed; those below the line. The items below the line are those our team considers optional (based on results of the initial survey); ideally, they will be included if possible, but since it is unlikely that we will be able to design a device which meets all of the requirements, those below the line can be sacrificed to achieve the more critical requirements.

Table 2: Sorted user requirements and engineering specifications

	User Requirement	Engineering Specification
Quality	Removes particulate matter	≥ 170 μm in diameter Filtering efficiency of 98%
	Does not damage blood cells	< 150 mmHg pressure
Safety	Closed system	0 openings to environment
	Noticeable if device malfunctions	Force on plunger >45 N
	Durable	Withstand drop from 2 m
	Can manage significant blood loss	≥ 2 L blood loss
Function	Flow rate removes blood sufficiently	≥ 0.5 L/min
	Measures total blood collected	≤ ±10 mL accuracy
	Easy to operate	Training time < 30 min 1 operator required < 5 steps for operation Force applied ≤ 48 N Diameter of grip ≤ 3 in.
	Low cost	$10-15
	Compatible with or replaces blood transfusion kit	≥ 20 drops/min infusion rate ≤ 450 mL blood bag volume Compatible with 3mm tubing on blood bag
	Quick to operate	Set-up time of < 2 min Time to first transfusion is ≤ 10 min
	Small and portable	≤ 15.5 kg filled
	Quiet	Operating level ≤ 50 dB

5.4 Detailed Specifications

Removes particulate matter: This requirement was consistently ranked one of the most important by all the clinicians and staff surveyed. Anecdotal interviews suggested that clots can be seen as large as 20 cm in diameter (Forson, 2010). Further research indicated that clots and particulates must be filtered to a level of 170 μm to reach a satisfactory risk level for transfusion. The standard level of efficiency for filters of any pore size is 98% (Hankins, 2001).

Does not damage blood cells: Our initial literature research indicated that a vacuum pressure greater than 150mmHg would result in increased cellular destruction of the whole blood, making the transfusion process ineffective or potentially harmful for the patient. Therefore, a maximum vacuum pressure of 150 mmHg is indicated as our engineering specification (Radl, 2010). Additionally, all of the materials the blood comes in contact with must be biocompatible.

Closed system: To ensure patient safety, contamination of blood from the surrounding environment should be minimal. To this end, Dr. Odoi expressed that he would like to minimize health care providers' physical contact with the blood by developing a closed system which

would transport the blood from the patient, through a filtration system, and either into a blood bag or directly to the patient for transfusion (Odoi, 2010).

Noticeable if device malfunctions: An alert of some kind to notify the surgical staff if the device was malfunctioning was requested by a senior resident (Larbi, 2010). He stated that the volume of a cell phone ring tone should be loud enough to get the attention of the surgeon. In additional interviews, technicians added that the frequency of an auditory device should not exceed 15 kHz (Akwaboah, 2010). However, more recent interviews with Dr. Odoi suggested that an alert should not be restricted to an auditory mechanism. Therefore, the specification was changed to indicate the point at which a clinician should be notified that the device is malfunctioning (Odoi, 2010).

Since moving to a purely mechanical, disposable system, this specification had to be redefined. Because the operator is using their own mechanical power to operate the device, they should be able to determine if the device is becoming more difficult to operate because of clogging. This was anecdotally proven during functional validation testing. The value of 45 N was measured as the maximum force (with error) needed to operate the device with no clogging present.

Durable: The durability of the device is best described as its ability to withstand the impact force of being dropped from a certain height, since that is the most probable method of damaging a handheld device. Two meters was chosen as that height because it is representative of the average height of an adult man.

Can manage significant blood loss: According to senior clinicians at both KATH and the University of Michigan Health System, the maximum blood loss that a patient can sustain before imminent death is 2 L (Amoah, 2010). Anecdotal evidence from literature indicates a maximum blood loss from ruptured ectopic pregnancies of 2500 mL (Hall, 1979). The device should be able to remove 2-2.5 L of blood without becoming clogged.

Flow rate removes blood sufficiently: In interviews, clinicians indicated that the flow rate of the current suction machine in use at KATH was ideal, and they would like to see a comparable flow rate on any similar machine (Adagebe, 2010; Quarshie, 2010). That flow rate was estimated at 3.5-6 L/min, based on benchmarking comparisons with similar suction machines (Atmos Record 55). However, in additional conversations with Dr. Frank Anderson, he stressed that the blood must be removed within 5 minutes of opening the patient's abdomen so that the surgeon can begin repairing the hemorrhage. With a maximum blood loss of 2-3 L, this results in a much lower minimum acceptable flow rate, in the range of 0.5 L/min (Anderson, 2010).

Measures total blood collected: It is important for the physician to be able to estimate both the amount of blood that the patient has lost and the amount that has been transfused in order to determine the proper course of treatment. Dr. Odoi has indicated that an accuracy of ±10 mL in measuring this value would be acceptable (Odoi, 2010).

Easy to operate: There is a serious human resource shortage in sub-Saharan Africa, especially in the area of skilled health workers (Chen, 2004). Therefore, this device should be designed such that anyone in the operating theater can use it with minimal training. Limited personnel are

available and only one person is required to operate the suction machine currently in use; therefore, the number of personnel needed should be minimal. Benchmarking with the current suction machine yielded a maximum 5-step set-up process. A maximum training time of 30 minutes was recommended by a senior clinician, and confirmed in the observation of training time designated for new equipment which arrived during our observation period (Konney, 2010). Additionally, the female 5th percentile force that can be applied in a position needed to operate our device is 48 N, so we set the maximum force to this value so that most users will be able to operate the device.

Low cost: Our original cost values of $350-700 for an initial investment and $2-4 per procedure were suggested by a clinician (Konney, 2010). However, these values were assuming the device was electrical in nature (much like the current suction machine) and reflect a much higher cost than is appropriate for a disposable device. We have attempted to look into benchmark costs of other disposable devices with little success. Dr. Johnson provided us with a disposable syringe-type device designed to evacuate the uterus for miscarriges. The device is designed for use in resource-limited settings, but we have been unable to find its cost despite several attempts to contact the distributing company.

We have sought to discuss issues of cost with several clinicians, including Dr. Odoi and Dr. Kibitala, who visited recently. We have been unable to get any ranges from them that make sense. Thus, we have had to estimate our ideal cost, at least for the time being. We do know that currently, patients at KATH are charged 18.50 GHS for blood transfusions, which corresponds to approximately $12.90. We would like to be in this range of costs for a disposable device, around $10-15.

Any discussion of cost should also include a mention of reimbursement by the national Ghanaian insurance plan, since it was anecdotally reported that the majority of patients are enrolled in the insurance plan. Additionally, the issue of cost is vital when considering scaling of this design, since cost is an important prohibitive factor in the purchase of any new technology, especially in limited-resource settings.

Compatible with or replaces current blood transfusion kit: The current blood transfusion kit has two ports on it that could be used as transfer points in the bag. The device will use standard tubing that can be attached to either port. Multiple doctors asked that this requirement be met; since the staff is already familiar with the use of the current transfusion kit, this would also serve to make the device easier to use (Odoi, 2010).

Quick to operate: The requirement that the device be quick to operate can be defined in multiple ways. We were able to quantify this concept in terms of the time needed to set up the machine (< 2 minutes) and the time between the first use of the machine on the patient and the availability of blood for transfusion (< 2-3 minutes). These values were the result of clinician interviews (Adagebe, 2010). Further research into transfusion protocol in trauma situations indicated that the fastest possible time to transfuse blood in emergencies in U.S. hospitals was in the range of 10-15 minutes (Legacy Health System, 2004). The time to reach hemostasis can be up to 18-29 minutes without adverse effects for the patient (Takeda, 2006). The time to first transfusion has thus been set to 10 minutes.

Small and portable: With the change to a handheld design, the main limitation for this requirement is the total weight. Anthropometric data showed a 10th percentile female isometric arm lifting strength of 22.8 lbs or 10.3 kg (Batti'e, 1989). This should be the maximum weight of the device when it is filled with blood. Blood has a density of 1.06 g/mL, and we plan to have a reservoir with a maximum volume of ~500 mL, so the maximum weight of the remaining materials is 10 kg. Additionally, the device should be small enough that it can be operated by anyone; the primary limiting factor is the diameter of the reservoir. We set the maximum diameter of 2.5 in. to fit the 5th percentile female hand size of 6.4 in (Woodson, 1992).

Quiet: In discussions of operating volume, hospital staff indicated that the operating volume of the current suction machine was acceptable. The benchmarking procedure described previously found an operating volume of similar machines to be in the range of 50 dB.

5.5 QFD

In addition to the procedure described above for obtaining user requirements and engineering specifications, our team also developed a QFD diagram to further examine the relationships and interactions between various engineering requirements and user specifications. The primary conflict revealed during this process was that between patient safety and cost efficiency.

Additionally, while completing the QFD diagram, several gaps in our engineering specifications became apparent. The two most important of these were in quantifying a measure of contamination and a clear definition of specifications regarding a backup power source.

6 Concept Generation

Our first step in concept generation was to create a functional decomposition diagram (Appendix 21.4) breaking up the tasks the device was required to perform. The categories that we included were precursory removal of large clots; insertion of the device into the open abdominal cavity; withdrawal of blood from the cavity; transportation to a container (reservoir); removal of clots, particulates, and microaggregates; prevention of new clots; and transportation of blood back into the body. These steps must also occur in the order outlined above, with the exception that the blood not necessarily be filtered before it is transported to a reservoir, but it must be filtered before it is transfused. We also created a category purely to analyze suction methods, since that was the basis of movement of blood throughout our system. We then held several in-depth brainstorming sessions, in which we generated concepts for each functional component as a group (Appendix 21.5). We also performed individual brainstorming for each component.

A Pugh chart was then created to compare the concepts we had generated for each functional component (Appendix 21.6). In terms of collecting blood, we concluded that suction or a siphon would be the top choice, which would be paired with a scoop wand including a screen or a dual chamber tube for clots and blood. We later discarded the siphon technique when the group realized the flow would stop if the device was not fully submerged in the blood, which would make it extremely difficult for the surgeon to use. The systems that were created to clean the blood were composed of a gravity-powered filter, a “salad spinner” technique, or a funnel with groves. All of these would connect to a storage reservoir, from which individual blood bags

would be filled and hung from the IV stand for transfusion, as is done in all current procedures. We also determined that silicon could be used within the device to help prevent the formation of new clots. The final issue was the decision of where or whether to inject additional anticoagulant, which is already present in the current blood bag.

A systems brainstorming session was performed with our class discussion section in order to discover the best way to integrate the components we had generated thus far in the selection process, and also helped identify new components we had overlooked.

7 Concept Selection

In evaluating ideas generated within our group and by the class, we developed five complete systems. We chose the system that integrated the most highly ranked components, was most feasible within the scope of our engineering skills, and most fully addressed our user requirements by making a pros and cons list for each design (Appendix 21.7).

The initially chosen concept was designated as the "Salad Spinner" design (Figure 9), in which the filter is spinning in a chamber. The chamber contains multiple filters, with the larger pore sizes in the center and the smaller in the outside of the chamber. In this way the filter with the smallest pore size has the largest surface area, which should reduce clogging of the system. Tubes would be connected to the inlet of the filtering chamber to the patient, and from the outlet to a reservoir from which a blood bag is filled. We also hypothesized that the centripetal force created from the spinning filter could potentially create a pressure differential large enough to withdraw the blood from the body. However, if this force is not strong enough, a pump would need to be added. Some possible setbacks that would need to be addressed in the design are the non-standard sizing of filters and the maintenance of moving parts.

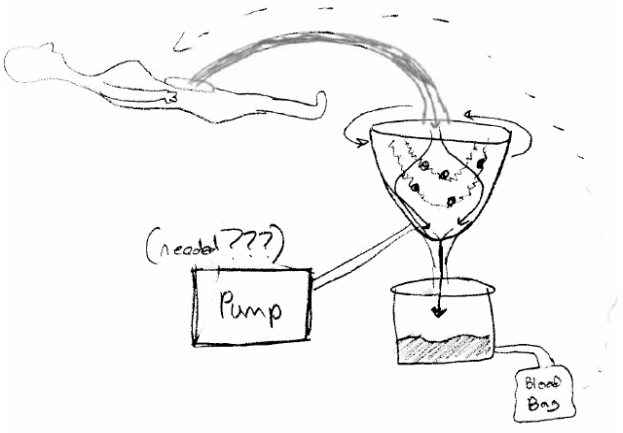


Figure 8: Salad spinner design

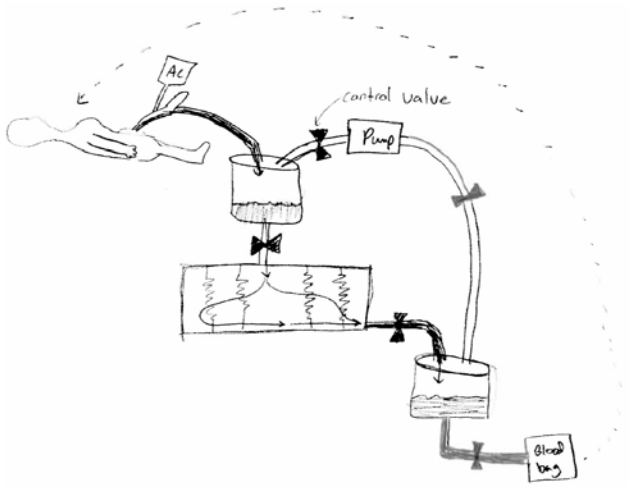


Figure 9: Dual action pump design

A more complicated concept was the "Dual Action Pump (Figure 9)." This design was composed of many separate components that scored well in the component-based Pugh chart. A pump is connected to two reservoirs. The first is located before the filtration system and collects unfiltered blood from the body. The second is located after the filtration system and collects

filtered blood which is then drained into blood bags for transfusion. The filtration system would be a simple gravity filter, helped along by the suction created by the pump through the second reservoir. In this way, the pump serves to both collect blood from the body and force it through the filtration system. The system also includes a series of valves, which would isolate the different components for greater control over individual flow rates. The complicated design includes many parts, which would most likely result in high manufacturing cost and increased maintenance. This fact alone limits the feasibility in our targeted setting.

In order to address the requirement generated at KATH that the device be electrically powered, while still attempting to create something that could be applicable to rural settings with unstable or non-existent electrical grids, the team devised a modular system (Figure 10). This device would be composed of a stand-alone suction machine and a stand-alone filtering system. Where electricity is readily available and reliable, the suction machine and filter module could be used together, but in cases without electricity, the filter module could be used separately with gravity-based filtration and a possible foot pump. The system would also directly fill standard blood bags with filtered blood to be hung on an IV stand. Major limitations of the design include the complexity, number of components, and high maintenance potential of the system.

A concept closely resembling a "water bottle," (Figure 11) was the idea that came very close to being chosen over the "salad spinner." The main reservoir would be compressed by the user, creating a negative pressure when released which would draw blood through the filter at the tip and into the reservoir. A valve is placed on the bottom of the reservoir to allow blood to flow out and either into a second reservoir or directly into a blood bag. The concept was exceptional in that the filter was handheld (making it very portable), was manually powered, and could possibly be used in a wide scope of settings. This concept was not chosen because it was determined that it probably could not handle a large amount of blood loss at once, there was a high potential for backflow if more than one compression is required, and the device would have to be fully submerged within the blood (the primary reason the siphon method was excluded). In terms of sanitation, the "Water Bottle" concept would have to be a flexible material, which likely would not be autoclavable.

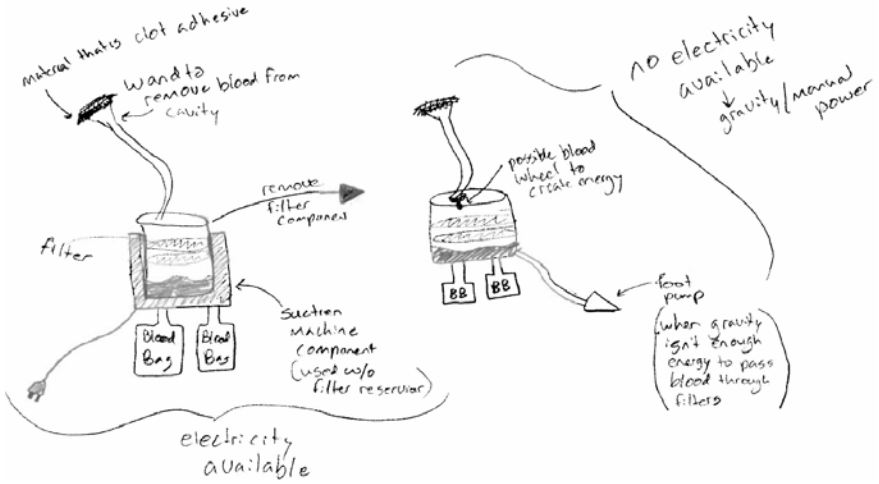


Figure 10: Modular design

After initially choosing the "Salad Spinner" concept as our alpha design, the team generated a fifth distinctly different system concept, in which we attempted to create a simple, small, hand-held concept, similar to the "Water Bottle" design. During brainstorming, we had initially overlooked simple system designs, instead focusing on generating components which could be combined into a whole system. This methodology resulted in very complex systems. While evaluating the pros and cons of each system, the simple "Giant Syringe" concept emerged. This is a self-contained, man-powered system with no expensive pump necessary, composed essentially of a large-scale syringe with an internal filter. Unlike the "Water Bottle" concept, the "Giant Syringe" would not need to be flexible, and thus could be manufactured from autoclavable material.

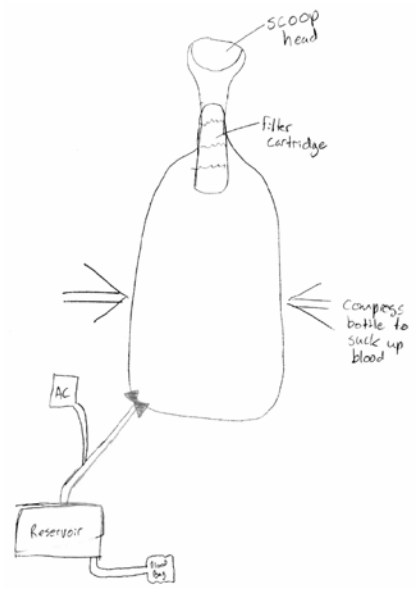


Figure 12: Water bottle design

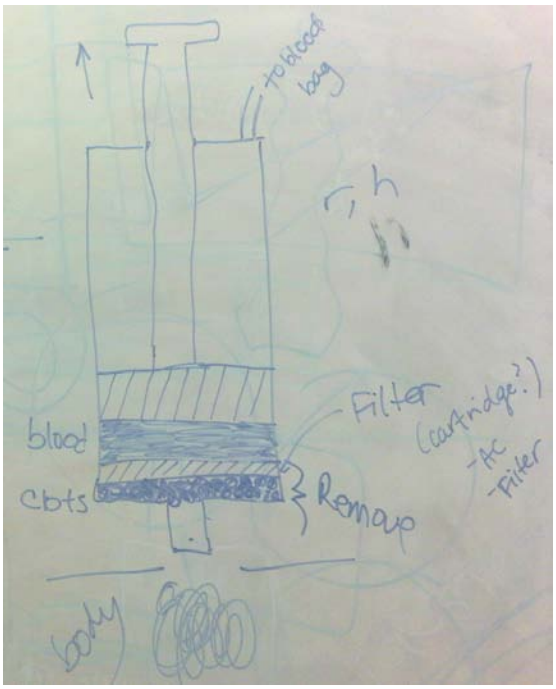


Figure 11: Giant syringe design

When analyzed against the user requirements and the Pugh chart, the concept made sense on almost all levels. The concerns that the team believes we can address in the future development of the prototype are the blood volume capacity, flow rate, and being prone to clogging. The energy required from the user to operate the device will also have to be a major point of focus when deciding whether to move forward with this concept. The device could feed directly into a blood bag, so the volume would not need to be larger than 450 mL, but would have to expand several times to collect all the blood in the cavity. The device could also be designed such that it would withdraw enough blood in one expansion to fill multiple blood bags, but that could result in it being rather heavy. A major concern was that the design might actually be too "low-tech" for our users at KATH, who are expecting a more complex, electrically powered solution. We have still been unable to hold a detailed interview with Dr. Odoi to receive his feedback on this design concept. However, in conversations with Dr. Johnson, he was very enthusiastic about this concept and confident that we were moving in the correct direction with this design. We will continue efforts to contact Dr. Odoi, but will move forward with this design based on Dr. Johnson's feedback.

8 Design Evolution

Our team has completed multiple iterations of our chosen design (the giant syringe), outlined in Table 3. The primary functional mechanisms of the design have not changed significantly between iterations. Each design includes three major functional components: tip (A), syringe reservoir (B), and exit valve connected to a blood bag (C). The device operates by first creating a negative pressure difference on the upward stroke of the plunger, which draws blood through the tip (A) and into the syringe reservoir (B). The plunger is then forced downwards (down stroke) and the blood is transferred into a blood bag through an outlet (C). This process is repeated in a continuous cycle until the blood intended for autotransfusion is completely evacuated from the patient's abdomen. Later designs also include one or more check valves to prevent clean blood from flowing back through the filter and out the tip.

Our initial design (alpha design) included a fine internal filter to remove clots and particulates ≥170 μm in diameter. An exit valve which would be attached directly to a blood bag was positioned at the top of the main reservoir. The major problem with this design was the lack of a mechanism to prevent backflow of filtered blood through the filter and out the tip when the plunger was compressed. The position of the exit valve to the blood bag meant that the plunger would have to be fully withdrawn before blood could be evacuated from the device. There was no mechanism (such as a coarse filter) to remove larger clots before they reached the fine filter, which would likely result in faster clogging of the fine internal filter. The method for attaching the internal filter was not considered. Additionally, no human factors were accounted for in the design: the hand size and the reservoir diameter, or the force needed to draw back the plunger.

Our beta design addresses some of these issues. The exit valve to the blood bag has been moved to the bottom of the reservoir, allowing greater freedom in evacuation of blood to the blood bag. A one-way valve has been added above the fine internal filter to prevent backflow of blood through the tip. The diameter of the reservoir has been changed to 2.5" to fit the 5^{th} percentile female hand size. Several problems still remain. There is still no coarse filter to remove the largest clots, and attachment of the fine filter remains unclear. The plunger handle is optimized for ease of manufacturing rather than for the user's comfort.

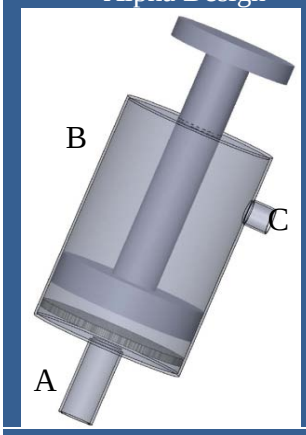
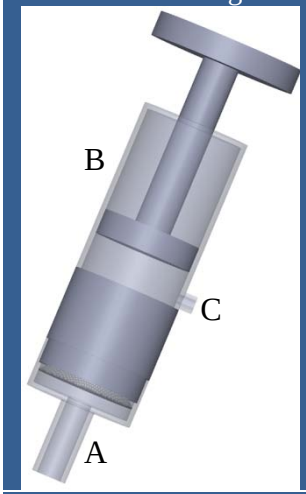
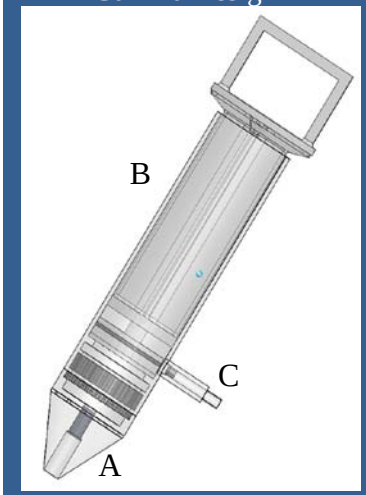
The third design, the gamma design, has a coarse internal filter as well as the fine one. A chamber has been added so that a filter manufactured by a third party can be easily placed inside, and internal lips provide attachment for the coarse filter, most likely with some sort of glue. There are a total of three one-way valves, one on either side of the filters and one on the exit to the blood bag, which prevent backflow, protect the filter from force on the down stroke, and prevent clean blood from being drawn back up from the blood bag on the up stroke of the plunger. A rubber O-ring is placed on the plunger to maintain an airtight seal. The plunger handle was redesigned so that it would be easier for the user to create a substantial force when drawing the plunger back. The tip of the device was changed to a tapered design, which makes the manufacturing process easier (in attaching the tip to the main body of the device) and may provide greater field of vision for the user.

Several problems remain with this design. The filters are still prone to clogging, but it is difficult to accurately predict the speed with which they might clog. Literature searches have yet to yield any definitive numbers on the size and quantity of clots found in cases of ectopic rupture. These factors depend primarily on the time between the initial rupture and onset of internal bleeding

and the start of the surgical repair (Takeda, 2006). The tapered tip, while easier to attach to the main reservoir, may need an extension piece to allow the surgeon to reach all areas of the abdomen where blood has pooled. Additionally, a cavity at the top of the tip piece is intended to store larger clots removed by the coarse filter. The number and size of clots is largely determined by the time between the initial rupture and the operation, and we have been unable to find information about either this time period or the rate of clotting. Anecdotal evidence suggests that ruptures can occur several hours before a patient is seen by a physician and that clots can be up to 20 cm in diameter.

During this design process, we decided to alter our design from a reusable device with a few disposable parts to an entirely disposable device. This decision was made primarily due to the added complexity that a partially disposable design entailed. The one component which would be disposable in all situations is the filter. Therefore, the filter would have to be removed and replaced, requiring additional training and increasing the time to set up the device, as well as adding a step which increases the potential for contamination, since the filter would likely be exposed during this process. The complications in the manufacturing process were also significant, since the piece containing the internal filter would need to be removable. We considered placing the filter outside the main body of the device, in the tubing to the blood bag, but rejected this because of the added bulk, which would detract from one of the primary advantages of our design (it is small and portable). Finally, the supply of consumable parts is unreliable in resource-limited settings (Malkin, 2007). This would result in our device becoming useless once the supply of filters has run out.

Table 3: Evolution of final design

	Description	Shortcomings
Alpha Design 	• Fine internal filter removes smallest clots and particulates • Exit valve to blood bag keeps clean blood inside system	• No coarse filter • Attachment of internal filter is unclear • Exit valve to blood bag is poorly positioned • No mechanism to prevent blood exiting from tip (backflow) • No human factors accounted for (diameter of reservoir, force to draw plunger)
Beta Design 	• Fine internal filter removes smallest clots and particulates • Exit valve to blood bag moved to bottom of main reservoir • One-way valve above filter prevents backflow • Main reservoir diameter sized to fit 5th percentile female hand size	• No coarse filter • Attachment of internal filter is unclear • Plunger handle is difficult to interface with (human factors)
Gamma Design 	• Fine internal filter removes smallest clots and particulates • Coarse internal filter • Three one-way valves allow greater control over fluid movement • Exit valve to blood bag at bottom of main reservoir • O-ring on plunger creates airtight seal • Tapered tip for ease of manufacturing and greater operator visualization of field • Main reservoir diameter sized to fit 5th percentile female hand size • More optimal plunger handle for user comfort	• Difficult to predict clogging of filters • Cavity to store clots may be too small • May need extension of inlet tube beyond tapered tip • Connection mechanism to blood bag tubing is questionable

9 Final Design Description

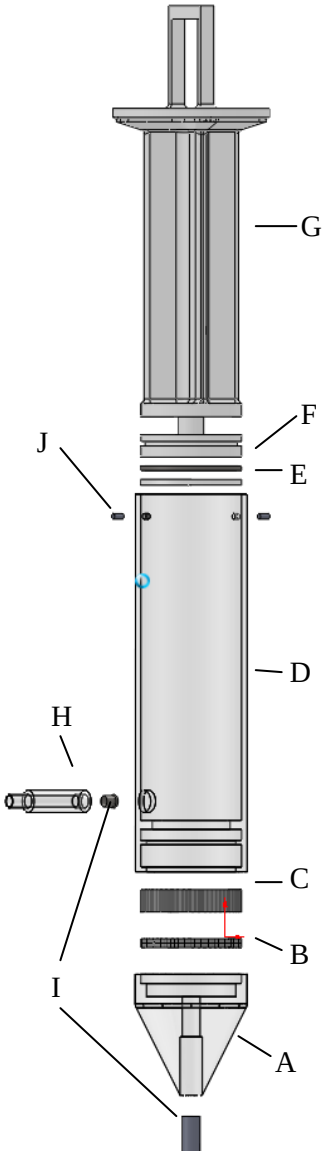


Figure 13: Exploded assembly view of final design

9.1 Prototype Design

The final design is very similar in both form and function to the gamma design presented above. The only change to the gamma design is the addition of dowel pins at the end of the reservoir; these will prevent the plunger from being removed from the syringe housing. The device contains the following parts (Figure 13): tip (A), coarse filter (B), fine filter (C), main reservoir (D), swing check valve (E), O-ring (F), plunger (G), exit valve to blood bag (H), two duckbill valves (I), and a pair of dowel pins (J).

9.1.1 Operation of device (Path of flow)

The device operates by creating a negative pressure differential on the upward stroke of the plunger, which draws blood through the tip (A) and into the syringe reservoir (D), passing through the first duckbill valve (I), the two internal filters (B and C) and the swing check valve (E). The plunger is then forced downwards (down stroke), at which point the positive pressure closes the swing check valve and opens the duckbill valve at the exit to the blood bag. The blood then exits the main reservoir and is transferred into a blood bag which is connected to the outlet valve (H). This process is repeated in a continuous cycle until the blood intended for autotransfusion is completely evacuated from the patient's abdomen.

9.1.2 Part-by-part Description

The tip (A) includes a rigidly attached internal filter (B) with a maximum pore size of 1 mm. This coarse filter will be used to remove larger clots before they reach the fine internal filter. The filter will be glued onto an internal lip (0.25" width) and has a diameter of 2.25". The tip also includes a hollow space beneath the filter, which is meant to store clots that are caught by that filter and reduce clogging.

The second filter (C) has a maximum pore size of 170 μm and is attached in a rigid housing element with a height of 0.5" inside the main reservoir housing. A filter with a pore size of 37 μm was obtained from a distributor in hopes of modifying it to suit our needs. The height of the housing element can be varied as needed to accommodate the filter, but is currently set to 1.5".

The next element the blood will encounter is a rubber swing check valve with a 2.25" diameter (E), which will be glued to a 0.125" lip in the housing of the main syringe. The valve will function like a torsional spring, opening on the up stroke of the plunger and closing on the down stroke.

The handle on the plunger allows the user to fully grasp the plunger when pulling upwards. When the plunger is extended in the open position, dowels pins (J) prevent it from being

removed from the reservoir housing. This is a safety mechanism which prevents accidental disassembly of the device and protects clean blood from environmental exposure. In this position, the reservoir will be filled with clean blood, and the plunger can be pushed down, forcing the duckbill valve at the outlet blood bag connector (H) to open and closing the swing check valve and the duckbill valve at the inlet. Blood is then fed into a blood bag. Ideally, each stroke of the device will fill an entire blood bag; at this point, the filled bag will be removed from the device.

The bag is then hung on an IV stand and transfused through an IV kit (which will control the infusion rate and prevent air embolisms using a drip chamber). Anticoagulant will not be introduced into the system, but is already present in the blood bag and will help prevent new clots from forming. This design will allow the syringe pump to operate continuously without overflow until the attached blood bag is filled, at which point operation can be paused while a fresh, empty blood bag is exchanged for the full one.

Another option to prevent the need to frequently pause operation to change the blood bag would be to split the outlet line to feed multiple blood bags simultaneously. The outlet could also connect to an additional reservoir so that the entire procedure can be continuous. The full bags can then be hung on an IV stand for transfusion, while salvage of blood from the abdominal cavity continues.

9.2 Final Design

The final design does not differ significantly in form from the prototype. The only change is that the dowel pins at the end of the reservoir will be replaced by a c-clip (Figure 14). This was not done in the prototype because we were unable to find a clip in an appropriate size with internal pins.

The primary differences between the prototype and the final product are in the materials and manufacturing processes. The prototype was constructed out of Plexiglas® for ease of manufacturing and availability of stock material. Manufacturing consisted of turning and milling operations. However, the main body and plunger of the final design will be composed of Makrolon® polypropylene and manufactured using injection molding.

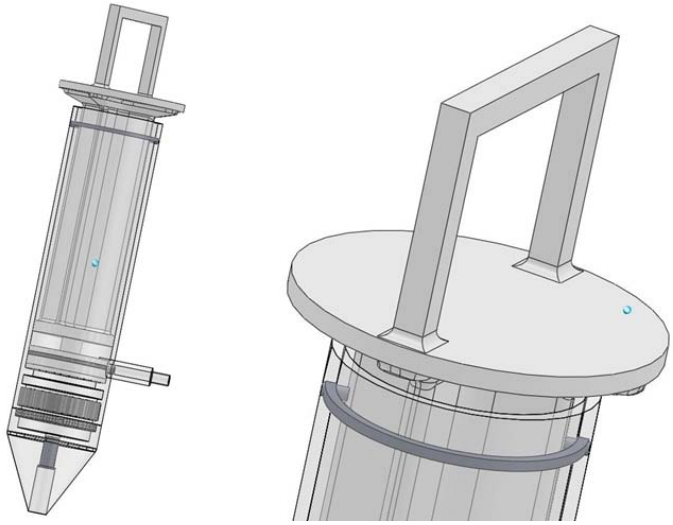


Figure 14: Final design CAD with close up of c-clip

9.3 Design Decisions

9.3.1 Final geometry

The final geometry of the design was driven by two elements: functional needs and associated human factors. The main functional driver behind the dimensions of the reservoir was the minimum volume specification of 450 mL. We aimed for a volume of 500 mL to allow for the possibility of accidentally aspirating air into the device; our final geometry yields a 488 mL reservoir. The other dictating factor in the final geometry was the 5th percentile adult female hand size, which limited the maximum diameter to 2.5". Similarly, the handle size on the plunger was dictated by the need to maintain the structural integrity of the piece while accounting for the 95th percentile adult male hand size.

The diameter of the inlet valve was dictated by the maximum diameter of readily available duckbill check valves. The outlet diameter was chosen to interface with the standard blood bag tubing size.

9.3.2 Check valves

In designing this device, we investigated several different types of check valves. We began by looking at umbrella valves, but found that they didn't allow a large enough area for blood to flow through at the inlet. At the outlet, they did not allow for flow in the correct direction. We then moved to duckbill valves, which allow for a larger diameter at the inlet and a different attachment mechanism at the outlet.

Until this point, we planned to place the inlet valve above the filter; however, the adoption of the duckbill valves necessitated movement of the valve. The largest diameter duckbill valve we were able to obtain has an outer diameter of 0.63". A filter of this size would clog too rapidly for our purposes, meaning that the diameter of the filter would need to be larger than that of the duckbill valve. Therefore, we switched the locations of these two components. This change necessitated the addition of a third check valve above the filter to prevent flow of filtered blood backwards through the filter on the down stroke of the plunger. Because we were unable to find an appropriate manufactured check valve, Bob Coury suggested that we design and fabricate a simple rubber swing check valve.

9.3.3 Tapered tip

We chose to add a tapered tip to the design for a number of reasons. First, the tip will now be used to store large clots that are filtered out by the first, coarse internal filter. This function means that we needed to have an enclosed volume at the tip of the device. Rather than simply extending the cylindrical body of the device, we chose to modify the tip, which provides this storage volume without further obstructing the user's view of the operating field.

9.3.4 Reusable vs. disposable

One of the major changes in our final design compared to previous iterations is that it is entirely disposable. Early designs were intended to be reusable with a few disposable parts. To justify this decision, we completed a preliminary cost analysis comparing the cost per unit to produce a reusable and a disposable device with the same geometry. Additionally, it is worth noting that the design for a reusable device would be slightly different from that for a disposable device; in

the reusable version, the filters would need to be removable. This factor has the potential to further complicate the manufacturing process.

The recorded cost of our targeted disposable polypropylene material (discussed further in Section 11) from Techapro was around $4 per a pound. The cost of Topas' autoclavable COC resin material was quoted at $7 per pound; if this material was used, the device could be autoclaved up to four times (validated by manufacturer specifications). Materials such as glass, which can have extensive life spans in the autoclave, were original considered, but rejected due to its tendency to shatter when dropped in addition to the manufacturing complexity of the design.

The volume of materials in the plunger, reservoir, and tip is 26.9 in^3. With Topas having a density of 0.037 lb/in^3 and the medical grade polypropylene having a similar density of 0.0308 lb/in^3, the resulting plastic material cost per unit was $6.97 for the Topas and $3.31 for the polypropylene. Other costs of the device included the $12 filter from Terumo Cardiovascular and small accessories such as the valves from Vernay and the O-ring from McMaster.

After consulting an industry professional, we concluded that the injection mold for manufacturing would cost in the range of $10,000 (Lapish). We then assumed production and distribution of enough units for one million uses, which would result in sales of 1 million units of the disposable polypropylene and 250,000 units of the reusable Topas. The resulting cost of the mold per unit was 10 cents for the disposable unit and 40 cents for the re-usable device.

The price of filters for the reusable device was set 25% higher than those in the disposable because of the additional manufacturing complexity that a removable cartridge and packaging would entail, as well as the additional distribution costs. A cost of 4 units was first directly calculated, since the reusable design must to be used four times to be fully utilized. We were then able to calculate a flat unit cost (Table 8). These calculations, assumptions, and conversations with industry professionals validated our decision to move forward with the disposable design.

Table 4: Projected cost of disposable and reusable parts

Cost	**Disposable (# of parts)**	**Reusable (# of parts)**
Plastic Material	$3.31 (4)	$6.97 (1)
Filter	$12.00 (4)	$15.00 (4)
Mold	$0.10 (4)	$0.40 (1)
Accessories (Valves & O-ring)	$2.00 (4)	$2.50 (4)
Cost for 4 units	***$65.64***	***$77.37***
Cost per unit	*$16.41*	*$19.34*

10 Engineering Background

10.1 Blood Biochemistry

Blood is made up of cells (and cell fragments) suspended in a liquid called plasma. The plasma contains dissolved proteins, metabolic wastes, and other molecules being moved between organs. There are two main types of cells present in blood, erythrocytes, or red blood cells, and leukocytes, or white blood cells. Erythrocytes make up 99% of the blood cells and are

responsible for carrying oxygen through the circulatory system. Leukocytes are part of the immune system and help protect the body against infection and cancer. The cell fragments present in blood are called platelets and function in clotting when blood vessels are damaged. The components of blood can be separated by centrifugation. The erythrocytes sink to the bottom of the centrifuge tube, and the plasma rises to the top. Platelets and leukocytes form the "buffy coat" between the layers of plasma and erythrocytes (Windmaier, 2006). If the blood is allowed to clot, the remaining fluid is termed serum. Serum is similar to plasma but lacks the protein fibrinogen (Mark, 2003).

There are several different methods to measure the amounts of each blood component. The percentage of blood volume that is intact red blood cells is defined as the hematocrit level. Normal levels of hematocrit are 45% in men and 42% in women. Hemoglobin concentration measures the concentration of the major oxygen-carrying pigment hemoglobin in whole blood. Normal levels of hemoglobin are 15 g/dL in men and 13.8 g/dL in women. The actual number of erythrocytes in a specific volume of blood (termed the RBC count) can also be calculated. Normal counts in men are 5.2 million cells/μL, and 4.6 million cells/μL in women (Schrier, 2009).

Anemia is a medical condition defined as a reduction in one of the measurements previously discussed. Anemia can be caused by a very wide variety of factors. Ruptured ectopic pregnancy patients almost always present with anemia due to hemorrhage. There is no exact lower limit to what is considered a normal hematocrit/ hemoglobin/ RBC count and what is anemic. The World Health Organization criteria for anemia are hemoglobin levels of <13 g/dL for men and <12 g/dL for women. However, these levels were intended to be used for nutritional evaluation rather than for a standard in the diagnosis of anemia (Schrier, 2009). Patients that present to hospitals in resource limited areas with ruptured ectopic pregnancy typically have a preoperative hematocrit of around 20% (Selo-Ojeme D. O.-W., 2007), which is less than half the normal level and clearly falls into the anemic range.

As previously discussed, high pressures can cause hemolysis of red blood cells. Hemolysis occurs primarily through mechanical injury to the cells caused by air bubbles that expand and collide with the cells, generating mechanical stresses. Thus, aspiration of air should be avoided whenever possible to reduce the incidence of hemolysis. Dilution of the blood with saline is an option to consider. Adding saline in a ratio with blood of approximately 1:1 reduces the incidence of hemolysis by 55-60%, even at suction pressures of 300 mmHg (Waters, 2007).

10.2 Fluid Mechanics

Fluid mechanics will be the most important relevant scientific field related to the function of the device. As the device will be dealing primarily with blood, it is important that we fully understand the fluid dynamics of blood for the device to function as needed.

Hemodynamics:

Although whole blood is technically a non-Newtonian fluid, a good approximation is that it may be considered a Newtonian fluid at vessel diameters greater than 0.3 mm, and above shear rates of 100 sec^{-1} (Mark, 2003). We will be using tubing significantly larger than 0.3 mm in diameter; however we do not yet know if we will be applying a shear rate greater than 100 sec^{-1}.

Blood Viscosity:

Whole blood has an average viscosity of about 4 centipoise and is incompressible (constant density). This is about 4 times higher than the viscosity of water (1centipoise) (Mark, 2003). As whole blood is a non-Newtonian fluid, the viscosity is dependent on the shear rate. Specifically, whole blood is a shear-thinning fluid, as apparent viscosity decreases with increasing shear rate. There are two factors that contribute to this: cell aggregation at low shear rates and erythrocyte deformation at high shear rates (Figure 14). Erythrocyte aggregation occurs in the presence of fibrinogen and globulin, two plasma proteins. The erythrocytes stick together to form aggregates called rouleaux (Figure 15, top panel). These rouleaux are broken up as the blood flows at faster rates, decreasing the particle size and lowering the overall viscosity. Experiments have shown that the rouleaux are broken up into single cells at a shear rate of 10 sec^{-1} (Figure 15, middle panel). As the shear rate continues to increase, the apparent viscosity continues to drop. This phenomenon is attributed to the elongation of erythrocytes at high shear rates, which further decreases the viscosity (Figure 15, bottom panel) (Mark, 2003).

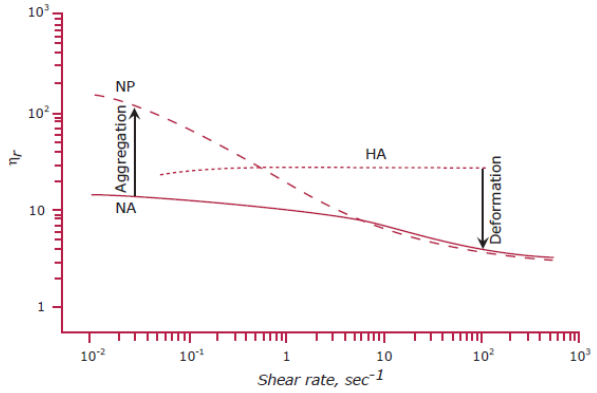


Figure by MIT OCW. After Fig. 3.4-2 in Fung, 1981.

Figure 15: Shear thinning properties of whole blood

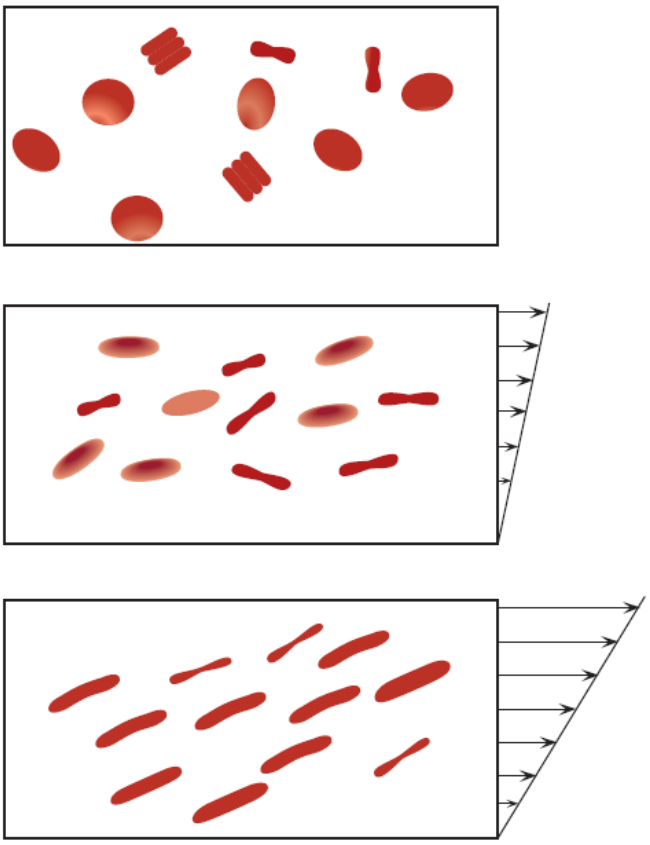


Figure by MIT OCW.

Figure 16: Physiologic changes during increasing shear rates

The viscosity of blood is also a function of hematocrit. The amount of erythrocytes present in blood changes how the blood will respond to an applied force. We can compile these factors influencing the viscosity of blood into a relationship that we can use to calculate the viscosity in a given circumstance to a more accurate level than simply using the average, 4 centipoise. If the shear rate is above $100s^{-1}$, the relationship is Newtonian and the viscosity is given in centipoise by:

$$\mu_N = (0.00221)\left(e^{\frac{1965}{T}}\right)(e^{2.31f})$$

T is the absolute temperature of the blood in Kelvin and f is the fractional hematocrit value. If the shear rate $\dot{\varepsilon}$ is below 100 s^{-1} (non-Newtonian behavior), the viscosity is calculated as:

$$\mu = \frac{\tau_y}{\dot{\varepsilon}} + 2\sqrt{\frac{\tau_y \mu_N}{\dot{\varepsilon}}} + \mu_N$$

Here,$\dot{\varepsilon}$ is the strain rate, μ_N is the Newtonian velocity, given by the same equation used if the strain rate is above $100s^{-1}$, and τ_y denotes the yield stress of the fluid expressed in $dyne/cm^2$. The value of τ_y is determined through the equation:

$$\tau_y = (f - .01)^2(c_f + .05)^2$$

In the above relation, f is the fractional hematocrit of the blood, and c_f is the concentration of fibrinogen expressed in g/dL (Qamar, 2010). These relationships will be important to consider as we further examine the operation of the device. In order to perform any type of velocity, flow or pressure calculation, we will need to know the viscosity of the fluid we are working with.

We will need to perform an analysis of the flow dynamics of the device, regardless of the form of the final design, to ensure that it meets all relevant engineering specifications. Flow rate and pressure will be the two most important parameters to consider. The flow rate must meet the specification of 10 L/min without exceeding the maximum pressure of 150 mmHg that can damage the red blood cells. The balance between these two parameters is both our design driver and our most difficult challenge. We will need to make decisions regarding the dimensions, force, volume, suction pressure that comprise the device in order to ensure these two specifications are simultaneously met.

Classification of Flow

There are several different fluid dynamics principles we will need to utilize to characterize the flow of blood through the device. First, we will need to determine if the flow is laminar or turbulent. This accomplished by calculating the Reynolds number, which is an expression of the inertial to viscous forces. Reynolds number is calculated using the expression:

$$Re = \frac{\rho v L}{\mu}$$

where ρ is the fluid density, *v* is a characteristic velocity, μ is the fluid viscosity and L is a characteristic length. When analyzing flow in a tube, as we will be for our device, the characteristic velocity is the average velocity and the diameter of the tube is the characteristic length. In cylindrical tubes, the flow is defined as laminar when Re<2100. Turbulent flow occurs when Re>4000. The intermediate region is termed the transitional flow region, where the flow is unstable and intermittently turbulent (Truskey, 2004).

Bernoulli Equation

The Bernoulli Equation relates parameters of a fluid flow along the same streamline. The use of the equation is restricted to certain flow situations. Viscous effects are assumed to be negligible, the flow is assumed to be steady and incompressible and the equation must be applied along a streamline. The general Bernoulli equation is expressed as:

$$p + \frac{1}{2}\rho v^2 + \rho g h = constant$$

Depending on our final calculation of the Reynold's number, the Bernoulli equation may or may not be a reasonable approximation of the flow. High Reyonld's number flows are dominated by inertial forces, and the viscous forces can be considered negligible. If the Reynold's number of the flow is large, the Bernoulli equation would be a reasonable approximation to the flow and we can forgo attempting to estimate the exact viscosity of the blood. If the Reynold's number turns

out to be small, viscous forces will dominate the flow and we will have to use one of the following equations to characterize the flow (Munson, Young, Okiishi, & Huebsch, 2009).

Conservation of Mass
We can also use the principle of conservation of mass. The conservation of mass holds for any type of flow and any type of fluid, and thus will be relevant no matter what results from the previous flow and viscosity calculations. Blood is an incompressible fluid, so we can write the conservation of mass as:

$$\oint_{cs} \vec{v} \cdot d\vec{A} = 0$$

This can also be written in an alternative formulation as the continuity equation: $\vec{\nabla} \cdot \vec{v} = 0$ (34) where ∇ is the del operator denoting the gradient.

Conservation of Momentum
We can also utilize the conservation of momentum, commonly called the Navier-Stokes equation. Like the conservation of mass, Navier-Stokes can be applied to any flow conditions and any type of fluid. The general form of the Navier-Stokes equation is:

$$\rho \frac{\partial \vec{v}}{\partial t} + \rho(\vec{v} \cdot \vec{\nabla})\vec{v} = -\vec{\nabla}\rho + \mu \nabla^2 \vec{v} + \rho \vec{g}$$

The fluid density is denoted ρ, the viscosity μ, the velocity vector $\vec{v}$, and the gravity vector $\vec{g}$. The complete Navier-Stokes equation is rarely used without simplifying assumptions, as very few exact solutions have been found (Mark, 2003).

Poiseuille Flow
One of the exact solutions to the Navier-Stokes Equation holds for laminar flow in a tube. If we determine the flow through the device to be laminar, we will be able to use Poiseuille's Law to characterize the flow. Poiseuille's Law relates the flow rate to the pressure drop for rigid tubes.

$$Q = \frac{\pi}{8\mu} \frac{a^4}{\Delta l} (P_a - P_b)$$

Here, a represents the radius of the tube, μ represents the viscosity; P_a and P_b represent the pressure at two different points along the streamline, with Δl being the distance between them (Mark, 2003).

11 Material Selection

This section will describe the materials that were chosen for the prototype and the final design.

11.1 Prototype Materials

Since our prototype will demonstrate the function of the device only, we chose a material that would be easy to machine and is clear. This material did not need to be of medical grade as the initial prototype will not be tested on patients and will only serve as a proof of concept. We chose Plexiglas (Cast Acrylic) to manufacture our prototype device. Plexiglas is not medical

grade and cannot withstand sterilization cycles but is easy to manufacture, inexpensive, and comes in standard stock sizes. A complete bill of materials can be found in Appendix 21.1.

11.2 Final Design Materials

The final design material selection was driven by the cost analysis that determined if our device would be disposable or reusable. The outcome of our cost analysis determined that our device should be disposable. Makrolon is a medical grade polypropylene polymer that is often used in medical devices that contact blood. This polymer is clear in color and inexpensive which makes it a good choice for use in a device that resembles a syringe. The material properties will allow each component to be made out of this material. Furthermore, Makrolon is supplied in pellets that can be easily used in injection molding machines, which is the manufacturing process that our final design will use.

12 Parameter Analysis

The analysis of the device parameters was completed using the material properties of medical grade polypropylene, shown in Table 5 below.

Table 5: Material properties of medical grade polypropylene (Ensinger)

Density	0.92
Yield Strength	33 MPa
Young's Modulus	2,068 MPa
Flexural Modulus	1,380 MPa
Hardness	100 MPa
Impact Resistance	690 J/m^2

12.1 Whole Device

12.1.1 Impact Force

Because the entire device is handheld, it has the potential to be dropped onto a hard floor and break due to the impact force. We can treat the device as a mass, *m*, falling from a height, *h*, onto a structure (the floor) which deforms to absorb the energy of the mass. The maximum velocity at which it impacts the floor can be easily calculated using the principle of conservation of energy.

$$\Delta PE + \Delta KE = 0 \rightarrow mgh = \frac{1}{2} m v_f^{\,2} \rightarrow v_f = \sqrt{2gh}$$

Assuming a straight line collision (no change in angular momentum), the net work done is

$$F \cdot d = \Delta KE = \frac{1}{2} m v_f^{\,2} = mgh \rightarrow F = \frac{mgh}{d}$$

where *d* is the distance the device travels after impact with the floor. This distance is dependent on the material properties of the floor.

A second method for determining the impact force uses the definition of force as the change in the momentum of the device.

$$F = \frac{\Delta P}{\Delta t} = \frac{m \cdot v_f}{\Delta t} = \frac{m\sqrt{2gh}}{\Delta t}$$

Here the problem is in estimating the time needed for the device to stop moving. As yet we have been unable to find a method to estimate this value. The method for determining the deformations of the floor also depends on estimates of the strain of the floor, and since we would also be choosing a floor material arbitrarily, this equation also results in unsubstantiated quantities for the impact force. Therefore, we have chosen to disregard this analysis with the assumption that our device will be manufactured from material that is already being used in handheld, disposable medical devices that has undergone rigorous testing in this area.

The components of our device most prone to failure due to an impact force are the tip, the exit valve to the blood bag, and the handle of the plunger. The tapered support in the current tip design should help minimize the adverse effects of an impact force. The other two areas remain vulnerable.

12.2 Plunger

12.2.1 Torsion

The plunger could be subject to torsion while it is in the extended position. The 95th percentile force for an adult male hand torque is 7.4 N-m (Woodson, 1992). The plunger can be modeled as a beam with a cross sectional area shown in Figure 16 and corresponding polar moment of inertia, *J*, derived below.

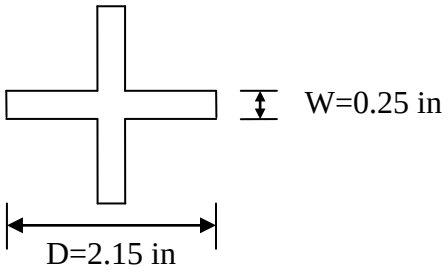


Figure 17: Simplified cross section of the plunger

$$J = \int_A r^2 dA = I_x + I_y = 2I_x = \frac{1}{6}\cdot D\cdot W^3 + \frac{1}{6}\cdot W\cdot D^3 - \frac{1}{6}\cdot W^4 = 0.419 in^4 = 17.44 cm^4 = 1.744\cdot 10^{-7} m^4$$

The maximum shear stress occurs at the outer surface of the plunger and is

$$\tau_{\max} = \frac{T\cdot c}{J} = \frac{7.4\cdot 0.05461}{1.744\cdot 10^{-7}} = 2.3 MPa$$

The maximum shear stress can then be translated to the plane stress using the principles of Mohr's Circle, such that

$$\tau_{\max} = \frac{\sigma_{\max}}{2} \rightarrow \sigma_{\max} = 2\cdot \tau_{\max} = 4.6 MPa$$

The yield strength of the material is 33 MPa, giving a safety factor of 7.2. This models the behavior of the plunger if it were rigidly attached to the reservoir tube. In reality, the plunger will rotate in torsion, with a frictional force created by the interference fit of the rubber ring. The maximum torque will be lower than this value, resulting in an even larger safety factor.

12.2.2 Bending

The position at which the plunger has the largest bending moment is when it is fully extended from the reservoir, supported only by the O-ring at the end. If a perpendicular force is applied to the end of the plunger and it is modeled as beam which is rigidly attached at one end, the bending stress is

$$\sigma = \frac{M \cdot y}{I_x} = \frac{F \cdot H \cdot \frac{D}{2}}{0.5 \cdot J} = \frac{199.2 \cdot 0.214 \cdot 0.044}{0.872 \cdot 10^{-7}} = 21.5 MPa$$

with F as the 95th percentile adult male pulling force (Wagner, Birt, Snyder, & Ducanson, 1996).

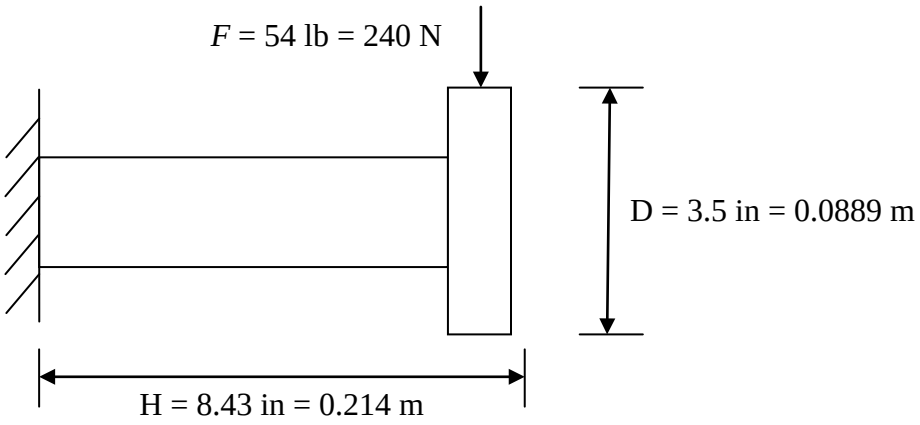


Figure 18: Simplified plunger diagram

Because the reservoir tube and the plunger are composed of the same material, it is only necessary to analyze the failure of one of these. These results yield a safety factor of 1.3. While this is a low value, it is unlikely that the total 240 N force will ever be exerted completely perpendicular to the plunger; there will likely always be a parallel component, reducing the bending moment.

12.3 Reservoir

12.3.1 Hoop Stress

The reservoir will be subject to a hoop stress applied by the user in gripping the reservoir during operation of the device. That stress was modeled using the following assumptions: 1) grip force of 622 N (95th percentile of adult males); 2) uniform pressure around the reservoir. The hoop stress is then

$$\sigma = \frac{p \cdot r}{t}$$

with a wall thickness of 1/8" and an external diameter of 2 ¼". The pressure can be calculated as

$$p = \frac{F}{SA} = \frac{F}{2 \cdot \pi \cdot r_i \cdot H} = \frac{622}{2 \cdot \pi \cdot 0.029 \cdot 0.1651} = 20.9kPa$$

$$\sigma = \frac{20.9kPa \cdot 2.25in}{0.125in} = \frac{20.9kPa \cdot 0.05715m}{0.003175m} = 376.2kPa$$

376.2 kPa is well below the yield strength of 33 MPa (with a safety factor of 88), so the reservoir will not fail.

12.4 Check Valve

We were unable to find a large check valve that could interface with the large inner diameter (2.25") of our device. Therefore, we decided to manufacture our own swing check valve out of rubber that will fit our large tube diameter in the reservoir. However, to ensure that the valve will open under the negative pressure in the reservoir tube, we performed a beam deflection calculation with one end fixed and a point load centered in the middle of the beam.

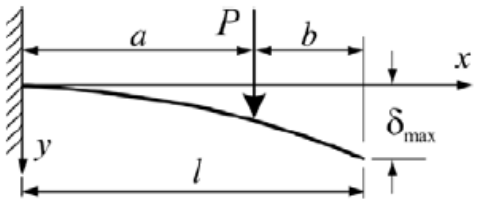


Figure 19: Beam defection (Hibbeler, 1993)

$$\delta_{\max} = \frac{Pa^2}{6EI}(3l - a)$$

Our specification does not dictate a minimum force on the plunger, only that the maximum force should be less than 43 N. Therefore, we chose a representative small force (P) of 2.5 pounds (a pressure of 1 psi in the reservoir tube over an area of 2.5in^2). The disc was simplified as a square of uniform cross section (1.5" x 1.5") for the calculation of beam deflection. The corresponding *a* value was 0.75" and the *l* value was 1.5". The moment of inertia (I) of the beam was calculated as $\frac{1}{12} l \cdot t^3$, where *t* is the thickness of the rubber (1/8"). The Young's modulus (E) provided by the manufacturer of the rubber was 5500psi. The resulting maximum deflection was determined to be 3.6", which means that the valve will open under a pressure of 1psi, and will therefore open with much larger applied forces on the plunger.

12.5 Dowel Pins

The plunger will apply a shear force (F) on contact to the two dowel pins (Figure 20). The dowel pins used in our prototype are made from stainless steel which has a shear strength of 186 MPa.

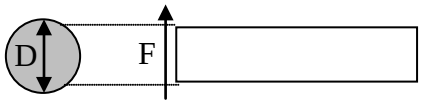


Figure 20: Shear force on dowel pin

To calculate the force, F, required to shear the dowel pins we use $\tau = \frac{F}{A}$ where A is the area of the two dowel pin surfaces in shear and τ is the shear strength of the stainless steel.

The area for the two dowel pins is calculated to be 35.63 mm^2. Therefore, the force required to shear the dowel pins is 6600 N which greatly exceeds the forces that will be applied on the plunger.

12.6 Fluid Flow in the Device

There are several different parts of the device in which we must characterize the fluid flow. We begin with the basic force equation, $F = ma$. We are going to make the simplifying assumption that the applied force to the plunger is constant, although few people would be able to apply a truly constant force. Examining the forces on the plunger we can draw the free-body diagram (Figure 21).

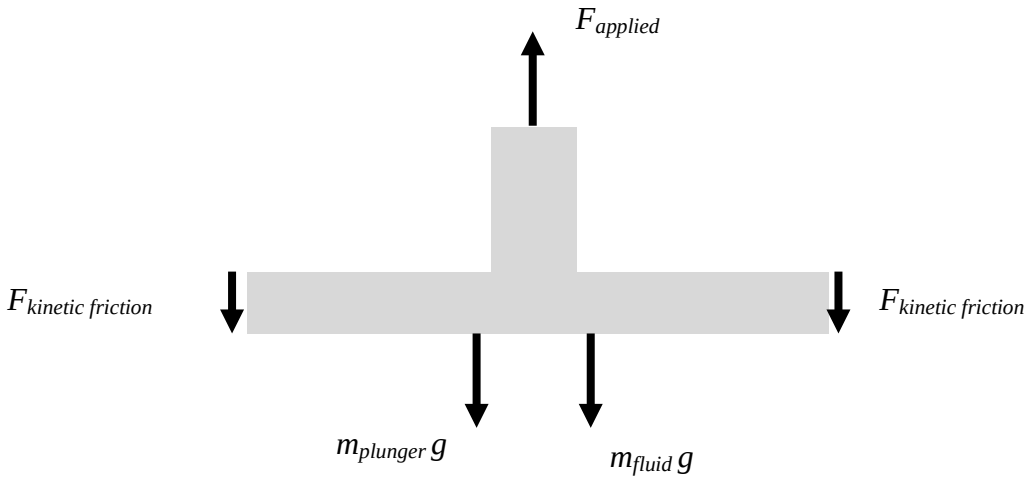


Figure 21: Forces on the plunger

As the weight of the fluid is much more significant than the weight of the plunger, we will neglect the weight of the plunger for now. We will also neglect kinetic friction. It is difficult to determine the kinetic friction in this case using the normal equation $F_k = \mu_k N$. There is no normal force due to the weight of the plunger, as the friction force acts completely perpendicular to gravity. Rather, the sealing pressure of the O-ring around the plunger caused by the interference fit creates the normal force. Additionally, the coefficient of kinetic friction is dependent on the velocity of the plunger, and is not constant in time. Assuming a constant plunger velocity of 100 mm/min, the friction force of a typical 3-piece syringe traces a curve of:

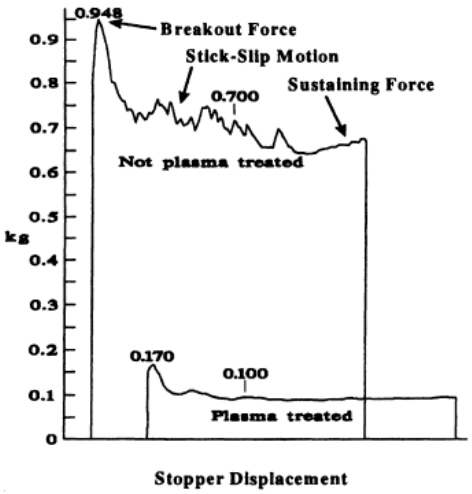


Figure 22: Friction force (Tsukruk, 1999)

In Figure 22, the top curve shows the friction force when using a basic silicone lubricant. The bottom curve shows the forces generated when the syringe barrel is treated with plasma to crosslink the lubricant and reduce the force.

Inclusion of kinetic friction when examining the plunger introduces a high degree of complexity. Friction forces normally have to be experimentally determined, and are something we will have to consider when performing validation tests. However, friction will have the ultimate effect of lowering the velocity of the plunger (and subsequently the fluid) so we do not anticipate that is will cause a harmful increase in pressure.

Returning to our basic force equation, we now are examining only two forces, the applied force in the +y direction and the weight of the fluid in the –y direction. As the mass of the fluid changes as the plunger is pulled back, we must produce an equation for the mass of the fluid as a function of time. This mass will be a piecewise function, as the suction tube fills prior to the barrel. We will define the first phase of filling as the time before the suction tube is full, and the second phase of filling as the time after the suction tube has filled and the barrel is filling.

$$m = \rho V = \rho \pi r^2$$

$$m = \begin{cases} \rho(\pi {r_1}^2 h_1), & m \le m_1 \\ \rho(\pi {r_1}^2 h_1 + \pi {r_2}^2 h_2), & m > m_1 \end{cases}$$

Here, parameters with a ‘1’ subscript denote the suction tube, while those with a ‘2’ denote the barrel. m_1 denotes the mass of the fluid in the suction tube, which does not change in time once full. The heights are related to the velocity of the plunger. We know that h_2 increases at the same rate as the plunger speed v, which means that h_2 can be expressed as $v \cdot t$. We can then rewrite the mass equation as:

$$m = \begin{cases} \rho(\pi {r_1}^2 h_1), & m \le m_1 \\ \rho(\pi {r_1}^2 h_1 + \pi {r_2}^2 vt), & m > m_1 \end{cases}$$

The speed at which h_1 increases is also related to the velocity of the plunger v. We can equate these parameters using the flow rate of blood through the device:

$$Q = A_1 v_1 = A_2 v$$

$$\pi {r_1}^2 v_1 = \pi {r_2}^2 v$$

$$v_1 = \frac{{r_2}^2}{{r_1}^2} v$$

This means that we can express h_1 as a function of v. This gives us:

$$m = \begin{cases} \rho(\pi {r_2}^2 vt), & m \leq m_1 \\ \rho(\pi {r_1}^2 h_1 + \pi {r_2}^2 vt), & m > m_1 \end{cases}$$

We can then take this mass and return it to our equation for acceleration:

$$a = \frac{F}{m}$$

$$a = \begin{cases} \dfrac{F}{\rho\pi {r_2}^2 vt}, & m \leq m_1 \\ \dfrac{F}{\rho\pi({r_1}^2 h_1 + {r_2}^2 vt)}, & m > m_1 \end{cases}$$

Using the definition of acceleration as the time rate of change of velocity, we can integrate this equation to obtain the velocity of the plunger as a function of time. Looking first at the first phase we have:

$$a = \frac{dV}{dt}$$

$$\frac{dV}{dt} = \frac{F}{\rho\pi {r_2}^2 Vt}$$

$$V\, dV = \frac{F}{\rho\pi {r_2}^2 t}\, dt$$

$$\int V\, dV = \int \frac{F}{\rho\pi {r_2}^2 t}\, dt$$

$$\frac{1}{2} V^2 = \frac{F}{\rho\pi {r_2}^2} \ln t + C$$

$$V = \pm\sqrt{\frac{2F}{\rho\pi {r_2}^2}\ln t + C}$$

We can disregard the negative case, as it does not make sense to have negative velocities of the plunger. We then get:

$$V = \sqrt{\frac{2F}{\rho\pi {r_2}^2}\ln t + C}, \qquad m \le m_1$$

We would like to be able to use the initial condition that the fluid starts out as stationary ($V(0)=0$), but as the natural logarithm of zero is undefined we cannot. Therefore, in order to determine an approximate value of the constant of integration *C*, we will choose a small value of *t* (*t=0.1s)* and assign the velocity at that time to be zero. We then solve for *C* and obtain:

$$V = \sqrt{\frac{2F}{\rho\pi {r_2}^2}\ln t + \frac{4.605F}{\rho\pi {r_2}^2}}, \qquad m \le m_1$$

For the second phase of filling, we can repeat the same procedure,

$$a = \frac{dV}{dt} = \frac{F}{m}$$

$$\frac{dV}{dt} = \frac{F}{\rho\pi({r_1}^2 h_1 + {r_2}^2 vt)}$$

This differential equation is not separable, and we must use numerical methods to find an approximate solution. This can be accomplished through the MATLAB function ode45. This function accepts a differential equation, time interval and initial condition as inputs and outputs a vector of numerical solutions. In our case, the initial condition is the speed of the fluid in the suction tube when it enters the barrel at some non-zero time.

At this point, we can use a range of radii and heights for both the barrel and suction tube to see what kinds of fluid velocities we obtain based on the geometries. We will then be able to relate the velocities to the pressure in the fluid to determine we are exceeding our maximum pressure limit of 150 mmHg, which could constrain what geometries we can use in the design of the device. Given some of the initial benchmarking specifications with the vacuum aspirator and the volume necessary to hold in the syringe, we determined an initial reasonable range of geometries shown in Table 6.

Table 6: Range of geometries

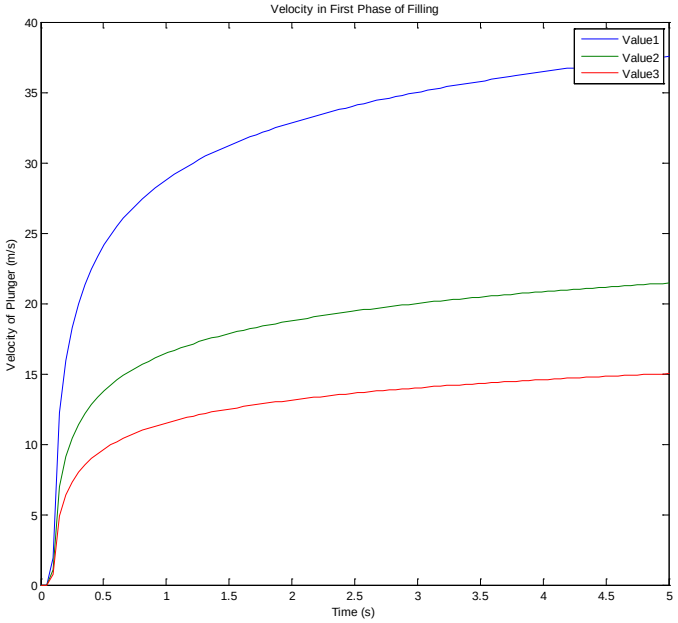
Geometry:	**Minimum (cm):**	**Maximum (cm):**
Suction tube radius (r_1):	0.5	2
Suction tube height(h_1):	3	7
Barrel radius (r_2):	2	5
Barrel height (h_2):	5	20

We can use these ranges to create a vector in MATLAB to find the range of velocities of the plunger based on the specific geometry. We can also input a range of values for the applied force. Based on our evaluations of anthropometric data, the maximum force exerted on the plunger (95^{th} percentile of male pulling force) is 199.2 N (Wagner, Birt, Snyder, & Ducanson, 1996). Returning to our first equation where the suction tube is filling, there are three variables that influence the plunger velocity; r_2, F and t. This makes plotting the influence of all three at the same time impossible without creating an animation in time. Thus, we will choose three representational values (Table 7) of the geometries and one force value in order to examine the effect of time on the plunger speed. We will choose the minimum, maximum and average geometries to ensure that we are analyzing the full range of possibilities.

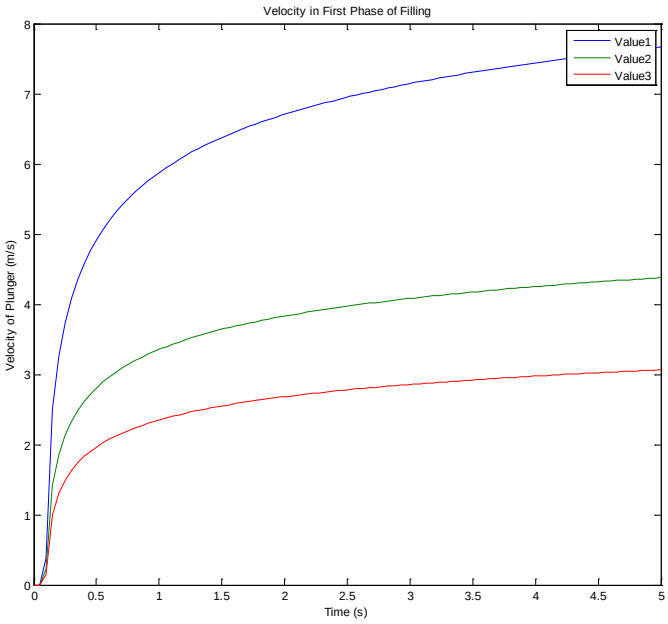
Table 7: Values to Analyze

Geometry:	**Value$_1$ (cm)**	**Value$_2$ (cm)**	**Value$_3$ (cm)**
Suction tube radius (r_1):	0.5	1.25	2
Suction tube height(h_1):	3	5	7
Barrel radius (r_2):	2	3.5	5
Barrel height (h_2):	5	12.5	20

We will use 199.2 N as our chosen force, as it represents the maximum that theoretically could be applied to the plunger. Computing the velocities in MATLAB, we obtain:

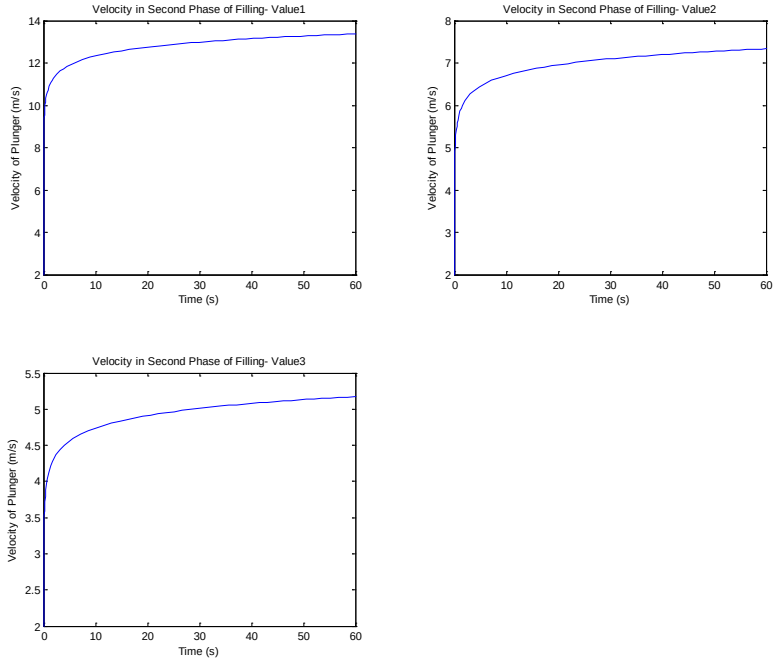


As expected, smaller geometries result in higher velocities of the plunger. We also note here, that our analysis produces extremely high velocities of the plunger. It is not reasonable to expect a user to pull back the plunger at 35 m/s or even 5 m/s. This large magnitude of error could come from one of two primary sources. First, we neglected kinetic friction, which contributes significantly to the force opposing the movement of the plunger. Second, using the maximum human pulling force of approximately 240 N is also not physically realistic. Applying a 240 N force is equivalent to putting a 54 lb weight on the end of the syringe, a truly huge force considering the situation. If we run the code again using a more reasonable 10 N force, we obtain:



These speeds of the plunger are significantly slower, but still are quite high, even for the larger geometries. This error can again be attributed to neglecting the kinetic friction between the rubber O-ring and the interior of the device barrel. We will continue with the analysis, however, to examine relationships among the parameters.

We can now take the asymptotic values of the velocity of the plunger at the end of the first phase and use them as the initial condition for the second phase. This is where we return to the equation for the velocity of the plunger that we must solve using numerical methods. The MATLAB codes are provided in Appendix 20.11. As MATLAB assigns the number of steps and step sizes used by the function, we cannot graph the solutions from the different value groups on the same plot. We must plot them separately:



As we saw with the first phase, increased size of the device reduces the velocity of the plunger. These velocities are again much higher than we would expect, which is likely due to the contribution of kinetic friction. We would expect the user to pull the plunger back at a velocity of about 1 cm/s, which is several hundred orders of magnitude lower than we obtained from the analysis.

We can now take the velocity of the plunger and work the different fluid parameters. Due to the no-slip condition, we can assume that the velocity of the fluid against the plunger is the same as the plunger velocity. We start by characterizing the flow using the Reynolds number.

$$Re = \frac{\rho v L}{\mu}$$

In this formulation, ρ is the fluid density, *v* is a characteristic velocity, μ is the fluid viscosity and L is a characteristic length. When analyzing flow in a tube, the characteristic velocity is the average velocity and the diameter of the tube is the characteristic length. In cylindrical tubes, the flow is defined as laminar when Re<2100. Turbulent flow occurs when Re>4000. The intermediate region is termed the transitional flow region, where the flow is unstable and intermittently turbulent (Truskey, 2004). When Re <<1, the flow is dominated by viscous effects, and when Re>>1, it is dominated by inertial effects.

The density of blood is 1060 kg/m^3 (Cutnell & Johnson, 1998) and we will choose 3.5 cm as our tube diameter (average of upper and lower range). We will estimate on the high side and choose 1 m/s as our characteristic velocity to account for the increased velocity in the smaller-radius suction tube (as well as the entry to the blood bag). We will use the average density of blood, measured at .004 Poise (Mark, 2003). This gives us a Reynolds's number of 9275, which is in the laminar region where inertial effects will dominate the flow. This means that we can

reasonably approximate the fluid as inviscid and model it using the Bernoulli equation. The Bernoulli equation relates two points on a streamline. We can consider a point in the blood still contained in the body cavity (subscript 0), a point in the suction tube (subscript 1), and a point in the barrel of the syringe (subscript 2) as being along the same streamline and related by:

$$p + \frac{1}{2}\rho v^2 + \rho g h = constant$$

$$p_0 + \frac{1}{2}\rho {v_0}^2 + \rho g h_0 = p_1 + \frac{1}{2}\rho {v_1}^2 + \rho g h_1 = p_2 + \frac{1}{2}\rho {v_2}^2 + \rho g h_2$$

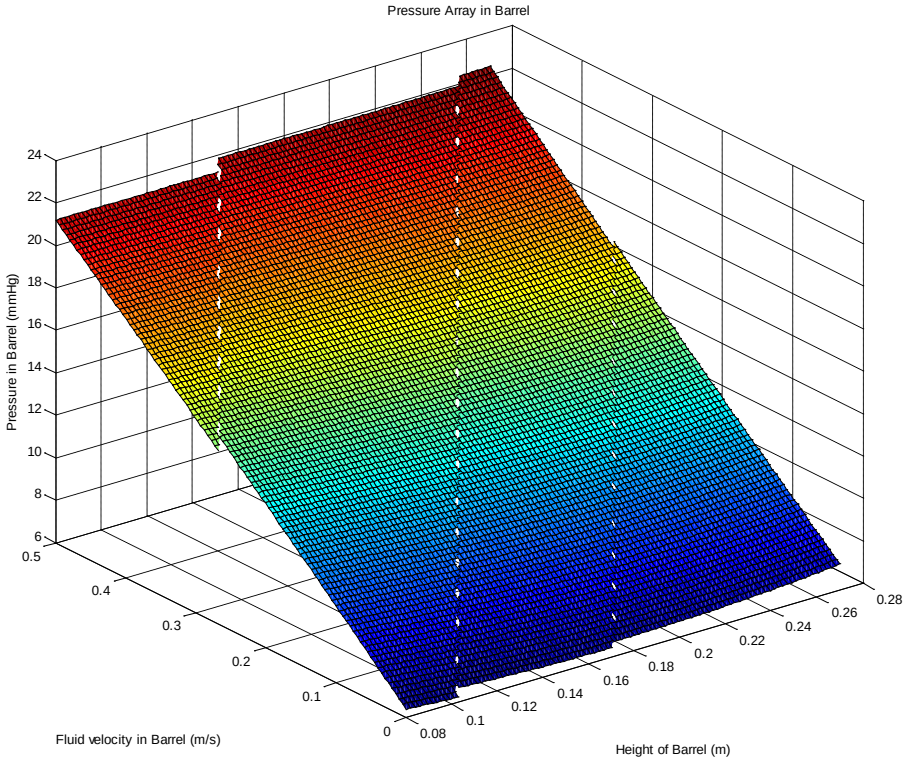
When the blood is still in the body cavity, it has no velocity and we can define the pressure and height there as 0. This simplifies the equation to:

$$0 = p_1 + \frac{1}{2}\rho {v_1}^2 + \rho g h_1 = p_2 + \frac{1}{2}\rho {v_2}^2 + \rho g h_2$$

If we assume that the device is held straight up, we can use the vector of heights from our previous analysis as input to h_1 and h_2. Our previous analysis also gave us the velocity of the fluid in the barrel v_2. This means that we can solve for the fluid pressure in the barrel after rearranging the previous equation:

$$p_2 = -\frac{1}{2}\rho {v_2}^2 - \rho g h_2$$

Using MATLAB, we can plot the pressure as a function of the height of the tube and the velocity. We will use the same range as provided in Table 7 and add the height of the suction tube since we have set our zero to be at the bottom of the suction tube. As previously discussed, the velocities we obtained from our analysis of the plunger were not physically realistic, so we will use a range of velocities of the plunger from 0 – 0.5 m/s to ensure we are including all possible velocities. We get a 3D plot of pressures:



We can see here that even at the smallest geometries and highest velocities we are well under the pressure limit of 150 mmHg. We can repeat the procedure for the pressure in the suction tube. We must first relate the velocity in the suction tube to the velocity in the barrel through the flow rate:

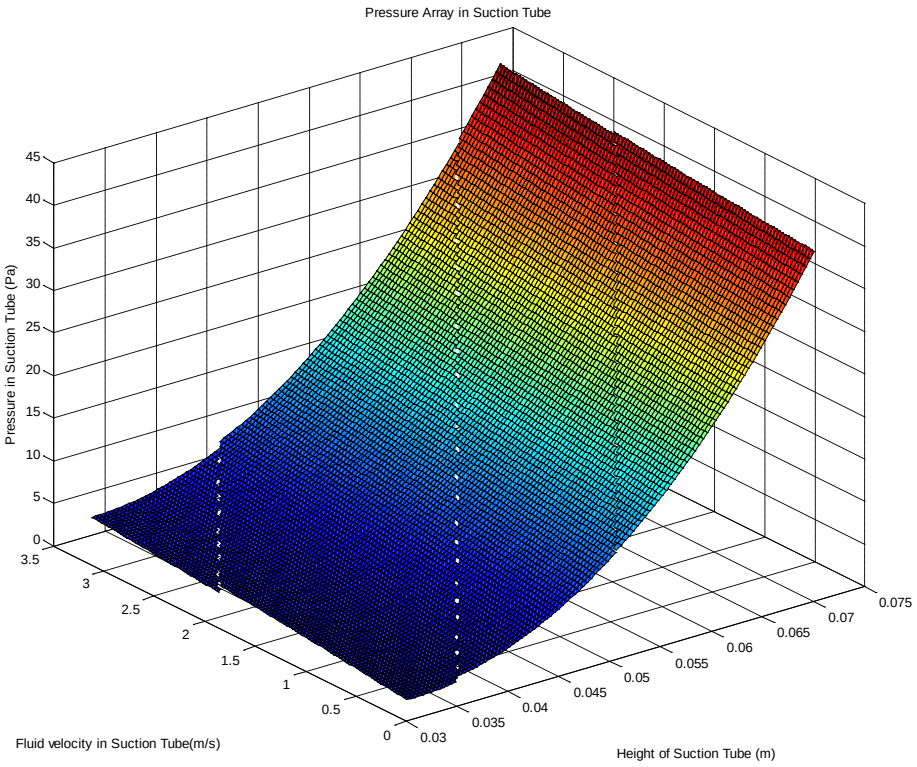
$$Q = A_1 v_1 = A_2 v_2$$

We can take the range of areas based on the range we set for the radii of both the suction tube and the barrel and the velocity range we used for v_2 and obtain the range of velocities v_1 in the suction tube to be 0 – 3.125 m/s. We can then rearrange the Bernoulli equation to find the pressure in the suction tube:

$$0 = p_1 + \frac{1}{2}\rho {v_1}^2 + \rho g h_1 = p_2 + \frac{1}{2}\rho {v_2}^2 + \rho g h_2$$

$$p_1 = -\frac{1}{2}\rho {v_1}^2 - \rho g h_1$$

Creating a similar plot in MATLAB of the pressure as a function of the velocity and the height, we get:



We can see here as well that for all the possible fluid velocities and geometries the pressure is still well under 150 mmHg. This means that we can freely choose dimensions of the device based on human factors within our ranges without exceeding the pressure limit.

We can also evaluate the pressures generated in the connection to the blood bag. We have to reset our zero point in the Bernoulli equation, as the blood in the IV tubing is not on the same streamline as we used previously. The two points we are now comparing are a point in the barrel and a point in the IV tubing, which we will denote with the subscript '3.'

$$p_2 + \frac{1}{2}\rho {v_2}^2 + \rho g h_2 = p_3 + \frac{1}{2}\rho {v_3}^2 + \rho g h_3$$

We can choose a point in the barrel such that $h_2=h_3$. We then can rearrange the equation for p_3:

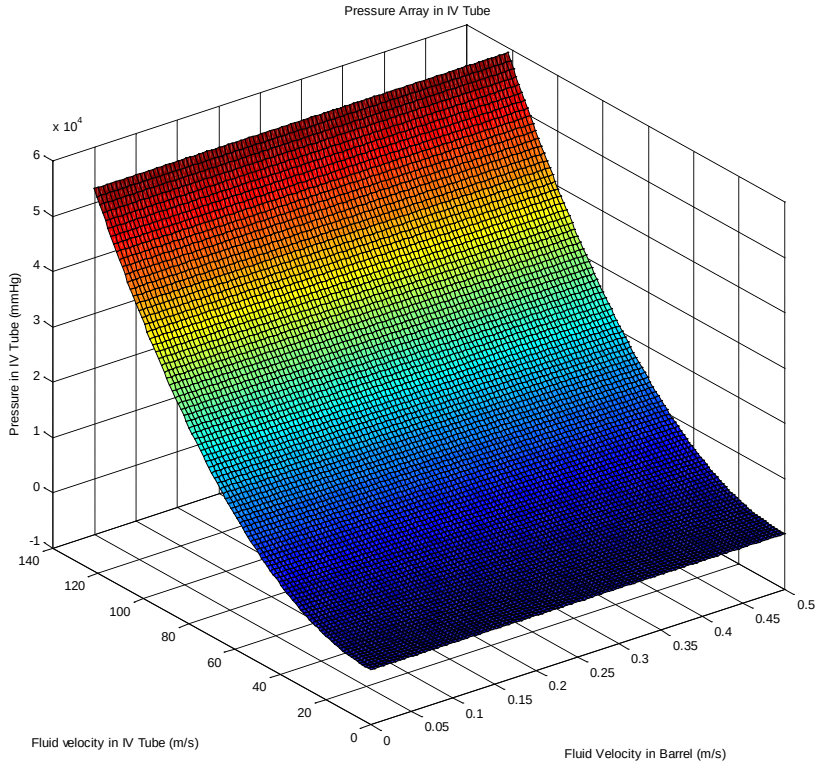
$$p_3 = p_2 + \frac{1}{2}\rho {v_2}^2 - \frac{1}{2}\rho {v_3}^2$$

$$p_3 = p_2 + \frac{1}{2}\rho ({v_2}^2 - {v_3}^2)$$

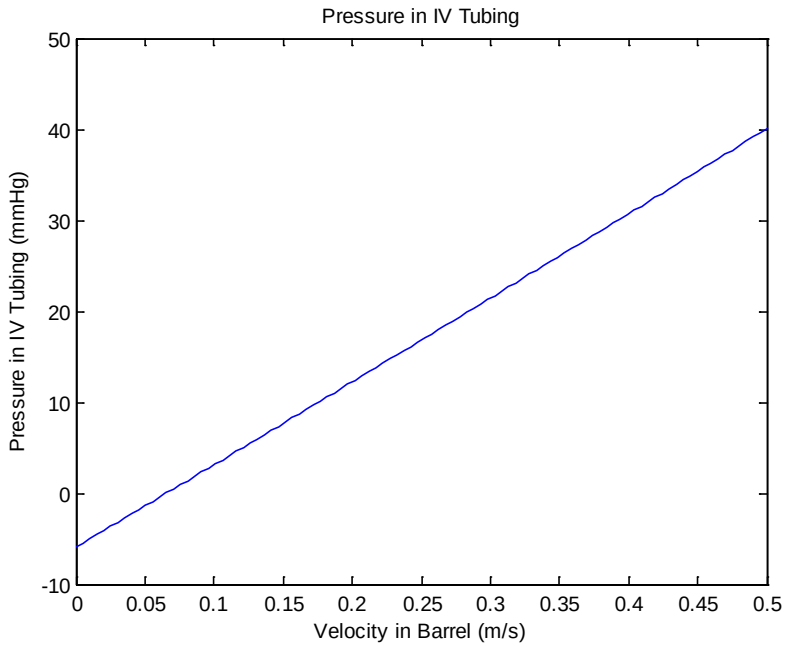
For p_2, we can input the pressure array we got previously, which gives us a range of about 0-24 mmHg. We will use the same range of velocities of v_2, and can relate them to v_3 through the flow rate:

$$Q = A_2 v_2 = A_3 v_3$$

The diameter of standard IV tubing ranges from 3-6.4 mm, which we can use to calculate a minimum and maximum area of A_3. We get that v_3 can range from 0-122.07 m/s. This upper limit is quite fast, which is not unexpected as the diameter of the IV tubing is so small. Plotting the pressures in MATLAB, we get:



The pressures generated in the IV tube are much higher than those that occur in the suction tip or in the barrel, and some exceed the limit of 150 mmHg. We will need to keep the diameter of the tubing as wide as possible to reduce the velocity through the tube. If we use the upper limit of the tubing size, 6.4 mm, we can calculate the velocity of the fluid in the tubing (using the same procedure as previously) as 1.22 m/s, a much more reasonable value. If we use this value and vary just v_2, we can plot the resulting pressure:



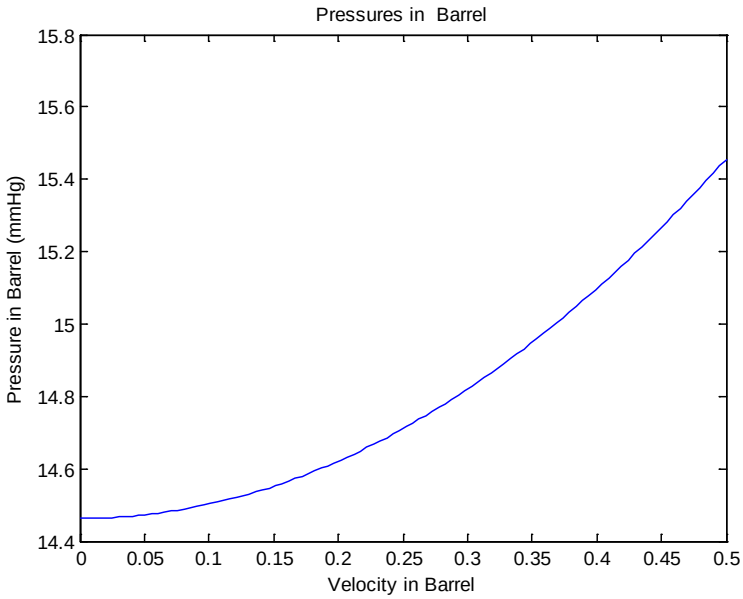
This shows that as long as we use the maximum size tubing in the IV line, we should not generate pressures greater than 150 mmHg.

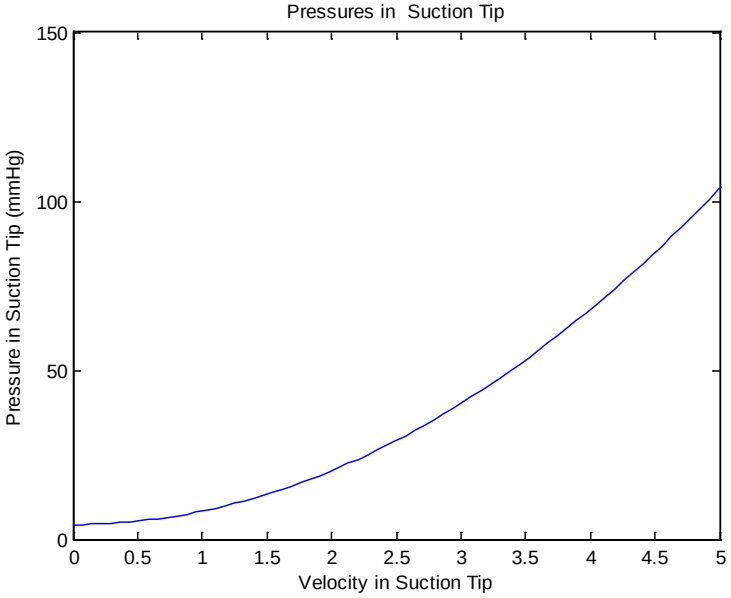
The final parameter to examine is the overall flow rate of blood. We have used the flow rate to equate the different velocities, but have yet to calculate it for the whole device. As the flow rates through the various parts of the device are equal, we can choose any one of them to work with. Let us choose the syringe barrel. As stated previously, we have a radius range of 2-5 cm and a velocity range of 0-0.5 m/s. Returning to the equation for flow rate, we have:

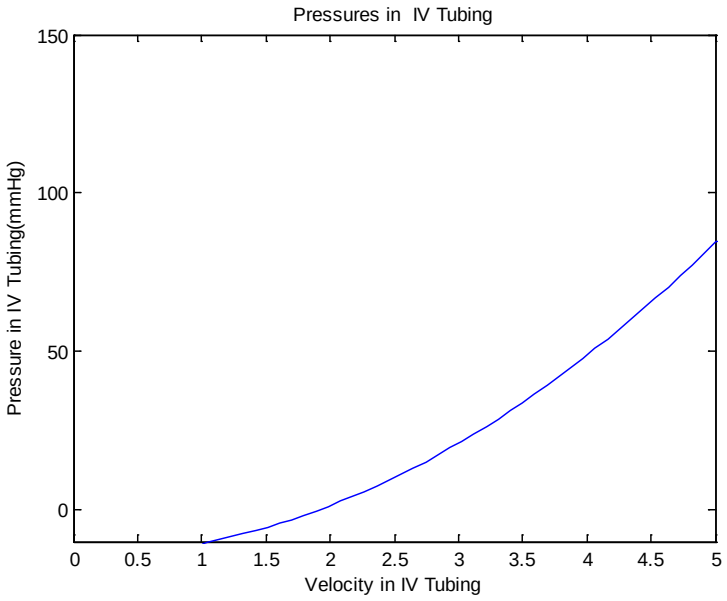
$$Q = A_2 v_2$$

If we plug in the maximum values for the area and velocity, we end up with a flow rate of 23.6 l/min, which is greater than the flow rate defined in our engineering specifications. If we use the smallest area of the barrel and a minimum velocity of .01 m/s, we obtain a flow rate of .75 l/min, which is lower than our defined specification but still a fairly significant rate. As the user will vary the pressure on the plunger, meeting the flow rate specification should not be much of an issue for the geometries used here.

After finalizing the dimensions of the device based on human factors and available stock sizes of materials, we run the analysis again using our specific values. We get:


Pressures in Barrel
Pressure in Barrel (mmHg)
Velocity in Barrel
15.8
15.6
15.4
15.2
15
14.8
14.6
14.4
0
0.05
0.1
0.15
0.2
0.25
0.3
0.35
0.4
0.45
0.5


Pressures in Suction Tip
Pressure in Suction Tip (mmHg)
Velocity in Suction Tip
150
100
50
0
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5



These final plots illustrate the pressures occurring in the various parts of the device. We can see that the pressures are under our 150 mmHg limit. We must realize however, that the analysis does make simplifying assumptions and it is still vitally important that we perform validation tests to experimentally determine that the fluid pressure never gets too high.

12.7 Relevant software analysis

We learned a significant amount from running the material selection analysis in CES. The analysis allowed us to show that we are using the appropriate materials given our mass and cost constraints. Furthermore, CES also allowed us to select the manufacturing process that best fits the materials and tolerances that we require. CES provided information on the cost, speed, and efficiency of different manufacturing processes that allowed us to perform a detailed evaluation

The SimaPro software allowed us to view the environmental impacts of the materials used in our device. We compared the two materials used in our device to one another to assess the environmental impacts. There is a significant environmental impact as a result of our device being disposable (short lifecycle) and the materials used being plastic. The data provided by the SimaPro program has allowed us to evaluate whether the device should be reusable or disposable.

The design for safety program (DesignSafe) provided us the opportunity to thoroughly evaluate all safety considerations during the manufacturing of our prototype. We were also able to assess the risks of certain operations and perform a risk reduction using a list of suggested techniques. After running the analysis and risk reduction, we determined that all of our hazards were of either low or negligible risk severity.

A more detailed discussion of the analysis provided by the software referenced above can be found in Appendix 21.3.

13 Prototype Manufacturing Plan

Our initial prototype device was manufactured in four parts: suction tip, reservoir barrel, blood bag connector, and plunger. We also custom manufactured one swing check valve to fit the large inner diameter of our reservoir barrel. The duckbill valves and the two filters were purchased from third party suppliers.

13.1 Suction tip

To fabricate the tip (Figure 23), we started with a stock 2.5" diameter cast acrylic rod and used a band saw to cut the rod to 2.75" in length. We then mount the rod onto a lathe and finished both ends of the rod, drilled and counterbored the inner diameters (C and D) of the opening in the suction tip. The part was then turned on the lathe and the larger openings (A and B) where the clots will be stored were bored out. The tool post was then moved on an angle with a cutting tool to create the taper (E).

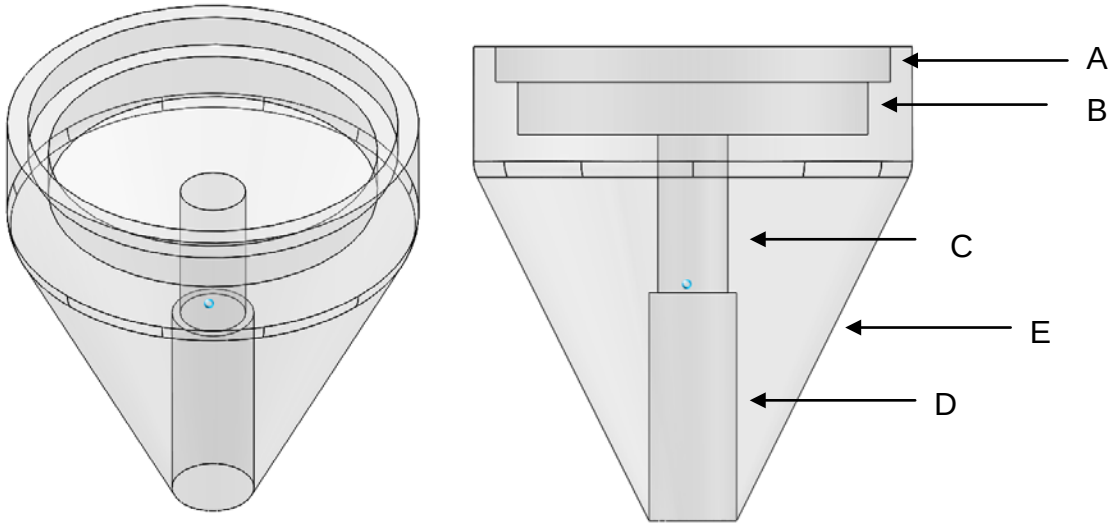


Figure 23: Isometric and side view of tip

13.2 Reservoir barrel

The reservoir barrel (Figure 24) was fabricated in two pieces (A and B) that were glued together using epoxy. We manufacture part A from a standard tube stock of cast acrylic (2.25" ID x 2.5" OD x 1' H). The tube stock was cut to a length of 7.3" using a band saw and then milled to its finished length. One 0.5" diameter hole (C) was milled and reamed to create an interference fit for the blood bag connector. Two 3/16" diameter holes (D) were milled and reamed to create an interference fit for two dowel rods.

Part B was manufactured from a stock 2.5" diameter cast acrylic rod. The length was cut down to 1.3" using a band saw, and then milled to its finished dimensions of 1.15." A CNC mill was used to mill out the inner diameters of 2" (F) and 1.75" (E). To obtain the lip that will support the swing check valve and the fine filter, we used a boring operation on the mill. Once both parts are created, they will be glued together using epoxy.

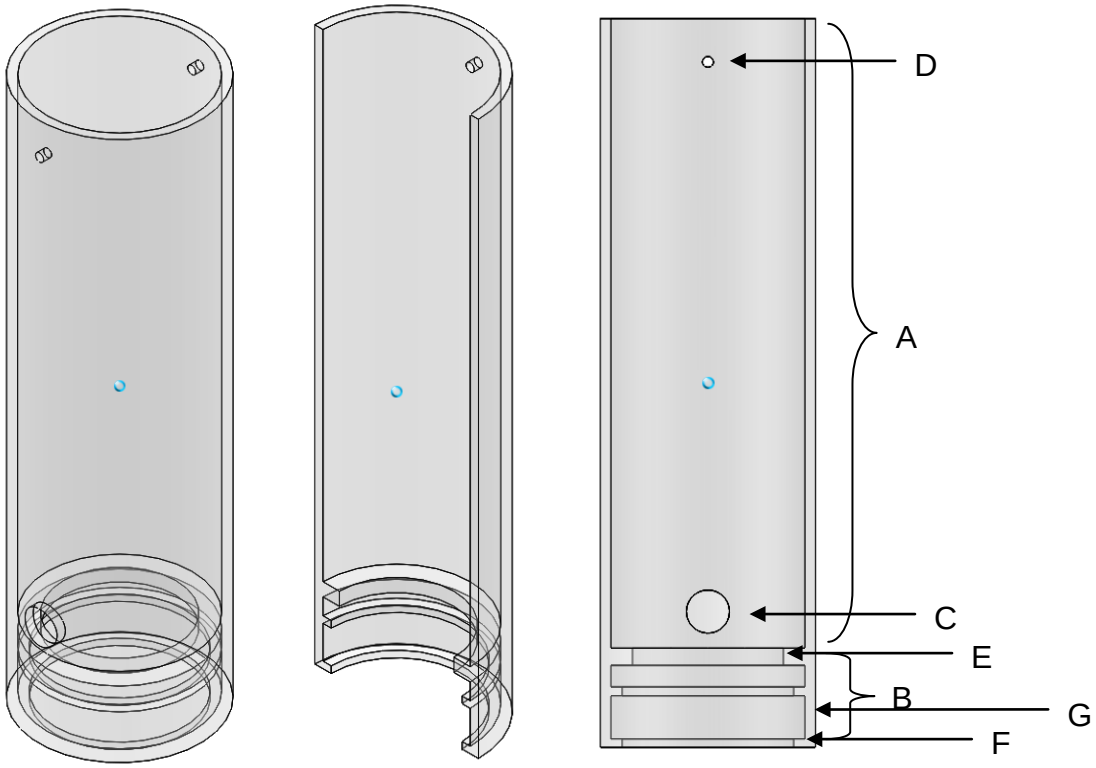


Figure 24: 3D cross section view of reservoir

13.3 Blood Bag Connector

The blood bag connector (Figure 25) can be created using a lathe. A standard stock 0.5” diameter cast acrylic rod was cut to a length of 2.2” using a band saw. This piece was then mounted in the lathe, and the inner diameters (A and B) of the rod were drilled and counter-bored to size. The part was then turned and a cutting edge was used to finish the end of the piece (C) to 0.3”.

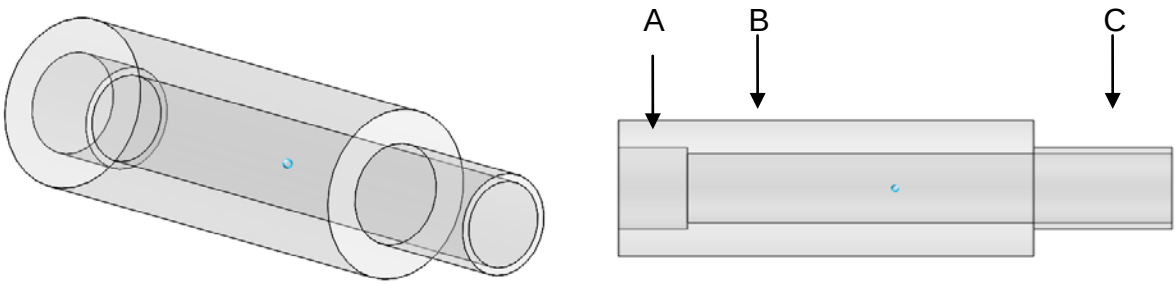


Figure 25: Isometric and side view of blood bag connector

13.4 Plunger

The plunger (Figure 26) for our device is made of complex features that would be difficult to machine in a lathe or mill. We used 3D printing to produce a rapid prototype for this part. The specific machine that was used was a Fused Deposition Modeling (FDM) machine that can produce parts made of ABS plastic. This 3D printer works by laying down material in layers. Plastic filament is unwound from a coil and fed through an extrusion nozzle that toggles the flow of the material. The nozzle is heated to melt the material and can be moved in both horizontal and vertical directions. The thermoplastic material hardens immediately after exiting the nozzle.

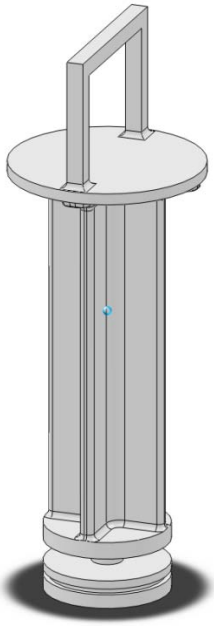


Figure 26: 3D view of plunger

13.5 Swing check valve

We needed to manufacture our own swing check valve (Figure 27) as we were not able to find a ready-made check valve that will fit our internal diameter of 2.25”. The material used to make this valve was 1/8” thick polyurethane rubber with a Durometer of 90A shore. A laser jet was used to cut a circular shape of the valve with an outer diameter of 2.25” and a 330° arc with a diameter of 1.85”.

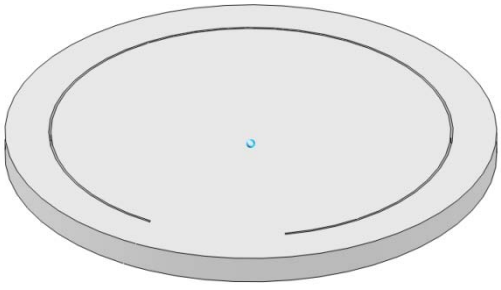


Figure 27: Swing check valve

13.6 Assembly

The duckbill valve was first inserted using interference fit (Part A, Figure 25; Part D, Figure 23) into the suction tip and the blood bag connector. Next, the coarse filter glued onto the lip of the suction tip (Part A, Figure 23). Ideally, the fine filter will then be inserted into the hollow opening of the reservoir (Part G, Figure 24); however, we were unable to attach this filter in constructing our prototype. The swing check valve was then glued to the inner lip (Part E, Figure 24) of the reservoir using epoxy.

Once all of the internal accessories were fixed, the suction tip, reservoir and blood bag connector were assembled using epoxy. When the epoxy dried, the o-ring was attached to the plunger and then inserted into the top of the reservoir. Finally, the dowel pins were press fit into the openings (Part D, Figure 21) on the reservoir barrel.

14 Final Design Mass Manufacturing Plan

The manufacturing process that we selected for the production of our housing (polypropylene) and plunger (COC) is injection molding. Injection molding is a quick manufacturing process that can yield the 100,000 units per year needed to meet demand. It can meet a production rate of 60 to 3000 units per hour. Although the capital cost is high initially ($10,000 for the initial mold), we can expect to distribute this cost amongst the large volume of units manufactured. Injection molding is also an ideal process considering the tight manufacturing tolerances needed in the barrel of the syringe—to create the seal necessary with the o-ring, the inside diameter in the barrel must be consistent to within 0.001”. Therefore, extrusion processes will not work to create tolerances needed. Both parts (housing and plunger) are symmetrical around one axis and can be easily injection molded.

The barrel will need to be injection molded in two parts: reservoir and suction tip. The blood bag connector can be attached in the mold of the reservoir. However, the suction tip and the reservoir will need to be separate pieces, as the filters and check valves will need to be inserted into the device prior to sealing it. Once the suction tip is molded, the fine and coarse filters will be inserted into the respective cavities and affixed using an adhesive. The large one way check valve and duckbill valves for the blood bag connector and suction tip will then be attached using a silicone adhesive. Once the filters and valves have been attached, the suction tip and reservoir can be connected together using a solvent adhesive.

The plunger can be injection molded in a single part. The o-ring will then be placed into the slot in the plunger and silicone lubricant applied to allow for smooth operation. The final step for assembly will be placing the c-clip on the top of the reservoir to ensure that the plunger cannot be accidentally removed during operation.

15 Validation

Our final design met all but one of our user requirements (Table 8). The one requirement which was not met was that the total blood collected be measured to within ±10 mL. We could potentially add markings on the outside of the reservoir which would allow the user to visually recognize the amount of blood that has been collected and filtered. However, since we are

connecting the device directly to a blood bag, the more logical way to measure the amount of blood collected would be to track the number of blood bags filled.

Table 8: Validation of user requirements

	User Requirement	Engineering Specification	Validation	
Quality	Removes particulate matter	≥ 170 μm in diameter Filtering efficiency of 98%	Not required Not required	
	Does not damage cells	< 150 mmHg pressure	Yes (Theoretical)	See fluids analysis (12.6)
Safety	Closed system	0 openings to environment	Yes	Closed submersion test resulted in no leaking
	Noticeable if malfunctions	Force on plunger >45 N	Yes	Fully clogged force of 75±20 N
	Durable	Withstand drop from 2 m	Not relevant	Different material used in prototype and final design
	Can manage significant blood loss	≥ 2 L blood loss	Yes	Functional validation tests with 2L of water
Function	Flow rate removes blood sufficiently	≥ 0.5 L/min	Yes	Functional validation tests yield a flow rate of 1.6±1.0 L/min
	Measures total blood collected	≤ ±10 mL accuracy	Not validated	
	Easy to operate	Training time < 30 min	Yes	Users received < 5 minutes of training
		1 operator required	Yes	1 operator was used for functional validation tests
		< 5 steps for operation	Yes	Less than 5 steps were required
		Force applied ≤ 48 N	Yes	Force applied to start movement of the plunger was 35±10 N
		Diameter of grip ≤ 3 in.	Yes	Diameter = 2.5 in
	Low cost	$10-15	No	See cost analysis (9.3.4)
	Compatible with or replaces blood transfusion kit	≥ 20 drops/min infusion rate	Not required	
		≤ 450 mL blood bag volume	Yes	Reservoir holds up to 488mL of fluid
		Compatible with 3mm tubing on blood bag	Yes	Blood bag can be attached using an adapter
	Quick to operate	Set-up time of < 2 min	Not validated	No blood bag available to test
		Time to first transfusion is ≤ 10 min	Not validated	

Small and portable	≤ 15.5 kg filled	Yes	920±80 g
Quiet	Operating level ≤ 50 dB	Yes	The noise from the device could not be detected as it was less than the ambient noise in the room

15.1 Functional validation

Functional validation tests were performed by two separate groups. In the first, trained users processed 2L of water through the device. The time to process was recorded, and the procedure was repeated ten times for each user. The processing time significantly decreased over the first 4-5 trials, but reached a stable point of 60±15s over trials 6-10. This indicates that the device has a maximum potential comfortable flow rate during operation which is acceptable based upon the relevant specification (≥0.5 L/min).

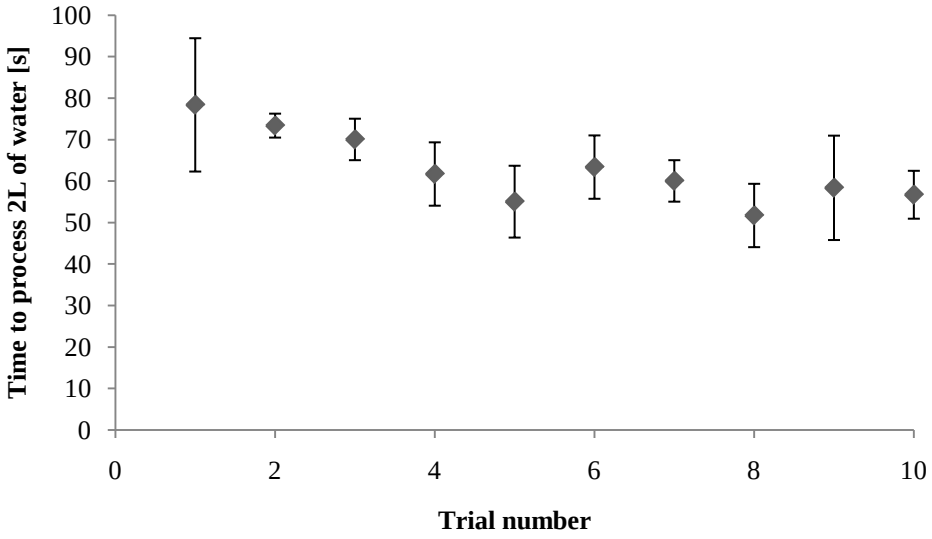


Figure 28: Time needed to process 2L of water over multiple trials (N=3)

The second group processed 1L of water twice without any training (Table 9). Time to process significantly decreased after only one use, even without any formal training.

Table 9: Process time for users with no formal training

	Mean time [s]	Mean flow rate [L/min]
First use (N=21)	40±20	1.6±1.0
Second use (N=44)	30±10	2.0±0.8

For both groups, the time needed to process 2L of water and the average flow rates meet our specifications of ≥ 0.5L. Furthermore, the device has been shown to be capable of processing 2L of liquid, can be operated by a single user, and requires less than 30 minutes of training time (since users unfamiliar with the device were able to operate it after only a brief, 5 minute conceptual description of the concept). Additionally, because the device is disposable, it would be presented to users fully assembled, so the only steps involved in readying it for use would be to connect it to the blood bag.

A force gauge was used to measure the force needed to draw the plunger back when the device was fully submerged in water. The measured force was 35±10 N, which meets our specification of ≤ 48 N. Additional testing was performed, in which the tip of the device was fully clogged, and the force needed to pull back the plunger was measured. This resulted in a force of 75±20 N, which is significantly higher than the unclogged pulling force, and is noticeable to the users.

15.2 Human factors validation

The human factors associated with the device operation were tested through the use of a short survey. Subjects were asked to operate the device by processing 1-2L of water and then completing a survey regarding the comfort and ease of use. Subjects performed the operation twice; once to gain familiarity with the device (as novice users), and a second time as experienced users. The results of the survey are shown below. A score of 5 indicates that users strongly agree and a score of 1 indicates that they strongly disagree.

Table 10: Human factors validation results (N=16)

Human Factors Survey Results	Mean Rank out of 5
Device was easy to use	4.2±1.0
Device was comfortable to hold	3.7±0.8
Handle was comfortable to hold	3.9±0.5
Was fatigued after completing the task	1.7±0.9

Shown in Table 10, users found the device easy to use, with a strongly positive ranking of 4.2±1.0. On comfort of both the device as a whole, and more specifically the handle, users had neutral to positive rankings of 3.7±0.8 and 3.9±0.5, respectively. This would indicate that a redesign of the device, and especially the handle, which weighs the human factors more heavily should be considered. Regarding the ease of operation, users ranked their fatigue after use as low to very low, with a score of 1.7±0.9.

Additionally, more open questions were included in the survey. Specifically, we asked the users how long they thought they could operate the device without becoming fatigued; what would make the device easier to use; what would make the device more comfortable to use; what was the least comfortable part of using the device; and whether they would prefer an alternate handle design. For the last question, we fabricated two additional handles, a T-grip and a knob (Figure 29).

Figure 29: T-grip and knob alternate handle designs

Users reported a wide range of projected times for operating the device without fatigue, ranging from 30 seconds to 2 hours. The average time was 20 minutes, which is significantly longer than we would expect the device to be in operation (a specification of 5 minutes was set previously in section 5.3).

Common comments regarding the ease and comfort of the device included the need for a grip on the barrel; a splash guard to prevent liquid from exiting through the back of the barrel (this happened frequently when the plunger was jerked, breaking the seal between the o-ring and the barrel); and a more ergonomic design of the existing handle. Specifically, users preferred the T-grip handle design over the knob and the current square handle, although many commented that a more ergonomically designed version of the current handle would be ideal (a curved rather than square fit, rounded edges).

16 Design Critique

During the validation of our device, several design critiques were determined. We divided these critiques into two categories: user critiques and functional critiques. User critiques were provided to us by survey respondents and functional critiques were determined based on our engineering judgment during the use of the device.

16.1 User Critiques

The two user critiques that were consistently mentioned in the surveys were the comfort of the plunger handle and the lack of a grip on the reservoir. The current plunger handle is a rectangular grip that forces a user into a certain hand orientation that may not be the most ideal position for reducing fatigue. Furthermore, the plunger handle had several sharp edges which reduced the comfort in holding the device.

The lack of a grip on the reservoir was the second user critique. During our validation tests with water, some residual water would frequently splash on the barrel of the device, making it very slippery during operation. Users would often grip the blood bag connector or the tip of the device to get an adequate hold on the device during operation.

16.2 Functional Critiques

Three functional critiques were determined during our validation testing: poor fitting of the duckbill valves, custom fit of the fine filter, and residual fluid left in the suction tip after use. The duckbill valves were attached to the device using superglue adhesive that bonds to rubber surfaces. However, after a few uses of the device both duckbill valves (at the suction tip and blood bag connector) became loose and fell out of the seats.

The fine filter (170µm) that we obtained from a free sample of an arterial blood filter did not fit to the dimensions of our filter compartment. The filter mesh was also very thin and could not be adequately secured to the housing. Since the filtering capacity was severely diminished due to the poor fitting, we removed the fine filter during operation and validation testing.

Residual fluid in the suction tip between the duckbill valve and the swing check valve amounted to 150mL after 2L of water was removed from the reservoir. This is a substantial amount of fluid that was left within the suction tip that did not pass through the filtering chamber. If this residual fluid had been blood, it would need to be discarded as it would not have been filtered.

16.3 Recommendations

16.3.1 Plunger Handle Design

We propose that the two alternate handle designs discussed previously be further evaluated, in addition to the rectangular grip. The knob and t-grip (Figure 29) are two grips that we believe may be more ergonomic by allowing the user greater flexibility in selecting a grip orientation.

16.3.2 Reservoir Grip

A rubber grip can be placed over half the circumference of the reservoir barrel that will give the users a better hold on the device during operation. The rubber grip should have indentations that allow fingers to fit comfortably without slipping. Additionally, it might be possible to reshape the barrel itself to create a better fit.

16.3.3 Mechanical Fitting of Duckbill Valves

We contacted the manufacturer of the duckbill valves and obtained additional information on attaching duckbill valves to a medical device. The manufacturer provided us with specifications for a mechanical fitting of duckbill valves. The mechanical fitting consists of a seat where the lip of the valve will sit and a mate that fits into the seat to compress the lip of the valve. Once the lip of the valve is compressed, the duckbill valve will not fall out of place unless the mate and seat become loose.

16.3.4 Reduction of Volume in Filtering Chamber

The 150mL residual fluid that is left within the filtering chamber can be reduced by decreasing the volume in the chamber. The volume of the chamber is primarily determined by the size of the filters, so reducing both their overall size (not pore size) and the space between the coarse and the fine filters is key.

17 Challenges and Recommendations

17.1 Broad Challenges

17.1.1 Design for Resource-Limited Settings

Background: We encountered many challenges working on a medical device within the constraints of designing the device for resource-limited settings. The device must ultimately be sustainable in the segment that we are targeting. Sustainable technologies in this must be low cost and maintenance, composed primarily of locally available materials, and environmentally and culturally sustainable. During our one month ethnographic study, we were able to find

preliminary requirements and specifications addressing the issue of sustainability; however, our group does not have a complete understanding of the background of some of these specifications.

We attempted to remain in contact with local mentors to continually refine our user requirements and specifications as they fit with the topic of a sustainable technology. We completed a preliminary survey of locally available materials and manufacturers while in-country. Each design report was sent to multiple local health care workers to ensure that our design remained in line with their expectations.

Recommendation: This component of the design process was one of the most challenging. Logistical challenges prevented us from maintaining close contact with our local mentors and other contacts. Phone calls were difficult to schedule and email responses were often not received until several weeks later. If another group plans to complete a project in collaboration with a local team or mentor, they should make every effort to develop a close relationship while in country, which should help to facilitate a continued working relationship once the team has returned to the US. Additionally, we found that it was often easier to contact people who were not particularly high up in the hierarchy of the health care system, as they frequently had more free time and were more willing to spend that time advising us than, for example, senior physicians.

17.1.2 Regulatory

Background: The autologous transfusion device that we designed is classified as a Class II medical device by the FDA (21CFR868.5830). Class II medical devices present a unique set of challenges in regards to the design of the device. These devices must include specific labeling requirements and mandatory performance standards to ensure patient and operator safety, which will drive the design of our device. Additionally, medical device export laws and international medical device regulations for countries that our device may be applicable in.

To help us with our challenges specific to medical device design, we require assistance from experts that have worked with medical devices in the past and have had experience working with the FDA and preferably international medical device regulations. We will design our device considering the impact of the FDA regulations in our specifications while continuing to research international regulations and revising our user requirements and engineering specifications as needed. We have contacted the International Transactions Clinic at the UM Law School, whose clients include providers of products at the base of the pyramid in emerging markets. Julia Papastavridis is our contact in the clinic, and is currently examining some of the regulatory issues surrounding the design and implementation of our device.

Recommendation: Despite promising initial conversations, our contact with the International Transactions Clinic has been minimal at best during the semester. We should have made more attempts to interact with them and explain our situation so that we could fully utilize the resources they might have provided. As of now, we have only minimal knowledge of FDA regulatory procedures, and no knowledge of export law.

17.1.3 Scope of Clinical Settings

Background: During our one month ethnographic study at KATH, we identified our user requirements and engineering specifications as it related to our users at a main referral hospital in Ghana. However, in our initial research we have identified an additional scope of use in district

hospitals present in developing countries that may not even have a current procedure for autotransfusion. We would like to include district hospitals in resource-limited settings within the scope of our project, but face the challenge of identifying user requirements and engineering specifications as they relate to users in these district hospitals.

During the semester, we researched the potential scope of use in district hospitals and the facilities available at these hospitals. Our contact at a district hospital in Ghana has stated that since 2005 there have been only 5 cases of ectopic pregnancy in her hospital. When a case occurs, the patients undergo surgery with blood transfusion units provided by blood donation from relatives, since there is no blood bank at the district hospital. Since this is anecdotal data from only one hospital, we are continuing to investigate the situation at district hospitals to determine whether this situation is representative of the country as a whole. Should we find that ectopic pregnancy rupture is a major issue in the rural hospitals, we will attempt to obtain sufficient information about the feasibility of such a device in district hospitals such that we can begin to translate these details into user requirements and engineering specifications.

Recommendation: While in-country, it would have been very useful for the entire team to obtain first-hand experience of more rural and district hospitals. Instead, only one member of the team had ever visited a district hospital, and we had limited contacts in those environments. As a result it was often difficult for the team to design around users with whom we had never had any contact.

17.1.4 Engineering Specifications

Background: Our user requirements and engineering specifications were largely defined with no specific design in mind. However, many of the original requirements imposed design constraints (such as being electrically powered), and about half of them were focused on things which became irrelevant after the move to a disposable, human-powered device rather than a reusable, electrical one.

Recommendation: A broader definition of the user requirements would have been helpful during the initial brainstorming phase. Some of the requirements (such as the rate at which blood should be removed) were defined this way and others (such as electrically powered) were not. Because of this, when we moved to a disposable design, we were forced to radically adjust a number of requirements, which required significant investments of time and research.

18 Summary and Conclusions

The lack of blood available for transfusions in the developing world is a critically important challenge that will require solutions from multiple disciplines. Likewise, ruptured ectopic pregnancy is a true obstetric emergency and is the largest contributor to maternal mortality in the first trimester of pregnancy. We believe that there is a true need for an autologous blood salvage device that can help address the lack of donated blood and improve outcomes for patients. We focused on ruptured ectopic pregnancy as a case study for the use of this device.

We generated our design requirements through an extensive interview process conducted with physicians, nurses, midwives, and technicians at Komfo Anokye Teaching Hospital in Kumasi, Ghana. These requirements were rank ordered through the use of surveys (Appendix 21.12). We

then translated these requirements into engineering specifications. These specifications were verified against the literature and current devices that perform similar functions.

The two most important categories of design requirements and engineering specifications are safety and functionality concerns. It is vital that the patient not experience any serious complications as a result of using this device. At the same time, the device is also required to remove, filter and transfuse the lost blood in a timely manner. Creating a balance between these two broad-level requirements is essential in creating a feasible design.

The concept generation phase of the design process comprised both component- and system-level brainstorming. Our alpha design concept, which we dubbed the "giant syringe" emerged from this process. We have since undergone multiple iterations in the evolution of the design to produce our final design. The overall function of the original alpha design has been retained. The final design includes three check valves, which provide greater control over fluid movement; an o-ring to create an airtight seal between the plunger and the reservoir housing; and a hollow, tapered tip which is used to store larger clots that are caught by a coarse internal filter before blood passes through an additional fine internal filter. Physical comfort for the operator was also addressed, with the main reservoir diameter size fitting to the 5^{th} percentile adult female hand size, and the inclusion of a plunger handle.

The tip of the device is inserted into the body cavity during a surgical procedure and the plunger pulled back to remove the blood, which passes through two internal filters and into the main reservoir of the syringe. On the down stroke of the syringe plunger, a check valve prevents blood from passing back out through the tip; it is instead diverted through an outlet and into a blood bag, which is protected by a second check valve. Once in the blood bag, the filtered blood will mix with anticoagulant, and the filled bag can be hung on an IV stand for transfusion.

Validation testing has proven the functionality of our initial prototype, with mean flow rates of 1.6±1.0 L/min and 2.0±0.8 L/min for novice and experienced users, respectively, without any formal training. Additionally, the device was shown to be capable of processing 2L of liquid, can be operated by a single user, and requires less than 30 minutes of training time. Because the device is disposable, it would be presented to users fully assembled, so the only steps involved in readying it for use would be to connect it to the blood bag.

Human factors testing revealed that while users were comfortable with the overall function of the device, there is room to improve in the design. Specifically, further analysis and redesign of the handle is recommended, as well as the addition of a grip or handle of some sort on the reservoir barrel, which will provide greater comfort for the user during operation of the device.

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20 Biographies

Theresa Fisher

Theresa is a 5th year undergraduate student in the College of Engineering at the University of Michigan. She is currently pursuing a Bachelors of Science in Engineering degree in Mechanical Engineering with a focus on international engineering and global health design. She was attracted to Mechanical Engineering because of its broad scope and applicability to many different fields. Theresa has previously interned with Mainstream Engineering Corp. and RWTH Aachen University, working primarily in research and design. She plans to pursue a graduate degree focusing on global health design and the use of technology in social entrepreneurship at the base of the pyramid. Theresa's free time is spent playing rugby, reading, and traveling.

Alexander Hobbes Harrington

Alexander is a 3rd year undergraduate student in the College of Literature, Science, and the Arts at the University of Michigan. He is currently pursuing a degree in Sociology while performing academic work in efforts of attending medical school and obtaining a MPH after graduation. Alexander is trying to bring an alternative and multidisciplinary view to the engineering design process to address maternal health injustices with public health and cultural understanding. His own interests concern addressing global health challenges and disparities through medicine, women empowerment, education, policy, social action, and sustainable partnership development, but understands medical devices and technology are a vital component in addressing these complex and important issues. Alexander is attracted to the issues of maternal health, environmental health, and social justice in the global health realm with a focus on Africa and the Middle East stemming from his experiences throughout Ghana and the USA in recent years.

Rajen Kumar
Rajen Kumar is a 4th year undergraduate student in the College of Engineering at the University of Michigan. He is currently pursuing a Bachelors of Science in Engineering in Mechanical Engineering with a focus on sustainable medical device design for resource-limited settings. Mechanical Engineering attracted him by allowing him to pursue many different career paths and obtain a solid background in the Engineering Sciences. Rajen has held two previous internship positions at GE Healthcare and Ford Motor Company. His professional interests lie in the design and marketing of medical devices, and the promotion of sustainable technologies for the base of the pyramid. In the future, Rajen's professional plans are to remain active in the healthcare industry and combine his skills in engineering with an interest business and marketing. Rajen's personal ventures lie in traveling, playing sports, reading, and taking long walks on the beach.

Caitlin Winget
Caitlin Winget is a 4th year undergraduate student attending the University of Michigan's College of Engineering as a Biomedical Engineering major. She was initially drawn to biomedical engineering for the strong connection to the clinical applications of engineering knowledge. Caitlin has spent time working in both academic research and industry. She spent a summer at a Research Experience for Undergraduates (REU) program funded by the National Science Foundation as well as this past summer as an intern at Abbott Laboratories. She continues her interest in research during the school year working in the Biotransport Lab. She is very interested in continuing to work in a clinical setting and learning the complexities involved with design, especially in developing countries as it relates to global health. Caitlin enjoys running, swimming, cooking and traveling in her free time.

21 Appendices

21.1 Bill of Materials

Part #	Description	Manufacturer	Cost
VL 235-112	Duckbill valve	Vernay Laboratories, Inc	$0 (free sample)
VL 614-112	Duckbill valve	Vernay Laboratories, Inc	$0 (free sample)
1CX*AF125X	Capiox Arterial Line Filter, 37 microns, with X Coating	Terumo Cardiovascular Systems	$0 (free sample)
8486K353	Clear Cast Acrylic Tube 2-1/2" OD x 2-1/4" ID	McMaster-Carr	$17.96
8528K41	Clear Cast Acrylic Rod 2-1/2" Diameter	McMaster-Carr	$33.07
109	2-1/4" OD Silicone O-Ring	Carpenter Brothers	$0.49
97155A413	3/16" OD Dowel Pin	McMaster-Carr	$3.11
8716K164	1/8" Thickness Polyurethane rubber sheet	McMaster-Carr	$12.95
N/A	3/8" ID Polyurethane Tubing, 3' length	Carpenter Brothers	$2.25
9227T412	Aluminum Woven Wire	McMaster-Carr	$7.44

	Cloth, 20 X 20 Mesh, .016" Wire Diameter		
		Total	$77.27

21.2 Description of Engineering Changes since Design Review #3

There have been several minor design changes since DR3, which came about primarily in the prototyping process due to availability of materials. These are listed below.

- Dimensions and material of the dowel pins
  - New diameter: 3/16" (old diameter was 1/8")
  - New material: stainless steel (old material was plastic)
  - New length: ½" (old length was ¼")
- Removal of the duckbill valve in the blood bag connector
  - The glue holding this valve in place failed during testing. Our solution was to purchase a three foot length of tubing and attach it with a hose clamp to the end of the blood bag connector. This tubing had to be manually plugged during testing but allowed us to complete validation testing.

21.3 Materials Selection Assignments

21.3.1 Functional Performance

21.3.1.1 Syringe Housing

Material Index $M = \frac{E}{\rho}$

Design requirement for the housing

Function: Act as a reservoir for the fluid coming into the device and allow the plunger to pass through
Objective: Minimize the mass
Constraints: a) Length L specified
b) Cost < $5/lb
c) Density < 0.0358 lb/in^3
d) Only thermoplastics for injection molding
e) Vickers Hardness > 7 HV

Top 5 Material Choices as identified by CES:

1) PE-HD (general purpose, molding)
2) PE-UHMW (molding and extrusion)
3) PMP (general purpose)
4) PP (homopolymer, 10% mica)
5) PP (homopolymer, 10% glass fiber)

Out of these top 5 material choices, we choose Polypropylene (homopolymer, 10% mica). This material is commonly used in medical components and can be injection molded, which is likely the manufacturing process that will be used for this device. Furthermore, the Young's modulus

is between 0.262-0.279 x 10^6 psi so this material can withstand the pressure loading on the housing from the external hand force. The Vickers hardness of the material is also above the specified value of 10.2 HV.

21.3.1.2 Plunger

Material Index $M = \frac{\sqrt{E}}{\rho}$

Design requirement for the Plunger

Function: Used as a piston for volume expansion and contraction to create a vacuum that will draw fluid into and out of the syringe.
Objective: Minimize the mass
Constraints: a) Length L specified
b) Cost < \$5/lb
c) Density < 0.0385 lb/in^3
d) Only thermoplastics for injection molding
e) Vickers Hardness > 7 HV

Top 5 Material Choices as identified by CES:

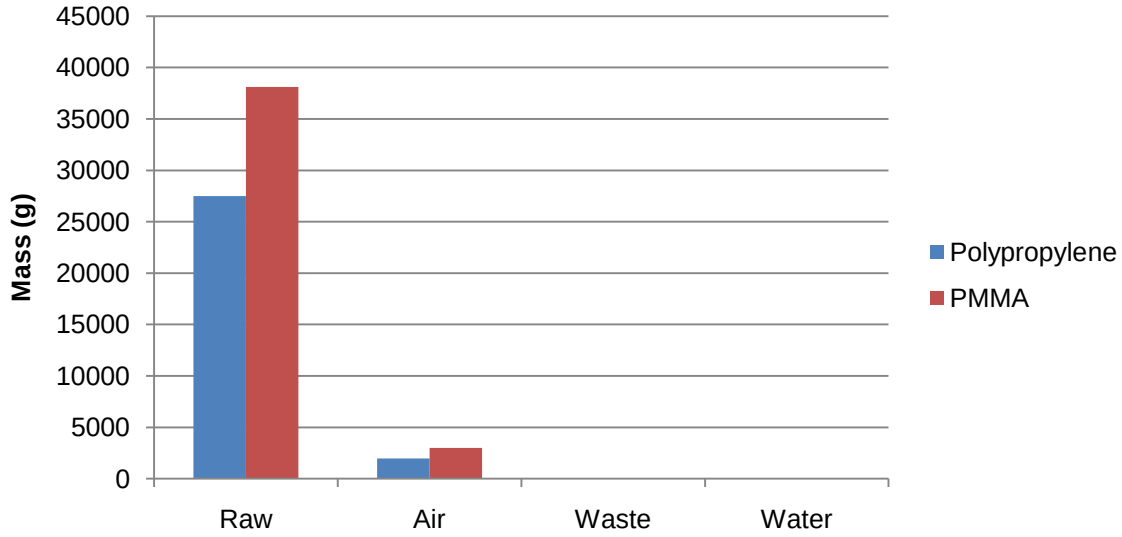
1) PP (homopolymer, 20% glass fiber)
2) PMP (10-30% glass fiber)
3) COC (general purpose)
4) ABS (Injection Molding, Platable)
5) PP (homopolymer, 10% mica)

Out of these top 5 material choices, we choose COC (general purpose) which is commonly used in medical devices and is inert with blood. The COC can be obtained in pellet form which makes this material ideal for injection molding. This material has a high tensile strength of 9.09 ksi so it can withstand the tensile strength being applied to the material when the plunger is pulled upwards. The material also has a compressive strength of 10.9 ksi so it can withstand the compressive forces being applied to the material when the plunger is pushed downwards. The Vickers hardness is between 8.36 – 9.35 HV which is above the constraint limit.

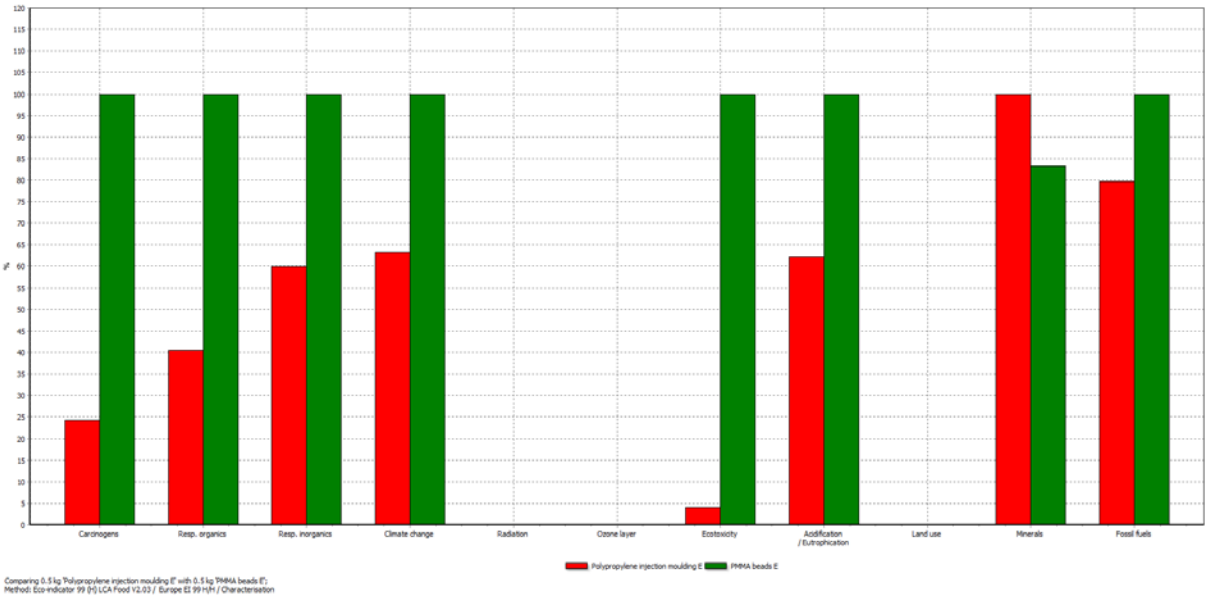
21.3.2 Environmental Performance

In our final design, we will require a mass of 0.5 kg of polypropylene and 0.5 kg of PMMA. These are the mass values that were used in our environmental performance calculations.

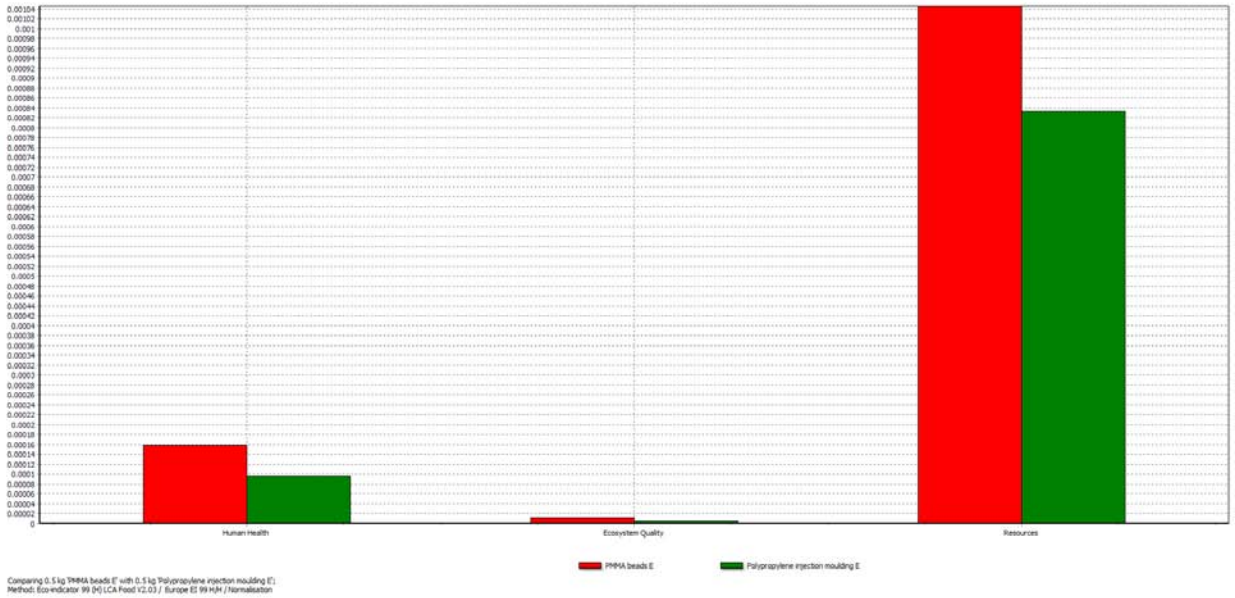
Excel graph of total emissions:



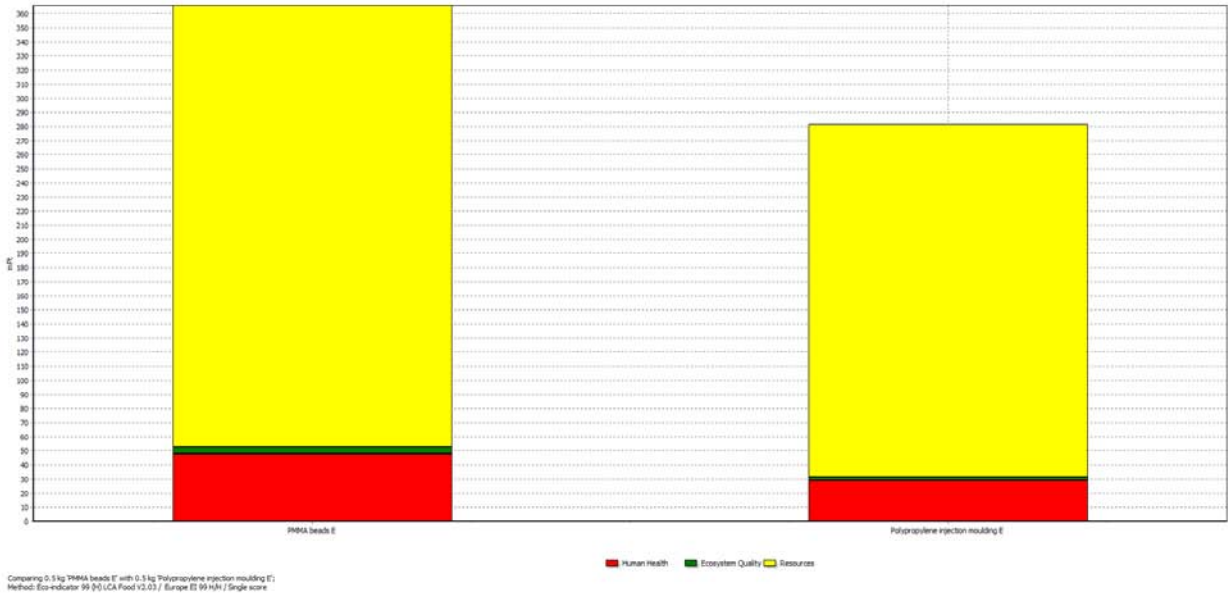
Relative Impacts in Disaggregated Damage Categories:



Normalized score in Human Health, Eco-Toxicity, and Resource Categories



Single Score Comparison in “Points”



The PMMA (equivalent to the COC polymer) has a bigger impact on the environment within all four of the EI99 damage classifications. This material also has the highest EI99 point value and is likely to have a bigger impact when the life cycle of the whole product is considered. The main resource that is used in substantial quantities during the manufacturing of PMMA is water.

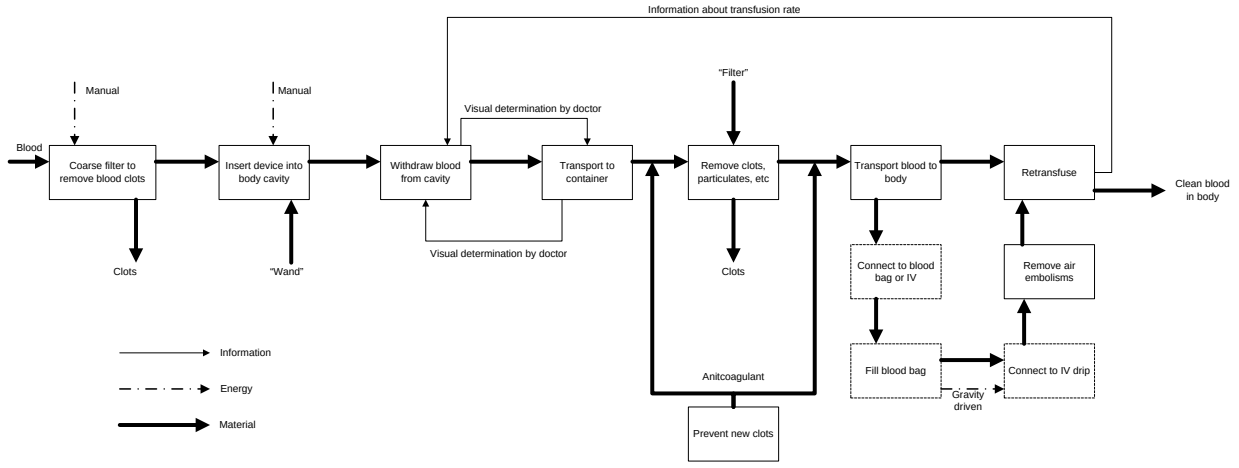
The lifecycle of this device in use would be at most 1 procedure as a disposable medical device. Therefore, the impacts of the PMMA polymer in the device lifecycle would have a substantially greater impact than the COC polymer. However, these two plastics fit within the environmental impact range of all plastics. Therefore, we would not need to select a different material based on this analysis. Furthermore, these are two plastics that are biocompatible with blood that is present in our device.

21.3.3 Manufacturing Process Selection

We have determined the real-world production volume for our project to be 100,000 units per year based on the incidence of ruptured ectopic pregnancies in the developing world.

The manufacturing process that we have selected for the production of our housing (Polypropylene) and Plunger (COC) is injection molding. Injection molding is a quick manufacturing process that can yield the 100,000 units per year needed to meet demand. It can meet a production rate of 60 to 3000 units per hour. Although the capital cost is high initially (~$500K), we can expect to distribute this cost amongst the large volume of units distributed. Injection molding is also an ideal process considering the tight manufacturing tolerances that we need in the barrel of the syringe. To create the seal necessary with the o-ring, the inside diameter in the barrel must be consistent. Therefore, extrusion processes will not work to create tolerances needed. Both parts (housing and plunger) are symmetrical around one axis and can be easily injection molded.

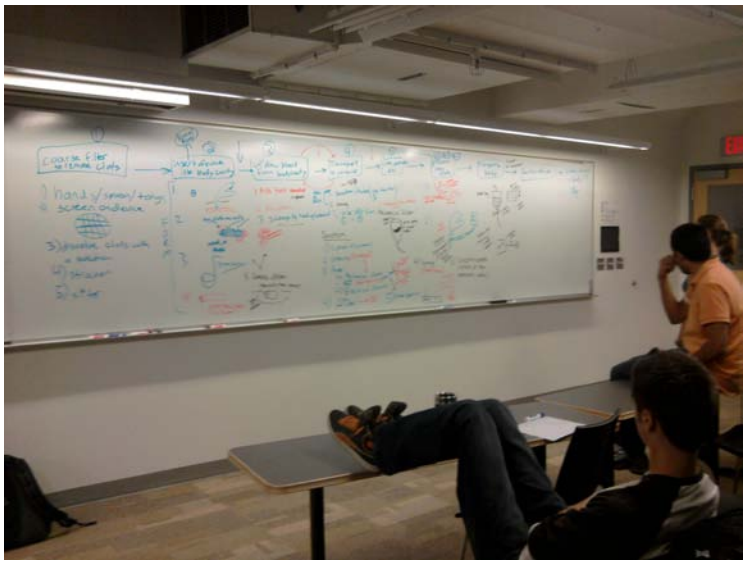
21.4 Functional Decomposition



21.5 Brainstorming

21.5.1 Brainstorming Overview

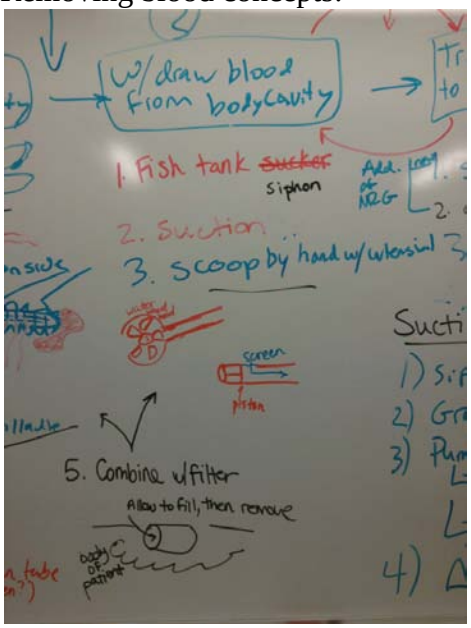
Concept generation was conducted in multiple phases, consisting of both systems-level and individual component-level brainstorming sessions.



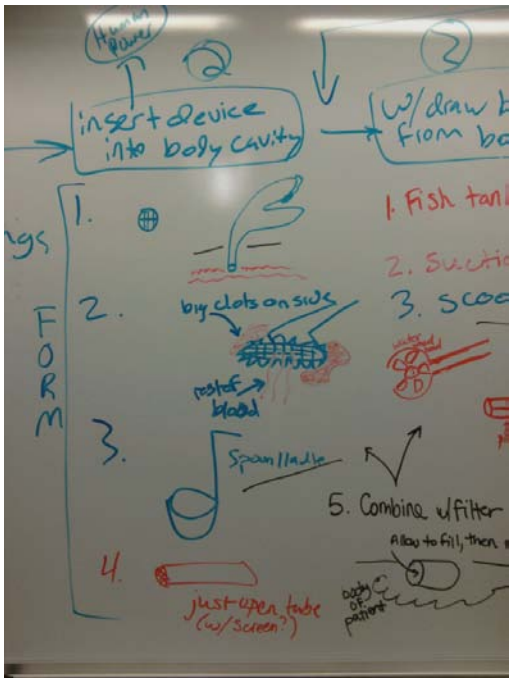
21.5.2 Component-Level Concepts Brainstorming

We conducted multiple brainstorming sessions for individual components based on the functional decomposition of the device. The images below show the results of the primary component-level brainstorming session.

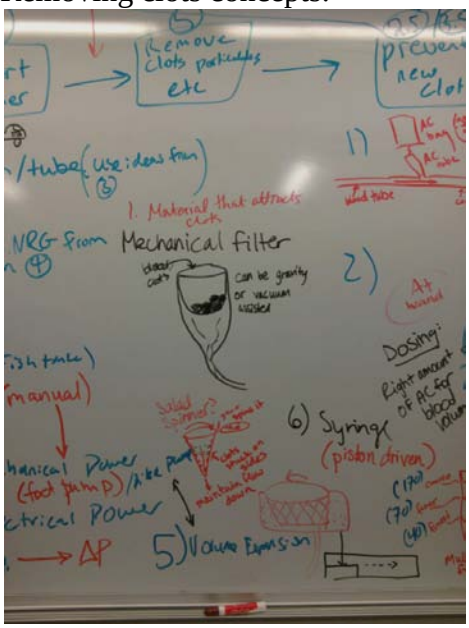
Removing blood concepts:



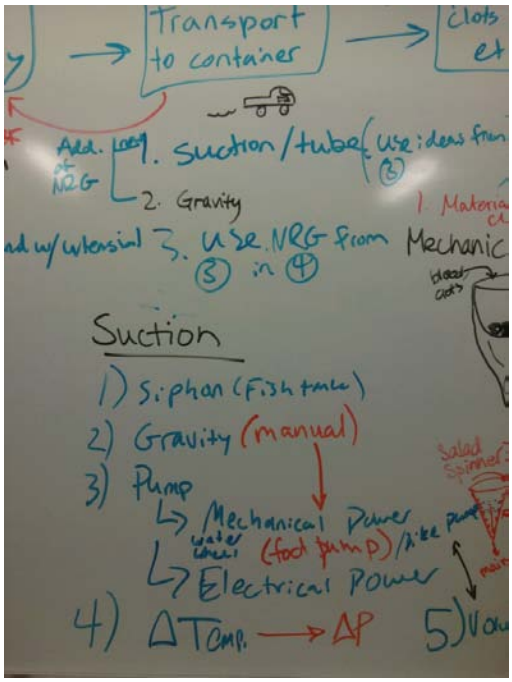
Insert device into body cavity concepts:



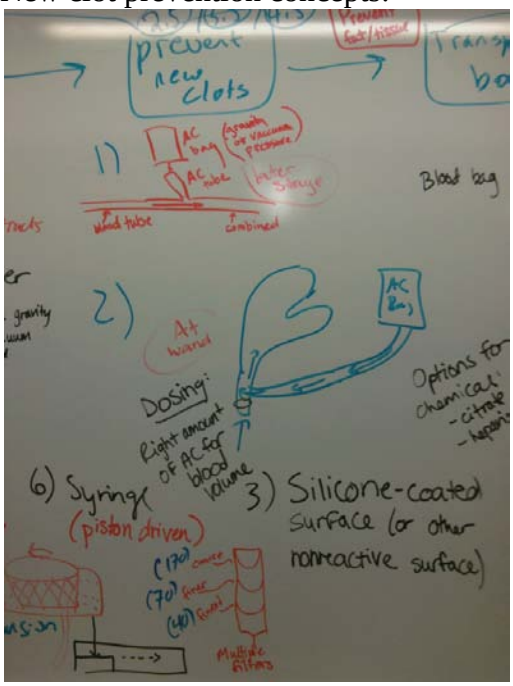
Removing clots concepts:



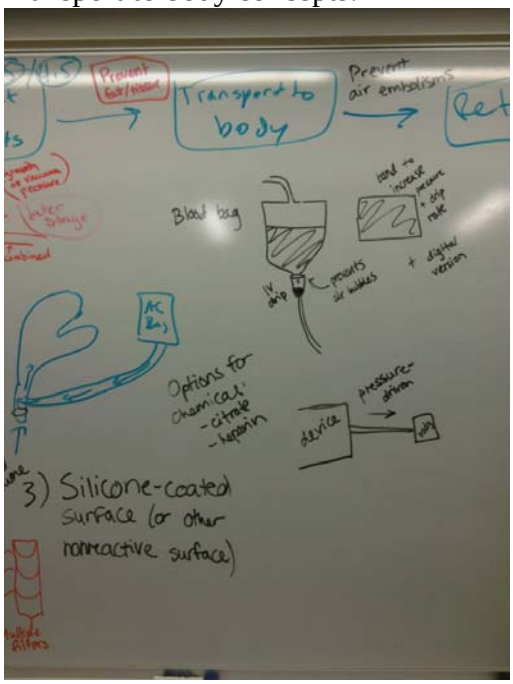
Transport to container concepts:



New clot prevention concepts:



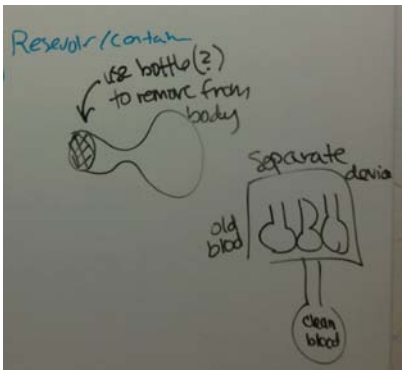
Transport to body concepts:



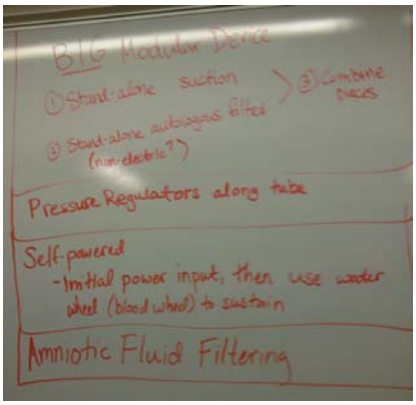
21.5.3 Systems-Level Concepts Brainstorming

Additional brainstorming sessions focused on systems-level concepts, in which we attempted to create an entire system which would accomplish all of the functional tasks without breaking up the functions into individual components.

Modular concept:



Separate insertion/filtration devices:



21.6 Pugh Chart

The Pugh chart was developed as a method for comparing the many concepts that resulted from our brainstorming sessions. The chart was broken down into eight functional components which were compared on a weighted scale based on the rank of the user requirements and their relevance to each component.

21.6.1 Remove large clots

Design Criteria	**Weighting Factor**	Hands/Spoon/ Tongs	Screen on Device	Dissolve with solution	Strainer/ Sifter	Clot Sword
Removes clots, microaggregates	0.93	-1	0	-1	0	0
Does not cause cell damage	0.86	0	0	-1	0	-1
Closed system	0.83	-1	0	-1	-1	-1
Sterilizable	0.8	0	0	1	0	0
Manage significant blood loss	0.73	-1	0	-1	-1	-1
Low maintenance	0.69	0	0	-1	0	0
Durable	0.68	0	0	0	0	0
Easy to operate	0.67	-1	0	-1	-1	0
Low cost	0.65	1	0	-1	1	0
Quick to operate	0.5	-1	0	0	-1	-1
Quiet	0.43	0	0	0	1	0
Weighted Sum		**-3.01**	**0**	**-4.56**	**-1.65**	**-2.92**

Comments	We chose the Screen on Device/Wand. Propose to add elements of "Clot Sword" to the Device/Wand.

21.6.2 Insert device into body cavity

Design Criteria	Weighting Factor	Hands-free clip	Wand that holds big clots on sides	Spoon/ ladle	Bag sealed around incision	Open tube	Dual chamber tube	Whole compartment**
Removes clots, microaggregates	0.93	-1	1	-1	-1	0	1	0
Does not cause cell damage	0.86	0	0	0	-1	0	0	0
Closed system	0.83	0	0	-1	1	0	1	1
Sterilizable	0.8	0	0	0	1	0	0	1
Manage significant blood loss	0.73	-1	0	-1	1	0	0	0
Sufficient flow rate	0.73	0	0	-1	1	0	1	0
Measures blood collected	0.72	0	0	0	0	0	0	1
Low maintenance	0.69	-1	-1	0	-1	0	-1	-1
Durable	0.68	-1	0	0	-1	0	0	0
Easy to operate	0.67	1	1	-1	0	0	1	-1
Low cost	0.65	-1	-1	0	-1	0	-1	0
Quick to operate	0.5	0	0	-1	-1	0	0	-1
Quiet	0.43	0	0	0	0	0	0	1
Weighted Sum		**-3.01**	**0.26**	**-4.39**	**-1.22**	**0**	**1.82**	**0.92**

Comments	The dual chamber tube came out on top in our weighted ranking, but we must consider the feasibility of this approach. The wand came in second.

21.6.3 Withdraw blood from body cavity

Design Criteria	Weighting Factor	Siphon	Scoop by hand	Suction	Water wheel	Water screw	Scoop with suction that filters clots	Resevoir
Removes clots, microaggregates	0.93	0	0	0	0	0	1	0
Does not cause cell damage	0.86	1	1	0	0	1	1	1
Closed system	0.83	0	-1	0	0	0	0	0
Sterilizable	0.8	0	-1	0	-1	-1	0	0
Manage significant blood	0.73	-1	-1	0	-1	-1	0	-1

loss								
Sufficient flow rate	0.73	-1	-1	0	-1	-1	-1	-1
Measures blood collected	0.72	0	1	0	0	0	0	1
Low maintenance	0.69	1	0	0	-1	-1	0	-1
Durable	0.68	1	0	0	-1	-1	0	0
Easy to operate	0.67	-1	-1	0	-1	-1	0	0
Low cost	0.65	1	1	0	-1	-1	0	-1
Quick to operate	0.5	-1	-1	0	0	0	0	-1
Quiet	0.43	1	1	0	0	0	0	1
Weighted Sum		**0.68**	**-1.6**	**0**	**-4.95**	**-4.09**	**1.06**	**-1.29**

Comments: The scoop with suction that filters clots came out on top, but we would still like to evaluate the use of a siphon.

21.6.4 Transport to container

Design Criteria	**Weighting Factor**	Suction through tube	Gravity	Resevoir	Siphon
Does not cause cell damage	0.86	0	1	1	1
Closed system	0.83	0	0	0	-1
Sterilizable	0.8	0	0	0	0
Manage significant blood loss	0.73	0	-1	-1	-1
Sufficient flow rate	0.73	0	-1	0	-1
Low maintenance	0.69	0	1	-1	1
Durable	0.68	0	1	0	1
Easy to operate	0.67	0	0	0	-1
Low cost	0.65	0	1	1	1
Quick to operate	0.5	0	-1	0	-1
Quiet	0.43	0	1	1	1
Weighted Sum		**0**	**1.35**	**0.52**	**-0.15**

Comments: Gravity came out on top, but realistically we will consider some sort of suction even if it is not electrical suction

21.6.5 Removes clots, particulates, microaggregates

Design Criteria	Weighting Factor	Gravity-driven mechanical filter	Material that attracts clots	Salad spinner	Funnel with grooves	Piston-driven	Multiple filters
Removes clots, microaggregates	0.93	0	1	1	1	0	1
Does not cause cell damage	0.86	0	-1	-1	0	-1	0
Closed system	0.83	0	0	0	0	0	0
Sterilizable	0.8	0	0	-1	0	-1	0
Manage significant blood loss	0.73	0	0	1	0	1	-1
Sufficient flow rate	0.73	0	0	1	0	1	0
Low maintenance	0.69	0	-1	-1	-1	-1	-1
Durable	0.68	0	0	0	0	-1	0
Easy to operate	0.67	0	0	0	0	0	0
Low cost	0.65	0	-1	-1	-1	-1	-1
Quick to operate	0.5	0	1	1	0	1	0
Quiet	0.43	0	0	0	0	0	0
Weighted Sum		**0**	**-0.77**	**-0.11**	**-0.41**	**-1.72**	**-1.14**

Comments	Gravity based filtering system comes out on top followed by Salad Spinner. Evaluate Salad Spinner and funnel more.

21.6.6 Prevent new clots

Design Criteria	Weighting Factor	AC bag attached to blood tube	AC at wand	Silicone coated surface	AC already in bag	Triple tube chamber	Add AC to reservoir
Does not cause cell damage	0.86	0	0	0	0	0	0
Closed system	0.83	0	0	0	0	0	0
Low maintenance	0.69	-1	-1	0	0	-1	1
Easy to operate	0.67	1	1	1	0	1	1
Low cost	0.65	1	0	-1	0	-1	1
Compatible with transfusion kit	0.64	0	0	0	0	0	0
Quick to operate	0.5	1	1	1	0	1	0
Weighted Sum		**1.13**	**0.48**	**0.52**	**0**	**-0.17**	**2.01**

Comments	AC added to the resevoir comes out on top. We still want to evaluate the silicone coating and its use in conjunction with another method. Think about location and timing of adding the AC.

21.6.7 Transport to body

Design Criteria	Weighting Factor	Blood bag	Reservoir	Pump driven
Closed system	0.83	0	0	0
Sterilizable	0.8	0	0	0
Prevents air embolisms	0.76	0	0	-1
Manage significant blood loss	0.73	0	1	1
Sufficient flow rate	0.73	0	1	1
Measures blood collected	0.72	0	0	-1
Low maintenance	0.69	0	1	-1
Durable	0.68	0	1	0
Easy to operate	0.67	0	0	-1
Low cost	0.65	0	1	-1
Compatible with transfusion kit	0.64	0	0	-1
Quick to operate	0.5	0	1	1
Controls transfusion rate	0.44	0	0	0
Quiet	0.43	0	0	-1
Weighted Sum		**0**	**3.98**	**-2.6**

Comments	Resevoir comes out on top. We could consider having the resevoir as a back-up to the blood bag in the event of overflow.

21.6.8 Suction methods

Design Criteria	Weighting Factor	Gravity	Pump	Temp. change	Piston	Syringe
Does not cause cell damage	0.86	0	0	-1	-1	0
Closed system	0.83	0	0	0	0	0
Manage significant blood loss	0.73	-1	0	-1	0	-1
Sufficient flow rate	0.73	-1	0	0	0	-1
Low maintenance	0.69	1	0	-1	0	0
Durable	0.68	1	0	0	0	-1

Easy to operate	0.67	0	0	-1	0	-1
Low cost	0.65	1	0	0	0	1
Electrical power	0.52	-1	0	0	0	0
Quick to operate	0.5	-1	0	0	0	-1
Quiet	0.43	1	0	0	0	1
Weighted Sum		**-0.03**	**0**	**-2.95**	**-0.86**	**-2.23**

21.7 Pro/Con Lists of Top Concepts

Salad Spinner

Pro	**Con**
Better flow rate	Standard filter size
Larger surface area	Maintenance of many parts
Expansion to other surgeries	Expensive
No manual power	Tolerance
Large amounts of blood	More possible opening s for contamination
Modular	Durability of Pump

Dual -Action Pump

Pro	**Con**
Modular	High Maintenance
Handle Large Volumes	Lots of parts
Generate High Flow Rate	Expensive/manufacturing
Control Each Component with valves	
No manual power	

Modular Concept

Pro	**Con**
Electrical/gravity	Lots of parts
Comes with suction machine for other uses	Maintenance

Water Bottle

Pro	**Con**
Portable	Small Scale
Doesn't require External Energy	Air Embolisms
Wide Scope	Must be fully submerged
	Need flexible material/not autoclaveable
	Squirt back out

Large Syringe

Pro	**Con**
Self Contained	Heavy to hold when filled with blood
Low mintenance/ Less removable parts	Force to pull plunger

Autoclavable	May require more than one person
Small/portable/durable	Manufacturing Tolerance
Doesn't require pump	Potential smaller SA on filter
Scope of location	Speed of removal
Cost	

21.8 Alpha Design CAD Model

21.9 Beta Design CAD Model

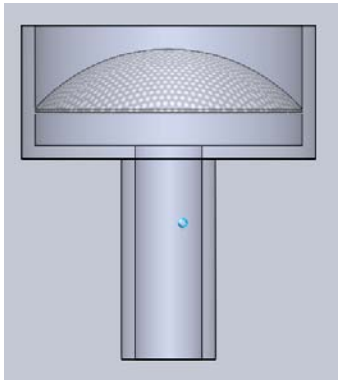


Figure 30: Needle Tip and Filter

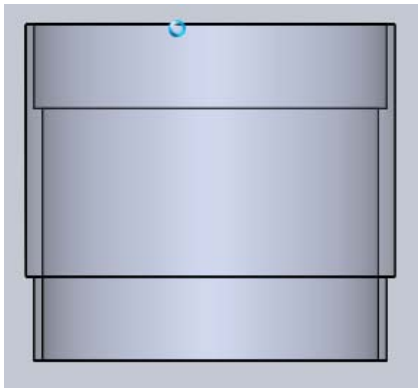


Figure 31: Ball Check Valve

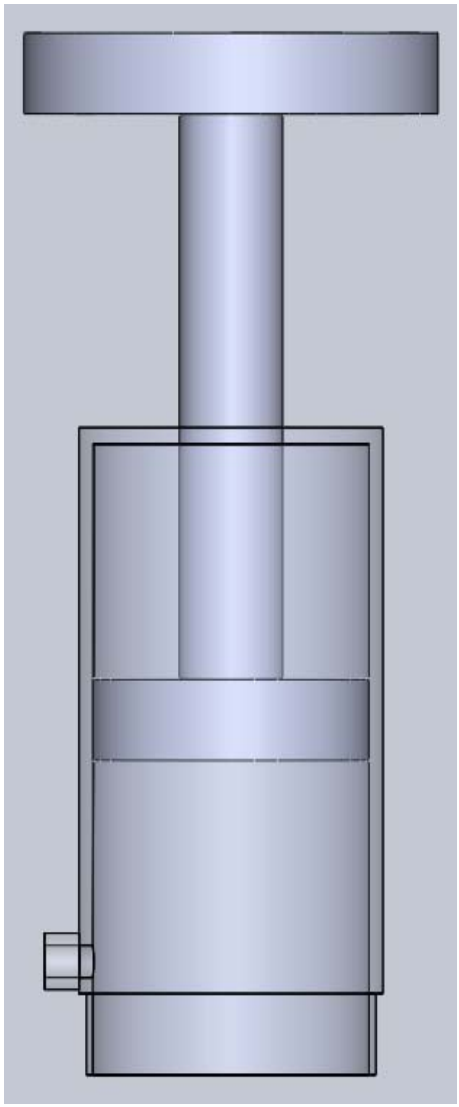


Figure 32: Plunger and Intermediate Reservoir

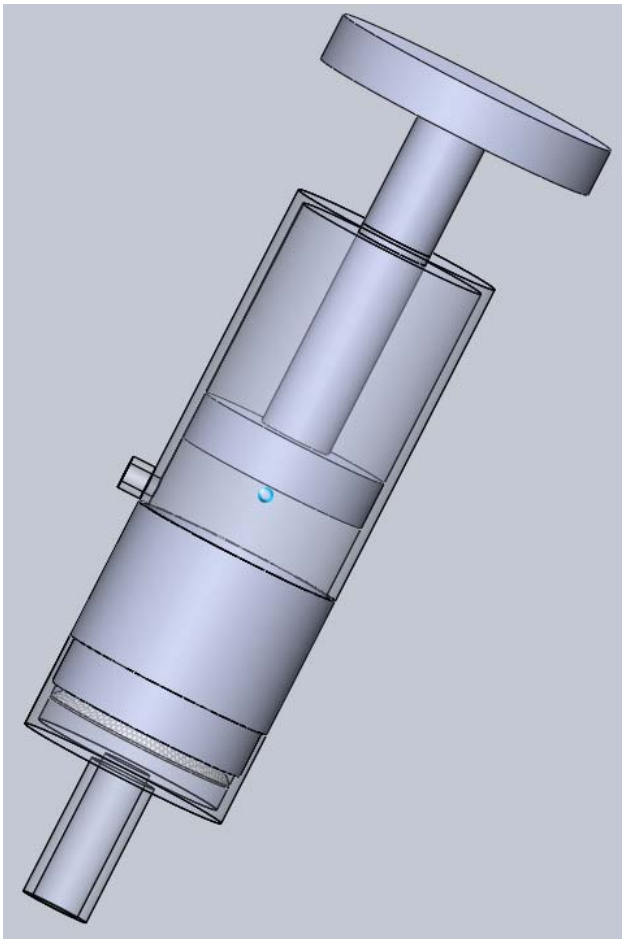


Figure 33: Overview Section

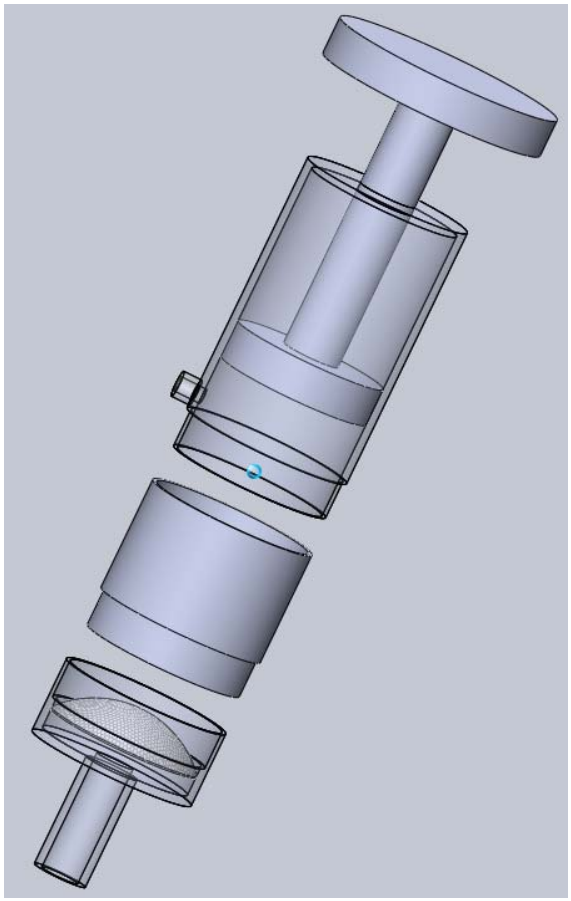
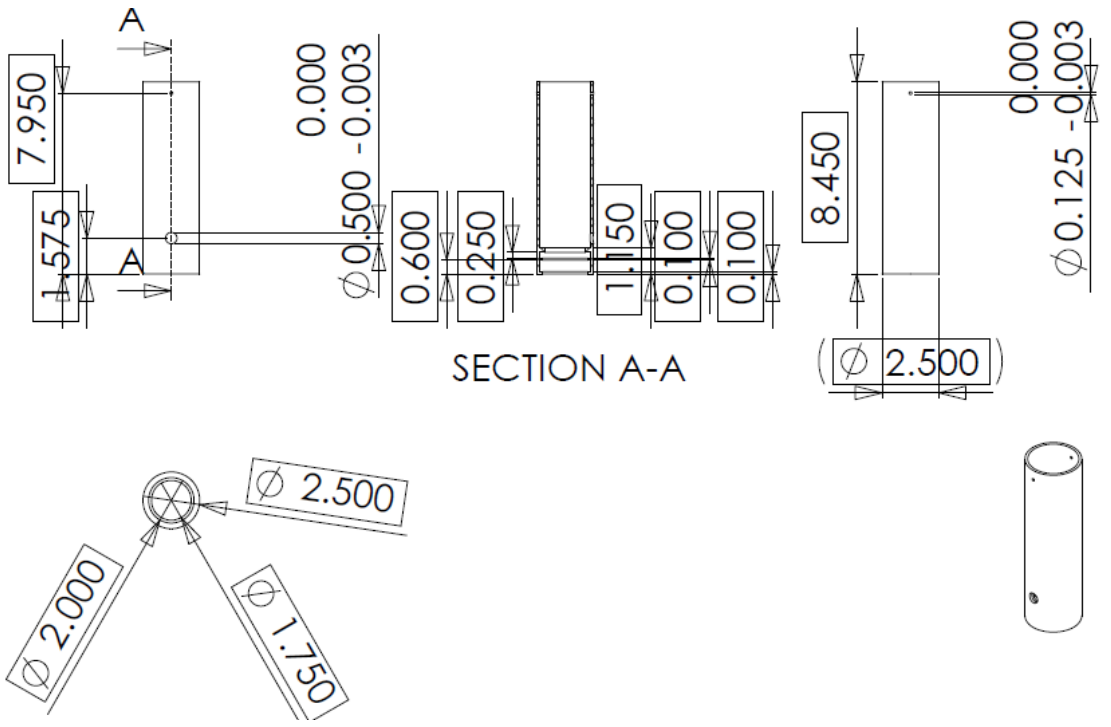


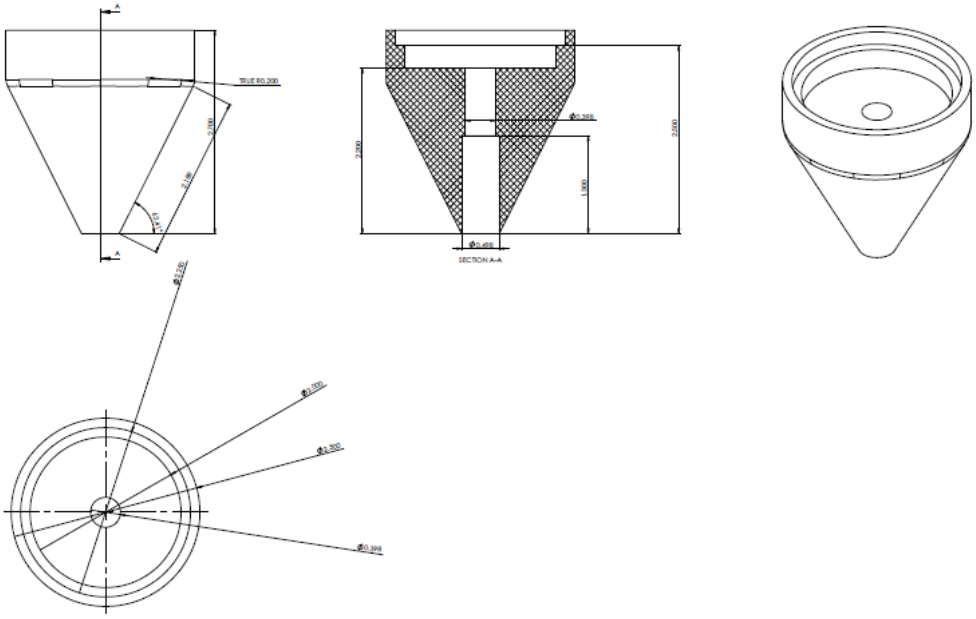
Figure 34: Exploded Assembly View

21.10 Prototype Design Dimension Drawings

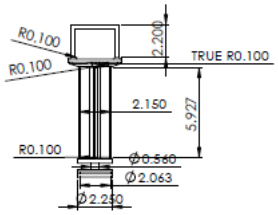
21.10.1Barrel

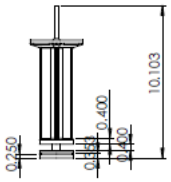


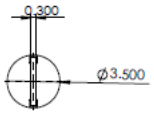
21.10.2Suction Tip



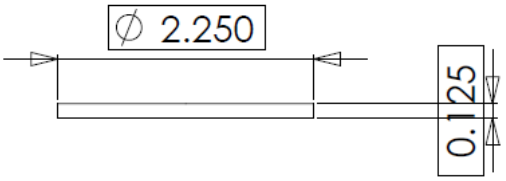
21.10.3Plunger

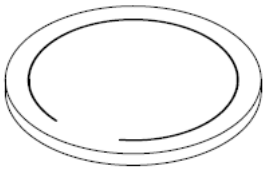


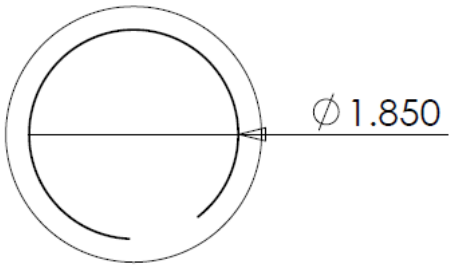




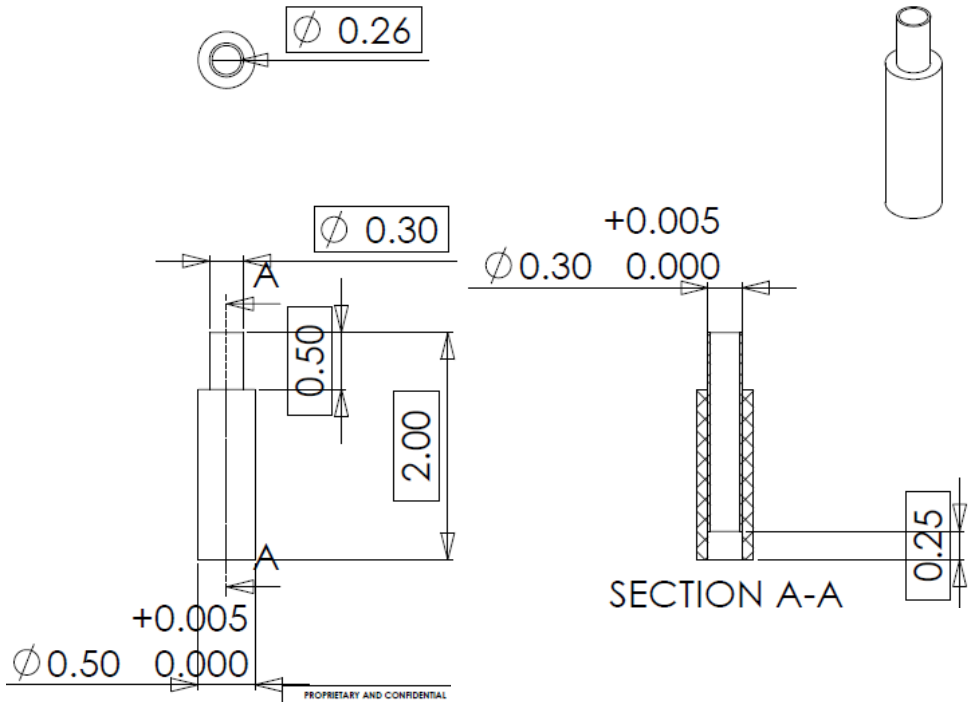
21.10.4Check Valve







21.10.5Blood Bag Connection



21.11 Fluid Analysis MATLAB Code

21.11.1Bernoulli Analysis

```
% Bernoulli Analysis

d = 1060; % density of blood (kg/m^3)
g = 9.81; % gravity (m/s^2)

% ------------------------ Barrel -----------------------------------
l2=linspace(0.08,0.27); %height of barrel
v2=linspace(0,0.5); %possible velocities

for i=1:length(l2)
   for j=1:length(v2)
      p2(i,j)= -0.00750061683*(-0.5*(d*(v2(j)^2))-(d*g*l2(i))); % mm Hg
   end
end

surf(l2,v2,p2)
xlabel('Height of Barrel (m)')
ylabel('Fluid velocity in Barrel (m/s)')
zlabel('Pressure in Barrel (mmHg)')
title('Pressure Array in Barrel')

%--------------- Suction Tube -----------------------------------------
```

```
% Point in reservoir to top of suction tube:
% l1 = heights of suction tube
% v1 = velocities in the first tube

l1=linspace(0.03,.07);
v1=linspace(0,3.125);

for i=1:length(l1)
   for j=1:length(v1)
      p1(i,j)= -0.00750061683*(-0.5*(d*(v1(j)^2))-(d*g*l1(i))); % mm Hg
   end
end

surf(l1,v1,p1)
xlabel('Height of Suction Tube (m)')
ylabel('Fluid velocity in Suction Tube(m/s)')
zlabel('Pressure in Suction Tube (Pa)')
title('Pressure Array in Suction Tube')

%---------------------- IV Tubing ----------------------------------------
v3=linspace(0,122);

for i=1:length(v3)
   for j=1:length(v2)
      p3(i,j) = -0.00750061683*( p2(i,j) + 0.5*d*((v2(j)^2)-(v3(i)^2))); %mmHg
   end
end

surf(v2,v3,p3)
xlabel('Fluid Velocity in Barrel (m/s)')
ylabel('Fluid velocity in IV Tube (m/s)')
zlabel('Pressure in IV Tube (mmHg)')
title('Pressure Array in IV Tube')

p21 = linspace(0,6000);
p31 = 0.00750061683*(p21+(0.5*d*((v2.^2)-1.49))); %mmHg
plot(v2,p31)
xlabel('Velocity in Barrel (m/s)')
ylabel('Pressure in IV Tubing (mmHg)')
title('Pressure in IV Tubing')
```

21.11.2Force on Plunger Analysis

```
%----------  Force Analysis ----------------------------------------
density=1060; %density of blood (kg/m^3)

r11=.005; h11=.03;
r21=.02; h21=.05;

r12=.0125; h12=.05;
r22=.035; h22=.125;
```

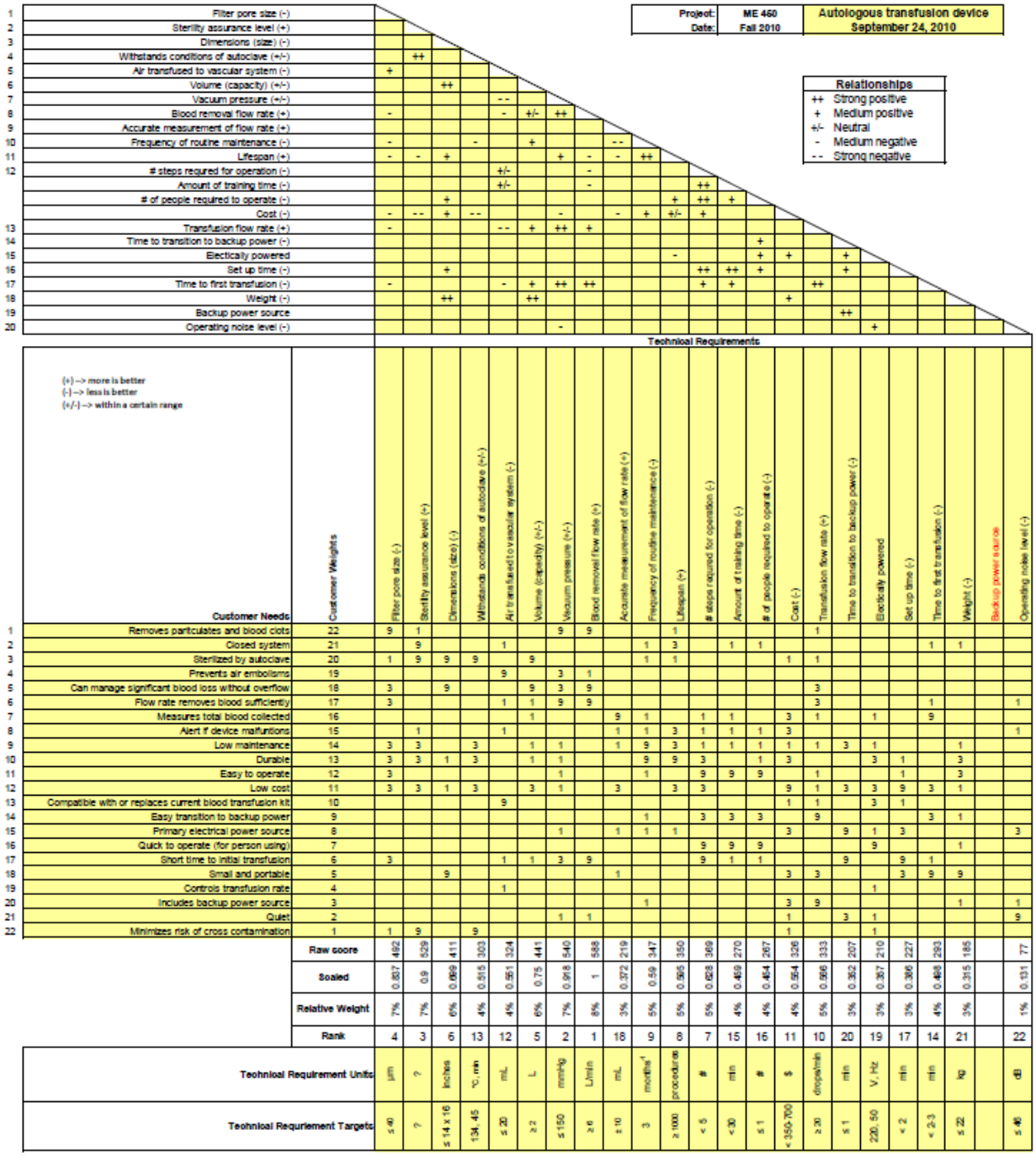
```
r13=.02; h13=.07;
r23=.05; h23=.2;

F=10;

%---------- First Phase ----------------------------------------------
t=linspace(0,5);

V1 = sqrt(((((2*F)/(density*pi*(r21^2))).*log(t))+ ...
    (4.605*F/(density*pi*(r21.^2)))));

V2 = sqrt(((((2*F)/(density*pi*(r22^2))).*log(t))+ ...
    (4.605*F/(density*pi*(r22.^2)))));

V3 = sqrt(((((2*F)/(density*pi*(r23^2))).*log(t))+ ...
    (4.605*F/(density*pi*(r23.^2)))));

plot(t,V1,t,V2,t,V3)
xlabel('Time (s)')
ylabel('Velocity of Plunger (m/s)')
title('Velocity in First Phase of Filling')
legend('Value1','Value2','Value3')


%----------------- Second Phase ----------------------------------------
dV1=@(t,V) F/((density*pi*(r11^2)*h11)+(density*pi*(r21^2).*V.*t));
[t,V4]=ode45(dV1,[0,60],2);

subplot(2,2,1)
plot(t,V4)
xlabel('Time (s)')
ylabel('Velocity of Plunger (m/s)')
title('Velocity in Second Phase of Filling- Value1')

dV2=@(t,V) F/((density*pi*(r12^2)*h12)+(density*pi*(r22^2).*V.*t));
[t,V5]=ode45(dV2,[0,60],2);

subplot(2,2,2)
plot(t,V5)
xlabel('Time (s)')
ylabel('Velocity of Plunger (m/s)')
title('Velocity in Second Phase of Filling- Value2')


dV3=@(t,V) F/((density*pi*(r13^2)*h13)+(density*pi*(r23^2).*V.*t));
[t,V6]=ode45(dV3,[0,60],2);

subplot(2,2,3)
plot(t,V6)
xlabel('Time (s)')
ylabel('Velocity of Plunger (m/s)')
title('Velocity in Second Phase of Filling- Value3')
```

21.11.3Design Dimension Analysis

```
%--------------- Specific Dimensions Analysis ----------------------------
d=1060;
F=10;
r1=0.007493;
r2=0.028575;
r3=0.006604;
h1=0.05588;
h2=0.18542;
g=9.81;

%--------- Barrel Pressure ----------------------------------------
v2=linspace(0,0.5);
p2 = -0.00750061683*((-0.5*d*(v2.^2))-(d*g*h2));

plot(v2,p2)
xlabel('Velocity in Barrel')
ylabel('Pressure in Barrel (mmHg)')
title('Pressures in  Barrel')

%--------- Suction Tip Pressure -----------------------------------------
a1 = pi*(r1^2);
a2 = pi*(r2^2);

v1 =(a2/a1).*v2;

p1 = -0.0075006168*(-0.5*d*(v1.^2)-(d*g*h1));

plot(v1,p1)
xlabel('Velocity in Suction Tip')
ylabel('Pressure in Suction Tip (mmHg)')
title('Pressures in  Suction Tip')

%---------------------- IV Tubing Pressure -------------------------------
a3=pi*(r3^2);
p21=133.322368.*p2;
v3=(a2/a3).*v2;

p3 = -0.0075006168*(p21+0.5*d*((v2.^2)-(v3.^2)));

plot(v3,p3)
xlabel('Velocity in IV Tubing')
ylabel('Pressure in IV Tubing(mmHg)')
title('Pressures in  IV Tubing')
```

21.12 QFD

System QFD



	Filter pore size (-)																									
2	Sterility assurance level (+)																									
3	Dimensions (size) (-)																									
4	Withstands conditions of autoclave (+/-)		++																							
5	Air transfused to vascular system (-)	+																								
6	Volume (capacity) (+/-)			++																						
7	Vacuum pressure (+/-)					--																				
8	Blood removal flow rate (+)	-				-	+/-	++																		
9	Accurate measurement of flow rate (+)																									
10	Frequency of routine maintenance (-)	-			-		+			--																
11	Lifespan (+)	-	-	+				+	-	-	++															
12	# steps required for operation (-)					+/-			-				++													
	Amount of training time (-)					+/-			-				++													
	# of people required to operate (-)			+								+	++	+												
	Cost (-)	-	--	+	--			-		-	+	+/-	+													
13	Transfusion flow rate (+)	-				--	+	++	+																	
14	Time to transition to backup power (-)														+											
15	Electically powered											-			+	+			+							
16	Set up time (-)			+									++	++	+				+							
17	Time to first transfusion (-)	-				-	+	++	++				+	+			++									
18	Weight (-)			++			++									+										
19	Backup power source																		++							
20	Operating noise level (-)							-												+						

Project: ME 450 — **Date:** Fall 2010 — **Autologous transfusion device** — **September 24, 2010**

Relationships	
++	Strong positive
+	Medium positive
+/-	Neutral
-	Medium negative
--	Strong negative

(+) --> more is better
(-) --> less is better
(+/-) --> within a certain range

Teohnical Requirements

	Customer Needs	Customer Weights	Filter pore size (-)	Sterility assurance level (+)	Dimensions (size) (-)	Withstands conditions of autoclave (+/-)	Air transfused to vascular system (-)	Volume (capacity) (+/-)	Vacuum pressure (+/-)	Blood removal flow rate (+)	Accurate measurement of flow rate (+)	Frequency of routine maintenance (-)	Lifespan (+)	# steps required for operation (-)	Amount of training time (-)	# of people required to operate (-)	Cost (-)	Transfusion flow rate (+)	Time to transition to backup power (-)	Electically powered	Set up time (-)	Time to first transfusion (-)	Weight (-)	Backup power source	Operating noise level (-)
1	Removes particulates and blood clots	22	9	1					9	9			1					1							
2	Closed system	21		9			1					1	3			1	1						1	1		
3	Sterilized by autoclave	20	1	9	9	9		9				1	1				1	1								
4	Prevents air embolisms	19					9		3	1																
5	Can manage significant blood loss without overflow	18	3		9			9	3	9								3								
6	Flow rate removes blood sufficiently	17	3				1	1	9	9								3				1			1	
7	Measures total blood collected	16						1			9	1					3	1		1		9				
8	Alert if device malfuntions	15		1			1				1	1	3	1	1	1	3									1
9	Low maintenance	14	3	3		3		1	1		1	9	3	1	1	1	1	1	3	1			1			
10	Durable	13	3	3	1	3		1	1			9	9	3		1	3			3	1		3			
11	Easy to operate	12	3						1			1		9	9	9		1			1		3			
12	Low cost	11	3	3	1	3		3	1		3		3	3			9	1	3	3	9	3	1			
13	Compatible with or replaces current blood transfusion kit	10					9										1	1		3	1					
14	Easy transition to backup power	9										1		3	3	3		9				3	1			
15	Primary electrical power source	8							1		1	1	1				3		9	1	3				3	
16	Quick to operate (for person using)	7												9	9	9				9			1			
17	Short time to initial transfusion	6	3				1	1	3	9				9	1	1			9		9	1				
18	Small and portable	5			9						1						3	3			3	9	9			
19	Controls transfusion rate	4					1													1						
20	Includes backup power source	3										1					3	9					1		1	
21	Quiet	2							1	1							1		3	1					9	
22	Minimizes risk of cross contamination	1	1	9		9											1			1						
	Raw score		492	529	411	303	324	441	540	588	219	347	350	369	270	267	326	333	207	210	227	293	185		77
	Scaled		0.837	0.9	0.699	0.515	0.551	0.75	0.918	1	0.372	0.59	0.595	0.628	0.459	0.454	0.554	0.566	0.352	0.357	0.386	0.498	0.315		0.131
	Relative Weight		7%	7%	6%	4%	4%	6%	7%	8%	3%	5%	5%	5%	4%	4%	4%	5%	3%	3%	3%	4%	3%		1%
	Rank		4	3	6	13	12	5	2	1	18	9	8	7	15	16	11	10	20	19	17	14	21		22
	Teohnical Requirement Units		µm	?	inches	°C, min	mL	L	mmHg	L/min	mL	months^{-1}	procedures	#	min	#	$	drops/min	min	V, Hz	min	min	kg		dB
	Teohnical Requirement Targets		≤ 40	?	≤ 14 x 16	134, 45	≤ 20	≥ 2	≤ 150	≥ 6	± 10	3	≥ 1000	< 5	< 30	≤ 1	< 350-700	≥ 20	≤ 1	220, 50	< 2	< 2-3	≤ 22		≤ 40

21.13 Survey

Auto Blood Transfusion Device

To be used in: Ectopic Pregnancy Ruptures, Myomectomies, Hysterectomies, and other clean abdominal surgeries (hemoperitoneum)

Need statement: There is a need for a blood salvage device that can be operated y a healthcare provider to collect, filter, and transfuse blood in the event of life-threatening blood loss, which would address the lack of donated blood and improve the prognosis for the patient.

Stakeholders User Requirement Ranking Survey

Name: _____ Phone Number: _____

Email Address: _____ Occupation/position: _____

Please circle one number for each requirement and circle your top 5 requirements and cross-out your 5 least important

1 = Very important (a critical requirement; required for operation)
3 = Important (required eventually but could wait until a later release if necessary)
9 = Somewhat important (would be nice to have someday if resources permit)

User requirements	**Very important**	**Important**	**Somewhat Important**
Removes particulates and blood clots	1	3	9
Minimizes contamination from environment	1	3	9
Main power source is electrical	1	3	9
Backup power source is mechanical	1	3	9
Quick transition to backup power	1	3	9
Connects to existing blood transfusion kit	1	3	9
Can be used in any clean abdominal surgery	1	3	9
Minimizes risk of cross contamination between patients	1	3	9
Easy to operate by any staff in surgical setting	1	3	9
Device can be operated quickly	1	3	9
Device is low cost	1	3	9
Device is low maintenance	1	3	9
Device is small	1	3	9
Device is portable	1	3	9
Alerts user when malfunctioning	1	3	9
Can contain large amounts of blood loss	1	3	9
Can change transfusion rate	1	3	9
Prevents air embolisms	1	3	9
Device is quiet	1	3	9
Measures amount of blood lost by patient	1	3	9
Measures amount transfused to patient	1	3	9
Durable and is long lasting	1	3	9

Do you have any additional user requirements? How would you rank them?

21.14 Additional Activities

Our team has been involved in a number of additional activities in conjunction with our primary objective of the technical development of the blood salvage device. These are listed briefly below.

- Dhani Jones presentation, October 15, sponsored by the Center for Entrepreneurship to highlight social entrepreneurship ventures on campus.
- Chicago Entrepreneurial Experience, October 18-19, sponsored by the Center for Entrepreneurship to bring local student companies to Chicago, including a pitch competition and networking session with successful UM Alumni-Entrepreneurs. Our team took third place in the pitch competition
- Global Health Day Poster Presentation, November 5, sponsored by the Center for Global Health
- Ann Arbor SPARK Entrepreneur Boot Camp, November 4-5