

Intravenous Fluid/Volume Control in Low-Resource Settings
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Team 14

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Executive Summary

Intravenous (IV) therapy is a common procedure performed by using a sterile needle to insert a catheter into the vein of a patient. It is used to maintain patient hydration and nutrition, administer drugs, and transfuse blood [1], [2]. Medication errors are the most common error within the United States' (US) hospitals [3] and can result in serious complications and even death [4]–[8]. Furthermore, the error rates are even worse in low-resource regions of Sub-Saharan Africa [9], [10], [11]. Within high-resource countries, IVs are handled by infusion pumps [12], [13], however, low-resource countries rely heavily on roller-clamps, which are much cheaper [14], [15]. Using the roller clamp method is inaccurate and time-consuming for nurses [12], [15]–[20]. There is a saturated solution space for low-cost and high-cost intravenous control devices, with no reusable solutions that provide safety features at a mid-range price point [13], [16], [17], [19], [21]–[25]. Based on this research, there is a general need for devices that increase the safety and accuracy of IV infusions, especially in low-resource settings. The targeted outcome of this project was a novel concept that is implementable in all medical communities, increases patient safety, and makes intravenous administration simpler for healthcare providers.

Six methods were used to generate concepts, which yielded 83 ideas. An iterative method was used to evaluate these ideas. After four passes and a weighted decision matrix, three ideas were chosen for further evaluation. The first was a peristaltic pump powered by a falling weight, the second was a solenoid/piston system to clamp the tube at discrete intervals, and the third was an elastomeric band or motor system to adjust the height of the bag as the fluid level falls to maintain hydrostatic pressure.

After engineering analysis was performed on these concepts, it became apparent that the focus of the project needed to change from flow rate control to volume control. Low-cost purely reusable flow control was infeasible with all concepts, and stakeholders were more concerned about the volume of medication given to the patient.

Thus, the team developed a timer and flow stopper mechanism that controls the volume of medication given to the patient and alerts the provider when an infusion is finished. This device would reduce the risk of patient overdose and improve continuous patient care. It is intended to be used as an add-on system to a roller clamp and/or another flow control device, such as the Dial-a-Flow. The device is relatively low-risk for the patients, as it is a safeguard against accidental overdosing, and would not introduce much additional risk if the patient was under normal observation.

The prototype outright passed most of the validation tests performed, meeting the majority of the specifications. Benchmarking, research, and clinical findings resulted in ten main requirements. The solution satisfies the following nine: control the volume of fluid administered [15], [16], [19], [20], [25]–[28], alert providers within the ward [15], [17], [24], [27], be portable [14], [16], [17], [23], [27]–[30], comply with current market standards [16], [17], [25], [27], [29], [31]–[33], be easy to use [14], [17], [22], [23], [28], be usable in low-resource settings [13], [15], [17], [23], [26], [28], [29], [34]–[36], be durable [14], [16], [19], [23], easy to maintain [15], [23], [36], [37], and provide patient safety [15], [16], [35]. The one requirement the solution does not satisfy is that the system needs to control the flow rate [14]–[16], [19], [20], [22], [25]–[27], [29], [30], [34], [38], [39]. This requirement, and all unaddressed specifications, are addressed in future work/recommendations.

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Problem Description and Background

Introduction to Intravenous Therapy

Intravenous (IV) therapy is a common method used to maintain patient hydration and nutrition, administer drugs, and transfuse blood [1], [2]. The therapy is performed by using a sterile needle to insert a catheter into the vein of a patient (Figure 1). Once the catheter is in place the needle is removed, and the catheter is connected to the rest of the line [1]. The fluid is then hung on a pole above the patient so the hydrostatic pressure allows the fluid to enter the patient's vein [40].

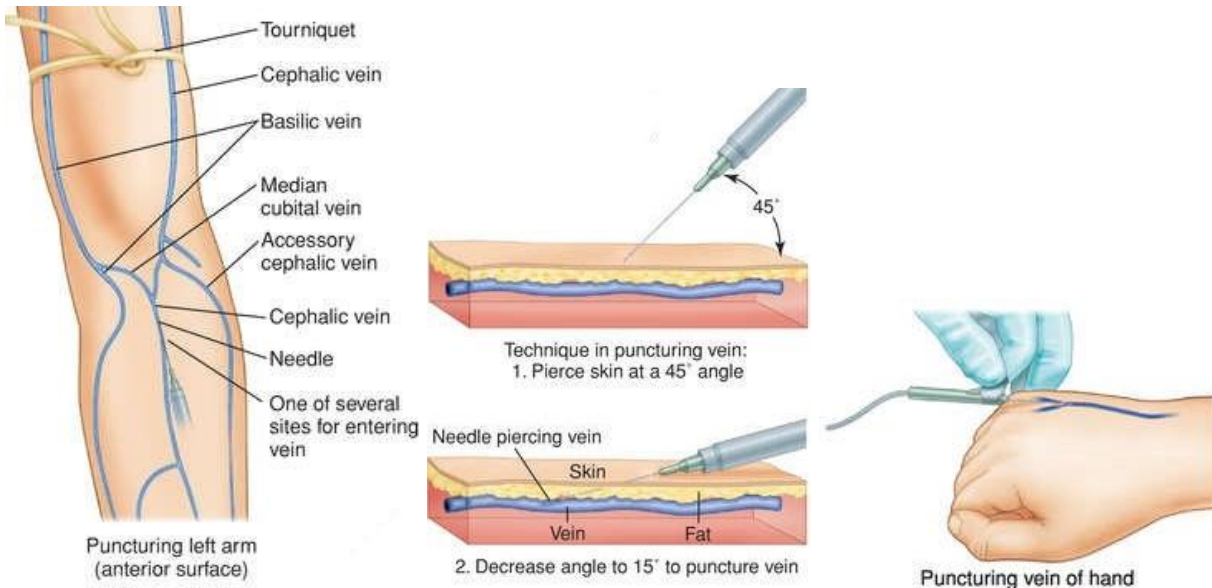


Figure 1. IV line insertion protocol. Image modified from [1].

All IV administration sets contain a drip chamber, roller-clamp, and adapter end for connecting to the cannula located in the patient's vein (Figure 2, page 5). The top of the drip chamber has a spike which is injected into the IV bag or bottle. A Y-site, where one line splits into two, is sometimes included for piggybacking medications, where a second smaller medication is connected to the main line, and a filter is included when necessary for certain kinds of medications or blood [41], [42].

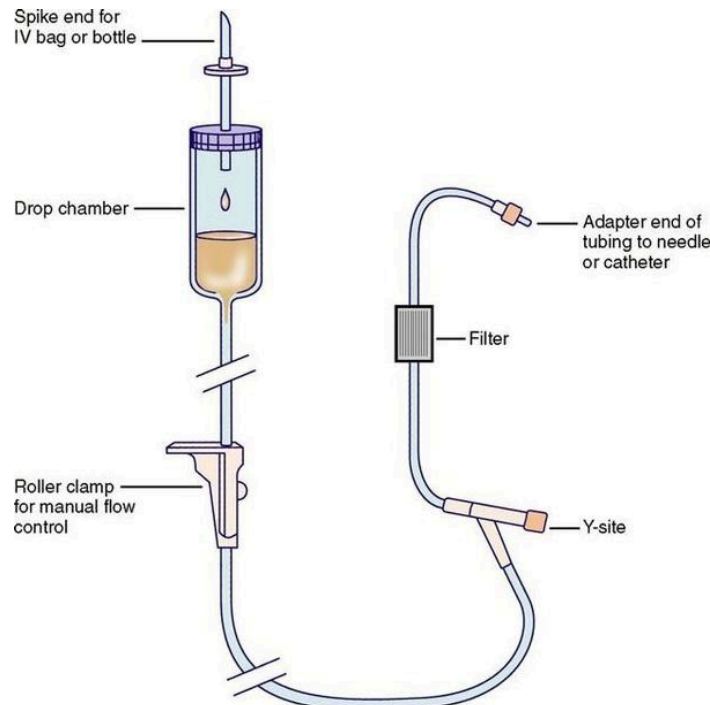


Figure 2. Diagram of IV giving set. Image copied from [43].

The IV can be attached to the patient through a peripheral line (inserted into a peripheral vein located in the extremities) or a central line (inserted into a vein in the chest or neck). Central lines are used for medications or nutrients that may irritate peripheral veins (e.g. chemotherapy drugs). Additionally, the risk of infection and bleeding are much higher with central lines, because they are so close to the heart. Their proximity to the heart also means that the medication is distributed throughout the body more rapidly. Peripheral lines are the most common type of IV. They are most often inserted into veins in the arms or hands, but the legs and feet can also be used [40]. Patients that may require an IV infusion or transfusion include, but are not limited to, patients who have had a large amount of blood/fluid loss as well as patients requiring chemotherapy, insulin, nutrients, antibiotics, or anesthesia [12], [41].

Problem Statement

Controlling IV infusions is an integral part of patient care. IV infusions are used worldwide throughout hospitals and clinics, from the emergency department (ED) to labor wards and operating rooms [44]. In US hospitals, nearly 200 million peripheral IV infusions are given annually [9], and over 6.7 million infusions are given in Ghana annually [45]. IV infusions/transfusions can be imperative for quickly providing life-saving treatment, but have the potential to cause complications [46]. Medication errors are the eighth leading cause of in-hospital death in the United States (US) and the most common error within hospitals, resulting in over 7000 deaths annually. Furthermore, these rates are even worse in low-resource regions like Sub-Saharan Africa [3]. For example, a review of 91 studies conducted in the US found an error rate of about 20% while a review of eight studies in countries in Africa found a median prescribing error rate of 57% [10], [11]. The same systematic review (of 31 studies total) found that 41.3% of medication errors were identified after prescribing, 20.6% were identified after

administration, and 16.7% were identified during monitoring; the most common error reported was prescription and/or administration of an incorrect dose. The most common reasons reported for medication errors were fatigue, lack of knowledge/training, distraction and high workload, and look-alike drug names and labeling deficits [11].

Patient overdose or underdose can result in serious complications or death [4]–[8]. A study at Harvard concluded that 19% of adverse events were the result of drug complications [47]. Another study by the same group found that drug administration errors account for 34% of adverse drug events [48]. Of these errors, the most serious outcomes generally came from medications administered intravenously [4]. While an infusion pump is the standard for controlling IV infusions within high-income countries, these devices are costly and not easily accessible in low and middle-income countries (LMICs) [12], [13]. The World Health Organization (WHO) says that health technologies created to address challenges in LMICs must: be safe for the user, patient, and environment; effectively address the health concern; adapt to local infrastructures in low-resource settings; be easy to use and maintain; have a low total cost of ownership, be cost-effective, and affordable; and be culturally and socially acceptable [49].

The roller-clamp that comes standard on all infusion sets is the current approach for controlling the IV flow rate for patients in the majority of hospitals in low-resource settings; this includes the adult ED at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana [14], [15]. The roller clamp adjusts the flow rate by squeezing the IV tubing to decrease the diameter of the tubing, thereby restricting flow. The roller-clamp method requires nurses to manually count the drop rate and monitor and adjust it over time. However, this process is time-consuming and impractical due to staffing constraints [12], [15]–[20]. Additionally, roller clamps have on average a 56% error in desired vs actual flow rate [50]. Other low-cost solutions designed for LMICs are available at KATH, but are inadequate due to limited device availability, patient population constraints, and lack of availability of customized replacement components [13], [16], [17], [19], [21]–[25].

Thus, there is a need to more quickly, accurately, and safely control IV infusions to reduce the time and effort required for nurses to administer IV medication. The outcome of this project was a novel concept that is implementable in all medical communities, increases patient safety, and makes intravenous administration simpler for healthcare providers.

Information Search and Benchmarking

Information Sources Used

The information search began in Ghana, where two team members recorded direct observations at KATH in Kumasi. Interviews were conducted with various members of the hospital staff, garnering information from nurses, doctors, maintenance, and procurement.

The research continued in the US when the team interviewed domestic nurses and doctors. The search was also expanded to include consultants, medical device industry professionals, and nursing students. The team also expanded its literature source diversity to include research papers, patents, FDA and ISO standards, and whitepapers.

During interviews, nurses and doctors discussed desirable features for an IV infusion control device, what makes the devices easy or hard to use, what they like and dislike about benchmarked solutions, and how the devices can be integrated into the existing environments. A team member also shadowed a doctor for a day and made direct observations in the Von Voigtlander Women's Hospital.

The KATH procurement office was interviewed and asked about the procurement process, where items are stored, and how much they would pay for a solution. The team also interviewed the hospital maintenance staff in Ghana and asked about the common ways devices break, how often they are out of commission, how long it takes to fix them, and what features they would like to see in a device they would service.

The team completed extensive internet research in the US on various standards, handbooks, whitepapers, patents, and research papers. From these documents, engineering specifications were generated and requirements were refined. The benchmarked solutions have guided many of the specifications and helped to find a niche in the market.

In early October, the team met with Dr. Sefa, an experienced emergency medicine and critical care provider who has worked in Rwanda and Ghana in both Teaching Hospitals and small village clinics. Dr. Sefa proved to be an invaluable resource for firming up difficult requirements and specifications that would inhibit the team from doing effective concept evaluation.

In November, the team met with Dr. Sean Ewing, who was integral in further fleshing out of specifications, providing valuable information needed for design considerations and validation, and acquiring equipment for testing.

Benchmarking

The benchmarked solutions have provided a plethora of information, not only about what works but additionally what is actually implemented and used in clinical settings. A subset of benchmarked solutions are covered in this section (Figure 3). There are two distinct types of fluid administration devices on the market; those that administer concentrated doses and those that administer diffused doses. The devices that regulate diffused doses do so through the use of an IV bag and tubing. These categories can be further broken up into fluid monitoring, mechanical methods, infusion pumps, syringe pumps, and elastomeric pumps.

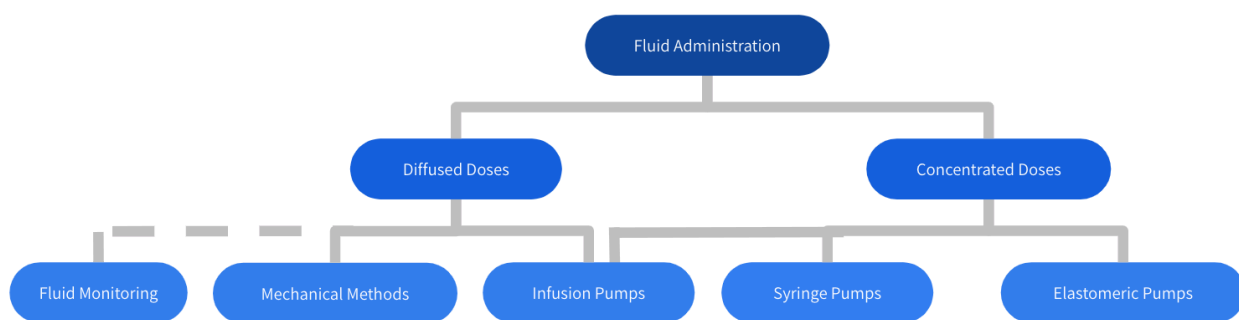


Figure 3. Categories identified during benchmarking.

Concentrated doses can be delivered by elastomeric pumps (Figure 4), which operates by squeezing a container of the IV fluid, much like a deflating a balloon.



Figure 4. Photo of an elastomeric pump. Image copied from [51].

Elastomeric pumps work in any orientation and do not rely on gravity or electricity to work. Unfortunately, since the pressure is applied directly to the fluid, these devices are single-use [52]. They can also cost tens to hundreds of dollars [53]. Given the importance of cost in low-resource areas, these are not an effective solution.

Syringe pumps can also be used to deliver concentrated doses. They typically use an off-the-shelf syringe that is placed into the device and compressed at a set flow rate. Thus, these pumps are limited by the volume of the syringe, and can only deliver concentrated doses. They are also very expensive, often costing as much as an infusion pump [54]. The syringe pump shown in Figure 5 is the same as the device used at KATH. There are only four of these devices (which were donated) within the entire ED at KATH. The ED generally has around 85 patients requiring an average of two infusions at all times [14], [15]. Stakeholders generally like using this device, as it is ‘easy to use’ and flow rate can be set accurately and quickly.



Figure 5. B. Braun syringe pump used at KATH. Image copied from [55].

The RMS Freedom60 syringe pump (Figure 6) is designed to be used by everyone, everywhere. It uses a 60mL syringe and the pump is wound up by a spring. The flow rate is regulated by proprietary RMS tubing [56]. When shown to stakeholders, it became clear that having different tubing sizes for different flow rates, as this device does, would be an unsustainable solution due to problems with procurement and keeping a full stock. The major advantage of this pump is that it costs about \$600 retail, versus the typical syringe pump cost of over \$1000.



Figure 6. Photo of the RMS Freedom60 syringe pump. Image copied from [56].

Infusion pumps (Figure 7), can deliver concentrated doses as well as diffused doses. There are different types, such as diaphragm and peristaltic pumps, that use electric motors to advance fluid through the IV tubing.



Figure 7. Photo of a BD Alaris Infusion Pump. Image copied from [57].

Infusion pumps can include any number of features, like fluid rate monitoring and control, pressure compensation, alerts for flow issues, and automatic adjustments based on patient and medication info. They can be used for medication, blood, and saline; and they work for every patient. They are also the most expensive type of device, starting at around \$1500 [57].

The most basic solution uses a purely mechanical method, known as a roller-clamp (Figure 8). These devices usually control the flow rate by applying pressure to the IV tubing and changing the cross-sectional area.



Figure 8. Image of the roller-clamp. Image copied from [58].

The roller-clamp is the solution that is currently used to control the flow rate for the majority of patients at KATH, and most other low-resource settings. In high-resource areas, the roller-clamp is only used to fully stop fluid flow, but in low-resource settings it is used to squeeze the tubing and adjust the flow rate [15]. The flow rate then has to be calculated by the caregiver who must count the drops that fall into the drip chamber over a period of time. Roller-clamping also causes cold flow creep in the tubing. This creep, along with the change in hydrostatic pressure due to the falling fluid level over time, results in a flow rate that changes with time, and thus, the flow rate is generally inaccurate [59].

A different type of mechanical variable rate controllers is the dial-a-flow (Figure 9). The dial-a-flow is an inline flow rate control solution that uses preset flow rates at given marked intervals. It only requires the caregiver to turn the dial to the desired flow rate, which stakeholders say makes it ‘simple’ and ‘easy to use’. Because it is inline with the tubing, the rate controllers are single-use, but because they are made of plastic and mass manufactured, they cost only a few cents to a few US dollars. This method is currently used at KATH. However, it is only used in the pediatric ED, and the patients’ parents must purchase the device for their child. Since it is a gravity based system, the flow rate is affected by changes in hydrostatic pressure [60].

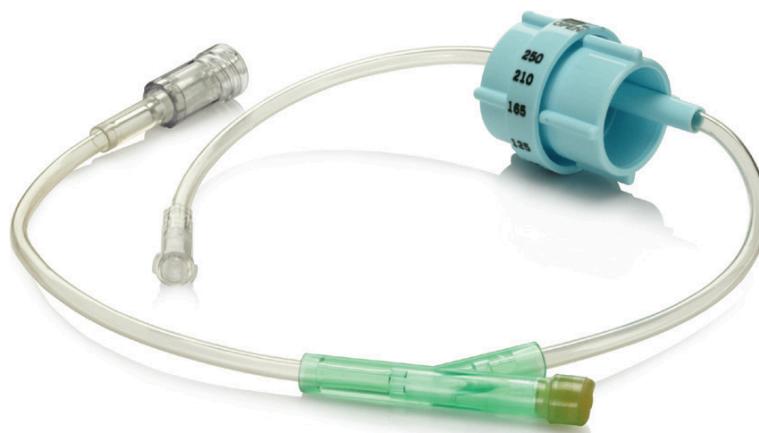


Figure 9. Photo of the dial-a-flow. Image copied from [61].

There are also devices that do not control the fluid flow rate, but instead monitor it and give feedback, like the DripAssist (Figure 10). This device attaches to standard IV drip sets and shows the flow rate, which allows for more precise control and saves time for caregivers. It also has an alert system that notifies the user when the flow rate changes suddenly or when flow stops. It is commercially available and costs about \$500 [62], [63]. When this device was shown to stakeholders, it became clear that a solution that only monitored the flow rate was not desirable.



Figure 10. Photo of the DripAssist. Image copied from [64].

Finally, there are other devices that target the low-resource IV market, such as the Acuset (Figure 11). It is a purely mechanical solution with a reusable flow rate controller. It also includes a proprietary IV bag with an elastic band that maintains hydrostatic pressure as the bag empties [38].



Figure 11. Image of the Acuset. Not pictured is the IV bag with integrated elastomeric band to maintain hydrostatic pressure. Image copied from [38].

The Acuset is not commercially available and has faced clinical trial and legal issues in the past [65]. Nonetheless, it is a good example of a feasible solution for low-resource areas. When shown to stakeholders, it was identified as a ‘perfect’ solution, aside from the lack of an alert function. It is unclear what the cost of this device is or where the inventors are in the marketing process. Multiple attempts were made to contact the inventors, but no response was received.

Infusion pumps are typically the best IV solution for most patients, but it would be very difficult to produce a better infusion pump in a matter of months, and even if it was done, that solution might be too costly to be implemented in low-resource settings. The common theme among these existing solutions is that they are expensive, and thus a lower cost method of accurately controlling and monitoring fluid flow has yet to be implemented. Purely mechanical solutions need constant hydrostatic pressure to be accurate, and there are very few solutions that accomplish maintaining that pressure on the market. Additionally, stakeholders have said that they would like a device that alerts them to changes in flow rate, if there is air in the tube or if the tube is blocked, and when the infusion is almost finished. No low-cost solutions were found that accomplish these functions. There are generally large gaps between the design and implementation of IV devices, as thousands of patents exist, but very few devices are commercially available. Despite the interest in this particular problem, no solution has been widely implemented in low-resource areas like sub-Saharan Africa. The benchmarked devices show that this is more than a design problem - it’s an operations problem too. The outcome of this project will be a concept in one of two forms: an incremental improvement over an existing device or a supplemental device for existing solutions to satisfy more requirements.

User Requirements and Engineering Specifications

The ten user requirements (Table 1, page 13-14) were generated through interviews, observations, and literature searches in Ghana. These information sources, along with additional research and benchmarking, were used to translate the requirements into engineering specifications that could be used to test whether or not the solution meets the need. These requirements and specifications have continued to develop as more research has been conducted in the USA, through additional interviews, observations, and more extensive literature searches. A priority scale is used for each specification.

The critical requirements that were used to drive concept generation and evaluation are the following: controls flow, stops flow at a volume set by the user, alerts provider when infusion stops, is compatible with drip chambers and IV tubing, does not use proprietary equipment, keeps air out of line, is low-cost, and is portable. These critical requirements are further explained on pages 15-17. The priority scale shows the importance of a specification and is ranked from 1 to 3: high priority - must have (1), medium priority - nice to have (2), and low priority - luxury item (3). The priority of each specification was ranked based on safety, trends between benchmarked devices, stakeholder feedback/requests, and any other relevant literature found with respect to the specification. It was decided to prioritize specifications rather than requirements due to specifications having a range of importance within each requirement category. If priority was placed on requirements, it would put more emphasis on less important specifications that aren’t as integral to device performance/safety.

Table 1. Requirements and Specifications

Requirement	Specification	Priority	Rationale/Justification	Sources
Controls Flow Rate	Controls flow between 0 mL/hr and 250 mL/hr and sustains accuracy to within $\pm 10\%$	1	<i>The majority of benchmarked solutions are adjustable within this range. Doctors and nurses have said that 99% of drugs are administered within this range.</i>	[14]–[16], [19], [20], [22], [25]–[27], [29], [30], [34], [38], [39]
Controls Volume	Stops the flow of medication/fluids at a volume set by the user between 0 and 500 mL and is accurate to within $\pm 10\%$	1	<i>Stakeholders have said that this is imperative to a device that they would use. Standard IV bag volumes are 500 mL and patients (usually children) often need volumes <500mL. Doctors say $\pm 10\%$ is a good range.</i>	[15], [16], [19], [20], [25]–[28]
Alerts Healthcare Providers Within the Ward	Alert the provider when an infusion has stopped	1	<i>Stakeholders say that they want to know if an infusion has stopped prematurely, and also want to know when it is finished. IV lines at KATH would often fill with blood if not flushed in a timely manner.</i>	[15], [17], [24], [27]
	Alert the provider when there is air > 1 mL in the line	2	<i>Air in the line could kill a patient. An anesthesiology study estimates that 10 mL of air in a peripheral line is safe. Doctors say that they would be comfortable with much less than that and 1mL fills a large length of the line.</i>	[15], [16], [35], [66], [67]
	Alert the provider when the IV becomes detached	2	<i>This was requested by a stakeholder. A detached line could allow air in and compromises the sterility of the fluid.</i>	[15], [24]
Is Portable	The center of mass needs to be within half the caster radius (10 cm) when mounted on an IV pole	1	<i>A basic calculation was done to estimate where the center of mass of the device needs to be for it to safely be mounted on a pole.</i>	[16], [23], [29]
	Weights ≤ 3.5 kg	1	<i>3.5 kg is the weight of current perfusors at KATH. Stakeholders have said weight doesn't matter very much as long as device goes on pole. NIOSH says 3.6-5.4 kg is safe for repeated lifting.</i>	[14], [34]
	Smaller than a rectangular tissue box (13cm x 13 cm x 23 cm)	2	<i>Based on ethnographic findings when asking 'how big is too big?'</i>	[16], [23], [27], [29], [35]
	Can be transported with one hand	2	<i>Stakeholders have said that the device needs to be able to be moved with the patient during transfer or procedures. Being able to do so with one hand makes transport much easier - even if its moving the pole around w/ device on it.</i>	[15], [17], [23]
	Takes less than 15 seconds to attach to the wall, bed, and IV pole	2	<i>Students timed how long it took to attach perfusors to poles at KATH. Stakeholders were happy with the attachment and how long it took.</i>	[14], [16], [17], [27], [35]
	Able to control the flow rate/volume administered of at least 2 different fluids independently at the same time	3	<i>A study at Michigan said patients have on average 2 infusions. Stakeholders in Ghana really wanted something that could administer more than one fluid at a time to reduce the number of devices stacked on a single pole and surrounding the patient in an already cluttered environment.</i>	[14], [16], [17], [23], [27]–[30]

Table 1 (Cont.). Requirements and Specifications

Requirement	Specification	Priority	Rationale/Justification	Sources
Complies with Current Market Standards	Compatible with drip chamber diameters between 1.3 cm and 2.11 cm	1	<i>Based on specs for drip chamber attachment on DripAssist - they found these numbers by purchasing giving sets from around the world and measuring the drip chambers.</i>	[64]
	Compatible with current IV equipment based on ISO 1135 and ISO 8536 international standards	1	<i>Standards that specify requirements for single use, gravity feed transfusion and infusion sets.</i>	[16], [17], [25], [27], [29], [31]–[33]
	Does not use proprietary or device-specific tubing/equipment	1	<i>There are currently infusion pumps at KATH that are not used because they don't have the tubing that works with the device. Stakeholders have said that this spec is really important.</i>	[15], [16], [24], [68]
Is Easy/Quick to Use	Allows the user to change the administration settings in ≤ 10 seconds	1	<i>Timed how long it takes to change the administration settings on current devices. Stakeholders say it shouldn't take more than 10 seconds.</i>	[15], [17], [26], [28], [39]
	Colocate all information relevant to device performance/function	2	<i>Nurses at KATH weren't sure how long the battery life on the perfusors were because they couldn't find the battery indicator.</i>	[14], [17], [22], [23], [28]
	Follows ISO/IEC Guide 37:2012 for instructions for use of products by consumers	2	<i>Guidelines for instructions: how to present information for ease of use and safety.</i>	[17], [22], [23], [28]
	The device is utilized in ≤ 3 steps	2	<i>When a '3 step' benchmarked solution was shown to stakeholders, they said that it would make the device really easy to use.</i>	[14], [24]
	Takes ≤ 5 min to go from one use to the next, including cleaning, if reusable	2	<i>Stakeholders said they wouldn't spend more than 5 minutes cleaning the outside of the device between uses/patients. Infusion pumps take about two minutes to clean</i>	[14], [15], [69], [70]
	Displays flow rate in mL/min and mL/hr	2	<i>A couple of nurses at KATH didn't seem to understand how to convert between mL/min and mL/hr.</i>	[14], [16], [17], [26], [27]
Can be Used in Low-Resource Settings	Costs $< \$0.10$ per use	1	<i>Calculated based on infusion pump cost for use 3 times per day for 15 years.</i>	[13], [19], [23], [28], [35], [36]
	Able to be independent of wall electricity source for 12 hours	1	<i>Blackouts in typical rural hospitals can last up to 12 hours. Being able to unplug the device and continue to use it makes moving patients into hallways (done often) and patient transport much easier.</i>	[15], [17], [23], [26], [29], [34]
	Does not use electricity	2	<i>Same as above. Stakeholders say that a device that does not use electricity at all would be preferable.</i>	[16], [24], [68]
Is Durable (If reusable)	Lasts for $> 60,000$ hours	1	<i>Calculated based on 3 uses per day over 15 years with an average of 4 hours per infusion.</i>	[14], [16], [19], [23]
Is Easy to Maintain (If Reusable)	Does not require specialized tooling to repair	1	<i>Stakeholders say that if the device requires specialized tooling to repair, it won't be fixed if broken, and would become useless.</i>	[15], [23], [36], [37]
Provides Patient Safety	Does not allow > 1 mL of air into the line	1	<i>Air in the line could kill a patient. An anesthesiology study estimates that 10 mL of air in a peripheral line is safe. Doctors say that they would be comfortable with much less than that.</i>	[15], [39], [71]
	Does not allow patient to tamper with the device	3	<i>Stakeholders say that patient tampering happens rarely, if ever. Children may play with the device, so something that prevents them from accidentally changing it would be nice.</i>	[15], [16], [35]

Control Flow Rate. Accurate flow rate control is important for safely administering IV medications. The flow rate is the amount of liquid that flows through the tube and into the patient over a certain amount of time. Being able to control this is crucial, especially for concentrated medications. This specification identifies a flow rate range for standard flow rate control of both concentrated and diffused medications. According to observations, benchmarks, and interviews, standard concentrated and diffused medications are not generally administered at a rate faster than 250 mL/hr [30], [38], [72].

Control Volume. This specification comes from interviews with nurses, where they have said that it can be difficult to stop infusions at the correct time if the volume required is less than that of the standard IV bag (equal to 500 mL) due to understaffing. If the volume cannot be controlled and the nurse is unable to stop the medication at the correct time, the medication would continually flow and potentially overdose the patient [16], [17], [22], [26]. Additionally, while students were in Ghana they observed blood backing up into the IV line as a result of the line not being promptly flushed after the infusion had finished. The blood could then clog the line, in which case the line would have to be changed (which takes away more time from the nurse) or, if the clot was small enough, the nurse could attempt to bust it by flushing the line, which could potentially result in a pulmonary embolism [14], [17], [19], [26]. Having a feature to stop the flow at the correct time would both increase patient safety and take pressure off the nurse. According to an interview with a doctor in the US, volume control is more essential than flow control, but this needs to be corroborated with an anesthesiologist [30].

Alerts Healthcare Providers Within the Ward. These specifications come from interviews with nurses and doctors, who both say that an alert for air in the line, a blocked line, changes in flow rate, a detached tube, and when the infusion is almost complete is necessary [16], [19], [24], [26], [66]–[68]. When an infusion is stopped, it may mean that the infusion is finished or it could be evidence of a blocked line or another issue. The nurse may need to start a new one, or they may need to flush the line and continue to monitor the patient. Alerting nurses that the infusion is stopped saves a lot of time between the infusion and further care. Additionally, it prevents blood from entering and blocking the line as discussed above. It also saves the nurse from having to continually check back and manually monitor the infusion [14], [17], [26], [66], [67]. Too much air in the bloodstream could cause serious complications or death, which is why it is important to alert healthcare providers of its presence [59], [71]. IVs can become detached by someone accidentally tripping over the tube, a patient moving their arm, and so on. A detached tube could allow air in the line and compromise the sterility of the fluid. The distance this signal needs to cover for a typical nurse in a typical African hospital needs to be further fleshed out with specifications for decibels for auditory, luminosity and color for visual, and frequency for both.

Is Portable. Stakeholders have said that portability is imperative, given that patients often need to be moved to make space for other patients and transferred to other wards for continued care. This requirement will be measured by six specifications relating to size, weight, build, speed of attachment, and ability to handle multiple infusions at once. These specifications address the need to mount the device on an IV pole so it can be easily transported with the rest of the infusion set-up, be easily carried during device or patient transport, not take up too much room due to overcrowding in the hospital, be quickly attached to different fixtures to save nurses time,

and infuse multiple fluids at the same time due to the severity of many patients conditions which often require more than one infusion pump [27], [29], [30], [35].

Complies with Current Market Standards. Proprietary tubing and/or equipment makes it hard for low-resource hospitals to use the product due to problems with procurement. Being able to get these, usually disposable, items reliably shipped to the hospital is not guaranteed [14], [16], [68], [73]. Many products with proprietary tubing and/or equipment just sit at these hospitals without use because the additional parts are not available [14], [73]. Three specifications were then generated from this information to ensure compatibility with available equipment. These specifications use standards for common intravenous equipment, as well as benchmarked solutions that interface with different sized components, and specify that device-specific equipment should not be required to operate the device.

Is Easy/Quick to Use. Allowing the user to change the administration settings in less than ten seconds directly addresses the part of the need concerned with caregivers' time. This value was determined by the corresponding time on benchmarked devices as well as stakeholders saying that they needed to change the administration settings in less than ten seconds [14], [17], [19], [26], [68]. The second specification came from interviews in Ghana, where nurses did not know how long the battery on the current perfusors would last because they could not locate the battery indicator [17], [22], [23], [27], [28]. The next specification about proficiency addresses the need to learn how to use the new device quickly to avoid frustration, misuse, and improve productivity [13], [14], [23], [70]. The specification about the number of steps came from conversations with stakeholders over a benchmarked solution that required three steps to operate, which they said made it 'easy to use' [16], [24], [68]. The time between uses came from a couple of interviews in the US about how long it usually takes completely reset and clean the device for a new line or patient [15], [70]. The last requirement came from interviews with one or two nurses in Ghana that were unsure about the conversion between mL/min and mL/hr [16], [27].

Can be Used in Low-Resource Settings. Low-resource hospitals cannot afford costly technologies for every patient. The team decided to use make the cost specification "per use" because it enables direct comparison of single use and reusable devices. In particular, ten cents per use was calculated based on the cost of using a peristaltic infusion pump three times per day for 15 years. Additionally, not all hospitals in Ghana consistently have electricity, and the team would like to develop a device that can be used at all hospitals in low-resource settings [16], [24], [68]. Because of this, the team has decided that it would be nice to have a solution that does not use electricity at all. However, in order to leave options open in terms of solutions and alarm systems, the primary specification was defined to be "usable without wall electricity for a minimum of 12 hours."

Is Durable (If Reusable). If the solution is disposable, this category will be removed or replaced. The specification comes from an interview with the KATH procurement office where students were told that the current perfusors were donated and have been in use for over 10 years, and were already around five years old when they were received [22]. 60,000 hours was calculated based on 3 uses per day over a 15 year period with an average time of 4 hours per infusion.

Is Easy to Maintain (If Reusable). This requirement is based on the device being reusable. If the solution ends up being disposable, this category will be removed or replaced. Needing specialized tooling to repair the device could result in the device remaining broken if the tooling is broken or lost, and it increases the overall cost. The team does not want to create a concept that ends up in a hospital equipment graveyard.

Provides Patient Safety. Safety is always the number one responsibility for any hospital, and therefore, very important for any device that enters a hospital or interacts with a patient. Crucial components of IV safety include not allowing air into the tubing and preventing the patient or patient's family from tampering with the device [17], [70], [71]. Too much air in the bloodstream could cause serious complications or death [59], [71]. If patients change the flow rate or volume control on the device they could hurt themselves, however preventing patient tampering is not as high of a priority because most current devices do not have this feature. This is likely because patients/families rarely tamper with flow rates and nurses need to be able to quickly change settings, so making it too difficult or take too long to change the flow rate could increase the risk to the patient [38], [59], [70].

Requirement Benchmarking. It is beneficial to compare current benchmarked devices to the requirements to find product weaknesses and market gaps. In particular, current low-cost devices lack volume control and robust alerts (expensive devices lack the ability to sustainably be used in low-resource settings). The identified market gaps can then be exploited in concept generation. A comparison of the benchmarked devices with regards to the requirements is shown (Table 2, page 18). A “Y” indicates that the device generally satisfies the requirement, although it might not meet every engineering specification in that category. An “N” indicates that the device does not generally satisfy the requirement, even if it happens to meet some of the engineering specifications. A “?” indicates that there is little to no information available on if this device satisfies the requirement and the associated engineering specifications. An “N/A” indicates that the requirement is not applicable to the device.

Table 2. Benchmarked solution comparison.

Requirement	Roller-Clamp	Dial-a-flow	Acuset	Syringe Pump (B.Braun)	Infusion Pump	DripAssist
Control Flow Rate	N ¹	Y	Y	Y	Y	N
Control Volume	N	N	N	Y	Y	N
Alerts Healthcare Providers Within the Ward	N	N	N	Y	Y	Y
Is Portable	Y	Y	Y	Y	Y	Y
Complies with Current Market Standards	Y	Y	N	Y	Y	Y
Is Easy/Quick to Use	N	Y	Y	Y	Y	Y
Can be Used in Low-Resource Settings	Y	Y	Y	N	N	Y
Is Durable (If reusable)	N/A	N/A	N/A	Y	Y	Y
Is Easy to Maintain (If Reusable)	N/A	N/A	?	N	N	Y
Provides Patient Safety	N	N	N	Y	Y	Y

1: Roller-clamps have the ability to regulate the flow rate, but they do not meet any of the specifications for accuracy or incremental flow

As seen in this table, no device meets all the requirements, this indicates possible room for improvement. There are also a few requirements that aren't satisfied by many devices. These are all potential areas to look into when beginning to narrow the focus of the project and find a niche when generating concepts.

Concept Generation

Methods

During concept generation, the team utilized a benchmark breakdown (a method invented by the team) to evaluate gaps in the market, SCAMPER, lateral thinking achieved by a trip to a hardware store, Design Heuristic Cards, Functional Decomposition, and a Benchmark Integration Technique (BIT) to generate concepts. No additional concept generation needs to be performed before analyzing current concepts and receiving feedback from stakeholders. During the benchmark breakdown, the team used benchmarked solutions to evaluate the current field of products and identify gaps in the market. This was done because the solution space is saturated and the team felt it was a good place to start generating novel concepts. This method helped identify functional needs in the market, which were later confirmed by stakeholders: a way to alert nurses when the infusion is finished or interrupted, a way to control the volume of fluid administered, and a way to maintain hydrostatic pressure. Two concepts were generated from this method; one of which was elastic band that maintains hydrostatic pressure. This device would keep the fluid level constant with respect to the ground and therefore maintain the hydrostatic pressure.

SCAMPER was used to try to improve an existing product. From this method, the team was able to generate 19 ideas. However, none of these ideas were novel and/or reasonable. Ideas generated with SCAMPER included an aqua globe as seen on TV (which would insert into the patient's vein and somehow push fluid in), an Acuset without proprietary tubing, and a combination of multiple flow rate devices like the Acuset and the DripAssist. This combination would be beneficial for both flow rate control and monitoring, effectively bridging the gap in the market. The drip assist would be able to monitor the flow rate and alert the provider if the flow rate changed, and the Acuset would be able to provide constant hydrostatic pressure and more accurately control flow rate.

The team used lateral thinking to look at the problem from new and unique angles. Nai'a and Alex went to Jack's Hardware Store and tried to work random pieces of equipment in the store into a concept to monitor or control the flow rate. This concept generation method led to 21 new designs. While at the store, the team looked at bathtub stoppers, which was incorporated into a concept to stop/control flow from the interface between the bag and the tubing.

Design Heuristic Cards were used to focus on specific design characteristics and also trigger lateral thinking. This was one of the most effective methods for generating novel and feasible concepts. The team developed 29 new concepts with this approach. This method was extremely helpful for discovering new energy methods and mechanical solutions. Notably, an iron lung concept and a mechanical peristaltic pump came out of this concept generation method. The iron lung would work by inserting the IV bag into a pressurized chamber. The pressure in the chamber would be adjusted to change the flow rate. The mechanical peristaltic pump would use a similar mechanism as an electric powered pump for controlling the flow of fluid, but would be 'powered' by a falling weight which would turn the rollers used to pump fluid out.

The team also used Functional Decomposition to isolate different methods of achieving important functions. The group was able to identify 11 primary functions with 9-18 methods for each function. Table 3 shows generalized concepts from the original list which were considered the most feasible.

Table 3. Condensed list of the most feasible methods from functional decomposition.

Function	Adjusts Fluid Flow Rate	Monitors Flow Rate	Moves Fluid	Stops Fluid	Energy into system	Alerts provider
Method 1	valve	optical sensor	syringe pump	pinch/clamp line	windup spring	bell
Method 2	various clamps	measure weight	gravity	inline stop	hydraulics	beep
Method 3	piston flow meter	pressure monitor	soap dispenser	equalize pressure	pulley/crank system	buzz
Method 4	change hole size	turbine blades	sink	run out of energy	batteries	light
Method 5	change pressure	doppler velocimetry	peristaltic pump		solar	
Method 6	soap dispenser	thermal mass	toothpaste tube		recycle movement	
Method 7	roll out fluid	rotary piston	BP cuff			
Method 8	more energy	coriolis				

One of the concepts to come out of this design method was a smartphone app. The smartphone app would allow the user to input known fluid information, like volume of bag, time of infusion, or the flow/drip rate, and would output the unknown values. This could reduce calculation errors and speed up flow control. The app could also use the phone's camera to count the drop rate and display the corresponding flow rate in mL/hr and/or beep when the desired flow rate is achieved.

The Benchmark Integration Technique (BIT) or Frankenstein method was used by the team to create new concepts from already established devices. This method was made up by the team and the idea was to take parts and functions of multiple devices and combine them into one device. The team was able to develop 11 new concepts with this method. One concept generated with this method was a solenoid design, which would push a piston back and forth to pinch the tube at specific time intervals to control the flow rate.

Generated Concepts

As seen in Figure 12 (page 21), these methods allowed the team to generate concepts that could achieve the two main functions of the device: monitoring and control. There were both mechanical and electromechanical designs for each of these device types. The flow rate

monitoring concepts utilized fluid weighing systems (one concept), discrete volume measurements (11 concepts), pressure monitoring systems (one concept), and turbines (three concepts). The flow-rate control concepts used functions like inline clamps/stops (13 concepts), discrete volume control (11 concepts), and pressure control (10 concepts).

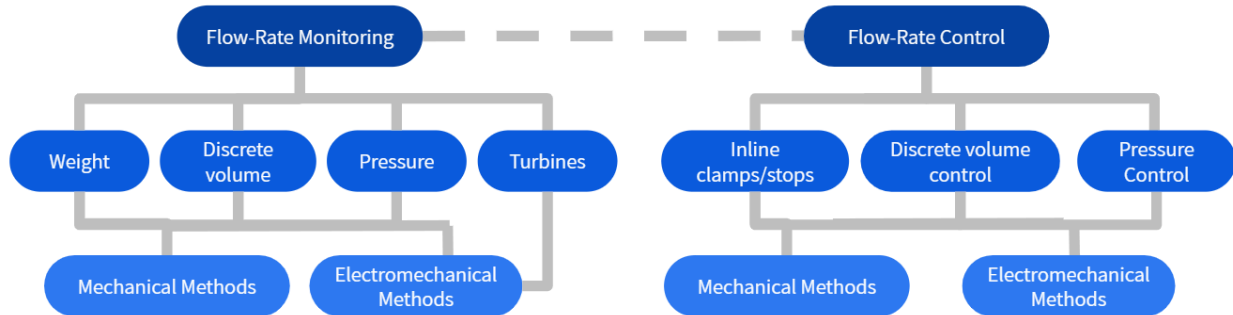


Figure 12. Concept types generated.

These design types can be further broken down into their functional methods. Eleven major design functions were determined by the team: internal and external clamping of the tube, internal and external discrete volume control, internal and external pressure control, external clamping of the bag, filtering, drop count monitoring, pressure monitoring, and weight monitoring.

For external clamping of the tube, the team developed eight unique concepts. These concepts all used some type of external force on the tubing to decrease its cross sectional area. An example of one of these concepts is a magnetic clamp (shown in Figure 13) that would increase its force on the tube by increasing the current that is passed through it. An advantage of this concept is that it would automatically clamp the tube when coupled with a closed loop monitoring system. Disadvantages are that it would require continuous power and the current outputted would have to be accurate enough for small changes in flow rate.

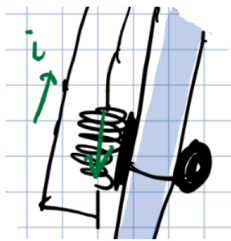


Figure 13. Magnetic clamp controlled by current flowing through an inductor.

For internal clamping of the tube, the team developed four unique concepts. Internal ‘clamping’ of the tube was defined as decreasing the cross sectional area of the tube from the inside. An example of this method (Figure 14, page 22) would be a disc with different hole sizes that could be rotated to change the flow rate. An advantage of this method is that it is very similar to the function of the Dial-a-Flow, and thus is very likely to work. A disadvantage is that the solution

would be disposable and have the same problems with implementation that the Dial-a-Flow has (patients would likely have to purchase it themselves) because it is a single-use device.

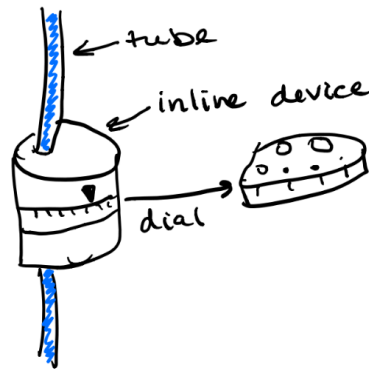


Figure 14. Single-use disc with different hole sizes for different flow rates.

For external discrete volume control, the team developed 6 concepts. An example of this method is a linear peristaltic pump (Figure 15) that uses one piston to push fluid out of the tube and a second piston to clamp the tube while the first piston moves back into position to push the same discrete volume of fluid out. Advantages of this system are that it uses the same mechanism as a peristaltic pump, which is a proven system, and the linear nature of the system makes it suitable for different sized tubes. A disadvantage of this system is that it is more complicated and has more moving parts than a peristaltic pump, which is already a very expensive system.

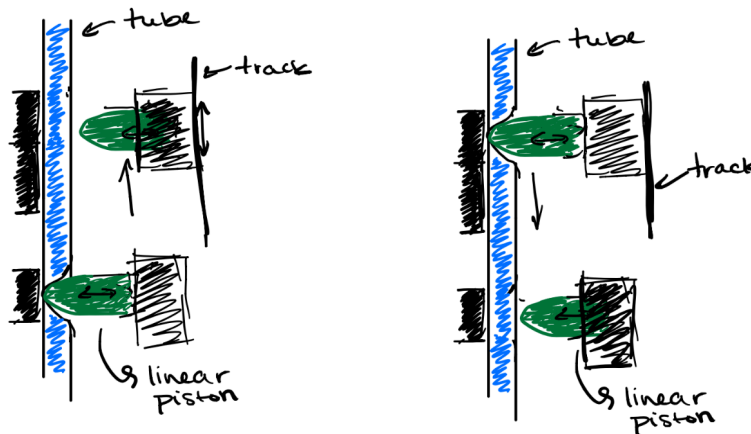


Figure 15. Linear peristaltic pump. The top piston moves up and down the track to push fluid out of the tube and the bottom piston moves in and out horizontally to stop fluid from flowing while the top piston moves back to the top of the track.

For internal discrete volume control, the group developed five unique concepts. An example of this function is the soap dispenser (Figure 16, page 23). The soap dispenser idea would utilize a wind up spring mechanism that would determine the length of time that the fluid is administered and power a piston to push discrete volumes of fluid through a one way valve into the drip chamber. Additionally, it would alert the provider when it wound down and hit a bell like an egg kitchen timer. Advantages to this system are that it does not require electricity to run and would

not require a secondary monitoring system, because the volume outputted is always known. A disadvantage is that the soap dispenser attachment would be specialized for this device and single-use, likely causing implementation problems.

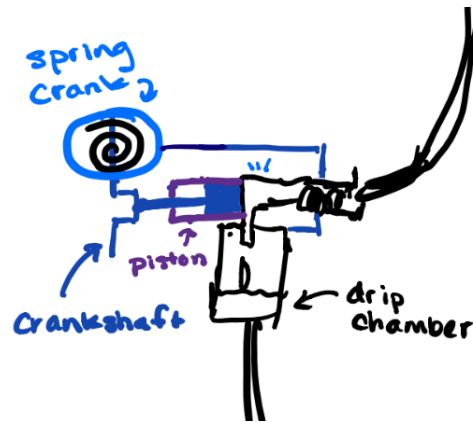


Figure 16. Soap dispenser system powered by a spring crank mechanism. The spring crank powers a crankshaft which forces a piston to push discrete volumes out of the soap dispenser.

For external pressure control, the team developed seven unique concepts. One example is a pulley and roller system (Figure 17) where the rollers remain stationary as the pulley raises the height of the IV bag and allows the rollers to push fluid out of the bag at a desired rate. An advantage to this system is that it would be reusable, however the device would not work on IV bottles or be able to stop flow.

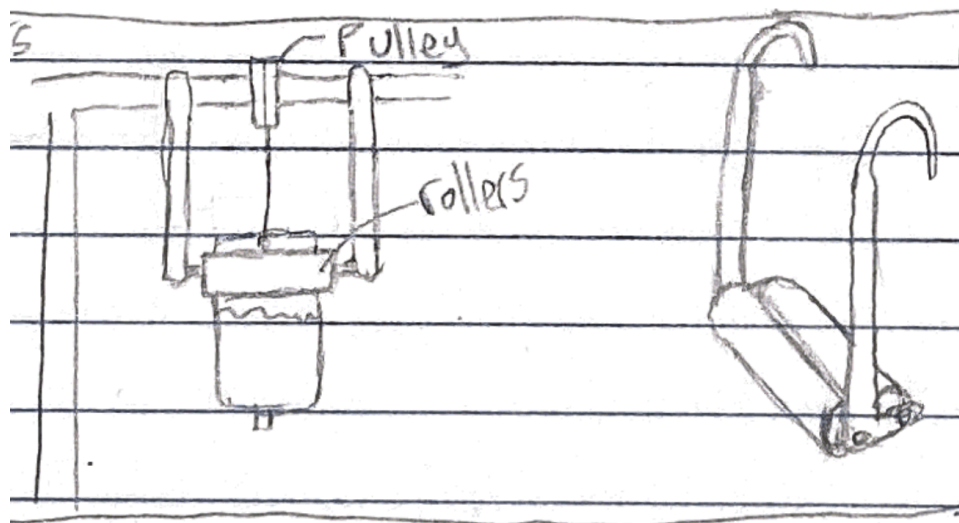


Figure 17. Pulley and roller system to push fluid out of an IV bag at a desired rate.

For internal pressure control, the team developed three unique concepts. One of these concepts (Figure 18, page 24) is a system that would pump air out of the drip chamber to lower the pressure and cause drops to fall into the drip chamber faster. This concept may reduce the risk of air getting trapped in the line, however it also would not stop flow and would have to be thrown out after every use.

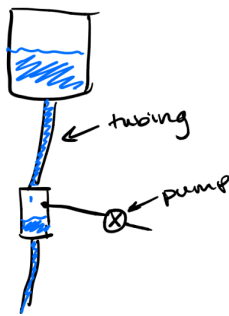


Figure 18. System to suck air out of the drip chamber and increase flow rate.

For external clamping of the bag, there was only one unique concept developed. This concept (Figure 19) involved clamping the IV medication bag instead of the IV tubing to regulate the flow rate of the medication. This was an interesting thought, however it would likely be harder to control than simply clamping the tubing and would not work on IV bottles.



Figure 19. A clamp for the IV bag (rather than the tubing) to control flow rate.

There was also only one unique concept generated for the filtering method. This concept (Figure 20) would work by stacking filters on top of each other to decrease flow rate. The user would have to add a set number of filters to achieve the desired flow rate. This would likely compromise the sterility of the system and add a lot of extra parts to its function.

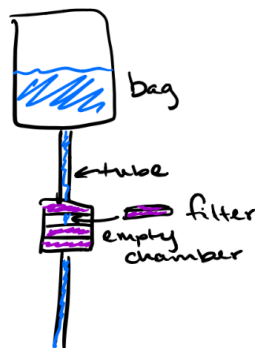


Figure 20. Filter-stacking flow control device which requires the user to add filters to decrease flow rate.

For drop count monitoring, there were two unique methods generated. One of these methods (Figure 21) would use an optical sensor placed on the drip chamber to count the drops and alert the provider if it increased or decreased below its desired rate. This is exactly the same as the DripAssist, which is proven to work, but expensive to purchase.

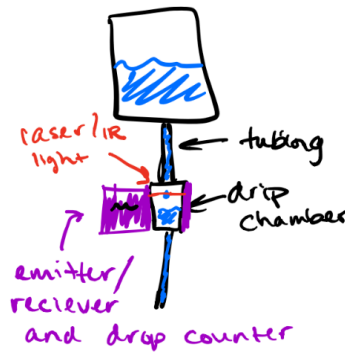


Figure 21. Optical drop counter exactly like the DripAssist.

For pressure monitoring, there was only one unique concept generated. This concept (Figure 22) would use a venturi meter with a differential pressure sensor to measure flow rate. This is a common method used to measure flow rate, however it would have to be a single-use device as it would require contact with the fluid.

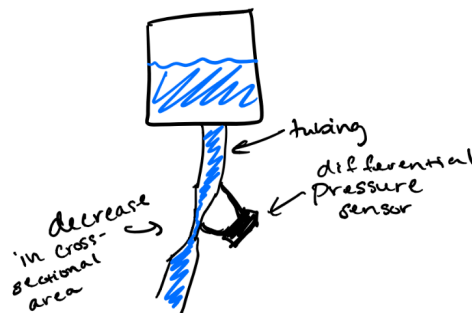


Figure 22. Venturi meter for flow rate monitoring.

For weight monitoring, there was only one unique concept generated. This concept (Figure 23, page 26) would use a spring-scale-type mechanism with a potentiometer to monitor changes in weight and thus flow rate. The potentiometer would measure the change in length of the spring or elastomer material, and based on the modulus of the material, the change in weight could be calculated. This system could be calibrated to maintain the fluid level with respect to the ground (to maintain hydrostatic pressure) and therefore increase accuracy of a coupled/secondary system used to clamp the line. Another advantage is that the system is external and therefore reusable and easily implementable. A disadvantage is that the system would have to be very accurate to calculate an accurate flow rate and creep in an elastomer could cause changes to the elastic modulus.

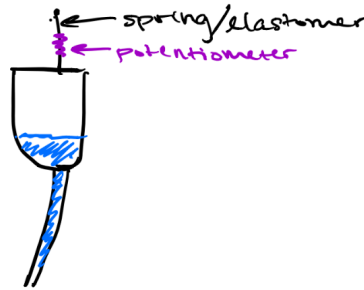


Figure 23. Spring-scale-type mechanism with a potentiometer to monitor changes in weight and thus flow rate.

Concept Evaluation

In order to evaluate the 83 concepts generated using the methods described above, an iterative approach was used (Figure 24). Five different tests were used to screen the concepts, winnowing the field down to one final concept.

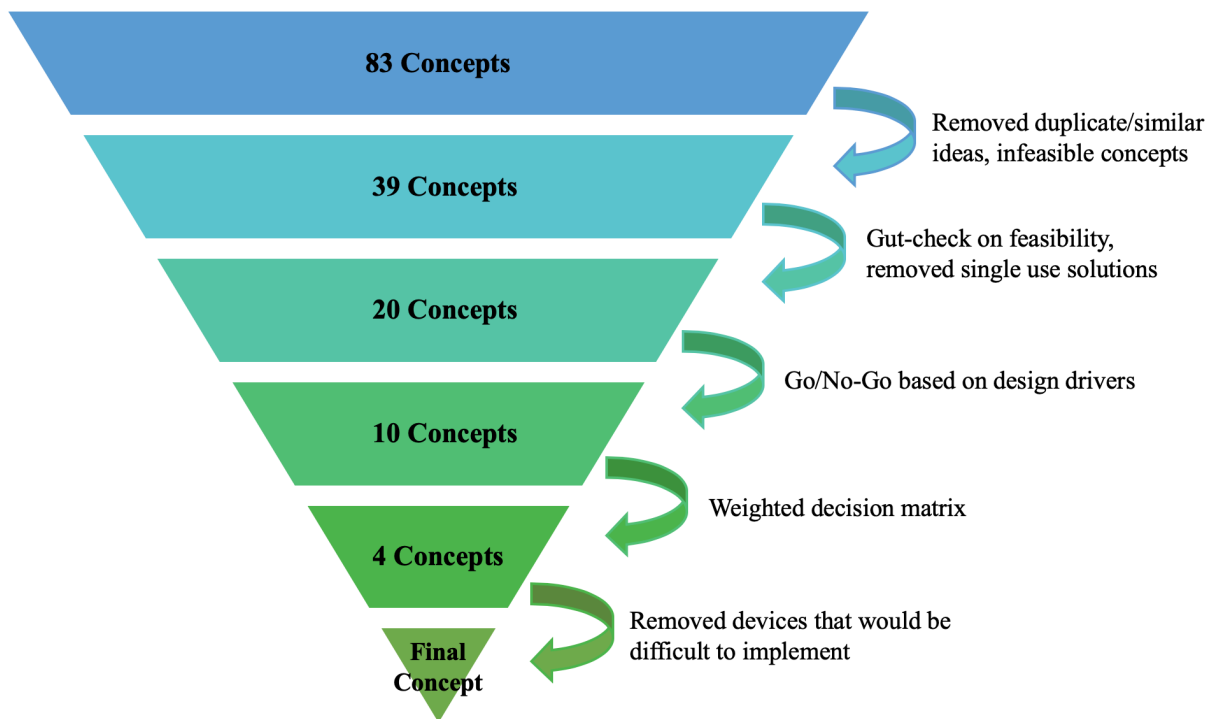


Figure 24. An inverted pyramid diagram illustrating the methodology for narrowing down the concepts and the number of remaining concepts after each step.

During evaluation, concepts were in the form of ideas that achieve one of the two primary functions necessary for the device: monitoring and control. For the first pass, ridiculous ideas, such as ‘bees wax to clog the line’, were eliminated and an affinity diagram was used to eliminate and combine repeated ideas. In the affinity diagram, all of the concepts were grouped into one of eight categories: discrete volume control, clamping, pressure control, pressure

monitoring, filtering, weight monitoring, drop counting, and features. Features were ideas that could be applied to multiple concepts and did not directly address monitoring or control, so they were ignored for the rest of the evaluation. After the first pass, 39 ideas remained. For the second pass, a gut-check on feasibility was performed and any system that required direct contact with IV fluid was eliminated, so that the solution could be reusable. This decision was made based on feedback from stakeholders who said disposable solutions may not be effectively implemented and the use of other disposable solutions at KATH (the patient's family must purchase them from the hospital stores even though they only cost a few cents) [14], [15]. The feasibility gut-check eliminated ideas like 'twisting the tube to reduce flow rate,' which the team thought would be flawed in accuracy and repeatability over a number of uses. After the second pass, 20 concepts remained.

For the third pass, a Go/No-Go approach was used with design drivers taken from top priority specifications. The design drivers used were: controls flow, stops flow at a volume set by the user, alerts provider when infusion stops, compatible with drip chambers and IV tubing, does not use proprietary equipment, keeps air out of line, is low-cost, and is portable. If the concept could potentially address all of these design drivers (even if it needed to be combined with another concept) it passed. There were 10 concepts remaining after this pass. For the fourth pass, a weighted decision matrix (Appendix B, page 85) was generated with criteria based on design drivers and the team's mission statement (to create a novel solution that is implementable in all medical communities, increases patient safety, and makes intravenous administration simpler for healthcare providers). Weights were given as percents (zero to one) and each concept was ranked from one (inadequate) to five (excellent). There were four concepts that scored much higher than the rest, and three of the top concepts were selected from this matrix. The fourth concept was the linear peristaltic pump described above and was not chosen because it is essentially a more complex version of the first concept selected.

The first concept selected (Figure 25, page 28) was essentially a peristaltic pump powered by a falling weight. Rollers are used to push fluid out of the tube in discrete volumes. The rollers rotate as the weight falls to a hard stop. The hard stop is adjustable for volume control and the flow rate is changed by adjusting the weight on the line and/or which gears are in contact with each other, similar to a car transmission. A crank is used to lift the weight back up to the spindle. Advantages of this concept include that the method to push fluid has been proven to work (it is the standard for an infusion pump in a high resource setting), it would not require a secondary monitoring system because a known volume would be pushed out of the line at all times, and it would not require power to run so it would be suitable in lower resource hospitals in more rural towns. Disadvantages of this concept include that it would require many gears/gear ratios and/or weights, adding clunkiness and cost to the system and the rollers would have to be designed to work with a specific tubing, because tubing sizes are not standard.

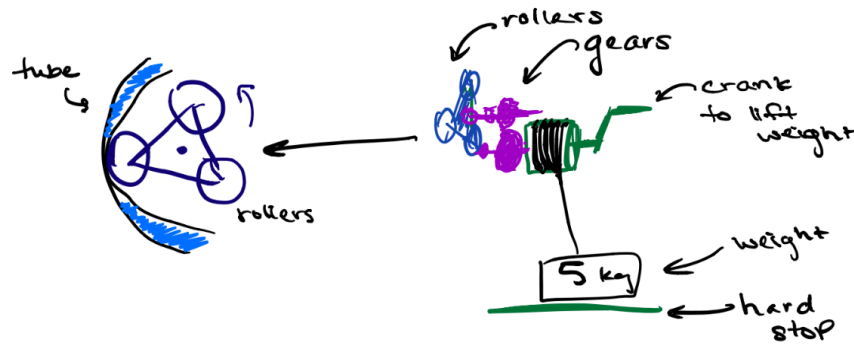


Figure 25. Peristaltic pump powered by a falling weight.

The second selected concept (Figure 26) is a solenoid/piston system that clamps the tube at regular intervals in order to let discrete volumes of fluid out. The main advantage of this design is that it is simple. Disadvantages of this method include that it would have to be coupled with a monitoring system (such as measuring the weight of the bag or optically counting drops in the drip chamber) to make sure the flow rate is being controlled as intended because changes to the system such as an increase in venous back pressure or a decrease in hydrostatic pressure in the bag as it empties could cause the flow rate to change.

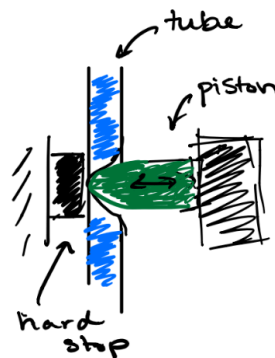


Figure 26. Solenoid/piston to clamp tube and stop flow at regular intervals.

The third selected idea is an add-on system to maintain hydrostatic pressure and therefore flow rate over time. There are two identified methods of achieving this, which are shown in Figure 27 (page 29). The first method uses an elastomeric band (similar to the Acuset) that decreases in length as the water level falls. A potentiometer could be installed on the band to measure the rate at which the fluid level is falling and therefore determine the flow rate. The second method would be to use a low-power motor to lift the bag over time. A potentiometer spring system could be installed on this method as well to monitor the flow rate. An advantage of this method is that it would be able to be used on any existing system to improve control and a disadvantage of this system is that it would not control flow rate on its own.

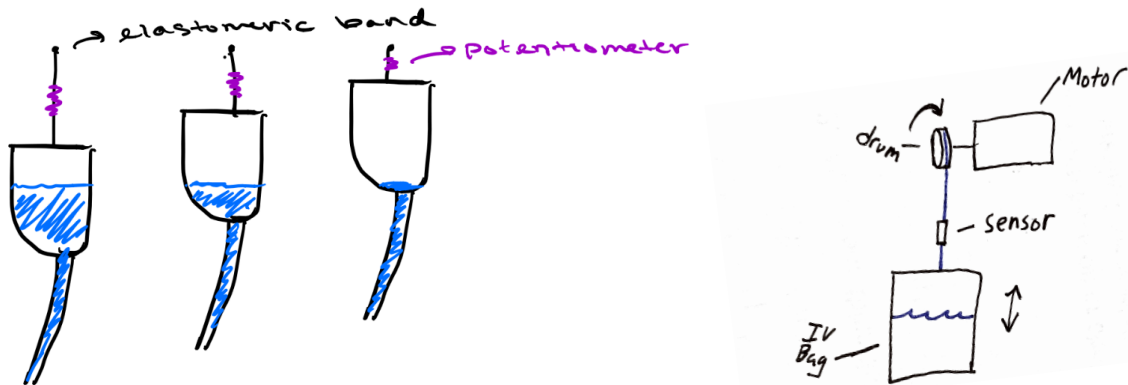


Figure 27. The sketch on the left shows the elastomeric band decreasing in overall length as the volume of the fluid in the IV bag decreases, thus maintaining a constant fluid level. The sketch on the right shows how a weight or strain sensor could be used to estimate the fluid volume in the bag and the flow rate, and this feedback could be sent to a motor that adjusts the height of the bag accordingly.

Engineering Analysis

Halfway through the semester, it became apparent that the initial scope of the project was too broad. While most of the design drivers held true, the team did make one major change: the primary driver became volume control, rather than flow control. The reasoning for this change will be discussed in this section of the report.

Initial Design Drivers

In order to evaluate, refine, and optimize the design, the team first had to decide on the direction of the project. Seven primary design drivers were generated, and are as follows: (1) The device must accurately control the flow rate of an infusion. (2) The device must stop the flow of medication/fluids at a volume set by the user, such that patients will not be overdosed by infusions running for too long. (3) The device must alert the healthcare provider when the infusion is over so that the providers are prompted to check on the patient and continue care by setting up the patient's next infusion if necessary. The device must be (4) low-cost so that it can be easily procured by hospitals in low-resource areas, (5) portable such that it can continue to work during patient transport and while patients are stationed in hallways, (6) reusable, and (7) work with equipment currently used in the ED at KATH to avoid problems with procurement. Current devices for controlling flow rate exist in the ED at KATH, but are not used because they require specific equipment that is not readily available.

These design drivers had changed slightly since they were used for initial concept evaluation. In particular, the driver to keep air out of the line was removed, because all solutions were external and did not increase the risk of introducing air into the line and the driver requiring the device to be reusable was added to eliminate the risk of patients having to buy their own equipment as they currently do with the Dial-a-Flow.

The initial design drivers used for engineering analysis were chosen based on observations, literary research, and interviews with healthcare professionals at KATH and at the University of Michigan Hospital in the US. Patients in critical care need medication quickly, precisely, and accurately. Although the healthcare providers at KATH are some of the best in the country, it becomes burdensome to meticulously calculate the rate and closely monitor each critical patient, especially because the hospital is overcrowded. Therefore, the team's goal was to mitigate some of the strain on the nurses by making a system that could quickly provide an accurate IV dosage to the patient and alert the provider when the infusion was complete to eliminate the risk of overdose.

The team also had many conversations with nurses about what features they desired in a medication delivery device. They often discussed aspects of portability and ease of use. For portability, nurses wanted a device that was smaller than a tissue box so that it wouldn't get in the way of treatment and lightweight so that it wouldn't be hard to move during patient transport. These design drivers helped the team navigate concept selection by eliminating concepts that didn't fit these requirements.

Failing the Mechanical Peristaltic Pump

The mechanical peristaltic pump was one of the concepts chosen after the initial concept evaluation. Stakeholders did not like this idea, because it would be too complicated and time consuming to set the flow rate. Additionally, the device would be large, heavy, and difficult to transport (i.e. failing the portability design driver). Because of this, this idea was abandoned and the next concept was evaluated.

Failing the Solenoid Concept

The solenoid concept was the second selected concept chosen after the initial concept evaluation. During empirical testing to evaluate tube deformation over time, the team found that the tube exhibited significant tube deformation after only 30 seconds of being kinked (see Figure 28). This suggested that the solenoid concept would likely fail, as repeatedly kinking the tube would result in unpredictable tube deformation, which would slow the flow rate, and reduce the accuracy of the solution.



Figure 28. IV tubing after being kinked for 30 seconds.

Failing the Band Concept

The band was the last concept initially selected from concept evaluation. This concept was dependent on the assumption that flow rate varied with the height of fluid in the bag (corresponding to a change in hydrostatic pressure) and that maintaining that height would aid in producing a more accurate flow rate over time. To test this assumption, calculations and a number of tests were done to monitor the flow rate over the length of an infusion. The calculations are omitted here (but shown in Appendix H, page 121) because the assumptions made were invalid and in talking to a fluids professor, empirical testing was the best way to model the system.

The test was conducted in two different ways. For both types of tests, a container full of fluid was hung on an IV pole about one meter above the cannula. For the first test method, the fluid ran through the tube and into a cup, which was on a scale. Measurements were taken from the scale every five seconds until the container was empty. For the second test method, the flow rate was measured periodically by counting the drops in the drip chamber for 30 seconds. A combination of these methods was repeated multiple times using different variables in order to verify results. Containers varied between a Ziploc bag to a feeding bag (as in Figure 29) to different sizes of actual IV bags. The fluids varied from water to saline. The flow-control mechanism varied from a roller-clamp to a Dial-a-Flow, and they were set at different rates ranging from slow to all the way open. Each test ended the same way; the flow rate stayed approximately the same from beginning to end. Two examples of these test results are shown in Figures 30 and 31 (Page 32).



Figure 29. Images showing the test conducted with the Ziploc bag (left) and feeding bag (right).

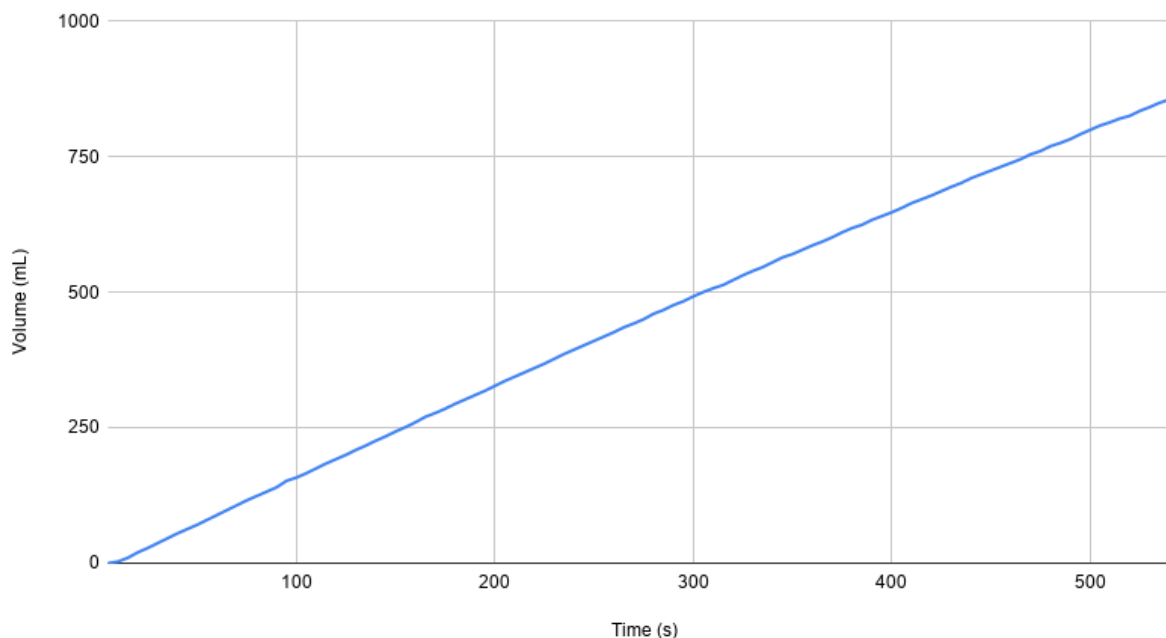


Figure 30. Volume versus time plot for saline flow out of an IV bag where data was taken every five seconds using a scale. Data showed that flow rate stayed approximately constant throughout the infusion process.

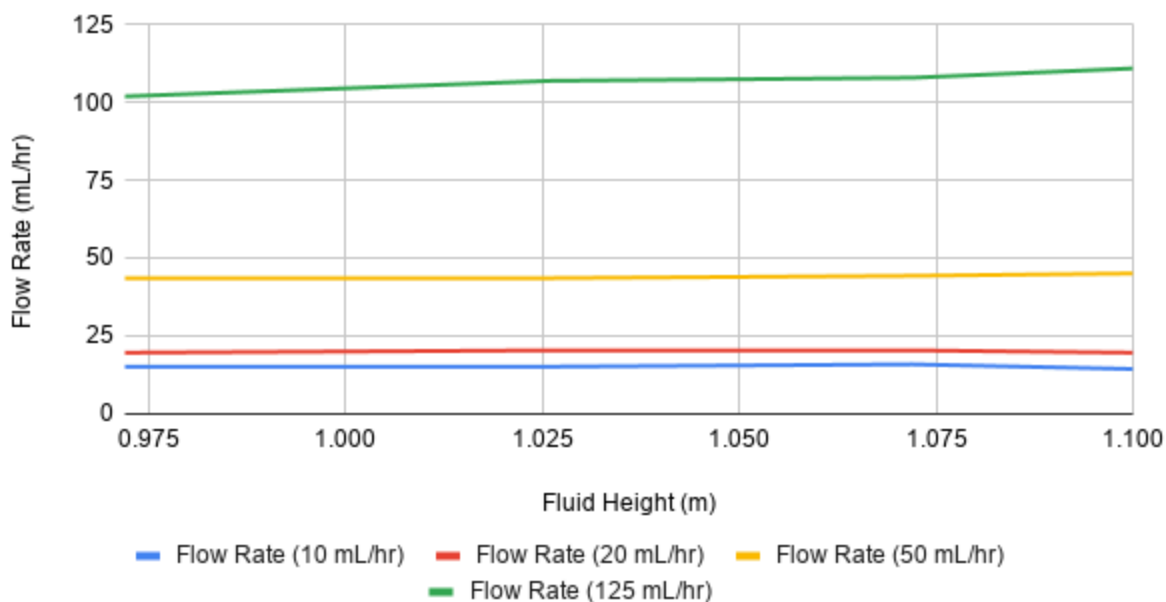


Figure 31. Flow rate versus fluid level height tested for four different flow rates. The container used was a Ziplock bag filled with water and duct taped to allow flow through the Dial-a-Flow. The results again showed that fluid level makes a negligible if any impact on flow rate.

Limitations of these tests included the error in drop counting/timing how long drops were counted for, accuracy of the scale (± 0.5 g), and timing exactly when the volume was read from the scale. These limitations were at least in part addressed through repetition and changing other variables that may have affected results (flow control mechanism, fluid type, bag type). Based on

these results, there is no need for a band that maintains hydrostatic pressure, because the effects of the fluid level dropping on flow rate are negligible.

Slot Clamp Flow Controller

After failing each of the concepts described above, the team went back to the drawing board and developed a concept (shown in Figure 32) that would slide onto the tube and pinch it for different flow rates. The user would move the slider on the mechanism to the intended flow rate and the tube would be pushed into that position. The user would then set the time needed for the infusion on the timer, and when the time was up, the tube would be completely clamped shut at the skinny end of the slot clamp. This was intended to be used to set very low flow rates (1-40 mL/hr) as those flow rates are very difficult to achieve with a roller clamp.

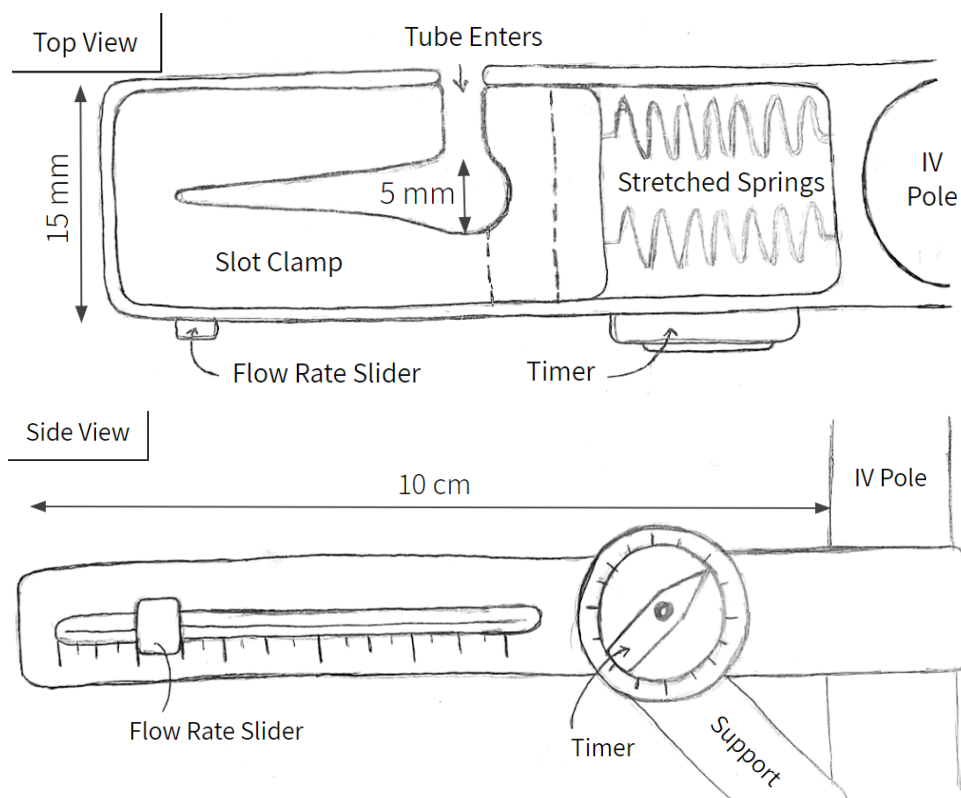


Figure 32. Slot clamp flow controller concept sketch. The flow rate slider would be used to set the flow rate and the timer (either mechanical or digital) would be set by the user. When the time was up the springs would engage to push the tube into the small end of the slot clamp and completely stop flow.

To test this concept, a pinch test of the tube was performed to find the workable range for flow rate adjustment. This test used a pair of calipers that pinched the line while fluid was flowing through it. The test started by first pinching the line shut and then opening it slightly to let fluid through. Unfortunately, the test concluded that a difference of 0.01 mm resulted in a 156 mL/hr change in flow rate; when there was no flow through the tube the caliper was clamped to 0.81 mm and when it was opened to 0.82 mm, fluid started flowing at 156 mL/hr. Limitations of the test include any deflection the caliper experienced, any deformation the tube underwent during clamping, and any inconsistency in how the team was clamping the tube. This test was repeated

multiple times and the same result occurred (i.e. there was a large change in flow rate with a difference of only 0.01 mm of clamping). The team considered the use of this device for a higher range of flow rates, but pinching the tube the same amount (as determined by the caliper) resulted in a different flow rate every time. Additionally, flow rates above 120 mL/hr are not common for medications and a device to accurately control the flow rate above that range would not likely be useful.

In addition to this tube pinching test, the team wanted to understand the other factors affecting the flow rate. One of the major factors is venous back pressure. Average venous back pressure is around 4 to 5 kPa, however, very sick patients can have a venous pressure of as low as nearly zero and as high as 13 kPa (note this refers to gauge pressure). To test the effect of venous back pressure on flow rate, the difference in flow rate with a back pressure of zero (atmospheric pressure) and 4 kPa (~30 mmHg) was tested. A tube was filled with water until the hydrostatic pressure at the bottom was 4 kPa. The IV tube was inserted into the tube until the cannula was at the bottom. The flow rate was set with a roller clamp and measured when the cannula was at the bottom of the tube by measuring the weight increase of the tube with a scale. The cannula was then removed from the tube without changing the flow rate and the flow rate was measured again with the cannula at the same elevation with respect to the bag. The flow rate was 36 mL/hr while the cannula was in the tube and 48 mL/hr while it was exposed to atmospheric pressure only (20% increase in flow rate).

Limitations of this test include the accuracy of the volume measured to fill the test tube to have the correct hydrostatic pressure, displacement caused by inserting the IV tube into the test tube, accuracy of the scale used to measure fluid volume increase (± 0.5 g), and the exact times at which the volume was read. The accuracy in volume and time measurements was reduced by measuring every five seconds over a two minute period to get a running average. The test concluded that venous pressure is a significant factor in fluid flow rate and could be very problematic for any system relying on gravity.

Project Direction Change

In talking to an anesthesiologist, it was discovered that this is not the only factor that could greatly impact the flow rate for a gravity infusion set. Piggyback lines, a change in tube fittings, and a difference in cannula size can also result in significant differences in flow rate. Based on these findings, the only viable solutions were solutions that relied on discrete volume control. The team did not identify any solutions that could cheaply achieve discrete volume control and satisfy the requirements (especially pertaining to being a reusable, low-cost solution that was compatible with current tubing and equipment used at KATH).

In further interviews with stakeholders, the team found that setting flow rates under average conditions is not very difficult to do and estimations are generally pretty accurate. There was still a huge concern over volume control and sustaining continued care for patients between infusions. Overdosing is a huge problem and happens too frequently. Nurses liked the idea of a device that would let them know when an infusion has been completed so that they could worry less about patients receiving too much medication if they did not have time to keep checking. This is especially important in the pediatric setting where volume control is crucial to patient safety.

Due to this feedback from stakeholders and findings discussed above, the focus for the project was shifted to volume control.

New Design Drivers

In order to evaluate, refine, and optimize the design based on the new direction of the project, the design drivers were revised. The six primary design drivers were then as follows: (1) The device must stop the flow of medication/fluids at a volume set by the user. (2) The device must alert the healthcare provider when the infusion is over. The device must be (3) low-cost, (4) reusable, and (5) portable. (6) The device also must work with equipment currently used in the ED at KATH.

Final Concept: Flow Stopper

From these revised design drivers, the final concept was developed. The final concept, shown in Figure 33, was similar to the slot clamp concept in that it was a mechanical timer that could be set by the user. When the time was up, it would completely clamp the tubing, stop the flow and alert the provider that the infusion had finished.

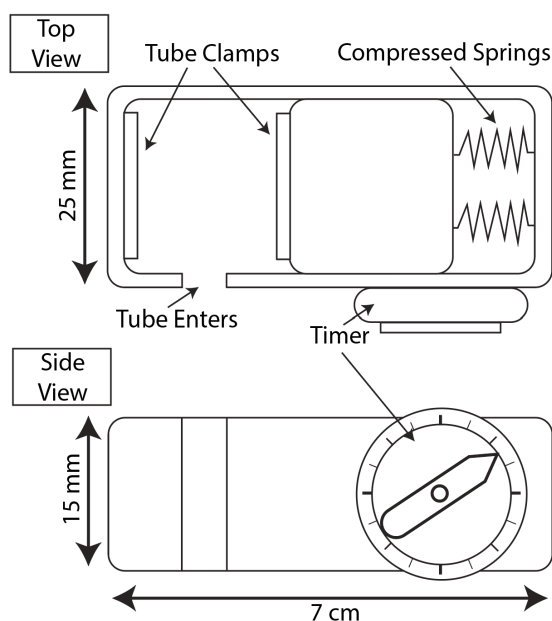


Figure 33. The initial final concept with a mechanical timer.

In showing this concept to stakeholders, it became apparent that it would be desirable to have the timer alert the provider both before and after the infusion had finished; something that would be difficult to achieve with a mechanical timer. Additionally, the team purchased mechanical kitchen timers to evaluate their function and determined that it would likely not be possible to develop a robust, low-cost mechanical timer capable of timing for up to 12 hours (maximum infusion time identified). Based on these findings, the team moved to an electromechanical solution. The original concept drawing for this final design is shown in Figure 34 (page 36). This was the last major design change.

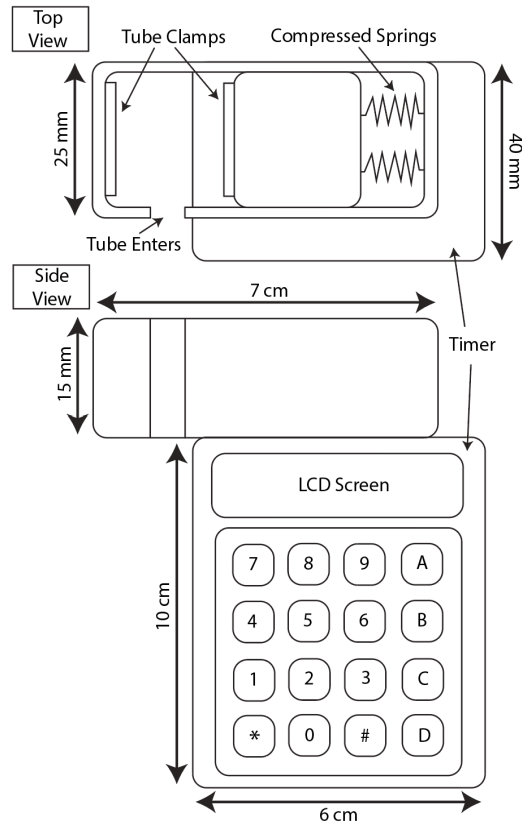


Figure 35. The final concept with electromechanical timer.

Initial analysis proved that the concept was viable. The design driver for reusability was satisfied by the initial concept. The driver for portability was satisfied by designing the device to be smaller than the dimensions specified, and include a battery that would allow it to operate without grid power when necessary.

The tube could be clamped to completely stop the flow as seen through previous prototyping and existing devices, indicating it could satisfy the volume control design driver. Through the flow rate testing described above, flow rate changing over the length of the infusion was not a concern, so as long as the flow rate could be set manually or by another existing solution to be within $\pm 10\%$, it was probable that the volume control would also be accurate to within that same range.

The mechanical part of the solution used to completely clamp the tube was prototyped and tested through an iterative approach by printing many different versions of the design. Some of these major design changes are highlighted in Figure 36 (page 37). Four different methods of clamping the tube were tested through this mockup approach and the one that interfaced best with the electrical components and had the best potential for reliably stopping the flow was chosen. That design was developed through another 14 iterations until the flow could be reliably stopped. Each iteration was tested empirically by using the device and observing the results. Results from these tests drove changes focused primarily on geometry, as it was discovered that the geometry used to pinch the tube was crucial for completely cutting off flow. This geometry changed in

every iteration and had to be modified such that the mechanism worked with tubing of different stiffnesses to satisfy the design driver regarding the solution's compatibility with the tubing available at KATH. Each iteration was tested on three different kinds of tubing with different stiffnesses to ensure this requirement would be satisfied.

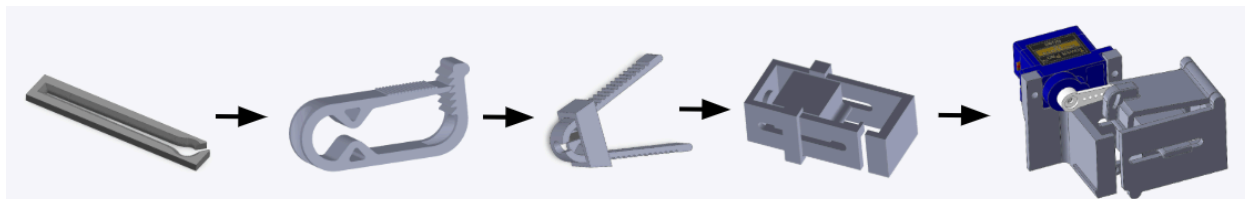


Figure 36. Major design changes made to identify a design capable of completely stopping the flow. The fourth design to the right is one of the first versions of the final solution. Fifteen total iterations of that design were developed, printed, and tested until a reliable, working version was achieved.

The force used to clamp the tube was also changed. The original design used one spring and the final design used four. This change was also driven by the results of empirical testing with different numbers of springs. It was found that the flow can be reliably stopped (500 out of 500 times) with three springs (totaling an effective spring constant of 0.99 N/mm), but the fourth was kept for safety.

The cost was not a huge concern for the mechanical portion of the solution, as springs and plastic are easy to acquire and produce and the actuator for the stopper was a two-dollar servo.

An accurate and robust timer was prototyped with an Arduino Uno (a cheap prototyping microcontroller). The cost was a concern, as electronics can add a lot of costs, however, the electronic components of the solution (not including the battery) totaled under \$20. The team thought it was cheap enough to continue to pursue as a low-cost solution, especially considering all parts could be purchased for cheaper in bulk or on sites with longer shipping times. Alerting the provider when the infusion was finished could be satisfied by design, as a buzzer was purchased and could be programmed to go off whenever desired. An early version of this prototype is shown in Figure 37.

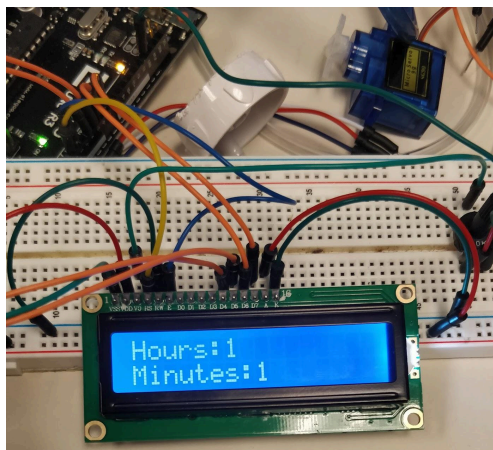


Figure 37. An early stage electronics prototype.

Final Design Solution

The final design solution shown in Figure 38 consists of a timer and flow stopper mechanism to reduce the risk of patient overdose and improve continuous patient care. This is intended to be used as an add-on system to a roller clamp system and/or another flow control device, such as the Dial-a-Flow. To use the device, the user would set the flow rate as they normally would on a roller clamp or other disposable flow controller. They would then type that flow rate into the timer, followed by the total volume they want to administer. The timer is set based on the flow rate and volume entered. When the time is up, the flow stopper mechanism is activated and entirely stops the fluid from flowing. An alarm also alerts the provider that the infusion has been completed. If desired, the user can also directly enter in the time needed for the infusion and start the timer that way. To reset the device, the user must manually pull the slider back and engage a latch to keep it in place, as shown in Figure 39, before resetting the flow rate/timer. Complete instructions are given in Appendix E (page 95).

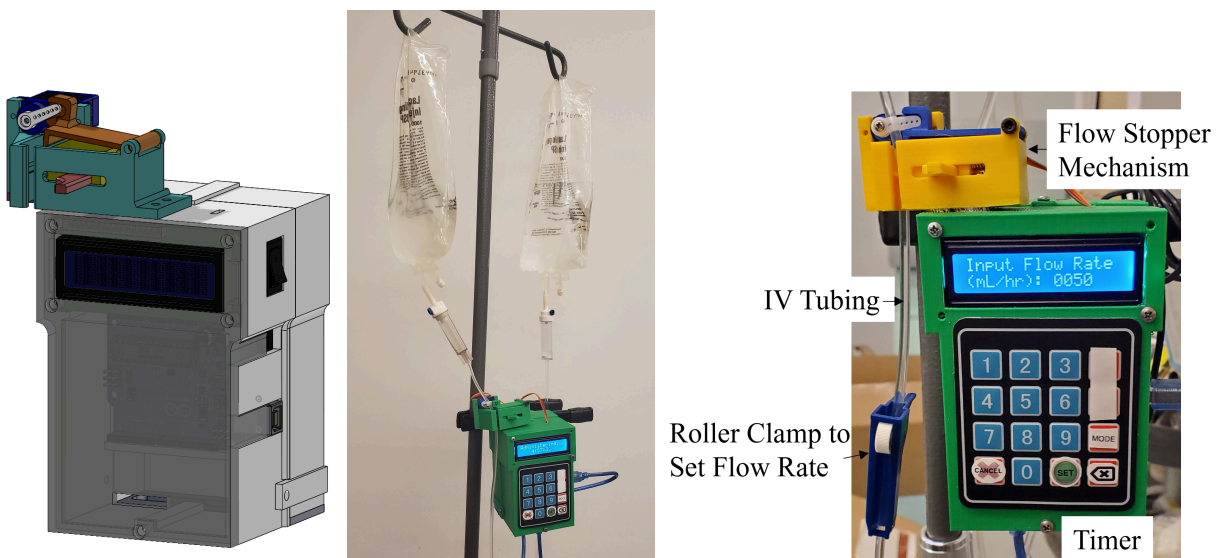


Figure 38. CAD model and images of the final design.

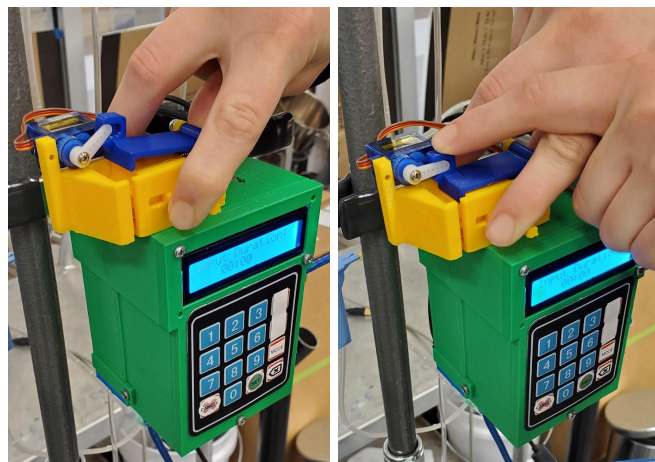


Figure 39. Pictures illustrating how to pull the slider back and engage the latch.

This solution is modular and an incremental improvement over the current system. It primarily addresses problems with patient overdoses caused by hospital overcrowding and the lack of alarm systems/medication tracking systems. Nothing like this device exists on or off the market currently. The most similar product by function would be the burette, shown in Figure 40, which is a single-use graduated cylinder that is filled up with the volume of fluids that need to be administered (can be filled up to 100 or 150 mL depending on the distributor). A comparison of the device functions is shown in Table 4.



Figure 40. Image of the burette: a single-use volume control device.

Table 4. Comparison of the team’s device function to the most similar product on the market.

Function	Burette	Team’s Solution
Reusable	NO	YES
Cost	\$2.50/use	\$50 (< \$0.10/use)
Alerts provider when infusion is finished	NO	YES
Stops flow at a volume set by the user	YES	YES

The team’s solution does not add any risk to administering fluids as the process for setting the flow rate would remain the same. More functionality could be added to the design in future iterations and this is discussed in more detail in the Discussion and Recommendations section.

The flow stopper mechanism, shown in Figure 41 (page 40), consists of the flow stopper wall and a slider controlled by springs, a servo, and a latch. When the time is up, the servo disengages the latch and the springs force the slider into the flow stopper wall. The novel geometry formed by the slider and flow stopper wall, shown in Figure 42 (page 40), kink the tubing to completely stop the flow. This geometry is crucial for completely stopping the flow. Fifteen iterations of this design were 3D printed and tested until a design that worked 500 out of 500 times tested was found. Dimensioned drawings for this piece are provided in Appendix D (page 91). Four springs are used in this design for an effective spring constant of 1.32 N/mm. The device completely stops the flow 500 out of 500 times using only three of the four springs (effective spring constant of 0.99 N/mm), but the last spring was kept as a safety measure. Assembly instructions are provided in Appendix E (page 95).

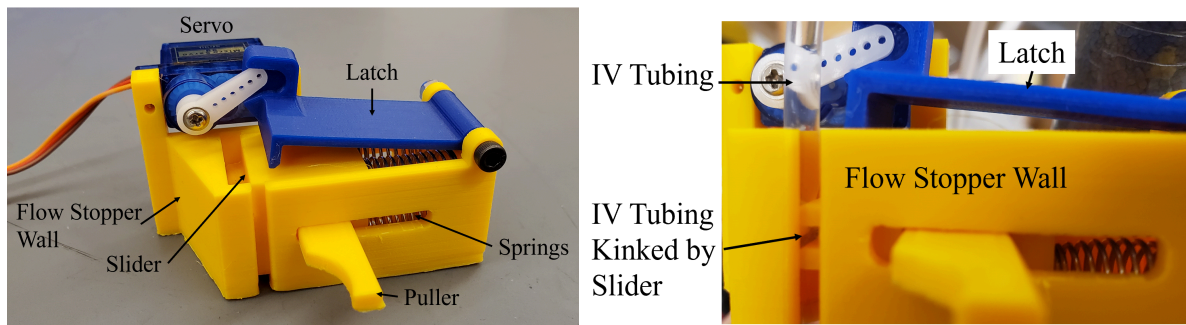


Figure 41. Diagram of flow stopper mechanism (left) and an image showing how the tubing gets kinked by the mechanism (right).

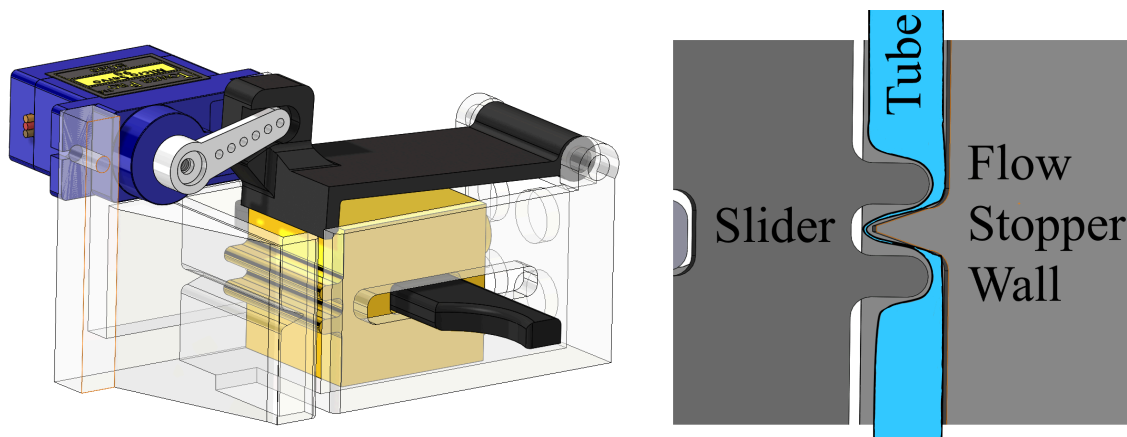


Figure 42. CAD drawings showing the geometry of the flow stopper wall and slider. The right image is a cross-sectional view of the geometry and illustrates how the tube is kinked by the design.

The timer is controlled by an Arduino Uno microcontroller (wiring diagram and code provided in Appendices E and G, respectively). A 16 by 2 LCD screen serves as the user interface and time indicator and a 4x4 keypad is used to enter all information into the system. The alarm and servo are wired to outputs of the Arduino such that they can be triggered when the infusion is finished. A diagram of the electronic components is shown in Figure 43 (page 41).

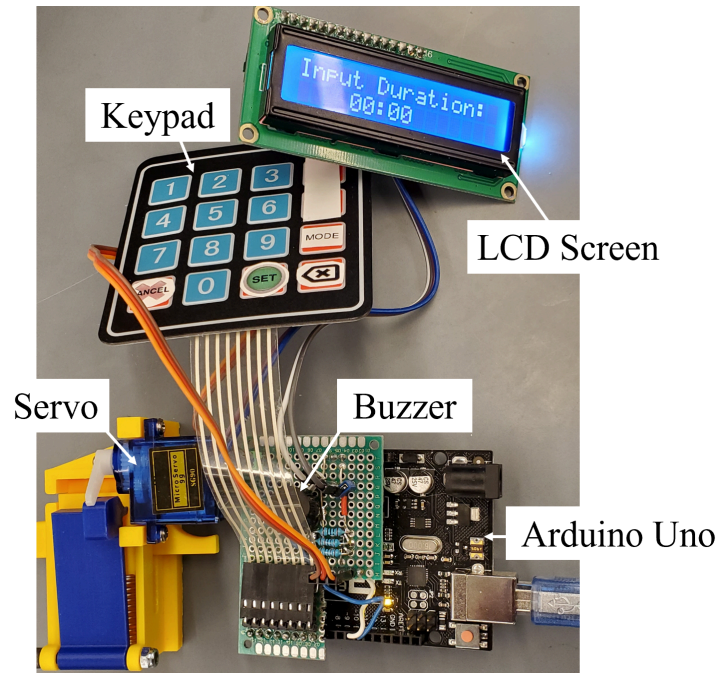


Figure 43. Diagram of electronic components in the final solution.

Risk Assessment

The team utilized a combined FMEA/Risk Analysis table to summarize the sources of risk associated with the team's project. The methods were combined in this way because the product is designed to improve a process and the team felt that a combined table would better reflect how both the components and use situations produce risk. The team chose not to use pFMEA (process failure mode and effects analysis) because there are no large risks associated with the manufacturing of the device as the design is fairly simple and accuracy is not largely dependent on the build. Table 5 (page 41) shows the various hazard levels associated with the final product, according to the risk acceptability matrix for medical devices in Appendix I (page 123) [74].

Table 5. Combined FMEA and risk analysis assessment.

Hazard	Hazardous Situations	Component & Function	Likelihood	Impact	Level	Technical Performance	Schedule	Cost	Action to minimize hazard
Stopper does not completely clamp tube	The infusion would not stop, the patient could overdose	Stopper housing and piston misalignment Tubing was incorrectly placed in the slot	Remote	Critical	3	Significant pitfall in technical performance: would defeat the purpose of the stopper, health care providers may stop using	Able to meet key dates	Unit cost increase	Perform testing to ensure flow stops completely every time and analyze when failure could occur, advise product lifetime based on analysis
Timer fails (does not go off)	The infusion would not stop, the patient could overdose	Arduino microcontroller fails Battery dies Servo breaks/ malfunctions Servo and latch do not mesh correctly Latch gets stuck Device was not set correctly	Remote	Major	2	Significant pitfall in technical performance: would defeat the purpose of the stopper, health care providers may stop using	Able to meet key dates	Unit cost increase	Perform testing to ensure timer engages flow stopper every time and analyze when failure could occur, advise product lifetime based on analysis
Timer fails (goes too long)	The infusion would not stop immediately, the patient could overdose	Arduino microcontroller fails Battery dies	Improbable	Major	1	Significant pitfall in technical performance: would require repair/reboot/charging to be used again	Able to meet key dates	Unit cost increase	Perform testing to ensure accuracy of timer and performance
Timer fails (goes off too early)	The infusion would stop too soon, the patient wouldn't get enough medication	Arduino microcontroller fails	Remote	Serious	1	Significant pitfall in technical performance: would require repair to be used again	Able to meet key dates	Unit cost increase	Perform testing to ensure accuracy of timer and performance
Flow rate is not set accurately	Product loses its function, would put patient at risk for further complications or overdose	External Factors: The wrong flow rate is set, the flow controller itself malfunctions, the flow rate significantly changes over time	Occasional	Critical	3	Significant pitfall in technical performance: would defeat the purpose of the timer, healthcare providers may discontinue use	Able to meet key dates	Unit cost increase	Perform testing to ensure accuracy of flow rate and accuracy of flow rate after x hours of use
Device falls off of pole	The timing mechanism would likely not work, there is a chance that the tubing would bend and stop the flow early	Pole clamp fails Attachment to device fails Clamp was improperly attached	Remote	Minor	1	Significant pitfall in technical performance: would reattachment and potential restart	Able to meet key dates	Unit cost increase	Perform testing to ensure mechanical reliability of clamp

All actions described in the table were aligned with requirements and are discussed in the validation section. In summary, most of the risk associated with the final product involves, in some way shape or form, the timing mechanism and the interaction between the electronics and the mechanical components. Extensive testing was performed to make sure that the latch is reliably triggered (500 out 500 times) and that the Arduino reliably counts down the time correctly.

Risk of Material Failure

While the product is plastic, the team has located regions of stress concentrations and reinforcements have been added to the newest iterations of the device. Individual cracks would not likely result in device malfunction, as cracked FDM components have had no effect on the overall function of the device thus far. The one occasion on which the device catastrophically failed occurred when the device was printed with an SLA printer (a far less robust manufacturing process). The design was updated to prevent this failure from occurring in the future, but the team recommends against using this manufacturing method for any of the components of the flow stopper assembly.

Risk of Servo Failure

The plastic servo would probably break during prolonged use. However, the team has been testing iterations of this device for weeks, running hundreds of tests and this particular servo is still functioning. A final housing and flow stopper mechanism could be made to be more robust with higher quality gears or a different kind of actuator if this becomes a problem.

Risk of Flow Stopper Mechanism

The aspect of the design with the highest risk is the flow stopper mechanism not completely stopping the flow. There were extensive trials to confirm that the geometry works with three different kinds of tubing and that the flow stops every time (500 out of 500 times tested). The worst-case scenario would occur if the user assumed that the device was functioning properly and expected it to stop the flow and the device failed for some reason (such as the latch not disengaging). This could lead to the very situation the device is designed to prevent: overdosing. A problem like this was never experienced during testing.

Design Revisions

In order to reduce the risks described above, the team looked at design changes that could be made to the components and functions of the device involved with the highest risk hazards.

In a future device, the team would like a larger display that could show more information during an infusion. It could show the flow rate that was set, and potentially even information about the medication being given. A bigger display would give room for a battery level indicator. This would reduce the risk of failure due to the battery dying. The device could have lights/LEDs that flash when the battery level is low to alert the healthcare provider, and a warning message when the battery level is low. Finally, the device could change to an embedded system and integrated circuit to reduce power consumption, thus prolonging the life of the battery. Additionally, a metal servo (or an entirely new motor/actuator) would be more resistant to the wear and tear that could

cause it to break after many cycles. The cost/benefits of switching components would have to be explored further. More future work can be found in the discussion and recommendations section.

Risk is at acceptable levels since this device is simply an add-on solution; the device does not perform any functions that hospital personnel do not already do, it is simply a safeguard to increase patient safety and reduce strain on healthcare providers. Theoretically, the device does not add any risk to the current system or workflow; nurses continue to set flow rates and check on patients as they normally would with this system as an additional safety feature. Because of this lack of risk and the nature of the design, the team believes the solution would be easier to integrate into the hospital workflow and implement in all settings.

Usability Testing

Usability testing was conducted both to validate a few specifications (discussed in the next section) and to get an idea of how easy the current prototype is to use, as well as what things might need to be changed in future versions to make the use more intuitive. This testing was conducted on six engineering students who had no prior knowledge about IV infusions. These students were selected to get a better idea of how intuitive it is to use the device in its current form, with little-to-no prior knowledge of the way it functions. Theoretically, if users without a health background can figure out how to use it, healthcare providers could easily interface with it.

The device started on a table next to an IV pole with hung fluids. Each student was given an instruction manual and told to set up the device with any flow rate and infusion time. Setting up the device included clamping the device to the pole, resetting the stopper mechanism, inserting the tube, setting a flow rate on the Dial-a-Flow, and beginning the timer. The total time taken to set up the device (while reading the instructions) on the first try was recorded, along with any user errors. To record the time taken to set up the device, a timer was started when the student reached for the device and was stopped as soon as the timer on the device began counting down. The first three subjects received the first instruction manual in Appendix F (page 105) and the second three received the second manual (also in Appendix F), which had been revised based on the use errors made by the first three students. The data is summarized in Table 6 (page 45).

Table 6. Results of usability testing conducted on six engineering students.

Instruction Manual Version	Test User	Use Errors	Notes	Total Time to Set Up
Version 1	1	Tried to pull back slider and expected it to snap in place - Repeated this two more times Didn't engage latch well enough - the clamp closed and user did not notice - user couldn't insert the tube because of this Set both the duration and flow rate/volume on the device	Device was clamped to pole quickly - seemed intuitive	3:31
	2	Attempted to pull back on one side of the slider only Had trouble inserting tube - received instruction on how to do so Set both the duration and the flow rate/volume on device	User said it was hard to figure out what to pull back on to engage the latch - in future designs this puller would be redesigned such that it and the slot for the tube are the only protrusions from the box Problems inserting tube have been addressed in the newest version of design (increased size of slot)	2:19
	3	Didn't pull slider back before attempting to insert tube Did not insert tube all the way - couldn't insert because clamp was engaged - left tube in the insertion slot Set both the duration and the flow rate/volume on device	A sticker showing where to insert the tube/where it should be located may help Third user in a row to set both the duration and flow rate/volume on the device and be confused by how to slide the slider back	3:31
Version 2: revised to eliminate some use errors	4	Undid latch to look at springs	Mention of springs being compressed should be removed from instructions	3:17
	5	Didn't know what 'latch' referred to Couldn't figure out how to pull back slider	User said they were confused because the pictures were spread across pages - didn't know where to grab to pull back the slider Stickers should be added to show where to grab the slider to pull it back/where it should be located when ready for administration	2:42
	6	Pulled slider back before attaching device to pole	User said pictures were confusing because they were spread across pages - wasn't sure which figures referred to each step Instruction manual should be changed to show which pictures refer to each step and should be printed such that the pictures don't get spread across pages	3:03

The first three subjects performed many of the same use errors. This included erroneously attempting to pull the slider into place, as shown in Figure 44 (page 45), such that the tube could be inserted as well as setting the timer twice; once by typing in the duration and once by setting the flow rate and volume, rather than doing one or the other. An edit to the instructions corrected the latter error in the last three subjects. However, those last three subjects also struggled to figure out out to pull the slider back. In a future design, the flow stopper mechanism would not be exposed as it is in this prototype, so the pulling mechanism would need to be redesigned anyway. However, it is useful to note that some sort of labeling on the device, indicating which parts to grab/pull would probably assist in usability.

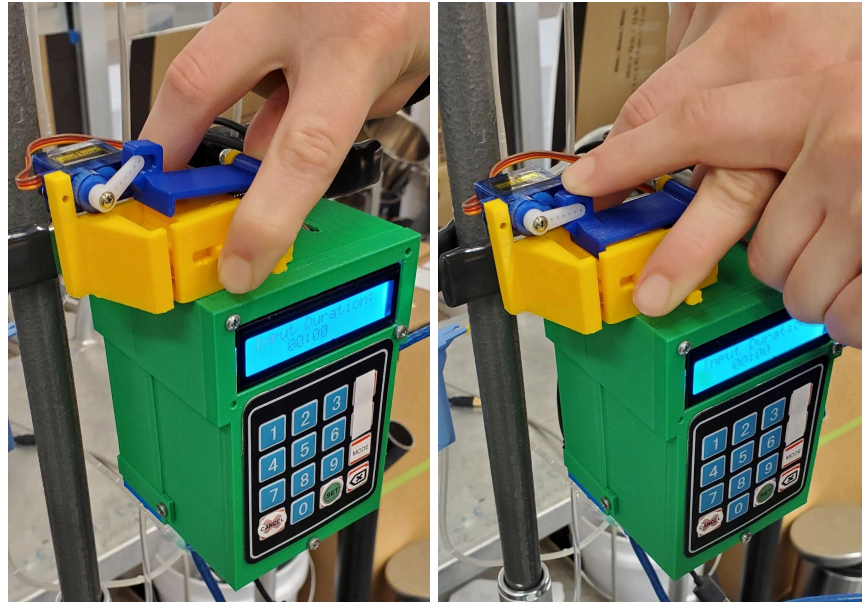


Figure 44. Pictures illustrating how to pull the slider back and engage the latch.

The first three students also struggled to insert the tube into the slot. The last three students did not seem to struggle as much, likely because a note had been added to the instructions saying the tube could be forced into place. It was physically difficult to insert the tube because the slot was too small. This slot size has been updated in the current version of the design, so this error should be eliminated. The instructions were updated again based on the second round of results and are provided in Appendix E (page #).

Validation

Validation testing was conducted to verify the performance of the device with respect to the identified requirements and specifications. Overall, it was found that the device performs its primary functions, in that it satisfies the design drivers, and works reliably. The design was therefore successful and the team thinks that with the design revisions described in the discussion section, the device could likely be successfully implemented.

To test solution adherence to the specifications, the specifications were divided into three distinct categories. Category 1 specifications are the specifications that can be met (or failed) by the design. Category 2 specifications can be verified using benchtop testing methods. Category 3 specifications require more extensive testing and/or clinical trials. The specifications are color coded and labeled to identify if they were met: green indicates that the design passed the validation testing for that specification, yellow means the design passed preliminary testing and analysis, but more testing is required to validate that specification (plausible), red means the design failed the specification, and blue means it the specification could easily be met in the future, but is not accomplished in the current prototype (future work). Table 7 (page 47) shows all the requirements and specifications with the validation category and results. More detail is given throughout this section.

Table 7. Requirements and specifications are shown with the associated validation category along with whether the specification was met by the design or testing

Requirement	Specification	Validation	Pass/Fail
Controls Flow Rate	Controls flow between 0 mL/hr and 250 mL/hr and sustains accuracy to within $\pm 10\%$	Category 1	Fail
Controls Volume	Stops the flow of medication/fluids at a volume set by the user between 0 and 500 mL and is accurate to within $\pm 10\%$	Category 3	Plausible
Alerts Healthcare Providers Within the Ward	Alert the provider when an infusion has stopped	Category 1	Pass
	Alert the provider when there is > 1 mL of air in the line	Category 1	Fail
	Alert the provider when the IV becomes detached	Category 1	Fail
Is Portable	The center of mass needs to be within half the caster radius (10 cm) when mounted on an IV pole	Category 1	Pass
	Weight ≤ 3.5 kg	Category 1	Pass
	Smaller than a rectangular tissue box (13cm x 13 cm x 23 cm)	Category 1	Pass
	Can be transported with one hand	Category 1	Pass
	Takes less than 15 seconds to attach to the wall, bed, and IV pole	Category 1	Pass
	Able to control the flow rate/volume administered of at least 2 different fluids independently at the same time	Category 1	Fail
Complies with Current Market Standards	Compatible with drip chamber diameters between 1.3 cm and 2.11 cm	Category 1	Pass
	Compatible with current IV equipment based on ISO 1135 and ISO 8536 international standards	Category 1	Pass
	Does not use proprietary or device-specific tubing/equipment	Category 1	Pass
Is Easy/Quick to Use	Allows the user to change the administration settings in ≤ 10 seconds	Category 2	Pass
	Colocate all information relevant to device performance/function	Category 1	Future Work
	Follows ISO/IEC Guide 37:2012 for instructions for use of products by consumers	Category 1	Future Work
	The device is utilized in ≤ 3 steps	Category 1	Pass
	Takes ≤ 5 min to go from one use to the next, including cleaning, if reusable	Category 2	Pass
	Displays flow rate in mL/min and mL/hr	Category 1	Future Work
Can be Used in Low-Resource Settings	Costs $< \$0.10$ per use	Category 2	Pass
	Able to be independent of wall electricity source for 12 hours	Category 2	Pass
	Does not use electricity	Category 1	Fail
Is Durable	Lasts for $> 60,000$ hours	Category 2	Plausible
Is Easy to Maintain	Does not require specialized tooling to repair	Category 1	Pass
Provides Patient Safety	Does not allow > 1 mL of air into the line	Category 1	Fail
	Does not allow patient to tamper with the device	Category 1	Pass

Category 1 Specifications

Category 1 specifications that are either met (pass) or not met (failed) based on the design of the device.

Controls Flow Between 0 mL/hr and 250 mL/hr and Sustains Accuracy to Within $\pm 10\%$ (Fail). The device is not currently designed to control flow, and therefore, doesn't pass this specification validation. However, if it were designed for this, it would be necessary to do a clinical trial after initial testing as there are hundreds of various use cases (i.e. short infusions, long infusions, human error, different bag sizes, etc). This would be necessary to ensure device safety in a hospital setting.

Alert the Provider When an Infusion has Stopped (Pass). The first category specification indicates that a healthcare provider must be alerted when the infusion has finished. To do this, the team included a buzzer into the final concept that beeps when the infusion has finished.

Alert the Provider When There is > 1 mL of Air in the Line (Fail). The device does not have a method to sense air in the IV tubing. If there were an alert for this, it would have to be tested to make sure it is accurate in detecting greater than 1 mL of air. In future iterations, an IR sensor could be implemented to detect air bubbles.

Alert the Provider When the IV Becomes Detached (Fail). The device cannot sense a detached IV, and thus it does not provide an alert.

The Center of Mass Needs to be Within Half the Caster Radius (10 cm) When Mounted on an IV Pole (Pass). To make sure that the device doesn't tip over while on the pole, it has to have a center of mass within half of the caster radius. The team validated this by designing the device to have a center of mass at about 6 cm off of the pole when it is mounted, and the entire device only extends about 12 cm off of the pole.

Weight ≤ 3.5 kg (Pass). Nurses wanted a lightweight device that was easily portable. To complete this specification validation, The team created a device that weighed well under the desired 3.5 kg limit. Our final concept weighs only 0.8 kilograms.

Smaller than a Rectangular Tissue Box (13cm x 13 cm x 23 cm) (Pass). To ensure that the device didn't get in the way of treatment, nurses wanted a small compact device. The team validated this specification by making a device that is 8cm x 8.5cm x 12.5cm.

Can be Transported With One Hand (Pass). Nurses wanted a device that could easily be transported with one hand so that they could move the patient with the other hand. The clamp on the concept can serve as a handle that makes gripping it with one hand very easy. Additionally, it firmly clasps the IV pole to reduce any complications while transporting the patient.

Takes Less than 15 Seconds to Attach to the Wall, Bed, and IV Pole (Pass). The current design utilizes a single squeeze clamp with a rubberized grip to prevent sliding. This takes only a

couple seconds to attach to any wall, bed, or IV pole - it is much simpler to attach than the current designs for heavier syringe pumps.

Able to Control the Flow Rate/Volume Administered of at Least 2 Different Fluids Independently at the Same Time (Fail). With the current design, it is not possible to control multiple infusions. However, future iterations could add a second flow stopper or increase the spring constant to control the volume of a second fluid. There are more pins for the servo to connect to on the Arduino, and the flow stopper could be twice as wide as it is. The biggest challenge would be finding a good way to make sure that the provider knows which infusion is being displayed on the LCD, which could likely be solved with a couple of LEDs and a switch.

Compatible with Drip Chamber Diameters Between 1.3 cm and 2.11 cm (Pass). It is important that the device is compatible with all types of drip chambers. Since the device attaches to the IV pole and only interacts with the tube and not the drip chamber it automatically passes this specification validation testing.

Compatible with Current IV Equipment Based on ISO 1135 and ISO 8536 International Standards (Pass). Since the device is meant to be universal, it is important that it works with all types of tubing. To accommodate this standard, the slot in the flow stopper has been made wide enough to work with any tubing compliant with these standards.

Does Not Use Proprietary or Device-Specific Tubing/Equipment (Pass). The device is reusable and is designed to work with any IV tubing. It is completely external and requires no proprietary equipment to function, and therefore passes this specification.

Colocate All Information Relevant to Device Performance/Function (Future Work). The current device does not have instructions included on the device. However, it does have an instruction manual, identifiable markings, and a simple interface. Future iterations could have a set of labeled instructions on the back of the device.

Follows ISO/IEC Guide 37:2012 for Instructions for Use of Products by Consumers (Future Work). The team currently does not have an instruction manual following the ISO/IEC Guide 37:2012 for Instructions for Use of Products. However, the instructions could be updated to follow the standards.

The Device is Utilized in ≤ 3 Steps (Pass). To use this device, the nurse only needs to do three main steps: 1. Insert the tubing into the flow stopper. 2. Enter the desired duration. 3. Hit the set button. However, there are other steps that could be necessary to use the device. For instance, the nurse may need to reset the flow stopper or click a couple more buttons to utilize some of the features of the device, such as the flow rate/volume input function.

Displays Flow Rate in mL/min and mL/hr (Future Work). The current design does not display the flow rate in mL/hour and mL/min as it utilizes a low resolution LCD. However, future designs could incorporate a larger display that shows the flow rate and volume set by the user.

Does Not Use Electricity (Fail). The device needs electricity to power the battery and therefore does not pass this specification validation. It can, however, operate for longer than 12 hours on battery power, which is longer than the worst-case scenario blackout durations cited by stakeholders.

Does Not Require Specialized Tooling to Repair (Pass). The device only requires standard tooling, such as small screwdrivers, to be repaired.

Does Not Allow Patient to Tamper with the Device (Pass). This device does not have tamper-proof features that unlock it, such as a password. However, the device would sound a beep and release the clamp if a patient tried to mess with the buttons, which would likely alert the providers.

Does Not Allow > 1 mL of Air into the Line (Fail). The device is not in-line with the tubing and isn't currently designed to filter out air or stop air from entering the tubing.

Category 2 Specifications

These are specifications that can be validated with benchtop testing.

Allows the User to Change the Administration Settings in ≤ 10 Seconds (Pass). During the usability testing, the six users were able to change the duration of the infusion in 8 seconds on average.

Takes ≤ 5 Minutes to Go from One Use to the Next, Including Cleaning, if Reusable (Pass). From user testing, the team has found that it is very feasible to go one use to the other in less than 5 minutes. During the testing, it took new users an average of around three minutes to read an instruction manual, place the device on the pole, engage the flow stopper, insert the tube, set a flow rate on the Dial-a-Flow, and start the timer. Each of the users had no previous exposure to IV infusion devices or the teams' product. Based on these results, a nurse that was trained on the device would have no problem setting up the device in only a couple of minutes, leaving plenty of time to clean the housing. A limitation of this validation is that the time needed to clean the device is unknown.

Costs < \$0.10 Per Use (Pass). In order to validate this, the team used the device over 510 times without it failing. Since the prototype device costs roughly \$51, it costs less than \$0.10 per use. However, from interviews with an operations and product development professional in the US, the procurement cost is expected to be twice that of the manufacturing cost [66]. This is a rough, conservative estimate based on the experience of the product development professional that was interviewed. If the device were to be mass manufactured, the material cost would dramatically decrease and so would the cost of procurement. Additionally, the device exhibited no signs of failure after 510 uses, likely meaning that it could withstand many more cycles and still cost less than \$0.10 per use.

Able to be Independent of Wall Electricity Source for 12 Hours (Pass). The device contains a 10,000mAh battery and only draws 89mA of current during operation, and thus by division the team expects the device to last for more than 112 hours. The device was also left on for 12 hours, and the battery was still nearly full.

Lasts for > 60,000 Hours (Plausible). It is likely that the device would be able to last for > 60,000 hours. The highest failure risk parts are the moving mechanical components. The team validated this by performing a fatigue analysis of the springs and trigger device by stopping the flow 400 times. The test concluded that there was visually minimally to no wear on the device.

Category 3 Specification

These are specifications that would need clinical trial testing to verify the benchtop testing already completed.

Stops the Flow of Medication/Fluids at a Volume Set by the User Between 0 and 500 mL and is Accurate to Within $\pm 10\%$ (Plausible). It would be necessary to do a clinical trial after initial testing to check that it works in human models. This would ensure device safety in a hospital setting. However, some of the initial testing for this has been completed. Five tests were conducted at increasing rates for twenty minutes apiece. As shown in Table 8, at each rate, the intended volume was calculated. Following the test, the actual volume was measured and compared to the intended volume to find the error. A comparison between the intended and actual volume is shown in bar graph form in Figure 45 (page 52). The flow rate stayed relatively consistent throughout each test with slight fluctuations, which are shown in Figure 46 (page 52). Overall, the volume was delivered as intended with the exception of 66 mL/hr. This could have been caused by a myriad of factors: the scale not being accurate (as it was a kitchen scale), the drop counting being slightly off (as even being a half drop off can highly affect calculations), and the fact that Alex poured between containers during the volume measuring process (though, this was likely negligible). It should also be noted that the volume control was never tested up to 500 mL or an extended time period - however, other flow rate tests confirm consistent flow rate hours into an infusion, and independent tests also confirmed the reliability of the timing mechanism. Taking all of this information into account, it is probable that the device would stop the flow of medication at a volume set by the user between 0 and 500 mL and is accurate to within 10%.

Table 8. Volume tests.

Rate (mL/hr)	Intended Volume (mL)	Actual Volume (mL)	Error (%)
39	13	13	0
66	22	19	13.64
102	34	34	0
138	46	47	2.17
153	51	51	0

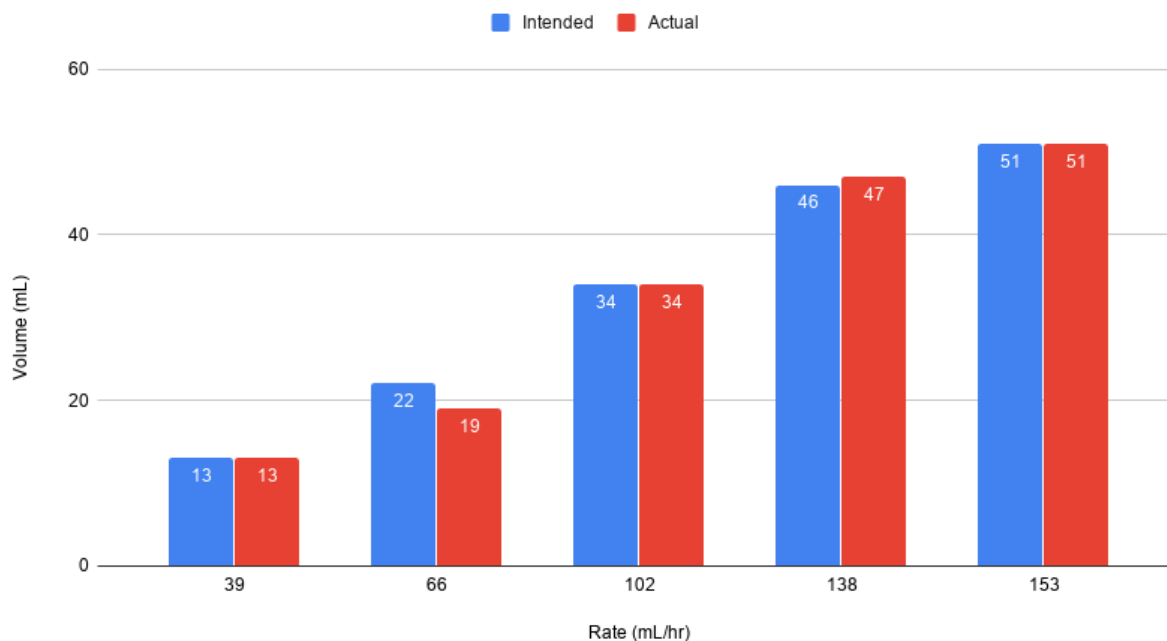


Figure 45. Chart comparing the intended volume in each test (as determined by the original set flow rate and time of test) to the actual volume measured at the end of the test. The disparity is seen in the 66mL/hr trial (13% error compared to an average of about 0.5% error) and is likely due to drop counting errors.

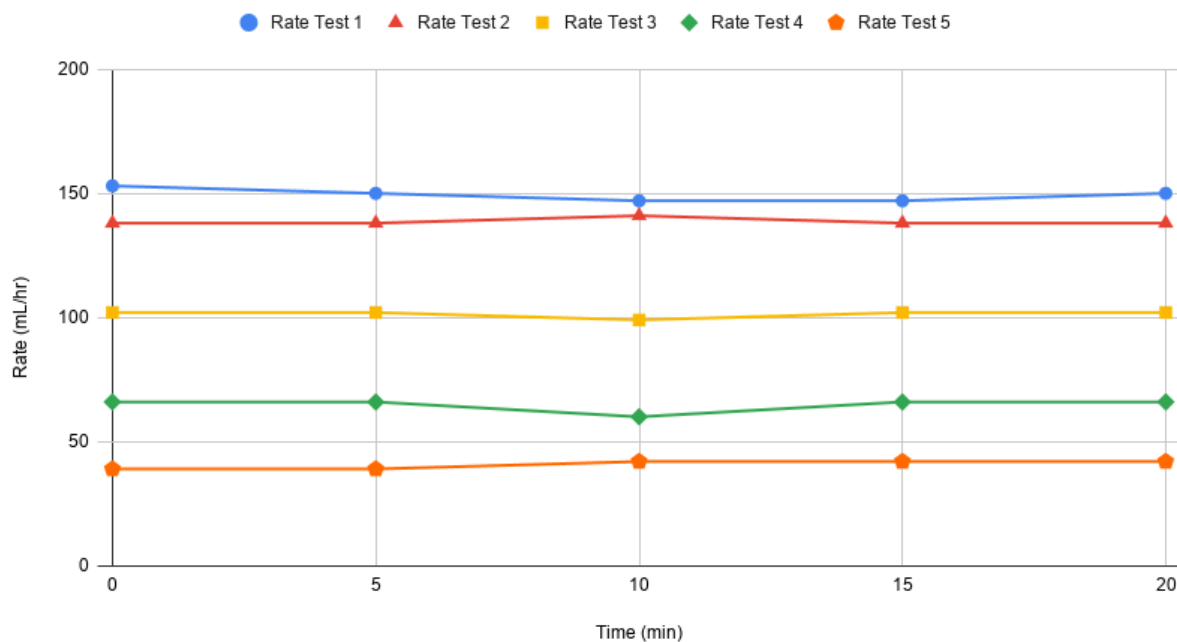


Figure 46. Graph showing how flow rate fluctuated over each test. The first marking at time = 0 corresponds to the set flow rate.

Discussion and Recommendations

Summary of Improvements Achieved by the Proposed Solution

The proposed solution is an incremental improvement over the current system used to administer IV fluids and medications. The proposed solution takes some weight off of the provider's shoulders by allowing them to focus on other patients without worrying about missing doses or letting fluids flow for too long. This has the most notable impact in pediatric populations where volume control is critical to maintaining stable patient vital signs. The solution also prevents blood from backing into the line by stopping the fluid flow while there is still a higher pressure in the line than in the vein. This blood back-flow occurs when the bag is left empty for too long. When blood backs into the line, it can clot the line, in which case the provider has to either start a new IV or attempt to bust the clot. If the clot is too large, it could cause a fatal pulmonary embolism. The device is unlike anything on the market, in that it adds some of the features of expensive infusion devices at a low cost.

Drawbacks of Proposed System and Summary of Findings

Despite these improvements, the solution obviously does not solve the initially identified problem of controlling the flow rate. Originally, this design included a flow controller that was supposed to clamp the tube for a lower range of flow rates. This original flow controller concept was a slot clamp, which is shown in Figure 47. These lower flow rates (0 to 60 mL/hr) are difficult to achieve with a regular roller clamp and by estimating the flow rate based on the drops per minute. Through testing, it was shown that clamping the tube an additional 0.01 mm with this slot clamp design can make a difference in flow rate of 156 mL/hr. This method of flow control for a low range of flow rates is therefore infeasible, but may work under very specific circumstances (a known venous pressure, bag height, cannula size, flow started within a specific range of time to limit the effects of cold flow creep, and no additional tube fittings) for a higher range of flow rates (likely >150 mL/hr).

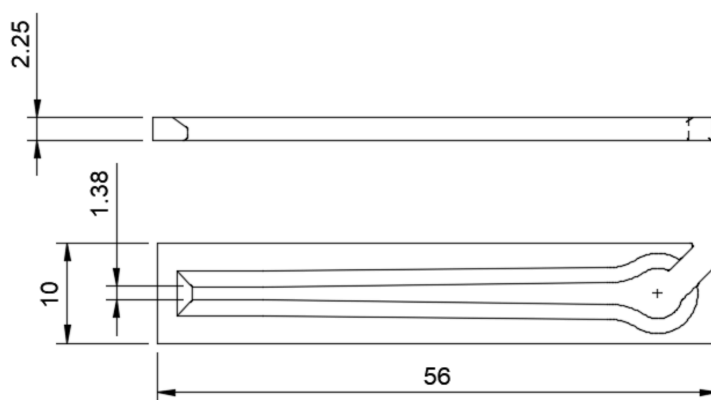


Figure 47. The original slot clamp design to control the flow rate.

After extensive interviews and testing, a gravity-fed system (system in which the mechanism driving fluid flow is hydrostatic pressure) is not the most accurate approach. There are too many variables affecting flow rate that gravity-fed systems cannot account for; such as bag height, tube

fittings, secondary attachments or piggyback lines, cannula size, cold flow creep, and venous back pressure. Most importantly, stakeholder feedback indicated that estimating flow rates is not terribly difficult to do within a reasonable accuracy and that volume control was still a huge concern, especially in pediatric populations.

A huge limitation to possible solutions is the constraint on disposable solutions. Due to implementation problems, the team decided to eliminate all concepts that would require disposable parts/fittings. The team still thinks this is the best approach for low resource settings, but the design is greatly complicated by this decision. At this point, the ‘best’ solution may be a peristaltic-type pump with discrete volume control such that the intended flow rate can be set with no dependence on any of the external factors mentioned above. An example of this is shown in Figure 48. This type of pump would be a reusable solution that would satisfy many of the lower-priority requirements identified, such as detecting when the flow has been unintentionally stopped due to a kinked line. A novel approach could be taken with this design by designing it such that it could be manufactured and assembled in Ghana, with parts from Ghana. This solution would also have to be developed to work with the tubing available at KATH, but ideally be compatible with all types of tubing. The team thought of this design after eliminating other flow control options, but had concerns about the deformation of IV tubing over time and how that would affect the accuracy of fluid output. Hands-on experience with stiff IV tubing showed that the tubing retained its shape after being deformed, as seen in Figure X on page x. Thus, this concept would likely not work with all tubing and may require soft single use tubing as other current peristaltic pumps do.

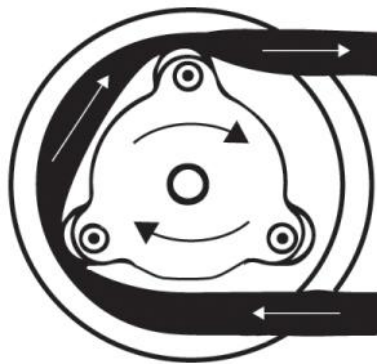


Figure 48. An example of a peristaltic pump.

Proposed Improvements and Functions to Add

Knowing everything that the team knows now, the team would have honed in on the need for volume control sooner. In doing this, the team could have explored additional functionality. It is not currently known how much it would cost to implement an optical monitoring system (such as is used in the DripAssist), but if this could be cheaply manufactured and implemented, the team would have liked to add this to the design to provide feedback to both the timer mechanism and user. A picture of this concept is shown in Figure 49 (page 55). This would allow the user to more quickly and accurately set rate, and allow for additional safety features. The device could tell if the infusion rate rapidly changed for any reason, such as if the IV became detached. It would also inform the provider of the actual flow rate which could improve the accuracy of

infusions. An optical monitoring system could allow for other “bonus” features that stakeholders wanted in a device. It could give the device the ability to sense air in the IV tubing, and the device could give an alert to the provider. A monitoring component is the primary recommendation of the team, as the addition of a feedback loop would make the device safer and add almost all of the features in infusion pumps (minus flow control) at a potentially low cost.

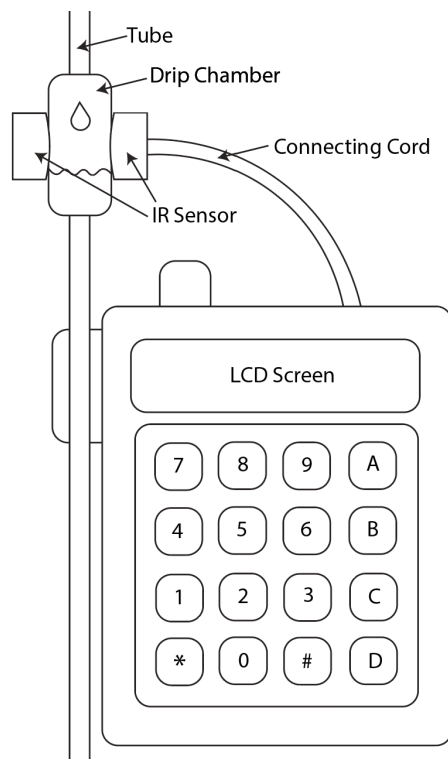


Figure 49. Concept showing the device with an optical monitoring system.

A future iteration could incorporate a larger, higher resolution display that gives the user more information about the infusion. The current design does not display the flow rate in mL/hour and mL/min as it utilizes a low resolution LCD. Future designs could incorporate a larger display that shows the flow rate and volume set by the user, as well as information about the medication being given. Dr. Sean Ewing made the suggestion that the team could include a library of commonly used medications and could notify the user if they were setting a rate outside the safe range for that particular drug, as is done in the BD Alaris systems. This would likely reduce errors commonly made due to fatigue.

Another suggestion made to the team included keeping a stored record of medications and rates being administered. This could reduce the effort required by nurses to document medications and rates for each patient by hand in each patient’s paper chart.

In order for the device to be usable, all parts should be encased with a water-resistant casing that can be easily cleaned with disinfectant. The casing could be injection molded if the wall thickness is reduced to two millimeters. Additionally, the casing should be redesigned such that

the part of the system where the tube is inserted and the lever used to reset the flow stopper are the only things protruding from the casing. A concept drawing of this is shown in Figure 50.

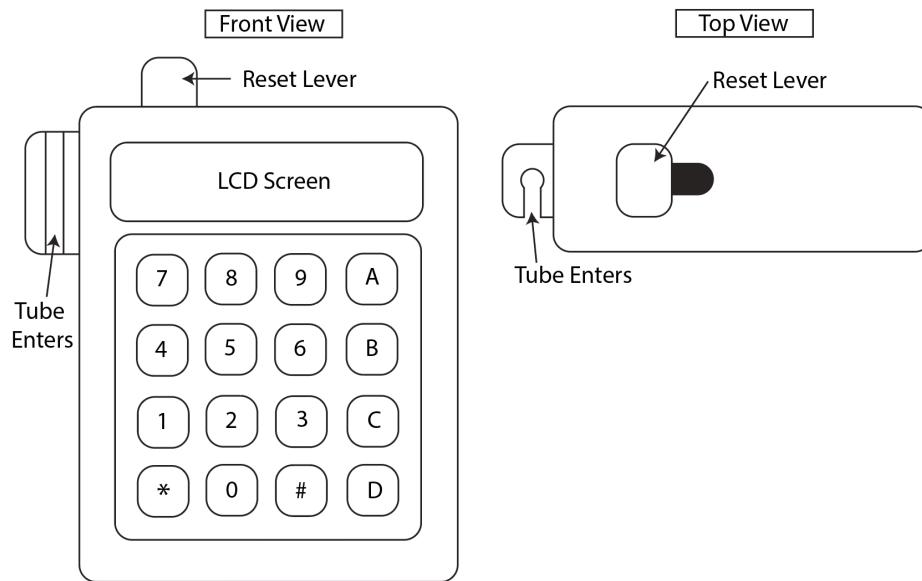


Figure 50. The device fully encased in a waterproof housing, with only the components that the user must interact with exposed.

Many other design changes could be made to improve ease of use. Firstly, the latch could be made to be easier to engage. Currently, pulling back the slider to engage the latch requires a lot of force. It also takes two hands to engage the latch: one to pull the slider back and the other to push down on the servo to set the latch. This would likely be addressed in the redesign discussed above, as the piece used to pull the slider into place would need to be redesigned to accommodate being placed outside the casing. A concept drawing of a potential release lever design is shown in Figure 51 (page 57). This new puller would likely be a larger lever that reduces the amount of force required to engage the latch and include an actuator/hinge design that automatically re-engages the latch when pulled back so the user does not have to manually push the latch into place. The location of this lever should also be convenient and comfortable for the user. In this new release lever concept, the latch mechanism geometry would have to be redesigned such that it worked with the location of the larger lever.

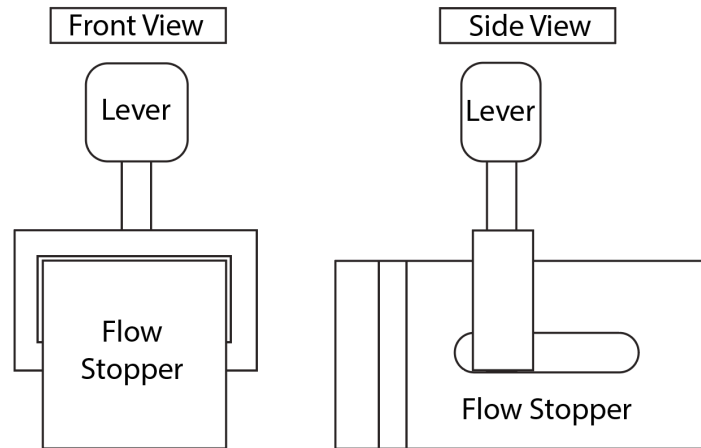


Figure 51. New release lever design concept.

For this new latch mechanism to work, the team recommends removing the 3D printed material under the servo arm so that it is only capable of lifting the latch up and can move back into position without the user forcing it down. A spring could then be added to the hinge to automatically push the latch into place and prevent the slider from moving forward. A sketch of these proposed changes is shown in Figure 52.

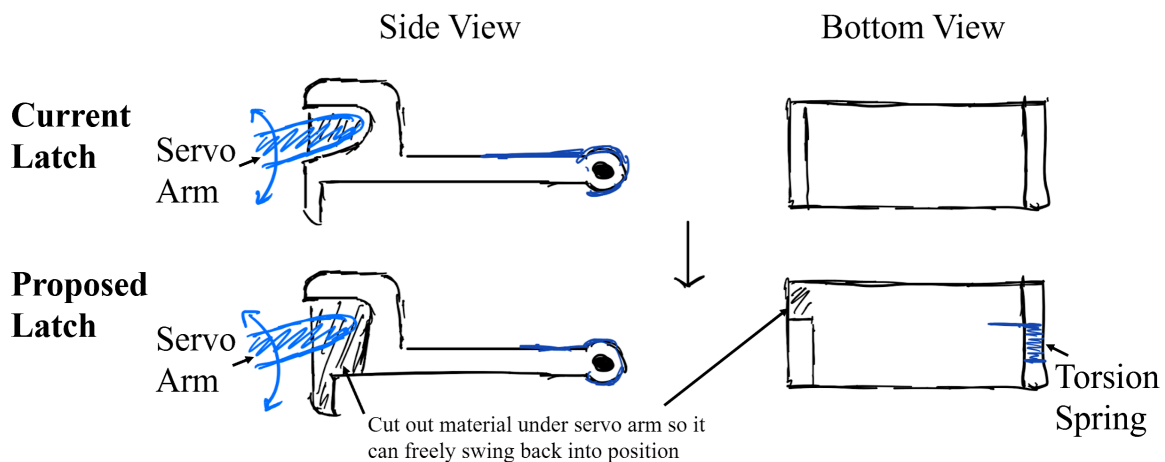


Figure 52. Concept sketch of proposed latch changes.

With the current design, it is not possible to control multiple infusions. However, future iterations could add a second flow stopper on the same casing to control the volume of a second fluid. There are more pins for the servo to connect to on the Arduino, and room can be made for an additional flow stopper mechanism to attach to the casing. The biggest challenge would be finding a good way to make sure that the provider knows which infusion is being displayed on the LCD, which could likely be solved with a couple LEDs and a switch or a second (or larger) LCD screen.

The team also noticed that the majority of usage errors that occurred during usability testing involved not knowing which parts of the solution to grab or pull. The device does have an

instruction manual, identifiable markings, and a simple interface. However, the revised solution should include device labeling that makes it clear which parts of the device should be interacted with and simple instructions located on the outside of the device.

The team would highly recommend using injection molding or FDM printing for all components of the flow stopper mechanism. SLA printing should not be used as these are structural pieces. When the finalized part was printed with a higher resolution SLA print, the part was loaded with four springs and catastrophically failed after only three load cycles. This was due to the SLA print, as parts printed in SLA tend to be much less tough than parts printed on an FDM printer. The team was able to complete over 500 load cycles with the same flow stopper mechanism design that was printed on an FDM printer. Additionally, the team had printed the part on four different types of FDM 3D printers and none of the final design versions (after stress concentrations had been removed) exhibited noticeable wear or cracking. After the piece broke, Alex did research on the structural integrity of SLA prints and found that they tend to be significantly more brittle despite the higher resolution. The team's recommendation would be to make injection molded parts for the final design, because they have higher strength than 3D printed parts and would make the device easier to clean due to the smooth surface.

The current prototype does not have a working power switch. This is because the switch was wired to cut off power to all of the components of the prototype except for the Arduino (shown in the wiring diagram in Appendix E). In doing this, there is a time delay before the battery stops supplying power completely. This time delay causes the Arduino to reset improperly if power is turned back on too soon. To avoid errors in the system that would likely confuse the user the function of the switch was removed in this version. In a future version, the power switch needs to be wired directly between the power supply and the power input to the Arduino. This was not possible to do with the prototype version because the battery being used is a portable phone charger battery with a USB output. There was not a good way to cut off the power being supplied through this USB cord. A different or custom rechargeable battery would likely be used in a non-prototype version, making this design change easier. The optimal type of battery power used for the device should be explored further. The team considered the use of AA batteries but were concerned about how frequently the hospital would have to replace the batteries (roughly estimated at every 23 to 34 hours based on current draw of prototype and mAh available in AA batteries). Even still rechargeable solutions can be faulty. The perfusors that exist at KATH are meant to be rechargeable, but the team never saw them operating on their backup battery and everyone the team talked to was not aware of how long those batteries lasted.

The alarm on the device may need to be louder, as it is a little bit hard to hear when inside the casing and in a crowded room. This can be done by increasing the voltage to the buzzer or by adding a second buzzer. Also, adding a potentiometer to the buzzer(s) would allow this volume to be adjusted as needed by the user. With the current code (located in Appendix G), the alarm goes off as soon as the infusion is complete and stops on its own after a few seconds. This can be easily changed to adjust for the needs of healthcare providers, but more work needs to be done to identify exactly when and how long the alarm should go off. Based on interviews and other comments made by stakeholders, the device should generate an alert five to ten minutes before the infusion is complete (and again when the infusion is complete if that timer is shut off

automatically). The team got conflicting opinions on how long the device should beep for. One stakeholder said that it needs to beep until the device has been manually turned off or reset and others said that it should turn off by itself sometime between one and five minutes. Different alarm frequencies were tested at KATH and 660 Hz was determined to be the most desirable. This is the current frequency set in the code for the alarm.

Recommendations to Stakeholders Once Design Has Been Revised and Refined

Based on the experiences and findings from this project, the team recommends use of the proposed timer/flow-stopper solution, once some or all of the design recommendations above are implemented and if/when it passes clinical trials/all other safety regulations and tests. The device could then be used as a safety feature for current IV administration. It can also be used in conjunction with the Dial-a-Flow or any other existing products that are used at KATH. One of these devices could be kept on each pole so that every patient could have one.

Parts could be ordered and the BME staff could assemble them to reduce cost of procurement. This is a low-risk device so assembly at the hospital could work for manufacturing the devices if approved by the IRB/any other safety boards. Once the design is refined, all plastic parts could be injection molded and shipped to Ghana or 3D printed at some place like 'The Hive' (a makerspace located in Kumasi). Another alternative would be mass manufacturing the entire device and selling it assembled. A cost-benefit analysis would need to be performed to determine the best course of action and the result would likely rely on the scale of which the device would be implemented.

Ethics Statement

The team has used a modified version of the Hippocratic oath for healthcare design as a code of ethics during the design process:

"I swear to fulfill, to the best of my ability and judgment, this covenant: I will respect the hard-won knowledge of the human condition of those designers in whose steps I walk, and gladly share such empathetic decisions as are mine with those who are to follow. I will apply, for the benefit of the people, all measures that are ecocentric and holistic avoiding those twin traps of behavioral manipulation and pure profitability."

The use of this oath facilitated conversation about ethics throughout the semester and kept the team in check regarding ethical decisions. The oath is a reminder to put into perspective the potential impacts of any decisions the team may make, especially in a healthcare setting.

The team has also abided by the National Society of Professional Engineers' code of ethics, which canons are as follows:

1. Hold paramount the safety, health, and welfare of the public.
2. Perform services only in areas of their competence.
3. Issue public statements only in an objective and truthful manner.
4. Act for each employer or client as faithful agents or trustees.

5. Avoid deceptive acts.
6. Conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession.

The combination of the oath and the canons helped the team ensure that all testing, validation, design decisions, and reporting were done objectively and honestly.

Along with the oath and code of ethics, the team has also gained insight through interviews with healthcare providers about safety concerns and ethical dilemmas that could arise. This also extended into the final design, as the team wanted a product that would not hurt the patient or standard of care. The end result improved patient safety without adding risk to the IV infusion process. Ethics was always kept in mind throughout the design and iteration process and only a few dilemmas presented themselves during the development of the project.

During validation testing, the team was faced with a quickly approaching deadline and many tests still left to run. In particular, the cost per use spec required that the device be tested more than 500 times. While this particular version had already gone through significant wear and tear during engineering analysis and design expo, it was unlikely that it had gone through 500 use cycles. The team considered extrapolating the durability of the device, as no significant wear or effect on function had been observed. However, in order to hold paramount the safety of the public and avoid deception, the team elected to run the additional trials to pass the specifications. The device was cycled through use more than 500 additional times, and the design requirement was passed without ethical qualms.

The team considered removing parts of the report from previous design reviews that did not line up with the final design. In order to issue this public report in an objective manner, the team found it essential to describe the design process in its entirety. Thus, the major change in direction was described and justified, but all previous information was left in the report.

Since this project was sponsored by the Global Health Design Initiative, one potential goal of the project was giving KATH a working prototype at the end of the semester. An overarching ethical dilemma was whether this device needed to be clinically evaluated before it was used in a real-world setting. Ghana, like other countries in Africa, has less regulation for medical devices than the United States. This device could likely be shipped and utilized in a hospital without raising any eyebrows and has the potential to make an immediate impact on patient care. However, while the team has performed bench testing and found no major drawbacks of using the device, the team would want to confirm the function and safety of it in clinical trials before implementing it anywhere. The team understands its lack of expertise in the medical device field and the importance of device safety, and thus recommended clinical trials before utilizing the device in the real world.

Environmental Impact Statement

Environmental impact was continuously considered throughout the design process. Most critically, one of the design drivers was that the device is reusable. The final product is a reusable

device that could lead to fewer alternative single-use solutions being used, thus decreasing material waste. The team also wanted the solution to be durable, as the longer a device lasts, the fewer overall devices that need to be made.

The environment was also considered during design iterations and prototype manufacturing. All prototypes were 3D printed and made of PLA filament, which is plant-based and biodegradable. The Arduino used in the final prototype should outlast the device and can be recycled to be used in future devices or projects. The plastic and metal components of the device can all be recycled as well.

There were some unavoidable negative impacts on the environment generated by this project. The device incorporates a lithium-ion (Li-on) battery, which even if properly recycled, is not environmentally friendly. However, to work in low-income countries, the device had to be able to be independent of wall electricity during power outages, and thus needed a method by which to store power. The team considered using both a rechargeable Li-on battery and disposable AA batteries in the prototype. A Li-on battery was chosen because the team did not want the hospital to have to frequently throw away and purchase new AA batteries, which is likely even less sustainable than the Li-on alternative. The battery used for the prototype is a power bank intended for use with smartphones, and can thus be reused after the project is over.

The final device is also made of mostly plastic, which negatively impacts the environment throughout its life cycle. Plastic harms the environment both through emissions during production and at the end of its life, as it is not typically biodegradable. The particular plastic chosen for the design process, PLA, is biodegradable, and thus mitigates some of the negative environmental effects. Plastic was also chosen for its low cost, as the intended users would be in low-income countries. This impact is somewhat negated since the device is small and would not be produced at a massive scale, since the goal is to give the device to KATH and other hospitals similar to it. Since the device would likely be manufactured on a small scale, the production process could be low material waste with the use of additive manufacturing and utilization of mostly biodegradable PLA plastics. Lastly, possible future delivery of the device to Ghana would result in a negative environmental effect, as the shipping process creates emissions. This negative impact could be decreased if parts used for the final product are locally sourced.

Standards Statement

There are not many engineering standards specific to IV infusions, but the team conducted a thorough information search to make sure that our device was compatible with available standards. The team also wanted to abide by the standards that the medical device industry utilizes to design their products. Since quality is an important factor in safety, the ISO standard 13485 was kept in mind throughout the process for future quality management systems and regulatory requirements for medical devices.

The standards ISO 1135 and ISO 8536 were used, as they specify requirements for single use infusion and transfusion gravity sets for medical use. These standards were necessary for a few reasons: to ensure compatibility with blood components and intravenous equipment, to ensure

compatibility with containers for infusion solutions and intravenous equipment, and to ensure the solution fulfilled safety requirements and was compatible with existing equipment. These standards were strictly followed through the design process, as they provided guidelines for specific design dimensions and safety.

While it was not fully incorporated, the ISO/IEC Guide 37:2012 for instructions for use of products by consumers was considered when designing the device instructions. Since the current prototype will not be distributed as it is currently designed, these standards were not adhered to. However, the team recommends the use of these standards when instructions are written that are meant for distribution and implementation.

Other medical device ISO standards were considered during the design process: ISO 14971:2007 for the application of risk management to medical devices, ISO 10993-1:2009 for biological evaluation of medical devices, and IEC 62366-1:2015 for application of usability engineering to medical devices. In future versions of this project, these standards would need to be fully followed.

Conclusions

High-resource areas have robust and accurate methods of maintaining patient hydration, administering drugs, and transfusing blood through IV therapy, but those methods often require the use of expensive electrical devices. These devices are hard to come by in low-resource settings, thus IV therapy is performed with outdated technology or devices that were made with different intent of use and don't have the necessary accuracy [14], [15]. KATH in Kumasi, Ghana is a great representation of the struggles hospitals see in low and middle resource areas. The hospital has only four devices that can administer concentrated fluids, and diffused fluids are controlled with rudimentary roller-clamps [14], [15]. There are cheap devices for IV therapy that are simply not used in hospitals like KATH, because they require replacement components or patients must purchase the devices themselves. Thus, there is a need for a low-cost IV therapy solution that in order to be implemented will satisfy a specific set of requirements [13], [16], [17], [19], [21]–[25].

Based on benchmarking, research, and clinical findings, there are ten main requirements that the solution should satisfy. The system needs to control the flow rate, [14]–[16], [19], [20], [22], [25]–[27], [29], [30], [34], [38], [39], control the volume of fluid administered [15], [16], [19], [20], [25]–[28], alert providers within the ward [15], [17], [24], [27], be portable [14], [16], [17], [23], [27]–[30], comply with current market standards [16], [17], [25], [27], [29], [31]–[33], be easy to use [14], [17], [22], [23], [28], be used in low-resource settings [13], [15], [17], [23], [26], [28], [29], [34]–[36], be durable [14], [16], [19], [23] and easy to maintain [15], [23], [36], [37], and provide patient safety [15], [16], [35].

Six methods were used to generate concepts for flow control, which yielded 83 ideas. An iterative method was used to evaluate these ideas. After four passes and a weighted decision matrix, three ideas were chosen for further evaluation. After engineering analysis was performed on these concepts, it became apparent that flow control was infeasible due to constraints on reusability, cost,

and project work time. Stakeholders were also more concerned about the total volume of medication given to a patient, rather than the flow rate. Thus, the focus of the project was changed from flow rate control to volume control.

The team developed a timer and flow stopper mechanism that controls the volume of medication given to the patient and alerts the provider when an infusion is finished. This device would reduce the risk of patient overdose and improve continuous patient care. It is intended to be used as an add-on system to a roller clamp and/or other flow control device, such as the Dial-a-Flow. The device is relatively low-risk for the patients, only adding safety features to infusions, rather than fully replacing an existing benchmark. This has the most notable impact in pediatric populations where volume control is critical to maintaining stable patient vitals. The solution also prevents blood from backing into the line by stopping the fluid flow while there is still a higher pressure in the line than in the vein.

The prototype is imperfect, namely lacking a method to control the flow of a fluid. Future features that would improve the function of the device are an optical monitoring feedback system, a waterproof housing, and an easier to use latching mechanism. These features would add to both the safety and function of the prototype and the team believes a final design that incorporated these changes could be implemented in low-resource settings and make a significant impact on patient care. The team recommends implementing the proposed timer/flow-stopper solution once some or all of the design recommendations above are implemented and if/when it passes clinical trials/all other safety regulations and tests.

The team took ethical, environmental, and international standards into account throughout the design process, and is proud to have designed a fully-functional prototype.

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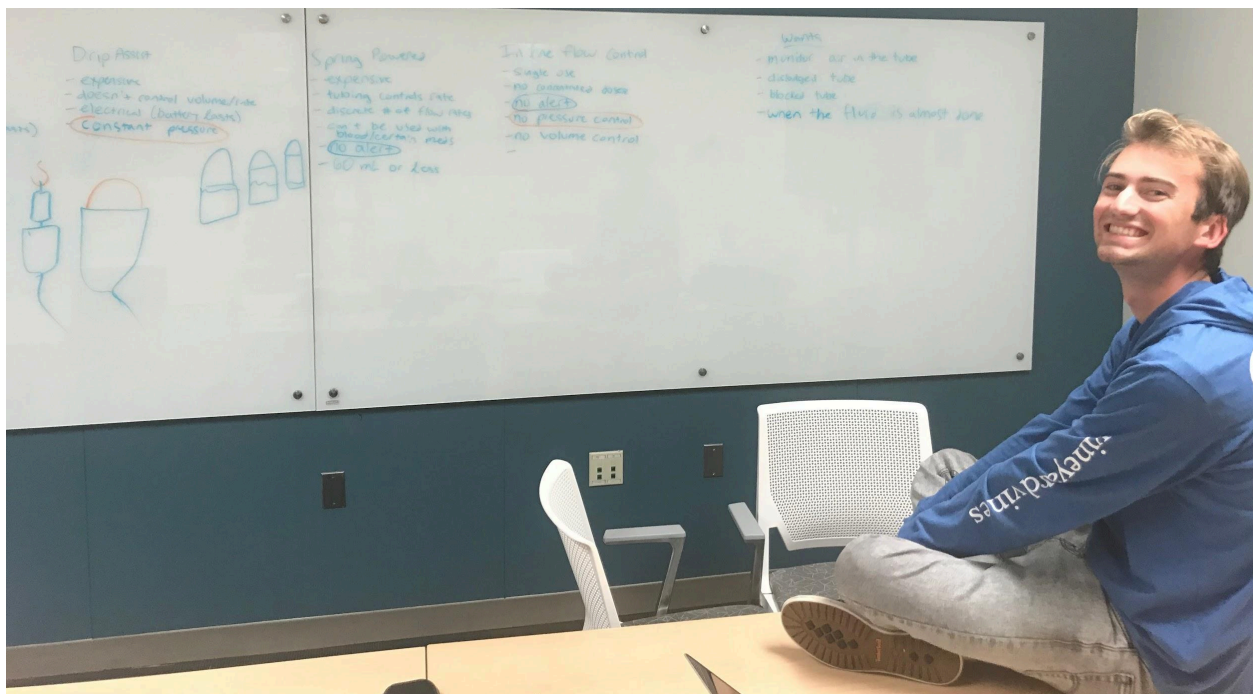
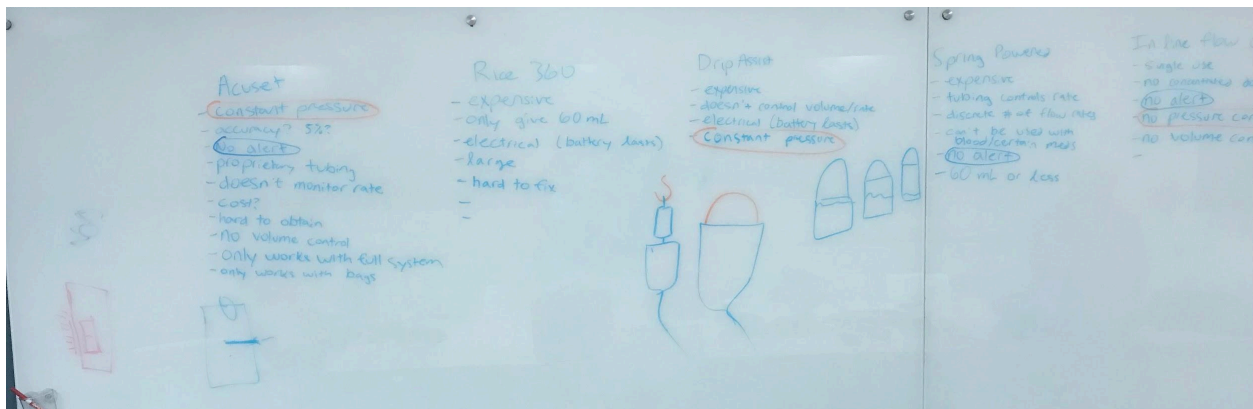
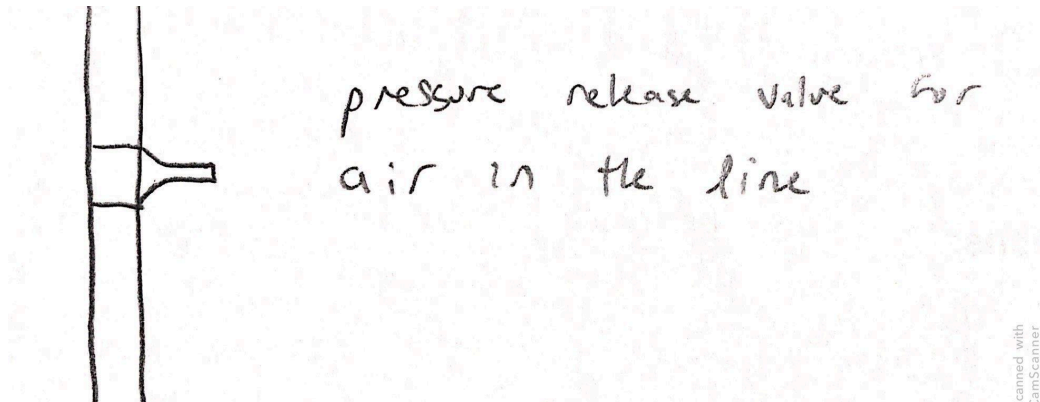
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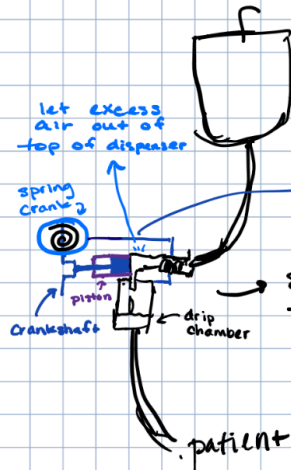
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Appendix A: Raw Concept Sketches



Functional Decomposition

B2
H3
I4
N5
R6
B7
C8
B9
I10
D11



→ spring + piston mechanism could be replaceable
↳ soap dispenser part disposable

→ could monitor flow via weight remaining

→ head of soap dispenser pushed w/ crankshaft piston powered by wind-up spring mechanism

→ soap dispenser for discrete volume of fluid
↳ pushes fluid into drip chamber

→ change gears to change flow rate

↳ when wound out bell dings from hitting hard stop

↳ stops flow when wound out of energy
↳ hard stop to prevent overturning @ set flow rate

↳ could have secondary system powered by first
↳ adjust gearing in between

↳ crankshaft part would attach to pole via clamp

G2 - battery

E3 - piston

G4 - primeline

N5 - stop supplying energy

D6 - piston flow meter

E7 - beep

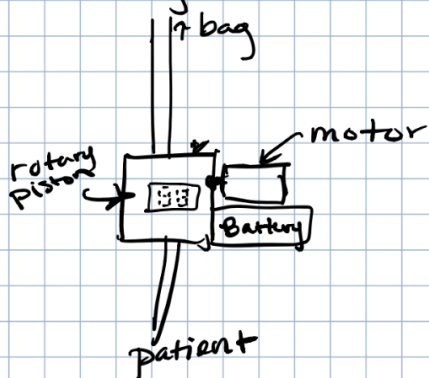
D8 - spring loaded clamp (like clip)

B9 - replaces IV set

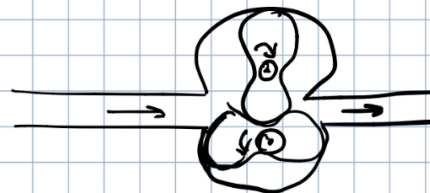
I10 - use one device to power other - adjust gearing

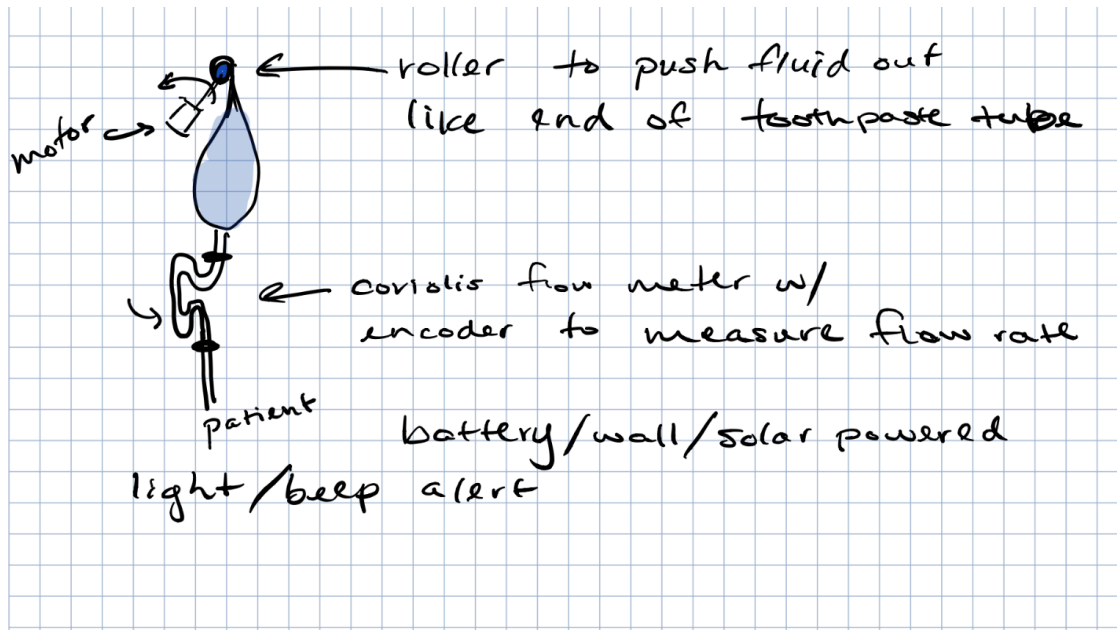
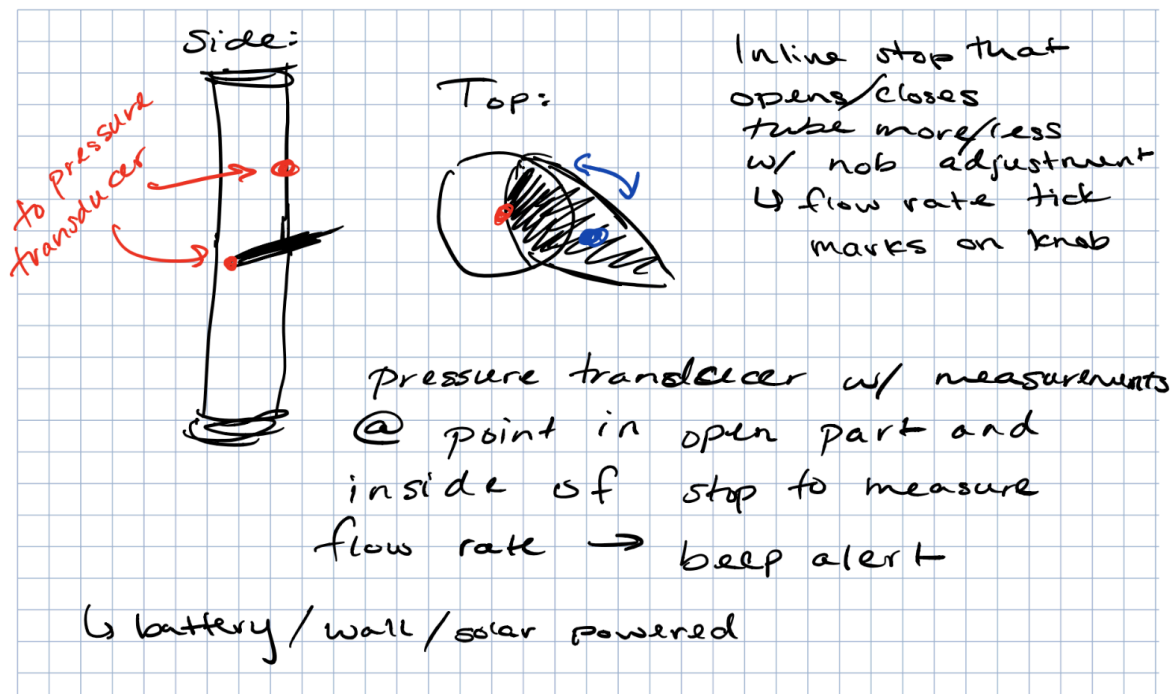
R11 - rotary piston

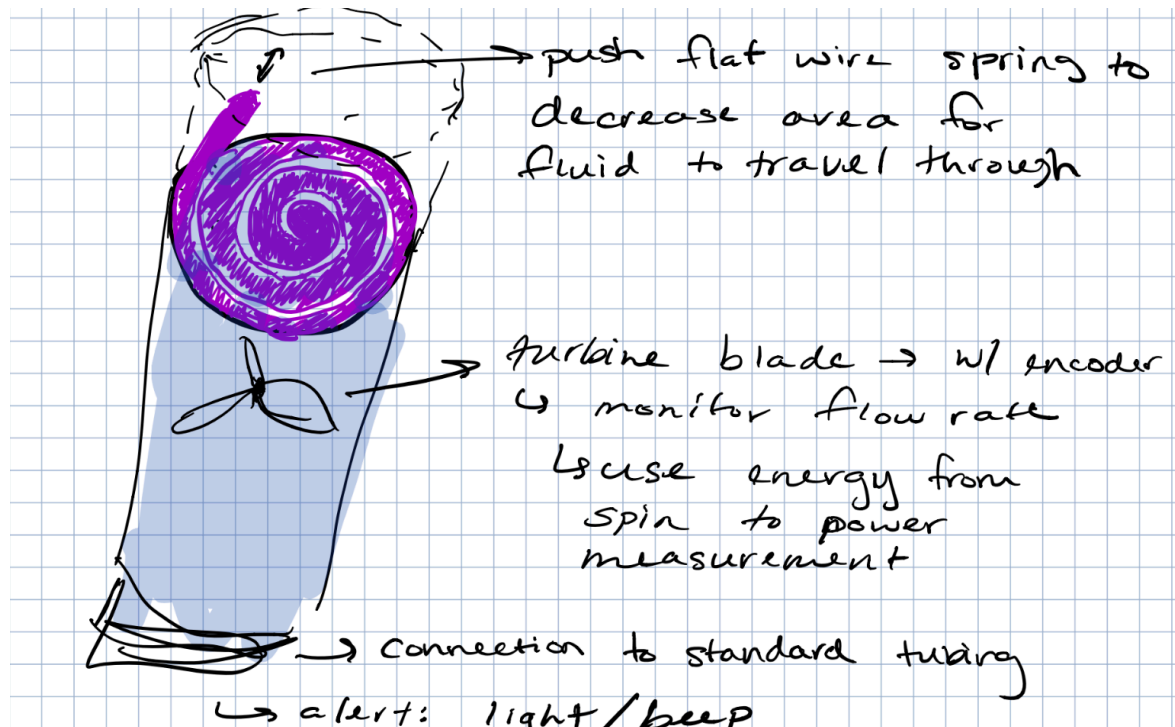
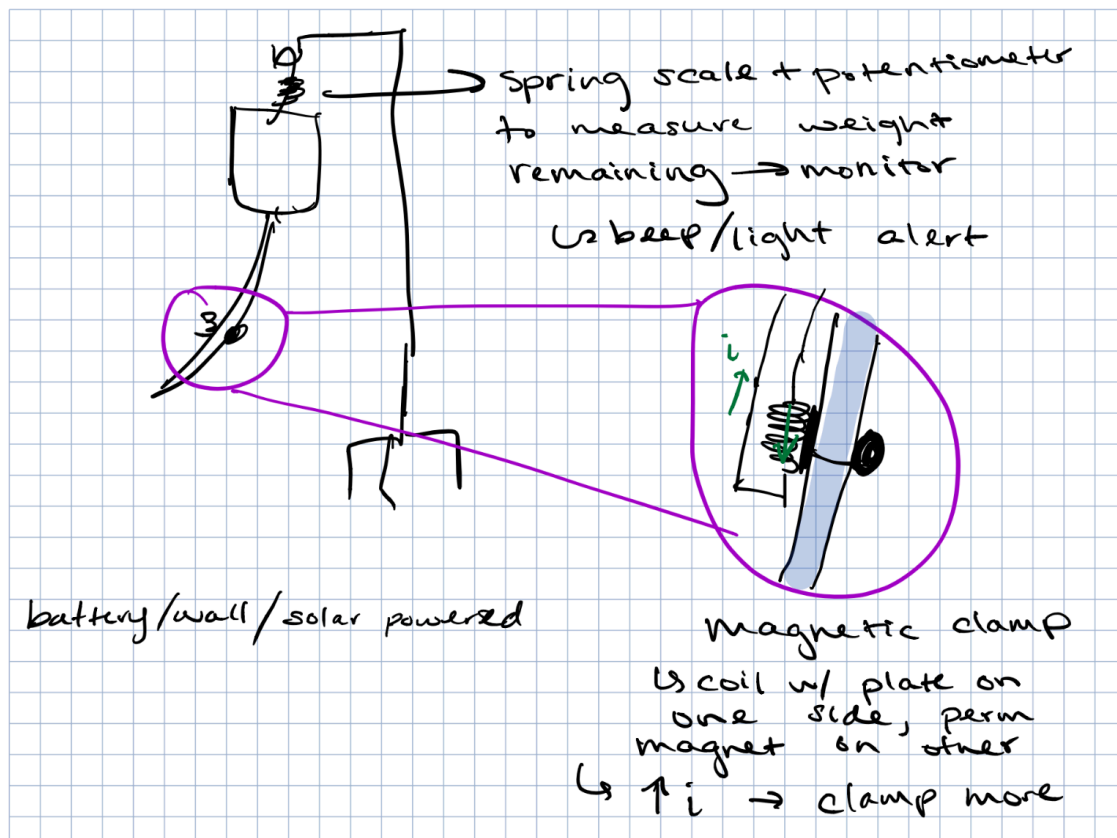
→ disposable inner chamber
→ reusable outside

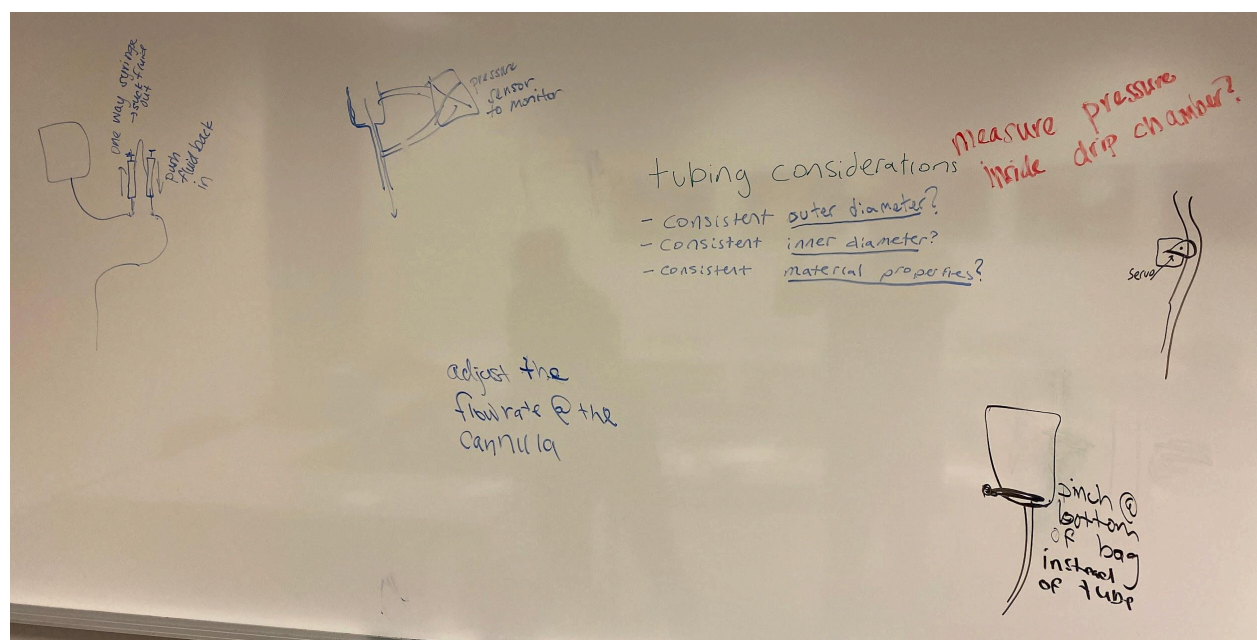
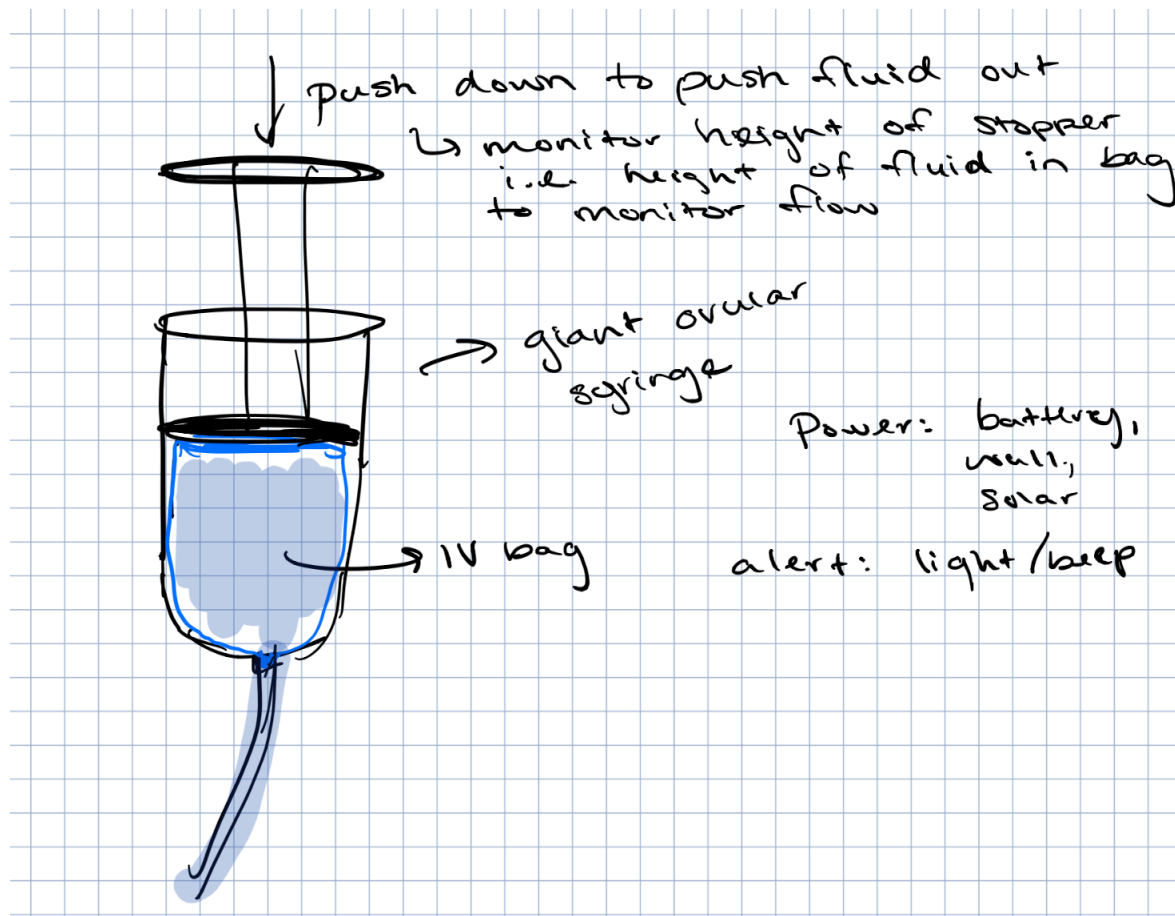


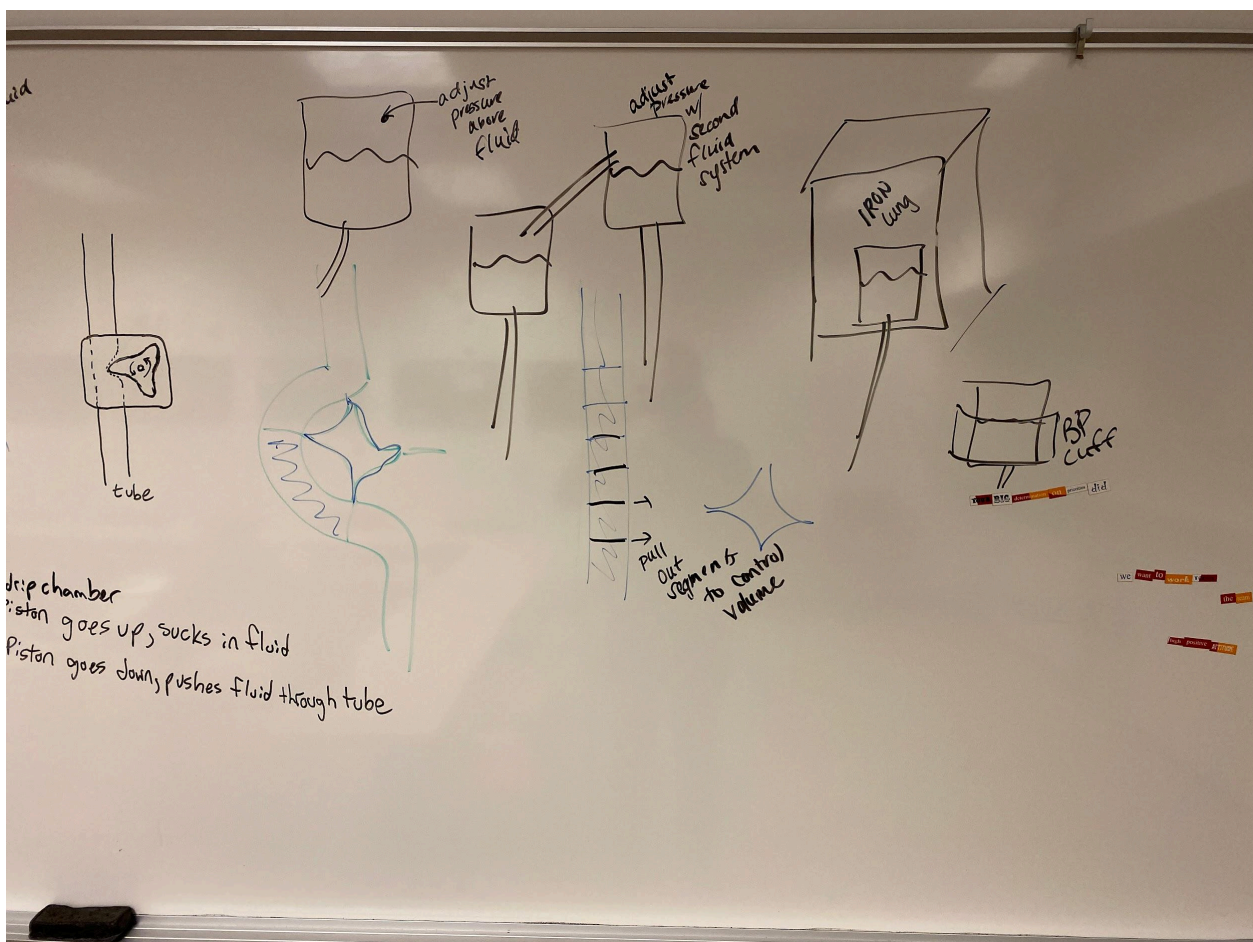
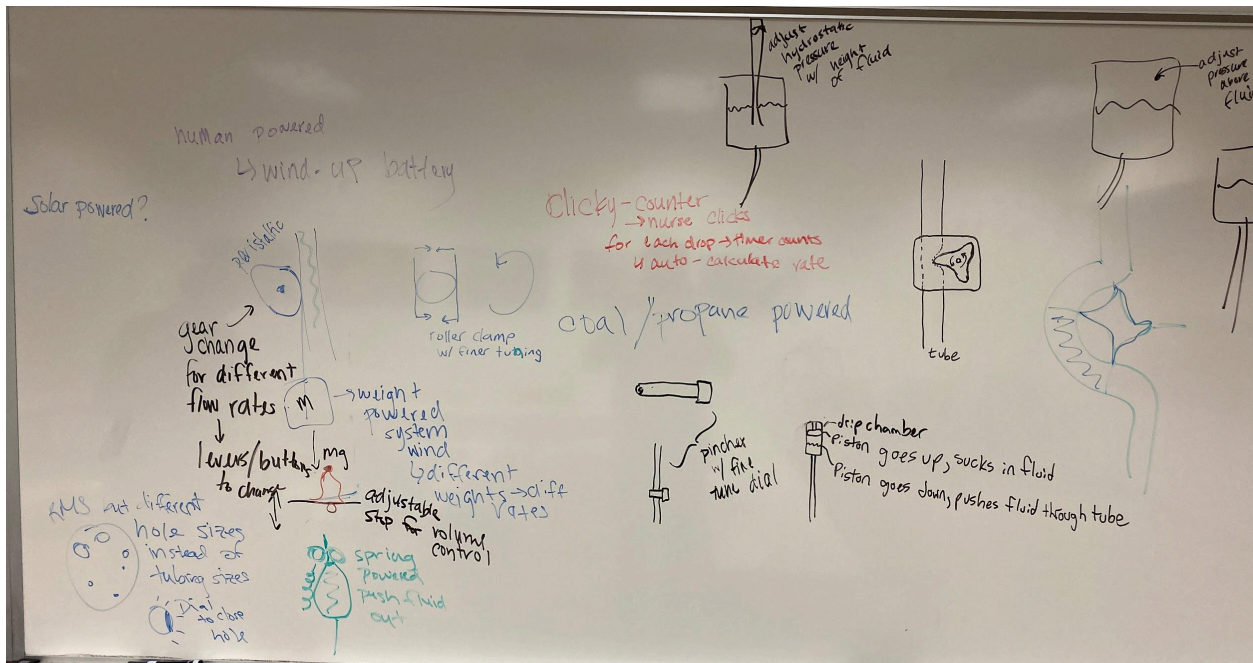
rotary flow meter pushes known volumes of fluids









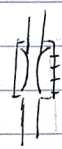


C4

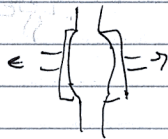


Mechanical watch

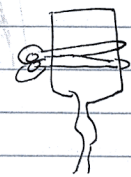
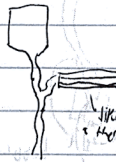
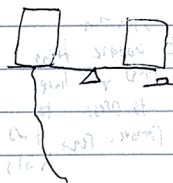
C5



C6



C7



C8



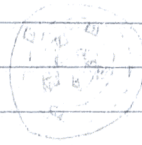
diff. signs



C13



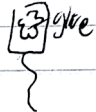
double roller



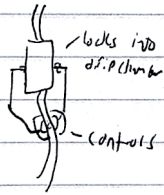
C14



different heights, different rates



C15/16



locks into d.p. chunk

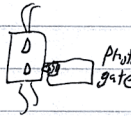
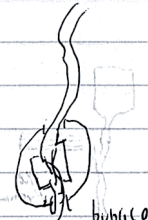


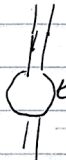
photo gate



C32



bubble



vitamin bottle this has you have to press to remove. Press two hands

C33



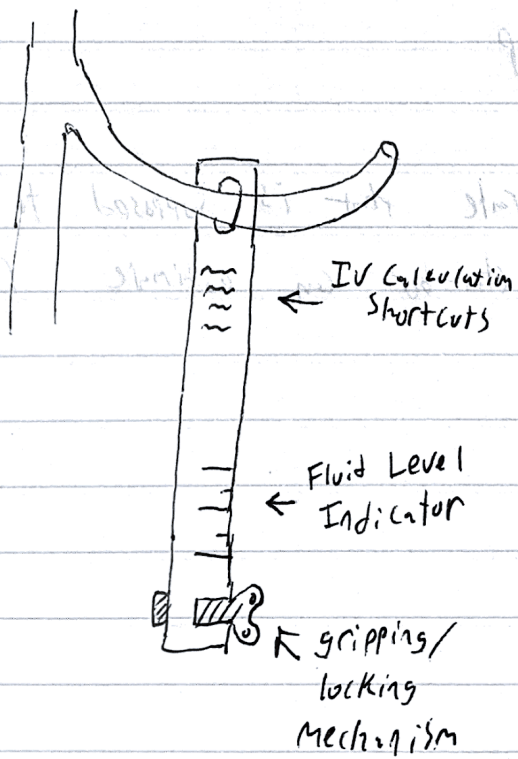
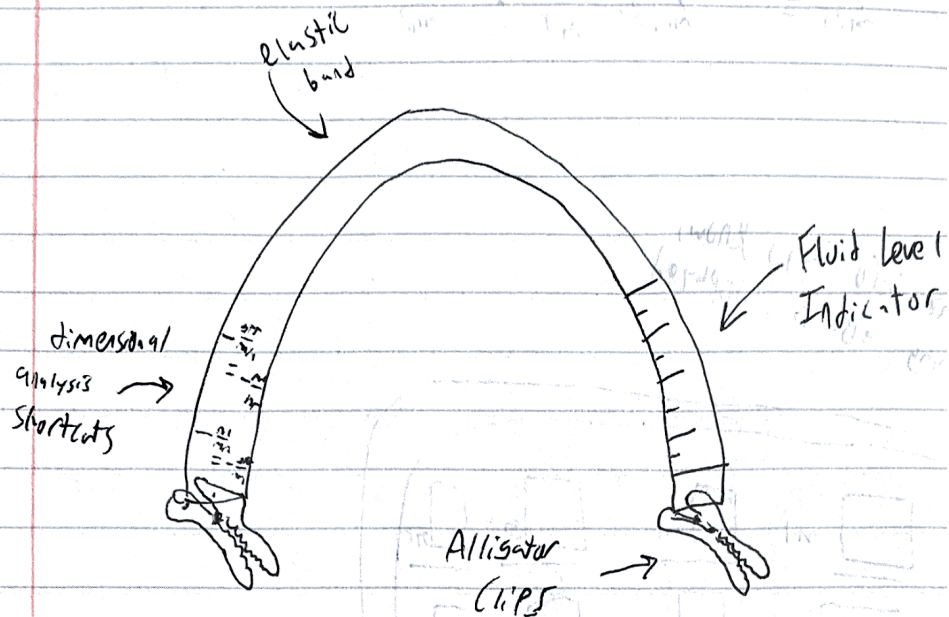
pressure sensor

Enter the info you know,
everything else is displayed

	ml		ml		gtr		gtr
	min		hr		ml		min

Device or App

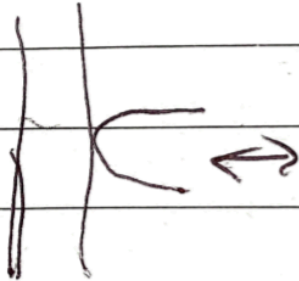
beeps @ the rate that is supposed to be dripping
Camera on drip chamber can estimate rate



irrigation valve



stack filters on top
of each other



mentals

coke

break

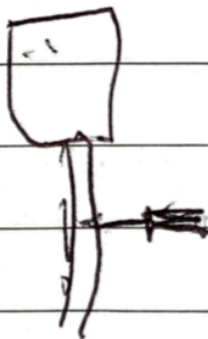
seal

like glow

stack

W build

pressure on
outside





- pulleys to raise/lower
bag $\rightarrow$ increase pressure/flow



telescoping

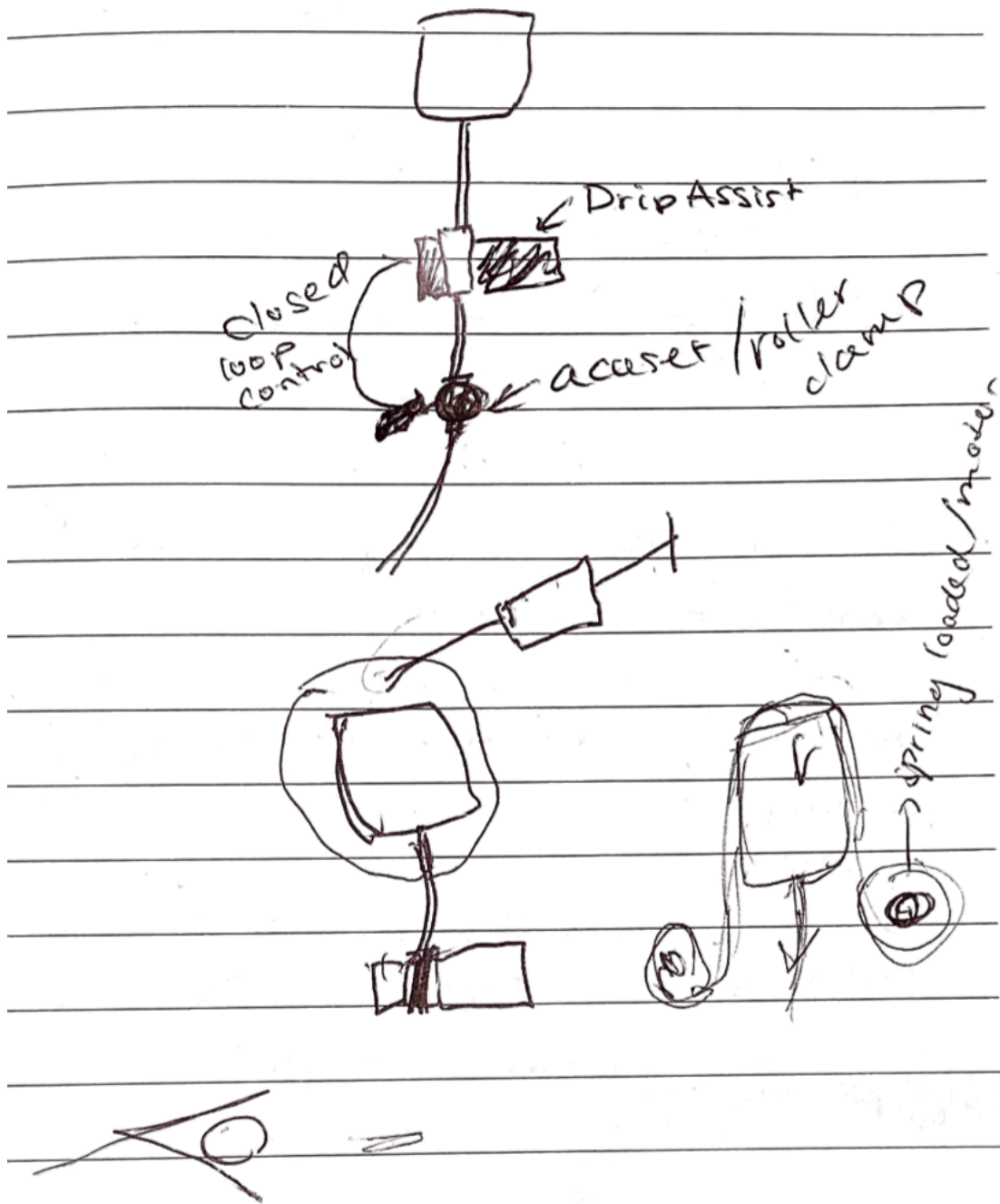
IV line

$\rightarrow$ twist for smaller
diameter

- longer roller clamp $\rightarrow$ more
fine control

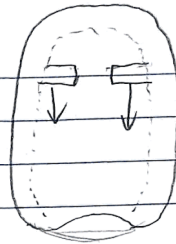
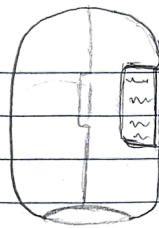
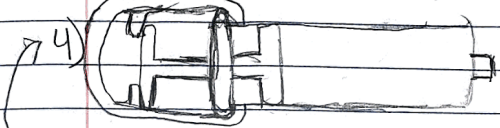
$\rightarrow$ gear up roller clamp $\rightarrow$ finer
control

carbonate IV fluid $\rightarrow$ shake
to build pressure + push
out



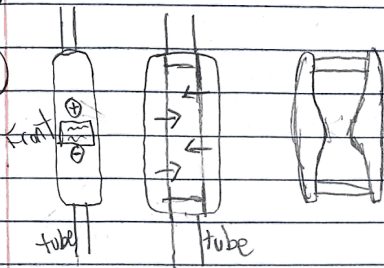


4, 5, 6, 7, 8, 13, 14, 15/16, 32, 33

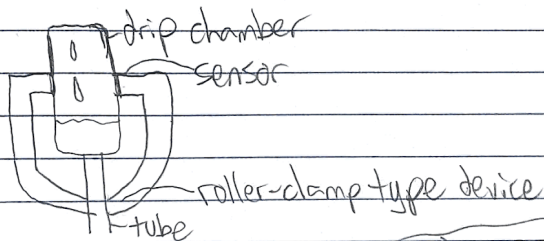


5)

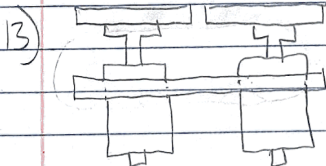
6)



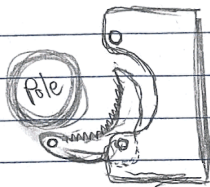
7)



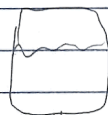
8) ?



14)



15/16)



controls pressure / flow rate / volume
inner disposable tube

32)

Card reader for Nurses/Doctors

33)

Device that detects air and releases it
Right before needle
in arm



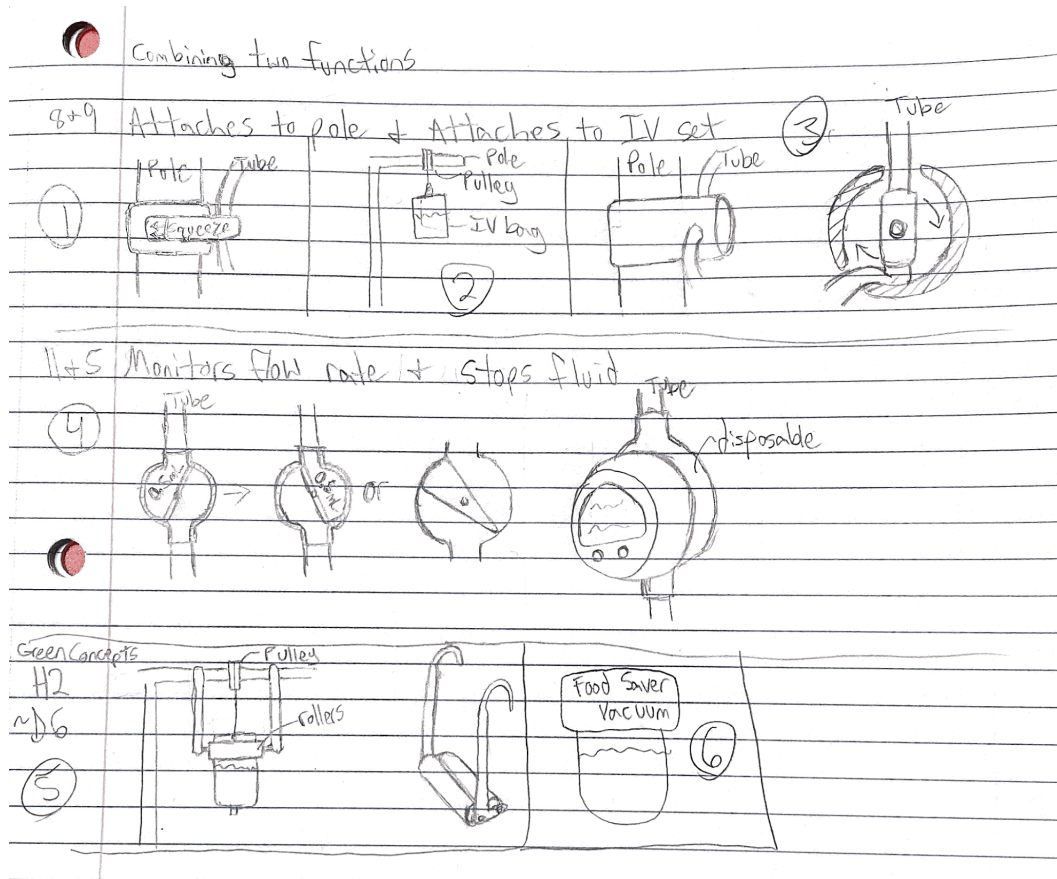


Table A1. Functional decomposition matrix. Green cells are ideas that were deemed somewhat feasible and were combined to generate complete concepts.

Function	Method 1	Method 2	Method 3	Method 4
Energy into system	springs - crankshaft/windup mechanism	hydraulics - raise pressure and have slow release	kinetic - use energy from steps around hospital, use pendulum	mechanical - pulley system, weight with crank
Moves fluid	balloon	hose (pressure gradient)	fluid injection pump	piston
Keeps air out of the line	no air	flex tape	duct tape	suction
Stops fluid	ball valve	kink line	pinch line	inline stop
Adjusts fluid flow rate	valve open more or less	roller clamp	piston flow meter	change hole size (rotate a disk to change the hole size)
Alerts healthcare provider	bell	flag	click	beep
Attaches to pole	pin in hole	clamp with screw	spring loaded clip (c clamp)	glue
Attaches to IV set	replaces IV set	glue	spring loaded clip (c clamp)	sticky - flex tape
Works with two (or more) fluids	2 of the same thing built into single device	mechanical peristaltic system with gearing in between to adjust flow between devices	attachment of 2 systems w/ velcro	System inspired by double barrel shotgun
Monitors flow rate	optical sensor: drop count	measure height of fluid: optically or with floating resistor	measure weight	pressure monitor: venturi, pitot, dall tube, orifice plate, cone meter, linear resistance meter

Function	Method 5	Method 6	Method 7	Method 8
Energy into system	gas generator	batteries	solar charge	wind charge
Moves fluid	syringe	gravity	soap dispenser	sink (the kind you press once)
Keeps air out of the line	siphon	prime line	air filter/drip chamber	one-way valve to let air out
Stops fluid	equalize pressure	cut line	remove fluid	clog or clot - chemical stop
Adjusts fluid flow rate	change tube size	change venous pressure of patient	change pressure in bag/bottle directly - pump fluid into top of bag	change pressure in line - inline pump, suction in line
Alerts healthcare provider	buzz	honk	light	tactile vibration
Attaches to pole	sticky - flex tape, stickers, tape in general	velcro	co-band/ gauze wrap	rope
Attaches to IV set	velcro	string	sew it	slide-on spring loaded clamp (like DripAssist)
Works with two (or more) fluids	Pressurized box that fits two IV bags	Rack that lets two syringes hang vertically with individual pistons to push fluid out	Syringes similar to two barrel epoxy tubes	use one device to power other - adjust gearing
Monitors flow rate	optical sensor: flow meter	vortex flowmeter - make flow swirl and count vorticities - are there vorticities in the flow already?	rotameter float	doppler velocimetry

Function	Method 9	Method 10	Method 11	Method 12
Energy into system	hydroelectric - put little turbine in sink and use fluid dumping to power device	natural gas	wall power	rechargeable batteries
Moves fluid	negative pressure (suction)	peristaltic	Twisting the top of the bag	rolls out the bag (toothpaste)
Keeps air out of the line	2 drip chambers	LED/IR sensor to sense air and stop flow	Vacuum system	Air filter that doesn't allow fluid through
Stops fluid	servo motor/pneumatic clamp	magnetic clamp	drop bag	wind up spring- mechanical timer to clamp
Adjusts fluid flow rate	pump discrete volumes (soap dispenser)	twist tube to decrease cross sectional area	change pressure in bag indirectly - put rollers on top of bag to push out fluid	change pressure in bag indirectly - iron lung box
Alerts healthcare provider	song	telepathy	bluetooth	
Attaches to pole	magnets	elastic band	strap (professional rope)	slide-on spring loaded clamp (like DripAssist)
Attaches to IV set	clip/hang on fluid bag	dart board style	grab around top of drip chamber	
Works with two (or more) fluids	Just make it cheap enough that two separate systems are viable			
Monitors flow rate	laser-based	radar	sonar	thermal mass

Function	Method 13	Method 14	Method 15	Method 16	Method 17	Method 18
Energy into system	nuclear	geothermal	recycling movement from something like wheels (similar to power from turning wheel on car)	build energy from moving switch back and forth like microverse of Rick and Morty	build energy from stepping on pedal like in the miniverse of Rick and Morty	
Moves fluid	Syringe pump	Squeezing the bag like ketchup (icing tube might fit better lol)	blood pressure cuff			
Keeps air out of the line	Put the OR in a vacuum					
Stops fluid	run out of energy/stop supplying energy	Squeeze clamp				
Adjusts fluid flow rate	change pressure in bag indirectly - BP cuff type thing	change pressure in bag indirectly - linear compression system that slowly clamps bag until fully compressed	change pressure in bag directly - turn bag into syringe - insert stopper to push	magnetic clamp - change current to clamp more/less	more energy/different gearing	adjust size of volume used in peristaltic pump
Alerts healthcare provider						
Attaches to pole	easy clamp					
Attaches to IV set						
Works with two (or more) fluids						
Monitors flow rate	lorentz-force velocimetry	magnetic flowmeters	ultrasonic	coriolis	rotary piston	turbine/fan blade flow meters - few different kinds

Appendix B: Concept Evaluation Details

Table B1. Concepts remaining after the first pass. Concepts eliminated in the second pass due to being single-use are highlighted in red and concepts eliminated due to feasibility are highlighted in orange.

Function	Methods of achieving	reason for cutting (feasibility)		
external clamping of tube	string around tube - pull to tighten like choke collar		2nd pass	get rid of internal systems
	longer roller clamp for finer control			gut check on feasibility
	gear up roller clamp for finer control (dial)			
	kink tubing	would result in cold flow creep, is very likely to have problems with accuracy		
	twist tubing	same as above		
	linear clamp with finer control			
	magnetic clamp			
	servo			
external clamping of bag	clamp bag			
internal clamping	bath tub stopper in bag			
	pressure shrink tubing - shrink tubing at lower pressures (higher flow rate)			
	disc with different hole sizes			

	valve			
	mechanical watch			
external discrete volume control	2 wheels on either side of line - peristaltic pump			
	scissor type mechanism to open/close (via clamping) line	solenoid would accomplish this more reliably		
	solenoid to open/close (via clamping) line			
	peristaltic pump using weight powered system - different weights -> different rates, or different gearing. note: feature for extendable pusher for different sized tubings			
	scissor type mechanism to push fluid out			
internal discrete volume control	irrigation valve			
	soap dispenser			
	rotary piston			
	fluid dial - push out sections of fluid - less complicated rotary piston			
	syringe w/ one way valve - takes fluid out of the bag, pushes it into patient			
filter	stack filters to decrease flow rate			
pressure external	bungees, spring, elastic band (maintain hydrostatic pressure), note: could include fluid level indicator and info on dimensional analysis, could use screw/lock mechanism to attach to bag			
	toothpaste roller			
	rollers that squeeze IV bag - could be spring/weight w/ pulley powered - could keep rollers stationary and pull bag, or could keep bag stationary and pull rollers			
	giant syringe to put entire IV bag into			
	pulleys to raise/lower bag - adjust hydrostatic pressure			
	roll up material around bag to push fluid out - elastomeric pump w/out elastomer			
	iron lung - with liquid/with air, with blood pressure cuff type chamber - could use a soccer ball pump to fill with pressure or chamber not in direct contact			
pressure internal	secondary IV bag system to regulate pressure			
	piston in drip chamber to suck fluid in, and then push out			
	vacuum air from drip chamber - create negative pressure			
drop count monitor	optical sensor on drip chamber			
	phone app with calculator			
pressure monitor	pressure transducer at inside of valve and at opening in tubing			
weight monitor	measure weight of bag			

Table B2. Design drivers used for the third pass. These came from top priority specifications.

	Design Drivers
control	Controls flow between 0 mL/hr and 250 mL/hr and sustains accuracy to within $\pm 10\%$
control	Stops the flow of medication/fluids at a volume set by the user between 0 and 500 mL and is accurate to within $\pm 10\%$
control/monitor	Alert the provider when an infusion has stopped
control/monitor	Compatible with drip chamber diameters between 1.3 cm and 2.11 cm
control/monitor	Compatible with current IV equipment based on ISO 1135 and ISO 8536 international standards
control/monitor	Does not use proprietary or device-specific tubing/equipment
	Does not allow > 1 mL of air into the line
	cost
	space/portability

Table B3. Concepts remaining after the second pass. Concepts highlighted in red were eliminated during the third pass based on a Go/No-Go evaluation of concepts based on the design drivers in Table B.2. The reasons for elimination are noted in the table.

Function	Method	Why bad? 🚫	Control	Monitor
external clamping of tube	string around tube - pull to tighten like choke collar	unnecessarily complicated - instead of directly constricting the tube or flow, it relies on yet another mechanism	Y	
	longer roller clamp/gear up roller clamp for finer control, automatic volume control with pulley system		Y	
	linear clamp with finer control		Y	
	magnetic clamp	unnecessarily complicated and may not provide consistent force over time	Y	
	servo		Y	
external clamping of bag	clamp bag (could be for volume or rate control)	will not work with bottles	Y	
external discrete volume control	solenoid to open/close (via clamping) line		Y	Y
	peristaltic pump using weight powered system - different weights -> different rates, or different gearing. note: feature for extendable pusher for different sized tubings		Y	Y
	scissor type mechanism to push fluid out		Y	Y
	syringe w/ one way valve - takes fluid out of the bag, pushes it into patient		Y	Y
pressure external	bungees, spring, pulleys, elastic band (maintain hydrostatic pressure), note: could include fluid level indicator and info on dimensional analysis, could use screw/lock mechanism to attach to bag		Y	
	toothpaste roller	will not work with bottles	Y	
	rollers that squeeze IV bag - could be spring/weight w/ pulley powered - could keep rollers stationary and pull bag, or could keep bag stationary and pull rollers	will not work with bottles	Y	
	giant syringe to put entire IV bag into	will not work with bottles	Y	
	pulleys to raise/lower bag - adjust hydrostatic pressure	takes up too much space, pressure difference likely insufficient	Y	
	roll up material around bag to push fluid out - elastomeric pump w/out elastomer	will not work with bottles	Y	
	iron lung - with liquid/with air, with blood pressure cuff type chamber - could use a soccer ball pump to fill with pressure or chamber not in direct contact	will not work with bottles	Y	
drop count monitor	optical sensor on drip chamber			Y
	phone app with calculator	does not alert - user could not stand there with their phone pointed at all times		Y
weight monitor	measure weight of bag			Y

Table B4. Weighted decision matrix used for the fourth pass. Rating scale: 1-Inadequate, 2-Weak, 3-Satisfactory, 4-Good, 5-Excellent. Concepts highlighted in green were the final four selected concepts.

Weight (%)	Criteria	longer roller clamp/gear up roller clamp for finer control, automatic volume control with pulley system	linear clamp with autonomous finer control	servo to automatically clamp tube	solenoid to open/close (via clamping) line	peristaltic pump using weight powered system - different weights - different rates, or different gearing. note: feature for extendable pusher for different sized tubings
15	Is a novel idea	2	3	3	4	5
15	Is a simple idea	3	3	5	2	2
20	Monitor and alerts	1	1	1	2	3
30	Controls rate (roller clamp=2)	3	3	3	4	5
15	Does not use proprietary tubing/products	5	5	5	5	5
5	Does not require electricity (5 definitely can be used w/out electricity, 3 maybe could be, 1 definitely needs)	5	1	1	1	5
100	Total	2.85	2.8	3.1	3.3	4.15

Weight (%)	Criteria	scissor type mechanism to push fluid out in discrete lengths on the tube	syringe w/ one way valve - takes fluid out of the bag, pushes it into patient	bungees, spring, pulleys, elastic band (maintain hydrostatic pressure), note: could include fluid level indicator and info on dimensional analysis, could use screw/lock mechanism to attach to bag	optical sensor on drip chamber	measure weight of bag
15	Is a novel idea	5	2	2	1	2
15	Is a simple idea	2	3	5	3	2
20	Monitor and alerts	3	3	2	5	4
30	Controls rate (roller clamp=2)	5	5	3	1	1
15	Does not use proprietary tubing/products	5	1	5	5	5
5	Does not require electricity (5 definitely can be used w/out electricity, 3 maybe could be, 1 definitely needs)	1	3	5	1	1
100	Total	3.95	3.15	3.35	2.7	2.5

Appendix C: Bill of Materials

Product	Company	Units	Cost/Unit	Single Item Cost	Qty	Total
---------	---------	-------	-----------	------------------	-----	-------

PCB Board Kit	Austor	pack(100)	\$15.99	\$0.16	1	\$0.16
16 Key Keypad Switch Module for Arduino	Nextion	pack(5)	\$8.99	\$1.80	1	\$1.80
5V Active Buzzer Electronic Alarm for Arduino	Cyclewet	pack (10)	\$6.98	\$0.70	1	\$0.70
10000mAh Power Bank, Ultra-Compact Battery Pack	RAVPower	ea	\$16.95	\$16.95	1	\$16.95
1" Spring Clamp	Anvil	ea	\$0.99	\$0.99	1	\$0.99
Metric Lock Nut M3	Unknown	ea	\$0.98	\$0.98	1	\$0.98
Metric Socket Head Cap Screw	Unknown	ea	\$1.10	\$1.10	1	\$1.10
LCD 16x2 Serial Interface Adapter Module Blue Backlight for Arduino (Pack of 2)	LGDehome	pack (2)	\$9.99	\$5.00	1	\$5.00
UNO R3 Board with USB Cable Compatible with Arduino IDE Projects	ELEGOO	ea	\$11.86	\$11.86	1	\$11.86
4Pcs SG90 9g Micro Servos for RC Robot Helicopter Airplane Controls Car Boat	Deegoo-FPV	pack(4)	\$9.99	\$2.50	1	\$2.50
Maxcraft 7707 Spring Assortment, 200-Piece	Vie Saga LLC	pack(200)	\$9.99	\$0.05	4	\$0.20
Stainless #4-40 x 3/4" Socket Button Head Cap Screws, Full Thread, Hex Drive, Stainless Steel 18-8, Machine Thread (4-40 x 3/4")	Chengango Supply, Co	pack(100)	\$8.99	\$0.09	5	\$0.45
Stainless #4-40 x 1/2" Socket Button Head Cap Screws, Full Thread, Hex Drive, Stainless Steel 18-8, Machine Thread (4-40 x 3/4")	Chengango Supply, Co	pack(100)	\$8.99	\$0.09	9	\$0.81
1/4" x 3/4" Stainless Steel Hex Bolts	Bolt Dropper	pack(100)	\$11.99	\$0.12	4	\$0.48
1/4"-20 Stainless Hex Nuts	Bolt Dropper	pack(100)	\$7.71	\$0.08	4	\$0.31
22AWG Stranded Wire,Electrical Wire, Tinned Copper Hookup Wire Kit 22 Gauge	LotFancy	180 feet	\$13.86	\$0.08	0.5	\$0.04
3D printed parts	Cura	ea	\$3.26	\$3.26	1	\$3.26
Rocker switch	Digi-key	ea	\$0.98	\$0.98	1	\$0.98
Resistor Kit Assortment	ELEGOO	pack(525)	10.86	0.02068571429	3	\$0.06
nuts to attach flow stopper to housing					3	0
12" alloy steel	Grainger	ea	2.25	2.25	1	\$2.25
#4-40 Hex Machine Screw Nuts, Grade 2, Electro Zinc Plated Steel & Clear Finish	Fastenere	pack(100)	\$5.37	\$0.05	3	\$0.16
				Total: \$51.03		

Appendix D: Engineering Drawings for Flow Stopper Mechanism

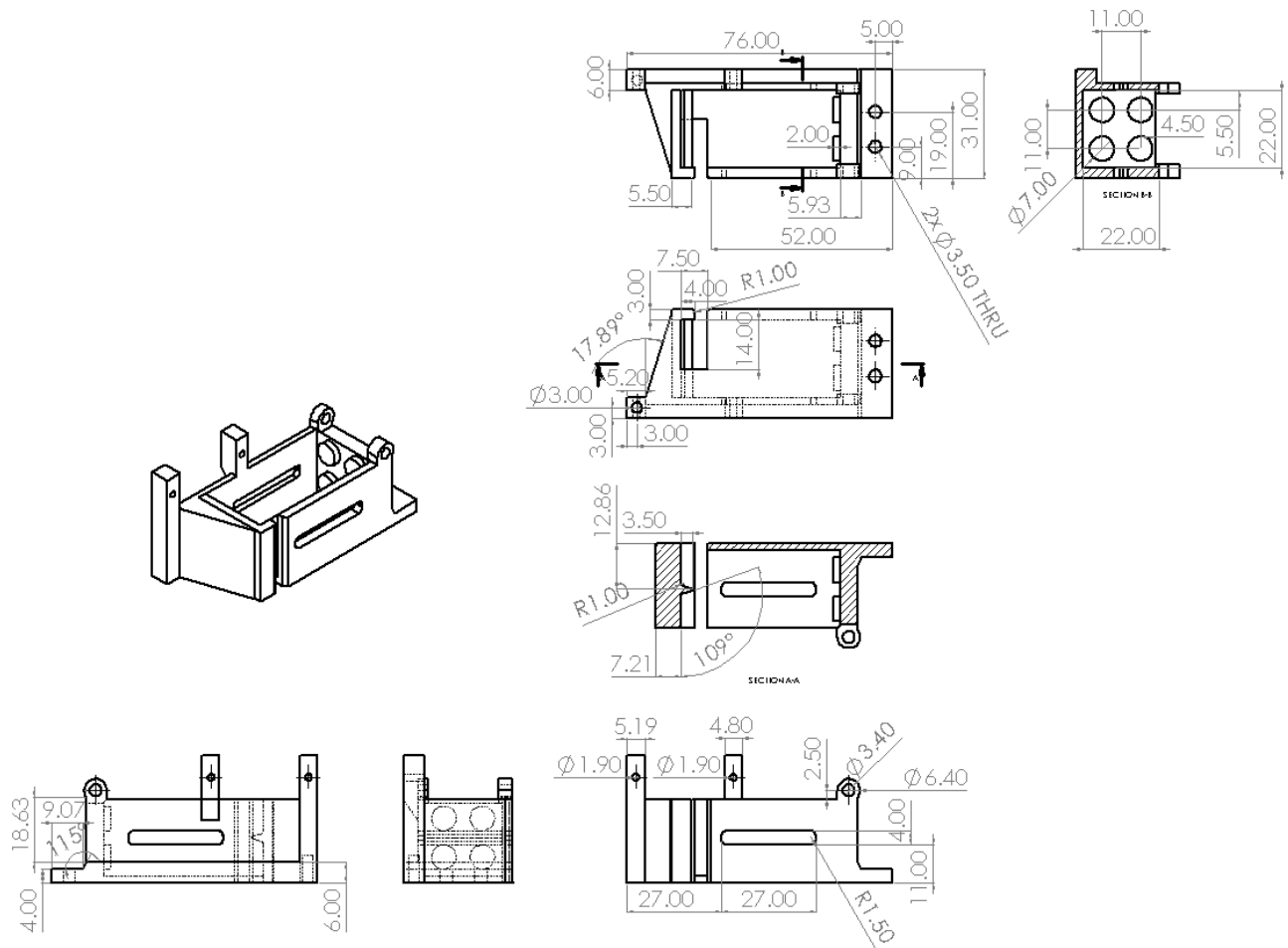


Figure D1. Flow stopper wall. All dimensions in millimeters.

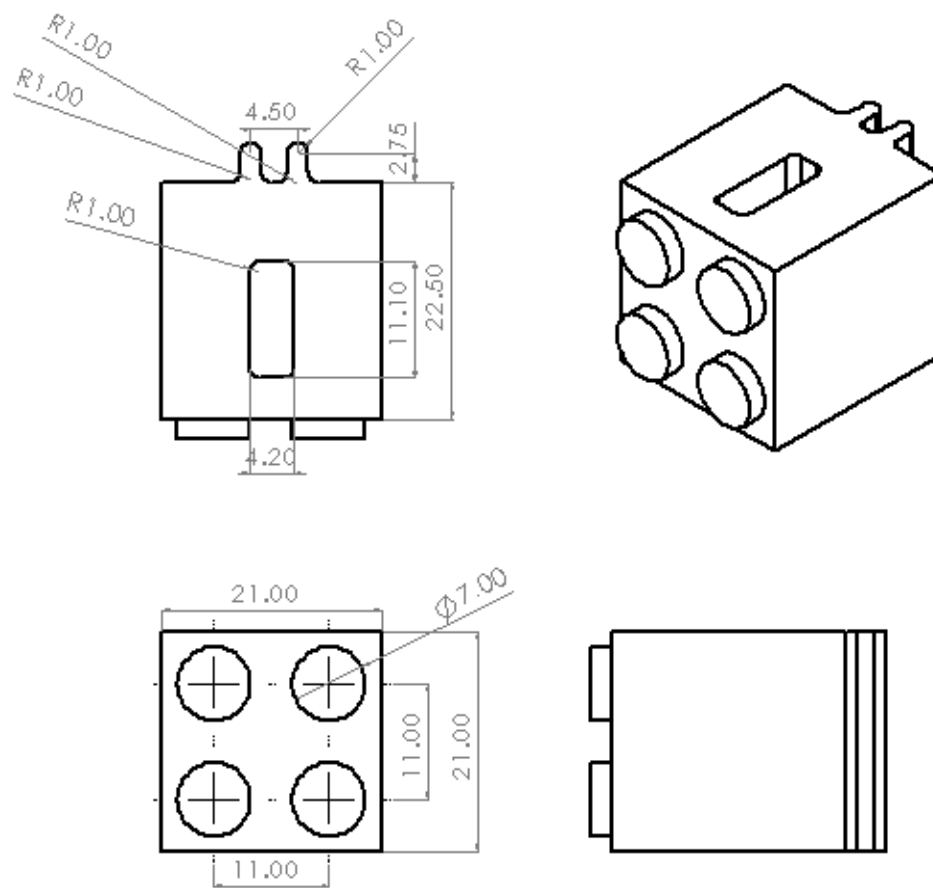


Figure D2. Slider. All dimensions in millimeters.

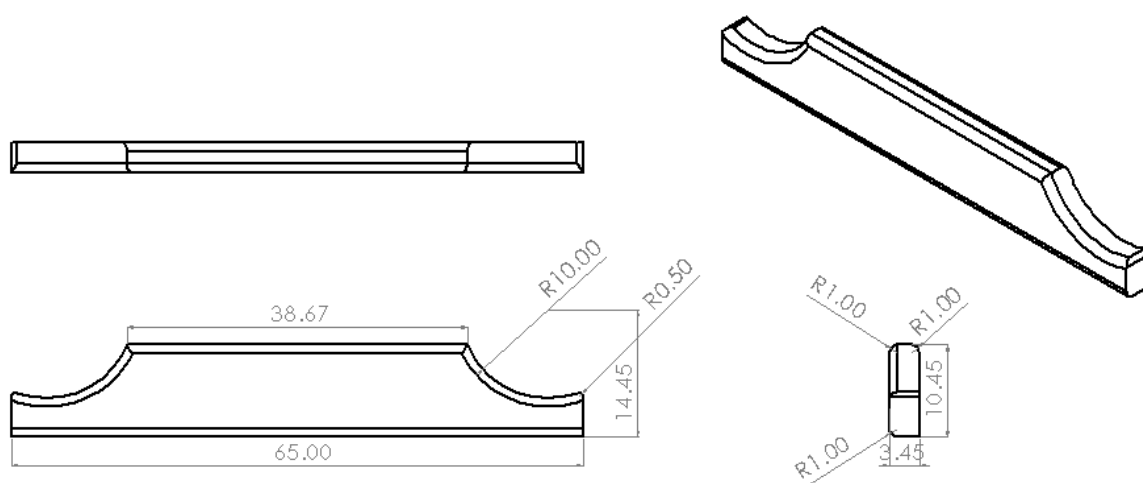


Figure D3. Puller. All dimensions in millimeters.

Appendix E: Assembly and Use Instructions

The following are instructions for assembly and use of the prototype as it is currently. These are intended to be for reference for any future teams that may take on this product and do not incorporate any of the suggested changes as mentioned in the Discussion.

Wiring Diagram. Figure E1 shows the wiring diagram for the Arduino Uno microcontroller setup. As pointed out in the diagram, the resistors have been added to allow the system to stay on while drawing power from a 10000 mAh phone charger battery. That battery was chosen because it can be charged and supply power to the circuit at the same time. Because the power drawn from the system is low, the resistors were required to keep current flowing out of the battery.

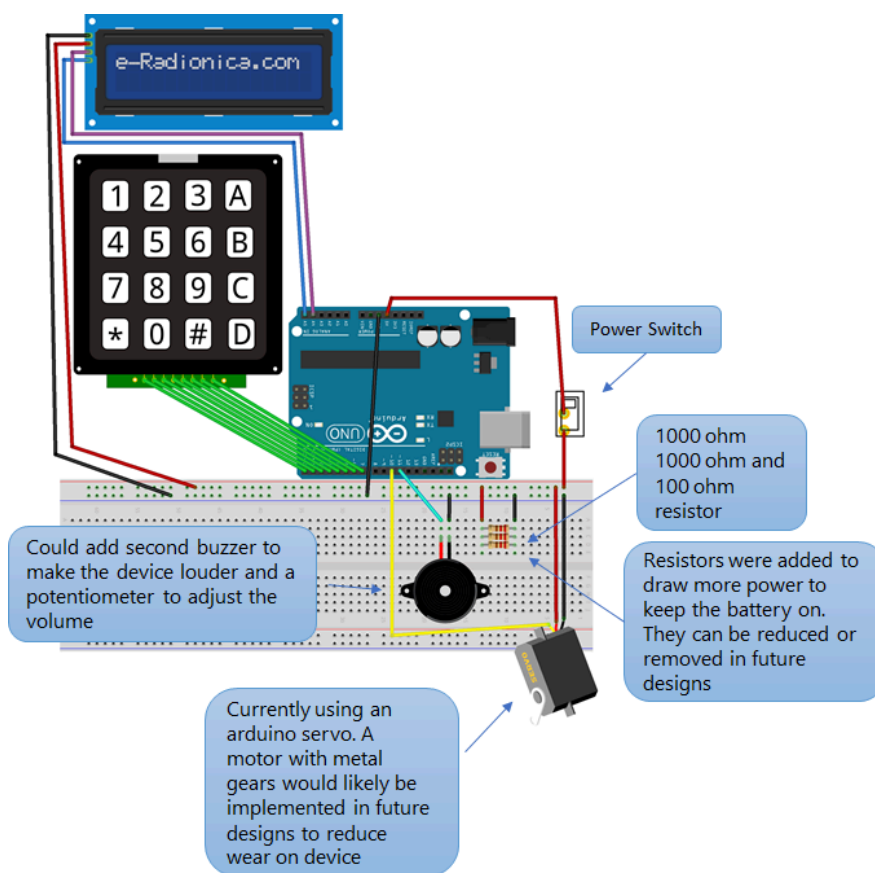


Figure E1. Wiring diagram for the current prototype.

The power switch in this configuration successfully turns the circuit off, but while off, the Arduino continues to get power, so when the switch is turned back on the system cannot be used. The switch needs to change positions such that it cuts off the power supply to the Arduino.

The buzzer is not very loud while inside the housing currently. An additional buzzer and potentiometer to adjust buzzer volume could be added.

Assembly Instructions.

Wiring

1. Follow the wiring diagram and ensure all components are attached to the specified output of the Arduino Uno (the code is set to be used with these outputs only)
2. If desired, solder all components onto a PCB board and plug the board into the Arduino

Components

The components referred to throughout this manual are shown below.



Figure E2. Parts for flow stopper mechanism (left to right and top to bottom): flow stopper wall, slider, puller, latch, springs.



Figure E3. Parts for casing. Left to right: battery casing, middle casing, case cover, L-bracket for flow stopper mechanism.



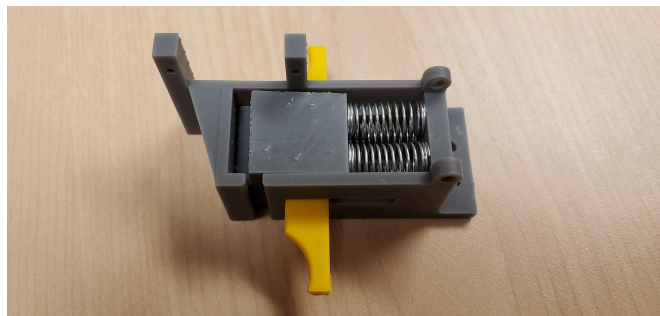
Figure E4. Additional components: left to right: keypad, battery, clamp, servo.

Flow Stopper Assembly

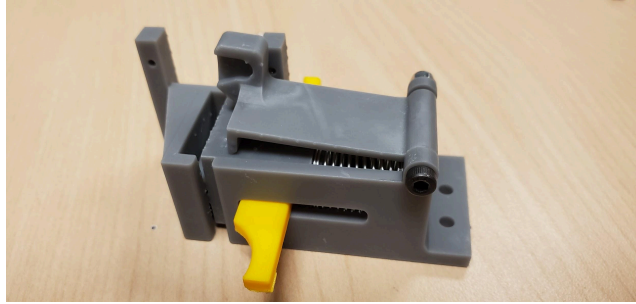
1. Insert the slider into the flow stopper such that the four circles on each piece touch each other
2. Insert the puller through the flow stopper and slider such that the curved edges of the puller face in the opposite direction of the four circles



3. Push the circles as far apart as possible and insert the springs such that they pop onto the circles



4. Insert the M3 socket head cap screw through the holes such that the hinge is held in place and securely fasten it with the M3 lock nut

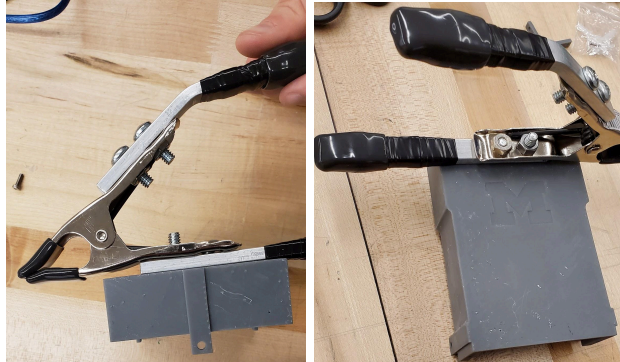


Battery Casing

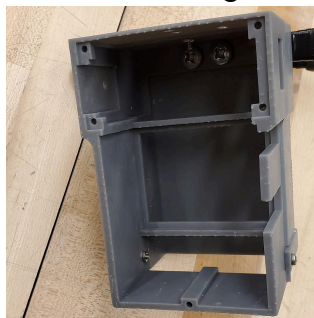
1. Drill 6.35 mm holes in two .25"x.5" metal stock pieces and the spring clamp 15 mm apart
2. Wrap the stock with electrical tape or another material to make grip easier to handle



3. On one side of the clamp, use the 1/4-20 screws to attach the battery casing to the clamp and stock



4. Align the two cases such that they are flush with each other and slide the middle casing on top of the battery casing such that the holes are lined up
5. Use the 4-40 screws to fasten the two cases together

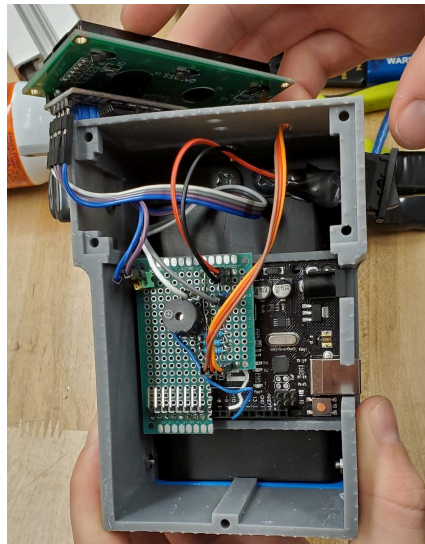


6. Slide the battery into the space between the battery and middle casings such that the usb ports are facing outward
7. Use the 4-40 screws to fasten the battery cover to the battery casing such that the edge of the cover is flush with the casing

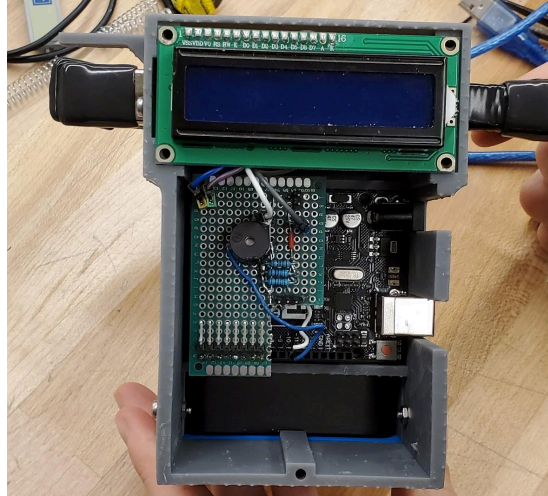


Middle Casing Assembly

1. Insert the Arduino and electronics into the middle casing such that the power inputs fit in the openings and the arduino fits snugly in place
2. Run the servo wires through the hole in the top of the middle casing and plug into the rest of the circuit as specified in the wiring diagram



3. Fasten the L-bracket to the middle casing using the 4-40 screws
4. Fasten the flow stopper assembly to the L-bracket and middle casing
5. Place the LCD screen so that it fits snugly in the indent at the top of the casing and such that the soldered pins are on the top left side



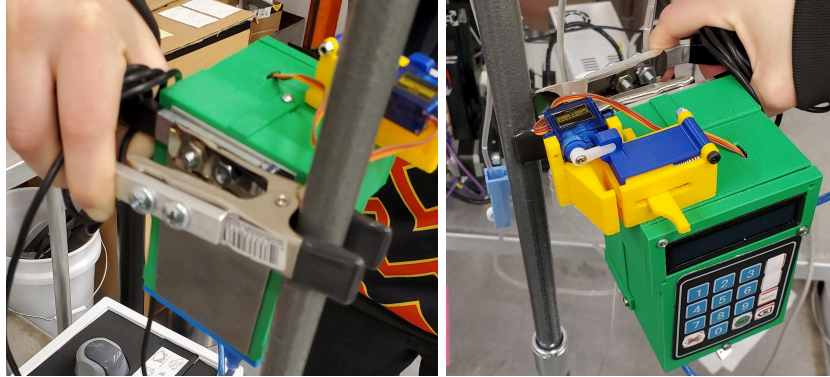
Case Cover to Rest of Casing

6. Slide the keypad wires through the case cover such that the keypad is facing outward and sits on top of the casing
7. Remove the sticker backing on the keypad and stick it to the case cover
8. Plug the keypad wires into the circuit as shown in the circuit diagram and place the case cover over the rest of the case
9. Use the 4-40 screws to fasten the case cover in place

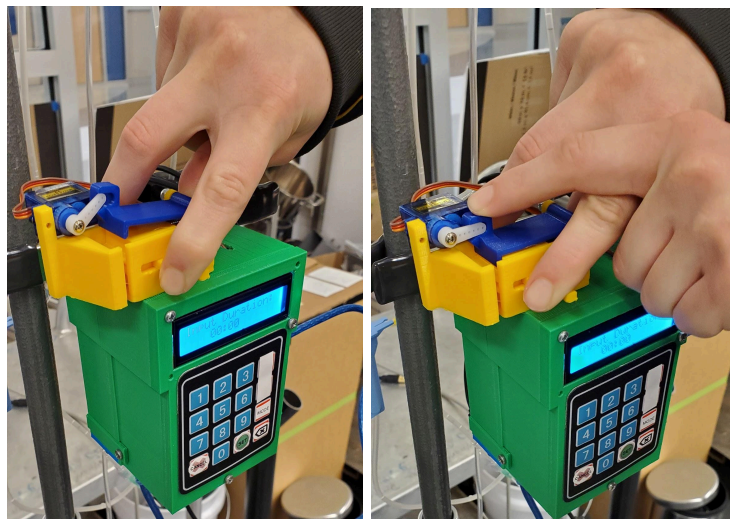
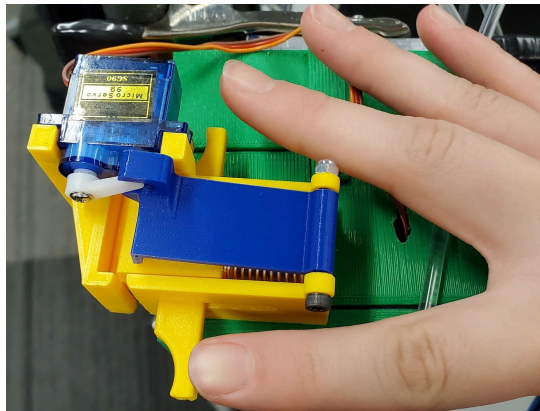


Instructions for Use. This device is only to be used to help monitor progress of IV infusions and notify healthcare providers when infusions are finished. It does not control or monitor flow rate.

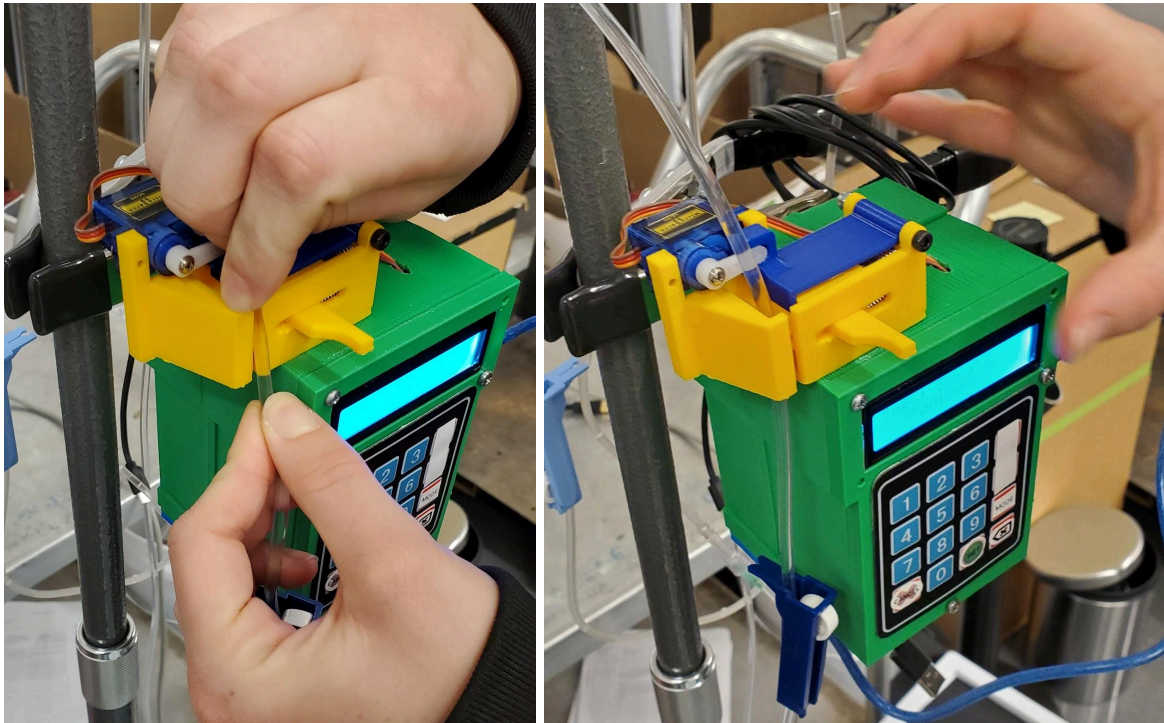
1. Clamp the device to the IV pole and plug the device into the wall. The device should be plugged in whenever possible. The battery is intended to act as a backup power supply.



2. Ensure the slider is pulled back such that the tube can fit in the opening behind the slot. Do this by using your index and middle finger to pull back on the curved bar and using your other hand to push down the latch to hold it in place as shown below. When engaged, there should be enough room for the tube to fit in the larger gap.



3. Insert the tube into the slot by squeezing it and sliding it in as shown below. You may need to force the tube into place.



4. Set flow rate on roller clamp or other flow control device.



5. You can set the timer by EITHER typing in the time for the infusion OR by typing in the flow rate and volume needed:
 - a. If you choose to set the timer by typing in the time:

- i. Enter the number of hours needed for the infusion by typing it into the keypad and hit “SET” (Note: 5 hours should be entered as 05:00)



- b. If you choose to set the timer by the flow rate and volume:
 - i. Hit the “MODE” button
 - ii. Enter the flow rate that was set in step 3 and hit the “SET” button
 - iii. Enter the volume needed and hit the “SET” button



6. If the device has been set properly, it should say “Administering...” and begin the countdown in the format “hours:minutes:seconds”



7. Done! Allow the infusion to go and check back as needed. The device will stop the flow rate and alarm you when the time is up.

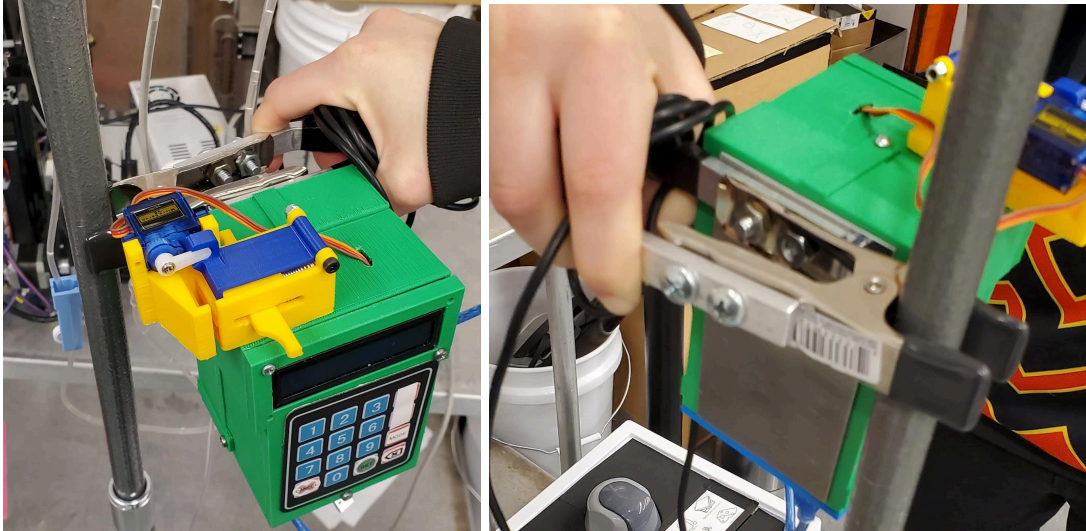


Appendix F: Instructions Used for Usability Testing

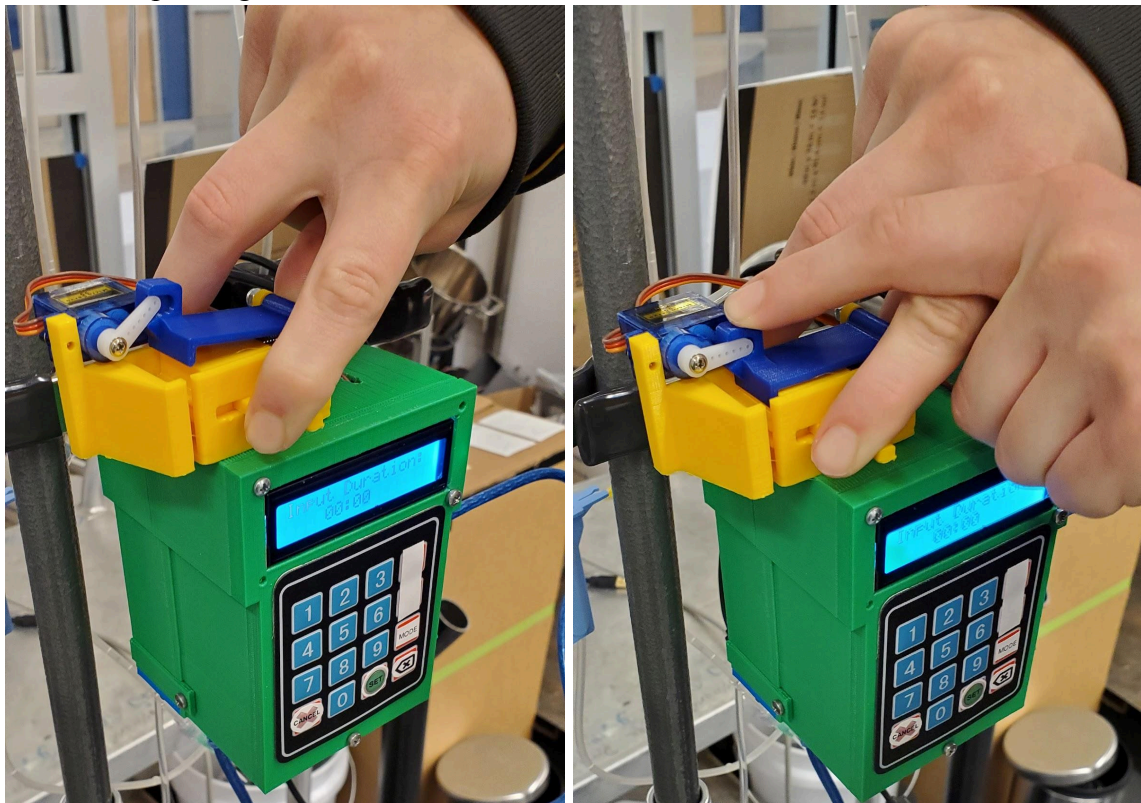
First Round of Usability Testing.

To set up device:

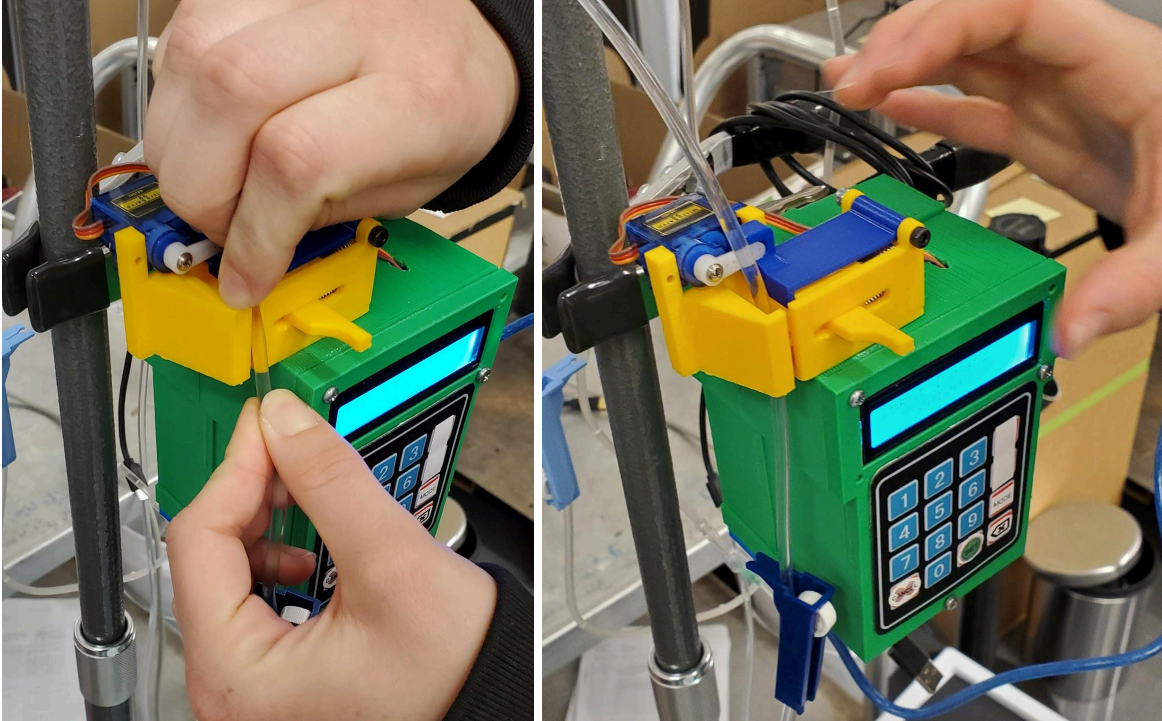
1. Clamp to pole and plug device into wall. The device should be plugged in whenever possible. The battery is intended to act as a backup power supply.



2. Ensure the springs are compressed and the latch is engaged by pulling back on the curved bar and pushing the latch down as shown below.



3. Insert the tube into the slot by squeezing it and sliding it in as shown below.



4. Set flow rate on roller clamp or other flow control device.



5. Set timer by either typing in the time for the infusion or by typing in the flow rate and volume needed:
- Type in the time:
 - Enter the number of hours needed for the infusion by typing it into the keypad and hit “SET” (Note: 5 hours should be entered as 05:00)



- b. Type in the flow rate and volume:
 - i. Hit the “MODE” button
 - ii. Enter the flow rate that was set in step 3 and hit the “SET” button
 - iii. Enter the volume needed and hit the “SET” button



6. If the device has been set properly, it should say “Administering...” and begin the countdown in the format “hours:minutes:seconds”



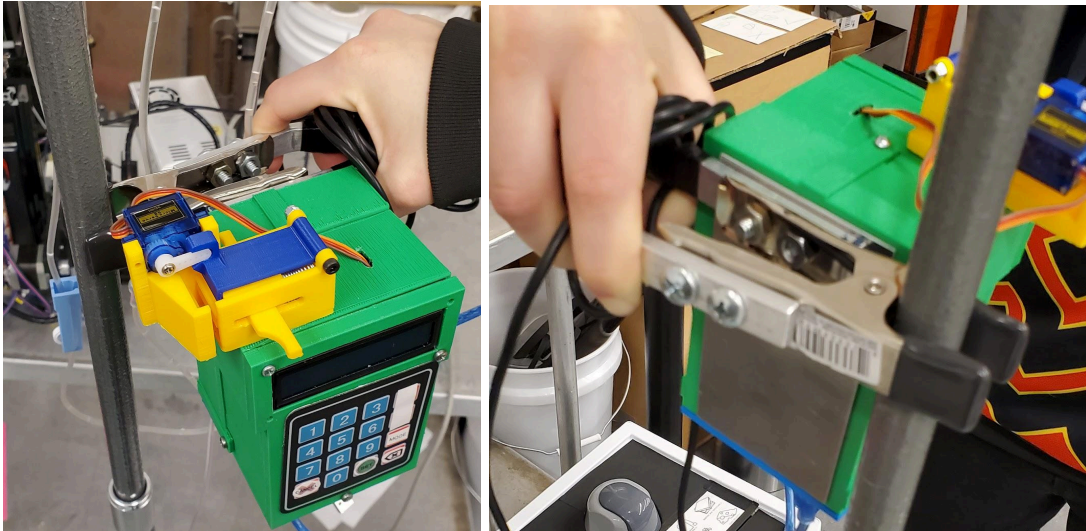
7. Allow the infusion to go and check back as needed. The device will stop the flow rate and alarm you when the time is up.



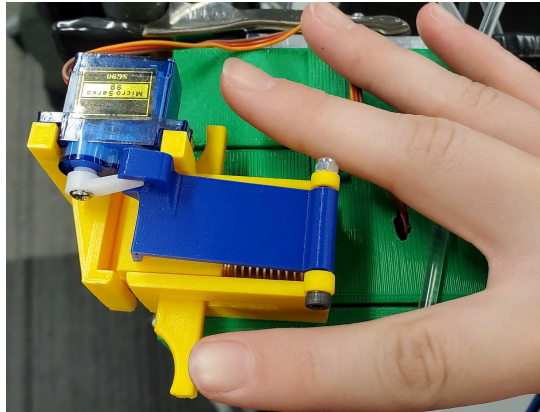
Second Round of Usability Testing.

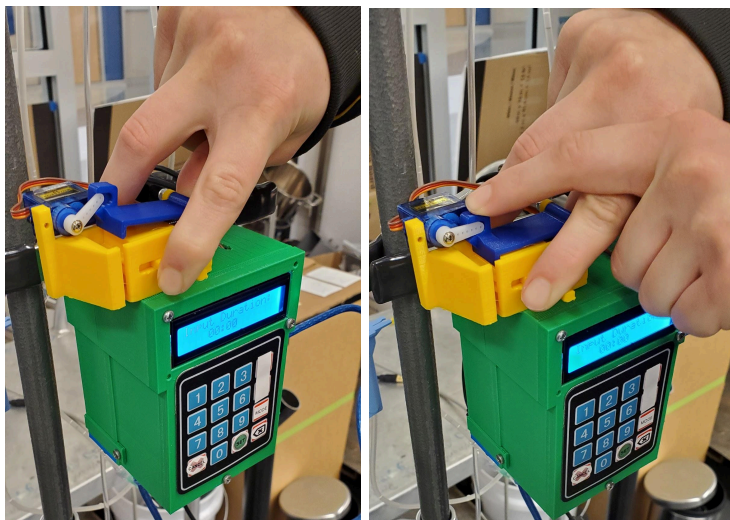
To set up device:

8. Clamp to pole and plug device into wall. The device should be plugged in whenever possible. The battery is intended to act as a backup power supply.

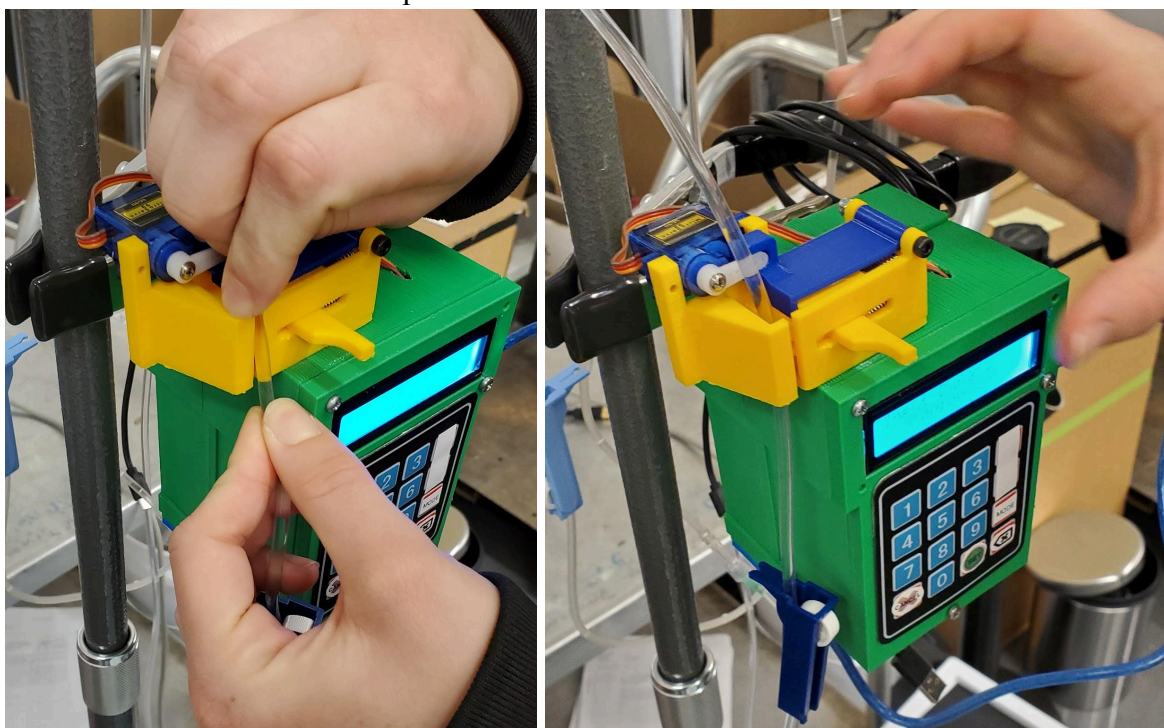


9. Ensure the springs are compressed and the latch is engaged by pulling back on the curved bar and pushing the latch down as shown below. When engaged, there should be enough room for the tube to fit snugly in the larger gap.





10. Insert the tube into the slot by squeezing it and sliding it in as shown below. You may need to force the tube into place.



11. Set flow rate on roller clamp or other flow control device.



12. You can set the timer by EITHER typing in the time for the infusion OR by typing in the flow rate and volume needed:

- a. If you choose to set the timer by typing in the time:
 - i. Enter the number of hours needed for the infusion by typing it into the keypad and hit “SET” (Note: 5 hours should be entered as 05:00)



- b. If you choose to set the timer by the flow rate and volume:
 - i. Hit the “MODE” button
 - ii. Enter the flow rate that was set in step 3 and hit the “SET” button
 - iii. Enter the volume needed and hit the “SET” button



13. If the device has been set properly, it should say “Administering...” and begin the countdown in the format “hours:minutes:seconds”



14. Done! Allow the infusion to go and check back as needed. The device will stop the flow rate and alarm you when the time is up.



Appendix G: Arduino Code

```
#include <Servo.h>
#include <Keypad.h>
#include <Wire.h>                                //ADDED
#include <LiquidCrystal_I2C.h>                    //ADDED

const int BUZZER_PIN = 11;

enum State {Input, InputFlowRate, InputVolume, Waiting, Done};
State state = Input;
State nextState = Input;

// Stores the inputted time digits
int TimeInput[4];
int FlowRateInput[4];
int VolumeInput[4];
byte TimeInputCount = 0;
byte FlowRateInputCount = 0;
byte VolumeInputCount = 0;
unsigned long endTimeMillis = 0;

const byte ROWS = 4;
const byte COLS = 4;
char KEYS[ROWS][COLS] = {
  {'1', '2', '3', 'A'},
  {'4', '5', '6', 'B'},
  {'7', '8', '9', 'C'},
  {'*', '0', '#', 'D'}
};
byte rowPins[ROWS] = {0,1,2,3}; // {7, 6, 5, 4};
byte colPins[COLS] = {4,5,6,7}; // {3, 2, 1, 0};
Keypad customKeypad = Keypad(makeKeymap(KEYS), rowPins, colPins, ROWS, COLS);

Servo servo; // create servo object to control a servo
const int SERVO_PIN = 10;
const int SERVO_TARGET_POS = 35;

LiquidCrystal_I2C lcd(0x27, 2,1,0,4,5, 6, 7, 3, POSITIVE); //ADDED
//LiquidCrystal lcd(0,1,2,3,4,5); //Pins: Rs, enable(E), D4,D5,D6,D7 //ADDED
bool timerStarted = false;
bool inputFlowRate = false;
bool inputtingFlowRate = true;

void setup() {
  pinMode(BUZZER_PIN, OUTPUT);
  lcd.begin(16,2); //16 by 2 display
```

```

//Serial.begin (57600);
RefreshInputDisplay();
}

void loop()
{
  switch(state)
  {
    // Receive input from the keypad and store up to 4
    // numbers. Once the '#' key is pressed, we calculate
    // the proper end time and set the state to Waiting
    case Input:
    case InputFlowRate:
    case InputVolume:
      InputUpdate();
      break;

    // Waiting for the end time to be reached. Once we do,
    // we trigger the servo and set the state to Done.
    case Waiting:
      WaitingUpdate();
      break;

    // Notify the person that transfusion is complete, then
    // begin taking input for a new run on '#' pressed.
    case Done:
      DoneUpdate();
      break;
  }
  state = nextState;
}

////////////////////
////////// STARTING //////////
////////////////////

void InputUpdate()
{
  char key = customKeypad.waitForKey();
  int converted_val;
  switch (key)
  {

    // Inputting a number to the saved numbers
    case '0': case '1': case '2': case '3': case '4':
    case '5': case '6': case '7': case '8': case '9':
      converted_val = key - '0';

```

```

if(state == Input)
{
    TimeInput[TimeInputCount] = converted_val;
    TimeInputCount++;
    RefreshInputDisplay();
    PlayBeepSound();
    if(TimeInputCount == 4) StartTransfusion();
}
else if (state == InputFlowRate)
{
    FlowRateInput[FlowRateInputCount] = converted_val;
    FlowRateInputCount++;
    RefreshFlowRateInputDisplay();
    PlayBeepSound();
    if(FlowRateInputCount == 4)
    {
        nextState = InputVolume;
        VolumeInputCount = 0;
        RefreshVolumeInputDisplay();
    }
}
else
{
    VolumeInput[VolumeInputCount] = converted_val;
    VolumeInputCount++;
    RefreshVolumeInputDisplay();
    PlayBeepSound();
    if(VolumeInputCount == 4) StartConvertedTransfusion();
}
break;

```

// Start early

case '#':

```

if(state == Input)
{
    PlayStartSound();
    StartTransfusion();
}
else if(state == InputFlowRate)
{
    PlayStartSound();
    nextState = InputVolume;
    VolumeInputCount = 0;
    RefreshVolumeInputDisplay();
}
else if(state == InputVolume)
{

```

```

    PlayStartSound();
    StartConvertedTransfusion();
}
break;

// Delete all chars
case '*':
    PlayDeleteSound();
    delay(100);
    PlayDeleteSound();
    TimeInputCount = 0;
    RefreshInputDisplay();
    break;

// Delete one char
case 'D':
    PlayDeleteSound();
    if(TimeInputCount != 0) TimeInputCount -= 1;
    RefreshInputDisplay();
    break;

// Change modes
case 'C':
    PlayBeepSound();
    if(state == Input) {
        nextState = InputFlowRate;
        FlowRateInputCount = 0;
        RefreshFlowRateInputDisplay();
    }
    else if(state == InputFlowRate || state == InputVolume)
    {
        nextState = Input;
        TimeInputCount = 0;
        RefreshInputDisplay();
    }
    break;

// Ignore bad input
case NO_KEY: default: break;
}
}

int arr_to_int(int* arr, int sz){
    int i, result = 0;
    for(i=0; i < sz; ++i){
        result = 10*result + arr[i];
    }
    return result;
}

```

```

}

void RefreshFlowRateInputDisplay()
{
    lcd.clear();
    lcd.setCursor(0,0);
    lcd.print("Input Flow Rate"); lcd.setCursor(0,1); lcd.print("(mL/hr):");

    // Prepare the chars from the input, loaded right to left
    int digits[4] = {0,0,0,0};
    for(int i = 0; i < FlowRateInputCount; i++)
        digits[4-FlowRateInputCount+i] = FlowRateInput[i];

    // Print the chars
    lcd.setCursor(9,1);
    lcd.print(char(digits[0] + '0'));
    lcd.print(char(digits[1] + '0'));
    lcd.print(char(digits[2] + '0'));
    lcd.print(char(digits[3] + '0'));
    lcd.setCursor(12,1);
    lcd.blink();
}

void RefreshVolumeInputDisplay()
{
    lcd.clear();
    lcd.setCursor(0,0);
    lcd.print("Input Volume(mL)");

    // Prepare the chars from the input, loaded right to left
    int digits[4] = {0,0,0,0};
    for(int i = 0; i < VolumeInputCount; i++){
        digits[4-VolumeInputCount+i] = VolumeInput[i];
    }

    // Print the chars
    lcd.setCursor(5,1);
    lcd.print(char(digits[0] + '0'));
    lcd.print(char(digits[1] + '0'));
    lcd.print(char(digits[2] + '0'));
    lcd.print(char(digits[3] + '0'));
    lcd.setCursor(8,1);
    lcd.blink();
}

void RefreshInputDisplay()
{
    lcd.clear();

```



```

lcd.setCursor(0,0);

lcd.print("Input Duration:");

// Prepare the chars from the input, loaded right to left
int digits[4] = {0,0,0,0};
for(int i = 0; i < TimeInputCount; i++)
    digits[4-TimeInputCount+i] = TimeInput[i];

// Print the chars
lcd.setCursor(4,1);
lcd.print(char(digits[0] + '0'));
lcd.print(char(digits[1] + '0'));
lcd.print(':');
lcd.print(char(digits[2] + '0'));
lcd.print(char(digits[3] + '0'));
lcd.setCursor(8,1);
lcd.blink();
}

void StartConvertedTransfusion()
{
    int volume = arr_to_int(VolumeInput, VolumeInputCount);
    int flowRate = arr_to_int(FlowRateInput, FlowRateInputCount);
    float hours = volume / (float)flowRate;
    StartTransfusion_impl((long)(hours * 60 * 60 * 1000));
}

void StartTransfusion()
{
    // Prepare the chars from the input, loaded right to left
    int digits[4] = {0,0,0,0};
    for(int i = 0; i < TimeInputCount; i++)
        digits[4-TimeInputCount+i] = TimeInput[i];

    long hours = digits[0] * 10 + digits[1];
    long minutes = digits[2] * 10 + digits[3];
    StartTransfusion_impl(hours * 60 * 60 * 1000 + minutes * 60 * 1000);
}

void StartTransfusion_impl(long duration)
{
    lcd.clear();
    lcd.setCursor(0,0);
    lcd.print("Administering...");
    lcd.noBlink();

    endTimeMillis = millis() + duration;
}

```

```

    nextState = Waiting;
}

//////////
////////// WAITING //////////
//////////

void WaitingUpdate()
{
    if(endTimeMillis < millis() || customKeypad.getKey() == '*')
        StopTransfusion();
    else
        RefreshCountdownDisplay();
}

void RefreshCountdownDisplay()
{
    long millisRemaining = (endTimeMillis - millis());
    long minutesRemaining = (millisRemaining / 60 / 1000); //+ 1;
    lcd.setCursor(4,1);
    lcd.print(minutesRemaining / 60);
    lcd.print(':');
    lcd.print((minutesRemaining % 60) / 10);
    lcd.print((minutesRemaining % 60) % 10);
    lcd.print(':');
    long secondsRemaining = millisRemaining / 1000;
    lcd.print((secondsRemaining % 60) / 10);
    lcd.print((secondsRemaining % 60) % 10);
}

void StopTransfusion()
{
    servo.attach(SERVO_PIN);
    servo.write(SERVO_TARGET_POS);
    delay(1000);
    servo.detach();
    PlayTone(660, 1000);
    nextState = Done;

    lcd.clear();
    lcd.setCursor(0,0);
    lcd.print("Completed.");
    lcd.setCursor(0,1);
    lcd.print("'SET' to restart");
}

//////////

```

```
////////// DONE //////////  
//////////
```

```
void DoneUpdate()  
{  
  if(customKeypad.getKey() == '#')  
  {  
    TimeInputCount = 0;  
    nextState = Input;  
    RefreshInputDisplay();  
  }  
}
```

```
//////////  
////////// UTIL //////////  
//////////
```

```
void PlayTone(int hz, int duration)  
{  
  tone(BUZZER_PIN, hz);  
  delay(duration);  
  noTone(BUZZER_PIN);  
}
```

```
void PlayBeepSound() { PlayTone(1000, 100); }  
void PlayDeleteSound() { PlayTone(600, 100); }  
void PlayStartSound() { PlayTone(1200, 100); }
```

Appendix H: Additional Engineering Analysis

The following calculations were also done during engineering analysis, but omitted because it ended up being irrelevant.

Calculations for Spring Constant. The team chose to analytically evaluate the spring constant needed for a spring or elastic band to maintain hydrostatic pressure. Assuming hydrostatic pressure is the primary contributor to the change in flow rate over infusion time and the flow rate is directly proportional to the height of fluid in the bag, this test was necessary to determine what kind of spring or what kind of elastomer to use. The team also assumed:

- Linear elastic
- Density of saline solution: 1020 kg/m^3
- 500 mL bag
- Empty bag weight = 30 grams
- Length of 500 mL bag = 0.14 m
- Weight of hanging tubing remains the same

For a spring at equilibrium: $kx = mg$, where k is the spring constant, x is total spring displacement, m is the total mass of the bag, and g is the acceleration of gravity.

Thus: $k = m_i g / x_i = m_f g / x_f$, where the subscripts i and f refer to the initial and final states.

And: $x_f = x_i - h_b$, where h_b is the length of a 500 mL bag

$$\text{Therefore: } m_i g / x_i = m_f g / (x_i - h_b)$$

$$x_i = m_i h_b / (m_i - m_f)$$

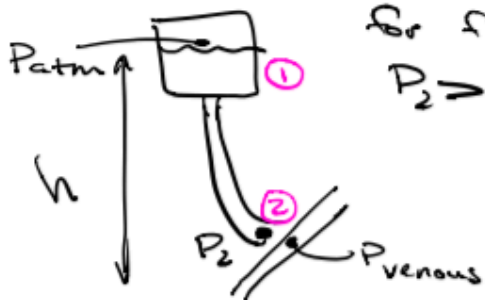
$$k = (m_i - m_f) g / h_b = 20 \text{ N/m which informs the types of materials/springs that could work.}$$

This analysis was limited by the assumptions made, specifically that the change in flow rate is constant with respect to the height of fluid in the bag. This assumption was determined to be incorrect.

Calculations for Fluid Flow Rate. The calculations in the image below were performed to model flow rate over the length of an infusion. However, the assumptions made for Bernoulli's equation were found to be not valid, so under the advice of a fluid mechanics professor, empirical testing was done to model the system.

Flow Rate through open tube

w/ fluid @ top of bag (bag full)



For fluid to flow
 $P_2 > P_{\text{venous}}$

$h = 1 \text{ m}$ (when full)

$P_{\text{venous}} = 1.47 \text{ kPa}$
 (normal, queue)

Bernoulli's:

$$P_{\text{atm}} + \frac{1}{2} \rho v_1^2 + \rho g h = P_2 + \frac{1}{2} \rho v_2^2$$

$$\Delta P = P_2 - P_{\text{atm}}$$

$$Q = VA$$

$$A_{\text{tube}} \approx 0.000012795 \text{ m}^2$$

($R_{\text{tube}} \approx 2 \text{ mm}$)

$$A_{\text{bag}} \approx 0.00281 \text{ m}^2$$

($R_{\text{bag}} \approx 0.0299 \text{ m}$
 $H_{\text{bag}} \approx 7 \text{ in}$)

$$\frac{1}{2} \rho \frac{Q^2}{A_1^2} + \rho g h = \Delta P + \frac{1}{2} \rho \frac{Q^2}{A_2^2}$$

$$\frac{1}{2} \rho Q^2 \left(\frac{1}{A_1^2} - \frac{1}{A_2^2} \right) = \Delta P - \rho g h$$

$$Q = \sqrt{\frac{2(\Delta P - \rho g h)}{\rho \left(\frac{1}{A_1^2} - \frac{1}{A_2^2} \right)}}$$

$$\Delta P = \rho g h + \frac{1}{2} \rho Q^2 \left(\frac{1}{A_1^2} - \frac{1}{A_2^2} \right)$$

if $P_2 = P_{\text{venous}} \rightarrow$ no flow

$\rightarrow$ assume flow rate and calculate ΔP



Figure H1. Images of the team performing the first round of empirical testing.

Appendix I: Risk Acceptability Matrix for Medical Devices

The team utilized the risk acceptability matrix for medical devices shown in Table I1. RBA stands for risk-based authentication.

Frequent (1 in 100)		Requires RBA	Requires RBA	Requires RBA	Requires RBA
Probable (1 in 1,000)		Requires RBA	Requires RBA	Requires RBA	Requires RBA
Occasional (1 in 10,000)			Requires RBA	Requires RBA	Requires RBA
Remote (1 in 100,000)				Requires RBA	Requires RBA
Improbable (1 in 1,000,000)					Requires RBA
	Negligible (No or negligible risk to patient)	Minor (Slight customer inconvenience, little to no effect on product performance, non-vital fault)	Serious (Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation))	Major (Severe, long-term injury, potential disability)	Critical (Loss of limb, life-threatening injury)

Author Bios

Alex. Alex is from Cleveland, Ohio and enjoys playing soccer, volleyball, and skiing. He is dual majoring in biomedical engineering and electrical engineering, because he would like to give back to the medical community that helped his family. After graduation, he hopes to work in the neural engineering field.

**Nai`a.** Nai`a is from the Big Island of Hawai`i and enjoys jumping out of planes and SCUBA diving. She chose mechanical engineering because she's interested in healthcare but wanted to leave her options open in terms of careers and grad school. After graduation, she hopes to contribute to the medical device industry so she can help someone like she was helped when she was able to learn how to walk again.

RJ. RJ hails from Traverse City, MI but he has visited over 30 states and 15 countries in an attempt to get out of Michigan as much as possible. He studied Mechanical Engineering because he wanted the chance to impact a lot of lives, and he hopes to work in the medical device industry after graduation.

Tyler. Tyler is from Hudson, MI. He began studying mechanical engineering for a few reasons: He gets bored easily, so the flexibility of changing projects, positions, or even industries is crucial; Elon Musk was a big inspiration; video games that focused on futuristic technology, such as Deus Ex, inspired him as well; and finally, the pay is pretty good.