Project ID:

Feeding Device for Premature Infants in Low to Middle Income Countries

A Major Qualifying Project Report submitted to the faculty of WORCESTER POLYTECHNIC INSTITUTE in partial fulfillment of the requirements for the degree of Bachelor of Science

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Authorship

This project was completed through a collaborative effort between project team members: Hannah Borges, Alexis Nichols, Shreya Puttagunta, Meghan Slaney, and Chris Son. Each group member had an equal contribution to all chapters of the paper, working together to write, edit, and discuss all sections.

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Abstract

In low to middle-income countries (LMIC) low birth weight is six times more likely to occur. This can affect the ability for infants to suck and swallow, creating the need for automated feeding devices. The goal of this project is to design an affordable automated feeding system, costing under 100 USD, as LMICs cannot afford expensive medical devices. Four design concepts were brainstormed, and the final design chosen was feeding via gravity due to its simplicity, low-power operation, and affordability. The device stops liquid flow once the selected volume is reached, monitors flow rate and volume within a 2% error of desired volume at 0.5 ± 0.1 mL/min flow rates. The device was taken to Ghana for clinician feedback, providing recommendations for present and future work.

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1. Introduction

The weight at birth of an infant can generate severe consequences in both short- and long-term time periods. There are three different weight categories; normal, too light, or too heavy (Abubakari et al., 2015). For an infant, it is harmful to be part of the too light category, which is birth weight below 2.5 kg, and the too heavy category, which is birth weight equal to or higher than 4.0 kg. The potential consequences of both these conditions include high infant mortality and childhood growth failure (Abubakari et al., 2015). Among the infants that do survive, some other consequences have been high prevalence of adult coronary heart disease and type 2 diabetes (Abubakari et al., 2015). In low to middle income countries (LMIC), the condition that is most prevalent is low birth weight (LBW). It is most commonly caused by a short gestation period (less than 37 weeks), retarded intrauterine growth, or the combination of both. Retarded intrauterine growth is described as being severely underweight for gestational age. It is often defined as birth weight that is under the 10th percentile of predicted fetal weight for the infant's gestational age and can lead to elevated neonatal morbidity and mortality (Wise, 2017). LBW has been shown to have effects on childhood development, school achievement, and adult capital, which includes achievements in height, economic productivity, and birth weight of offspring (Abubakari et al., 2015).

In LMICs, 11% of all newborns are born at term with LBW; that rate is six times higher than in developed countries (Agbeno et al., 2021). Prematurity is not only the major cause of LBW but it is also the leading cause of death before the age of 5. Figure 1 below shows the global neonatal mortality rate, estimated in 2019 (UN Inter-agency Group, 2019). In Ghana, there are 128,000 preterm births annually and out of those, 8,400 die before the age of five (Agbeno et al., 2021). Their rate of preterm births doubled from 9.3% to 18.9% over the past 15 years and their prevalence of LBW is 13% (Abubakari et al., 2015). These infants are at high risk of serious consequences, such as pneumonia and growth compromise, since they have not fully developed and are likely to experience oral, pharyngeal, and/or esophageal phase dysphagia. Dysphagia is defined as a swallowing dysfunction that occurs from a lack of coordination of timing and sensorimotor senses required for safe swallowing (Ferrara et al., 2018). This condition leads to the challenge of this project, which is that premature infants that have LBW and dysphagia are less likely to achieve a healthy weight unless they are carefully fed.

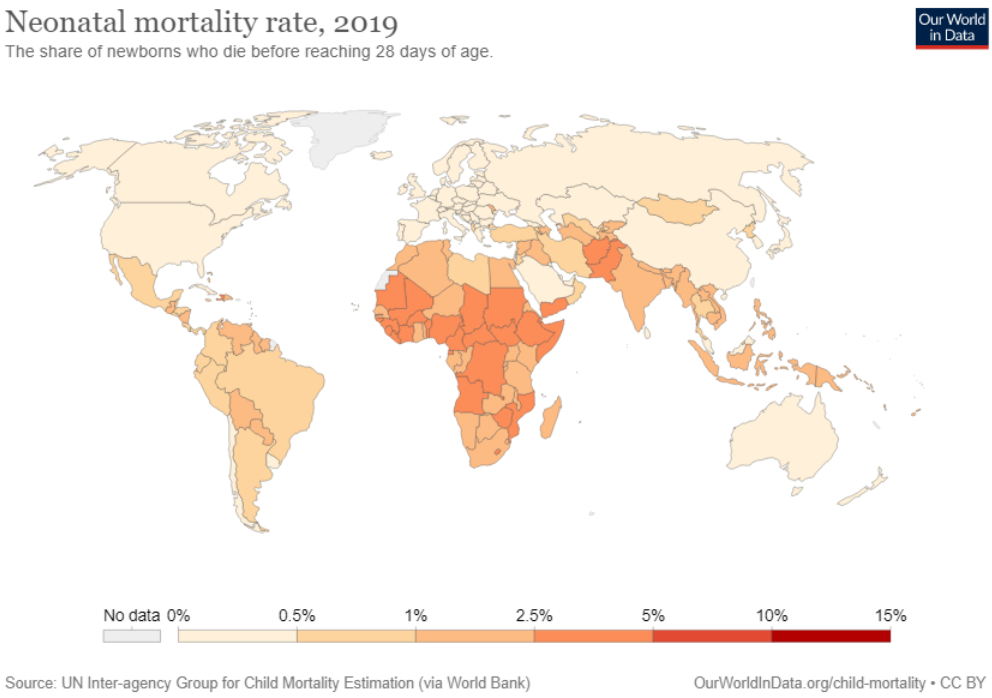


Figure 1. 2019 Neonatal Mortality Rate Across the Globe [1]

It is essential that these infants acquire optimal nutrition, but there are not any set standards to do so. Most infants that spend time in the NICU experience a growth lag due to intercurrent acute and chronic neonatal morbidities (Singh et al., 2012). For feeding, there are many different options for milk sources, but human milk is the most accepted as the best type of nutrition (Singh et al., 2012). The feeding methods vary between manual and automatic, and they each have different effects on the infants (Singh et al., 2012). For the scope of this project, the focus is on nasogastric and orogastric feeding tubes because they are the tubing most commonly used for premature infants for both manual and automatic methods. The benefit to using these types of feeding tubes is that they are non-surgical, as they go through the infant's nose or mouth, and have been associated with weight gain, as well as preventing waste of the nutritional supply (Gisel, 2008).

When interviewing Dr. Eunice from the Eastern Regional Hospital in Ghana, it was found that one clinician supervised up to 15 infants at a time. When caring for infants with dysphagia and LBW, most of their feeding protocols used are manual. However, this creates a problem

[1] *UN Inter-agency Group for Child Mortality Estimation, (via World Bank). Neonatal mortality rate, 2019. [Digital] https://ourworldindata.org/grapher/exports/neonatal-mortality-WDI.svg*

since it is not possible for each infant to be carefully fed by the clinician. This showed the need for an automated feeding device, as there are not enough clinicians to tackle the problem, causing mothers to have to assist in feeding as well. However, since the mothers do not have the proper training on feeding their premature babies, the clinicians believe a device to help assist them would be useful.

The goal of this project is to design a feeding system that is automatic, low cost (under 100 USD), able to deliver a determined amount of nutrition, reliable (can operate during power outages), and user friendly (easy to repair and maintain). This project is a continuation of the previous Major Qualifying Project done in the 2020-2021 academic year at WPI (Deshpande et al., 2021), although our team decided to take an alternative route that does not include the previous team's work. Four different designs were created and the final prototype the team selected was the feeding via gravity design. The concept of the final prototype is to deliver fluid to premature infants through gravity. The device is able to monitor flow rate and volume, deliver a specific amount of fluid, and has many features that make it easy for a user with minimal training to use.

The following chapters of the report detail the process of constructing the device and all the design and testing process behind that. Chapter 2 of this report is a literature review with many topics that are relevant for our device. It discusses the physiology, pathology related to premature infants, the applicable treatment and their clinical outcomes as well as feeding methods performed around the world and the current devices in the market. Chapter 3 details the device's specifications, objectives and requirements in addition to designs considered. Chapter 4 details the design process, how the final design was chosen and the prototyping process. Chapter 5 describes the design verification for the device and goes into detail on the tests that were done. Chapter 6 discusses the design validation of this device and goes into detail on how several aspects were considered during this project, as in economics and environmental impact. Chapter 7 is the discussion section of our report where results are described and explained. Chapter 8 describes the work to be done in the future that can improve the device and the conclusion of our project.

2. Literature Review

In order to begin designing the device the team first gained an understanding of the purpose of the project and the current methods being used to satisfy the team's goal. In this chapter the team first discusses the physiology behind premature birth in section 2.1 and in section 2.2 discusses the background behind dysphagia, a common issue caused by premature birth, then the team discusses the clinical treatment methods in section 2.3 including some current devices on the market. Finally, the current feeding methods in Ghana are discussed in section 2.4.

2.1 Physiology

Birth before 37 weeks gestational age or 259 days is classified as preterm birth (Moutquin, 2003). Table 1 displays the gestational age range and the number of weeks that classify them. Very preterm birth accounts for 10% of preterm births (Moutquin, 2003). Under 28 weeks is referred to as extremely preterm, that account for less than 5% of preterm births, which has a high mortality rate in addition to up to 50% of severe handicap conditions for the infants below 26 weeks. There has also been survival among extremely low gestational ages which is between 24 and 25 weeks (Moutquin, 2003).

Table 1. Gestational Age Range Classification Based on Number of Weeks Preterm

Gestational Age Range	Very Preterm Birth	Preterm Birth	Mild Prematurity	Moderate Prematurity
Number of Weeks	28-31	Before 37 weeks	32-33 weeks	34-36 weeks

Three clinical conditions lead to preterm births which are medically indicated preterm birth, preterm premature rupture of membranes (PPROM) and spontaneous preterm birth (Moutquin, 2003). Medically indicated preterm birth is defined as induced labor or when an infant must be delivered through a cesarean section (Stout et al., 2014). A preterm premature rupture is when the amniotic membrane around the infant before week 37 of pregnancy which can lead to an increase in risk for infection and spontaneous preterm birth is when the individual goes into labor before 37 weeks of gestation. The amniotic membrane can be intact or ruptured

(Deressa, 2018). Medically indicated birth accounts for about 25% of preterm births, the indications being commonly related to complications such as severe hypertension, abruptio placentae or any condition that endangers the fetal well-being. PPROM accounts for 25% of preterm births and occurs more often among disadvantaged populations and Afro-American women. Spontaneous birth accounts for 50% of preterm births and is frequent among women with no established risk factors (Moutquin, 2003). In addition to the three conditions, multiple pregnancies are also a common cause of preterm birth (Moutquin, 2003).

There are many complications due to preterm birth that can be sustained through the infant's life affecting their survival and further development. Some of these include respiratory distress syndrome, chronic lung disease, injury to the intestines, compromised immune system, cardiovascular disorders, hearing and vision problems as well as neurological insult (Behrman et al., 2007). These are caused by immature organ systems and the more premature the infant is, the more it requires life support (Behrman et al., 2007).

2.2 Dysphagia

Premature infants are commonly affected by dysphagia, which is the difficulty to swallow (Prasse & Kikano, 2009). Swallowing is a process that involves coordination of muscles of the lips, tongue, palate, pharynx, larynx and esophagus (Prasse & Kikano, 2009). Swallowing appears during development at around 11 weeks of gestation while sucking appears around 18 to 20 weeks (Prasse & Kikano, 2009). A near-term fetus ingests around 700 mL of amniotic fluid per day in addition to mimicking breathing movements and those actions are an important milestone for the fetus (Prasse & Kikano, 2009). A lack of neurological maturity causes dysphagia and many infants, majorly the ones born the earliest, do not develop those abilities until what is equivalent to a full-term gestation (Bingham, 2009). These premature infants, that have not yet fully developed and do not have fine motor coordination, have difficulty in coordinating all the movements to oral feed in addition to breathing (Prasse & Kikano, 2009).

Around 70% of premature infants are diagnosed with a form of dysphagia which can be oral, pharyngeal and esophageal and the severity is inversely related to gestational age (Ferrara, 2018). To identify this condition, the signs can range from more visible ones as in projectile vomiting, coughing and choking, to more subtle ones such as silent aspiration (Prasse & Kikano, 2009). In addition, the infant can show no interest in feeding, straining of muscles during

feeding, extensive time required to feed, spilling of the feeding, emesis, coughing and gagging during feeding, challenges with breathing during feeding and failure to thrive (Prasse & Kikano, 2009).

2.3 Clinical Treatment for Premature Infants

There are different treatments available on the market to assist premature infants with any complications, which can include under-developed suck/swallow capabilities. The conventional care of premature infants has a high cost and requires highly trained personnel, which are resources that are limited in LMICs. Financial resources as well as trained staff is limited in these countries, which can have overcrowded hospital wards. It is significant to explore treatments that can reduce mortality as well as cost (Conde-Agudelo & Díaz-Rossello, 2016).

2.3.1 Kangaroo Mother Care

Kangaroo Mother Care (KMC) is a simple, yet effective way to help treat premature babies (Chan et al., 2016). KMC can help with infant development, such as establishing an effective suck and swallow physiology (Zhang et al., 2020). The World Health Organization (WHO) defined KMC as early, continuous and prolonged skin-to-skin contact (SSC) between mother and preterm baby; exclusive breastfeeding or breast milk feeding; early discharge after hospital-initiated KMC with continuation ad home; and adequate support and follow-up for mothers at home (WHO, 2003). Even though the components of KMC are well defined, there are many variations associated with the timing of initiation, duration of SSC, positioning, necessary equipment and supplies, discharge criteria, follow-up frequency, indicators and measurement, and health workforce needed. All these different components and their variations can have different effects on the infants and their outcomes (Chan et al., 2016).

The main component of KMC is the skin-to-skin contact between a parent and baby (Cleveland Clinic, 2020). The parent is bare-chested and the baby only has on a diaper. The baby is situated in an upright position and then a cloth or towel can be wrapped around both the parent and baby to facilitate the process (Cleveland Clinic, 2020). Figure 3 below illustrates the proper method to conduct KMC. Each KMC session lasts at least 60 minutes and there are many benefits to it which include more successful breastfeeding, stabilizing baby's heart rate, improving baby's oxygen saturation level among many others. KMC was first developed in

Colombia in the 1970's when the death rate of premature babies reached around 70% (Cleveland Clinic, 2020). Studies found that many premature infants died from complications, such as infections and respiratory issues, because of an overall lack of attention. With KMC, the parents pay attention solely to the infant for the amount of time the session lasts for, therefore causing less complications to the baby (Cleveland Clinic, 2020).

Figure 2. Execution of the skin-to-skin component of Kangaroo Mother Care [2]

When KMC started to be implemented, it would start once the infant was considered stable, and first would be a period of conventional care in which their respiratory, thermal and feeding functions are stabilized. However, nowadays stabilization has a broader significance and there have been evaluations of the effect of KMC starting right after birth in locations with little access to neonatal intensive care equipment. Overall, this treatment has shown to create a greater bond between mother and child, to shorten periods of stay in the hospital and the associated costs as well as reduction of neonatal morbidity (Conde-Agudelo & Díaz-Rossello, 2016).

[2] *HNN Team. (2018). Kangaroo Mother Care [Photograph] https://www.healthynewbornnetwork.org/blog/kangaroo-mother-care-capacity-building-workshop-for-sub-saharan-africa/*

2.3.2 Tube Feeding

Consuming nutrients through oral feeding requires active effort by infants. The timing and coordination for sucking, swallowing, and breathing must be coordinated to allow the infant to consume nutrients from the breast or bottle. Many premature babies have trouble with oral feeding, and this is because the primary measurement for successful feeding has to do with weight gain during infancy and the first few years of life (Arvedson, 2006). With more studies, a correlation between the gestational age and an infant's level of sucking maturity was found (Arvedson, 2006). Premature babies are not usually able to gain the correct amount of weight before being born, leading to complications with oral feeding (Arvedson, 2006).

Feeding tubes can be used to help feed premature babies that are not able to get nutrition on their own (Ratnam, 2020). There are three types of feeding tubes that are commonly used; Gastronomy tubes, Nasogastric (NG) tubes, and Orogastric (OG) tubes. Gastronomy tubes, also called G-tubes or PEG tubes, are placed through the abdomen to the stomach and are usually relatively short (Ratnam, 2020). They are typically used when a baby needs to be tube-fed for a prolonged period of time. Nasogastric tubes are thin and flexible tubes that are placed through the nose and connected to the esophagus and stomach. They are the most used option as it is effective but also very easy to use. The tube also comes in different lengths and widths which makes it easy to reach different parts of the gastrointestinal tract. Orogastric tubes are identical to a nasogastric tube, but are inserted through the mouth instead of the nose (Ratnam, 2020). Figure 3 below shows the placement of both NG and OG tubes, which are most commonly used when feeding infants. There are a couple types of systems that use tubes to feed premature infants. One uses a syringe without a plunger, which uses gravity to push liquid through the tube, and another uses an automated feeding pump, which uses a powered mechanism to push the liquid through the tube and into the infant's stomach.

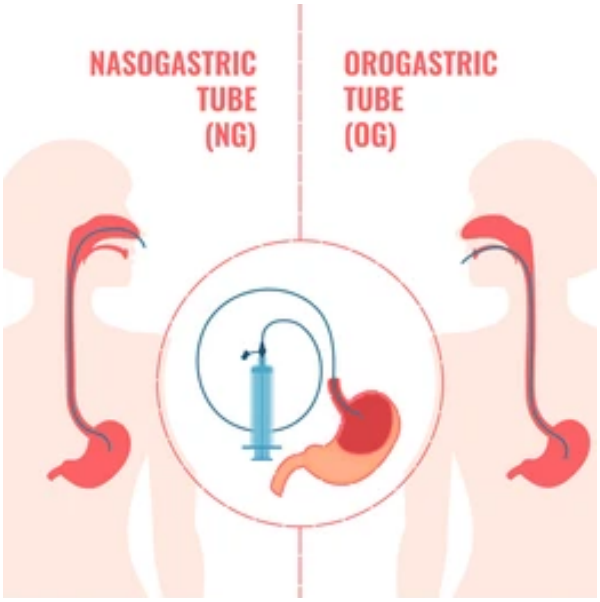


Figure 3. Nasogastric and Orogastric Tube Placements

Without tube feeding, since these infants are not able to suck or swallow, they would not get the nutrients they need to survive. However, the use of tube feeding in the long term can cause development issues on these infants. It does not help the infant to develop their suck and swallow skills, but instead, it makes them dependent on this mode of feeding. The scheduled feeding can prolong the period of the dysphagia as well as interrupt sequences of appetitive and ingestive behaviors, causing the infant to not learn and develop as expected. A way to avoid some of these issues is introducing a pacifier to stimulate nonnutritive sucking (Bingham, 2009).

In the United States, according to the American Academy of Pediatrics, an infant needs to be fully fed orally in order to be discharged (Bingham, 2009). For that reason, it is important to properly identify when the baby can switch from tube to oral feed. Clinicians use the patients' gestational age, respiratory status and tolerance of the enteral feeding tube to decide, since there is not a standardized protocol in place. Depending on the infant's response to that process, which can present feeding refusal, feeding proficiency, tachypnea, bradycardia and cyanosis, the course of the transition will be determined and the duration of the process which could be days or many weeks (Bingham, 2009).

2.3.3 Current Feeding Devices

Since dysphagia is a common condition that affects premature infants, it is often necessary to resort to feeding devices. When looking at current feeding systems, there is a difference between what is standard practice in high income countries versus LMICs. Taking a look at the US, which is considered a high income country, the gold standard devices used for feeding premature infants are automated feeding systems. On the other hand, in LMICs, cup and syringe feeding are typically used. The difference between feeding systems used in these different places has a lot to do with availability and price. Automated feeding systems are typically expensive and use parts that are not easily accessible in LMICs.

2.3.3.1 Kangaroo Joey

One of the most popular automated feeding systems on the market is the Kangaroo Joey. In the United States and many other developed countries, enteral feeding is done automatically through this pump. This equipment makes use of feeding tubes to deliver the nutrition, however the process of delivery and the rate are automatic, not requiring constant nurse supervision, only the initial user input (Cardinal Health, 2021). It is defined as a precision enteral feeding pump with feed/flush technology (Cardinal Health, 2021). As seen in Figure 4 below, it has a compact and portable design, an intuitive user interface, and stop light LED array that indicates the pump status. It also includes an audible alarm to indicate any errors or pump set loading conditions and stores 72 hours of feeding and flushing history. With all of these features though comes a downside; the cost. This feeding system costs on average between $500-$700 (Cardinal Health, 2021).

Figure 4. Kangaroo Joey Enteral Feeding Pump[3]

The volume of feed as well as the rate are customizable and can be adapted for each feed. This equipment does require a reliable power source to function continuously. At the Boston Children's Hospital, in the United States, all infants are assessed daily for potential enteral feeding. The guidelines for the initiation and advancement of this type of feeding are determined based on the weight of the infant and are shown in Table 2 below. The full feeding volume is 150mL/kg per day and the target of energy intake is 110-130 kcal/kg per day. For infants below 1000 grams the protein intake is 4.0 to 4.5 g/kg and for infants between 1000 to 1500 grams the protein intake is 3.5 to 4.0 g/kg (NICU Nutritional Committee, 2015).

[3] *Cardinal Health (2020). Kangaroo Joey Enteral Feeding Pump. [Digital]. https://www.cardinalhealth.com/en/product-solutions/medical/enteral-feeding/kangaroo-joey-enteral-feeding-pump.html*

Table 2. Boston Children's Hospital's protocol for enteral feeding (NICU Nutritional Committee, 2015)

Weight (grams)	Initial Rate (mL/kg/day)	Volume Increase up to mL/kg/day
<1000	10	15-20
1001-1250	10	20
1251-1500	20	20
1501-1800	30	30
1801-2500	40	40
>2500	50	50

The use of the Kangaroo Joey equipment allows accurate feeding and eliminates many of the problems associated with the syringe and tube feeding. However, this equipment is very expensive for LMICs. For the scope of this project, the current team will consider the issues generated with the manual feeding systems and analyze automatic systems, such as the Kangaroo Joey, to possibly implement their key aspects. It is fundamental to meet the current needs of LMICs while maintaining a low cost.

2.3.3.2 Automated Syringe Pumps

In many neonatal intensive care units, syringe pumps such as Figure 5 below, are used to deliver nutrition to infants through NG and OG tubes. Syringe pumps are used to deliver accurate volumes of fluid, less than or equal to 60 mL ± 2% error (Chau, 2016). These pumps can also deliver small amounts of fluid for long periods of time, such as 0.1 mL/hour (Chau, 2016). Infants, especially premature ones, can not handle large amounts of nutrients in small periods of time, syringe pumps serve as a helpful device in delivering nutrients to premature infants.

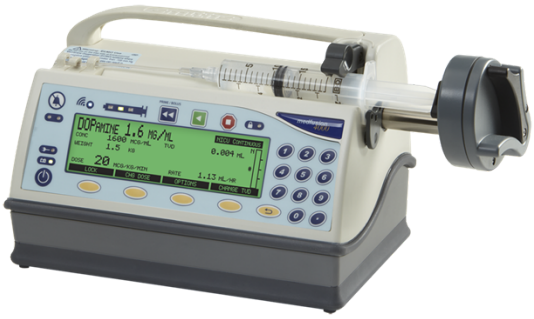


Figure 5. Automated Syringe Pump [4]

This pump works by inserting the syringe snug into the device using designated clips, which hold the syringe and plunger. The device then uses a motor to slowly push the syringe plunger, therefore pushing liquid through the other end of the syringe. Prices can vary anywhere from 500 USD to 7000 USD, which corresponds to their quality and amount of functions and specifications (Chau, 2016). Because syringes can only hold smaller amounts of liquid, these are not always ideal for infant feeding, at least for those needing larger numbers of nutrition.

2.3.4 Current Ghanian Feeding Methods

Continuing from the previous WPI Major Qualifying Project (MQP), it was learned from interviews conducted with nurses in Ghana that the standard practice for feeding used for almost fully developed infants is cup feeding. While syringe feeding is used for moderate to extreme cases (Deshpande et al., 2021). In the more moderate cases, an OG tube is used in combination with a syringe pump and the feeding is done intermittently, while in the more extreme cases, an nasogastric NG tube is used together with a perfusor and the feeding is done continuously. More detailed notes about the interviews and methods of feeding are found in Appendix A.

Both of these types of feeding, syringe and cup, the nurse is required to accompany the infant for the entire feeding period. According to Walker and Kenner, the nurse to baby ratio in high income countries is 1:2 in intensive care and 1:4 in special care while the nurse to baby ratio in LMICs is much higher (Walker & Kenner, 2019). In the Ridge Hospital in Ghana, it is usually a 1:6 nurse to infant ratio, while in more rural areas of Ghana, that ratio can go up to 1:15 (Deshpande et al., 2021). In many cases, a nurse in a LMIC takes care of a large proximity of

[4] *Smiths Medical (2022). Medfusion 4000 [Digital]. https://www.smiths-medical.com/en-us/products/infusion/syringe-infusion/syringe-infusion-pumps/medfusion-4000-wireless-syringe-infusion-pump*

babies in one room, approximately 45 babies, without assistance or breaks. This drastically affects the quality of care these nurses can provide, because of the need to treat a large quantity of infants at once (Walker & Kenner, 2019).

2.3.4.1 Manual Syringe

From the data collected from interviews conducted at the Ridge Hospital in Ghana by the team before us, we learned that manual feeding is commonly used to feed premature infants with developmental delays. When interviewing Dr. Eunice, a clinician at the Eastern Ridge Hospital in Ghana, this year, we found that the feeding methods in the hospital have not changed. For one type of feeding done, an NG tube is used and on the other end there is a syringe filled with formula or breast milk. This syringe has to be held up by the clinician during the whole process, so that the liquid can travel to the infant via gravity. It is a stressful and time consuming process for the nurse.

At this hospital, they also have a semi-automated process, which uses a perfusor, shown in Figure 6 below. However, there is a limited amount of these available in the hospital and it is not an equipment made for feeding. For this type of feeding, the practices are different based on the state of the infant. For the infants that are in a more critical state, affected by conditions such as birth aspiration, for example, an NG tube is used in combination with the perfusor to feed continuously. If the case is not as critical, but is not capable of sucking or swallowing, the OG tube is used with a syringe pump and feeding is done intermittently. Once the preterm's condition improves, and this infant has some sucking capabilities, the feeding is then done with the use of a calibrated cup. Refer to Appendix A for more details about interviews conducted by last year's team.

Figure 6. Perfuser used at the Korle-Blu Teaching Hospital in Accra, Ghana[5]

2.3.4.2 Cup Feeding

Cup feeding uses a small cup, such as a medicine cup, that is filled with the nutrients that are fed to the baby (Oasis Lactation Services, 2013), shown below in Figure 7.

Figure 7. Process of Cup Feeding an Infant[6]

The cup feeding has multiple issues associated with it. According to the nurses at the Ridge Hospital, some of the problems are that the baby can be aggressive in swallowing resulting in a baby aspirating or spilling the breast milk. The likelihood that a baby may vomit the nutrients increases with cup feeding and cup feeding requires a skilled nurse to perform this type of feeding (Deshpande et al., 2021). Another issue with cup feeding is that currently there is no standard size of cup. Also, metal or hard plastic cups can cut the skin of the infant which can create a risk of infection. The cups usually used have wide rims which require more skill to

[5] *Nathaniel Adibuer and Audrey Tetteh (2020).*
[6] *Heather Marcoux (2018). Motherly.*
https://www.mother.ly/parenting/baby-feeding-schedule/baby-feeding-tips/cup-feeding/

manipulate, making it difficult for a new mother. Improper technique can cause a cycle of poor feeding. A rapid or inconsistent rate of feeding can cause spillage, as much as 30% of the milk per feed, stress for the infant, stress for the mother, as well as possible infant coughing or aspiration. With this type of feeding, the infant's condition can escalate to chronic insufficient caloric intake which puts the infant at risk for undernutrition, failure to grow, infection, and death (McKinney et al., 2019).

3. Project Strategy

In this section, the initial and final reviewed client statements are defined. In addition, there is an overview of the design specifications, objectives, and requirements. Lastly, towards the end of this chapter, the team's project approach is discussed.

3.1 Initial Client Statement

The initial client statement for this project is: Design a low-cost feeding system for low-to-middle income countries that will deliver neonatal infant feeding formula and medication to premature babies at a prescribed rate. This device should be minimalistic, constructed with widely accessible materials and be easy to assemble and disassemble.

3.2 Design Requirements (Technical)

The design requirements for the project were divided into separate lists. The lists included are split into performance and functional specifications. These were created in order to guide the team in the direction of the necessary functionalities of the devices. The objectives listed below made it possible to then create strategies on how to approach a solution and achieve these objectives. This list was created by reviewing the current products in the market and their functionality, as well as reviewing the device created by the previous MQP group. These specifications are as follows:

1. **Performance specifications**
    a. Cost under 100 US dollars
    b. Administer the correct amount of nutrition (with 5% error)
    c. Be able to measure the flow rate (with 5% error)
    d. Be able to last for at least 2 days on battery power
    e. Light weight (less than 1kg)
    f. Ability to measure drip rate (with 5% error)
    g. Maintain temperature of the liquid (room temperature)

2. **Functional specifications**
    a. Accessibility to produce in Ghana
        i. Inexpensive hardware available (eg. Arduino Nano)
        ii. Manufacturability available
    b. User-friendly
        i. Color coded buttons
        ii. Interactive display screen
        iii. Color coded LED alert system
    c. Portability
        i. Battery powered so does not need to be close to an outlet
        ii. Compact and lightweight
    d. Screen that allows clinician to view information
        i. Flow rate
        ii. Battery life
        iii. Volume that has been administered
    e. LED Indicator for clinicians
        i. Green LED indicates feeding is complete
        ii. Red LED indicates feeding tube is clogged or flow rate is too fast
        iii. Blue LED indicates device is in use and working properly

By going into detail about the specifications, it was possible to develop a clear method of how to accomplish them, shown in Table 3. The team was able to create specific tables by analyzing and organizing each specification separately.

Table 3. The overall specifications of the project and the methods to accomplish them.

Specification	Method of Accomplishment
Low-cost under 100 dollars	Materials should be accessible in Ghana to guarantee easy access and ability to manufacture and repair
Administer correct amount of nutrition	Integrate drip sensor that calculates amount of feed that has been delivered
Monitor flow rate	Integrate Arduino board and C++ coding to translate drips into flow rate
Reliable power source	Guarantee that the battery provided has the sufficient voltage to power the device for 2 days
Lightweight/Portable	Use minimal amount of parts with lighter components
User-friendly	Create a manual of instructions and minimalistic input from the user
Allow clinician input	Use LCD screen in combination with buttons to allow personalized feeding
Alarms system	Integrate LED lights with Arduino code

3.3 Design Requirements (Standards)

When looking through design standards, ISO 20695:2020 Enteral Feeding Systems was found to be the most important standard to use when creating the final version of the device. This standard focuses on feeding devices that facilitate the delivery of enteral feeding through the mouth or nose. ISO 18250-3:2018 Medical devices - Connectors for reservoir delivery systems for healthcare applications, is another important standard to use as it has to do with making sure the connections between the IV bag and feeding system are up to standard. Moving onto sterilization, ISO 11135:2014 Sterilization of healthcare products - Ethylene Oxide and ISO 17665-1:2006 Sterilization of health care products - Moist Heat are important standards to use as they let us know how to correctly sterilize our device.

Table 4. ISO Standards and Description

ISO Standards	Description
ISO 20695:2020	Enteral Feeding Systems
ISO 18250-3:2018	Medical devices- Connectors for reservoir delivery systems for healthcare applications
ISO 11135:2014	Sterilization of healthcare products - Ethylene Oxide
ISO 17665-1:2006	Sterilization of health care products - Moist Heat

3.4 Revised Client Statement

The goal of this project is to design a low-cost feeding device for low-to-middle income countries that will efficiently and accurately deliver neonatal infant feeding formula and prescribed medication to premature babies at a set volume and time inputted by the clients. The goal is to reach a cost less than $100 USD. The device will be constructed with a minimalist appearance, but the functionality would perform similarly to Kangaroo feeding pump products. This device should be adaptable to any standard issued IV bag, applicable with widely accessible materials, and be user-friendly to operate and assemble. Lastly, the device should be able to withstand a battery life longer than a period of 2 days.

3.5 Project Approach

In order to complete the project, the team followed crucial steps to complete the design process. First, it was necessary to identify the need and have a deep understanding of the background behind it. Once the unmet need was understood, the current practices in Ghana as well as the current devices on the market were researched to gather information about their mechanisms and prices so the team could expand on them. Having knowledge of those, it was possible to create performance and functional specifications and initiate the concept brainstorming process, which included four different device ideas. With those concepts in mind and what end goal needed to be achieved, the team was able to narrow down the ideas to one final design through a Pairwise comparison and Pugh analysis. Following that, the modeling

process took place, which was the most time consuming part of the project. Our device was divided into three major components, one being the prototype build, second being the circuitry and third being the software. Individual components were tested throughout the whole process and once the device was completed it was tested for accuracy and precision when delivering liquid.

To stay organized throughout the project, many tools were used by the team. Some of those include Slack for communication, Outlook calendars for scheduling, Google Drive for documentation and Gantt charts for week to week planning. For our documentation, we created an agenda in which we would set weekly goals and summarize our daily work, meeting minutes for every meeting with our advisors, and end of term presentations to track progress. Figure 8, 9, and 10 below, shows our Gantt charts created for the school year and shows in more detail how the team was able to keep track of tasks. Although we had our schedule all planned out, there were times where circumstances changed and the team had to quickly adapt to them. For example, the team was informed a week before the flight that an advisor was going to Ghana and, if possible, wanted to bring the device with them. The team thought this was a great opportunity, so we changed our goals and schedule for the week, pivoting all of our time and effort into creating the device. Although it was a big change, the team was able to successfully shift gears and adapt to the change.

	B TERM							
Task	**Week 1 (25-29)**	**Week 2 (1-5)**	**Week 3 (8-12)**	**Week 4 (15-19)**	**Week 5 (22-23)***	**Week 6 (29-3)**	**Week 7 (6-10)**	**Week 8 (13-16)**
Prototyping								
Gravity Pump								
Laser diode and photoresistor								
Construct board								
Interview for prototype parts (LCD, temp., etc.)								
Add pinching mechanism - microserver motor								
Peristaltic Pump								
Incorporate peristaltic pump								
Laser diode and photoresistor								
Construct board								
Interview for prototype parts								
3D print new rollers for pump to test								
General Prototyping								
Improve coding for laser diode								
Set up larger LCD, or multiple LCD's								
Brainstorm form of user inputs								
Revising code and CAD models								
Design casing for board and drip chamber								
Choose final design (decision matrix)								
Testing for specifications								
Testing flow of gravity pump								
Testing peristaltic pump								
Test laser diode on drip chamber								
Measuring liquid leaving the tube								
Calibrate drip sensor accordingly								
ISO 20695:2020 Enteral Feeding Systems								
ISO 18250-3:2018 Medical devices - Connectors for reservoir delivery systems for healthcare applications								

Figure 8. Gantt Chart Created for B-Term of the Fall Semester

	C-TERM						
Task	**Week 1 (1/18-1/21)**	**Week 2 (1/24-1/28)**	**Week 3 (1/31-2/4)**	**Week 4 (2/7-2/11)**	**Week 5 (2/14-2/18)**	**Week 6 (2/21-2/23)**	**Week 7 (2/28-3/4)**
Prototyping							
Integrating prototype parts							
Incorporate battery pack into case							
CAD back cover for case							
Attachment to IV (CAD arm component on back cover)							
Coding							
Integrate all component codes together							
Testing							
Test pinching mechanism							
Flow rate accuracy							
Volume accuracy							
Test duration for battery							
Test complete prototype							
Incorporating User Recommendations							
TBD							
Report							
Chapter 4 - Design Process							
Chapter 5 - Testing							
Chapter 6 - User Recommendations							
Presentation							
B-Term							
C-Term							

Figure 9. Gantt Chart Created for C-Term of the Spring Semester

	D-TERM					
Task	**Week 1 (3/14-3/18)**	**Week 2 (3/21-3/25)**	**Week 3 (3/28-4/1)**	**Week 4 (4/4-4/8)**	**Week 5 (4/11-4/15)**	**Week 6 (4/18-4/21)**
Final Prototype						
Incorportate battery						
Create 2 more prototype						
Testing						
Accuracy of volume at different rates						
Pinching accuracy - stopping drops						
Time it takes to pinch tube						
Battery life						
Report Writing						
Edit & finalize previous chapters						
Write D term chapters						
Make final edits						
Write 2 page summary						
Final presentation						
Create final powerpoint presentation						
Incoporate Ghanian clinicians interviews & videos into pres.						
Practice presentation						
Get feedback from clincians						
Reach out to clinicians						
Conduct interviews						
User Manual						
Create a user manual to send to Ghana						

Figure 10. Gantt Chart Created for D-Term of the Spring Semester

4. Design Process

In this section, the team elaborates the experience and development of the design process for the various iterations of designs and prototypes. These are illustrated and explained through the different components that make up the device. Each section goes into more detail about how each design works and why our team created them. In the later chapters, the manufacturing process of the final design and the final selection process are explained. Additionally, the need analysis is described as well as the final prototype design and construction.

4.1 Needs Analysis

Our team made a list of specifications we found most relevant and added them to a Pairwise Analysis, which compared each specification's importance. We did this by ranking each specification as 0, 0.5, or 1. A score of 0 means the specification in the row is less important than the specification in the column. A score of 0.5 means they are equally as important, and a score of 1 means the specification in the row is much more important than the specification in the column. A total score column was added to compare the scores of all specifications with each other.

Table 5. Pairwise Analysis used to find most important design specifications

Objective	Affordable	Administer nutrition accurately	Reliable power source	User-friendly	Monitor flow rate	Ability to measure drip rate	Total Score
Affordable	X	1	0.5	1	1	1	4.5
Administer nutrition accurately	0	X	1	1	1	1	4
Reliable power source	0.5	0	X	1	1	1	3.5
User-friendly	0	0	0	X	0.5	1	1.5
Monitor flow rate	0	0	0	0.5	X	0.5	1
Ability to measure drip rate	0.5	0	0	0	0	X	0.5

Through the Pairwise analysis, we found that affordability ranked the highest with administer nutrition accurately in close second. Affordability in our case means the device should be under 100 USD so clinicians in Ghana can purchase the device. Administer nutrition accurately refers to giving the infant the right amount of nutrition within a 5% error. Next came having a reliable power source, being user-friendly, and regulating flow rate, respectively. The least important specification we found was ability to measure drip rate. Based on the Pairwise Analysis, our team was able to move forward with creating a Pugh Analysis.

4.2 Conceptual Designs

For the design process, many initial designs were considered with their individual features and means of accomplishing the specifications. Four different preliminary designs were created, which serve a purpose of potentially meeting the requirements set in the specification

list, shown in the table in Chapter 3.2. The final design that the team has chosen is determined later in this chapter of the report.

4.2.1 Design 1 - Feeding Via Gravity

The approach to this design consists of operating feeding by using gravity to deliver fluid. The intention is to utilize an IV bag and the components that come along with a standard issued IV bag, such as the roller clamp which determines the flow rate. The goal for this design is to allow the drip chamber to be attached to the device having the drips being measured and simultaneously have the information displayed in a screen placed right below the drip chamber. It will be easy for clinicians to take the device on and off the IV bag and stand whenever needed. The device functions by an Arduino board with C++ coding and a battery source of 12 volt battery. This design offers clinicians a cheaper solution for a feeding pump due to the minimal components needed.

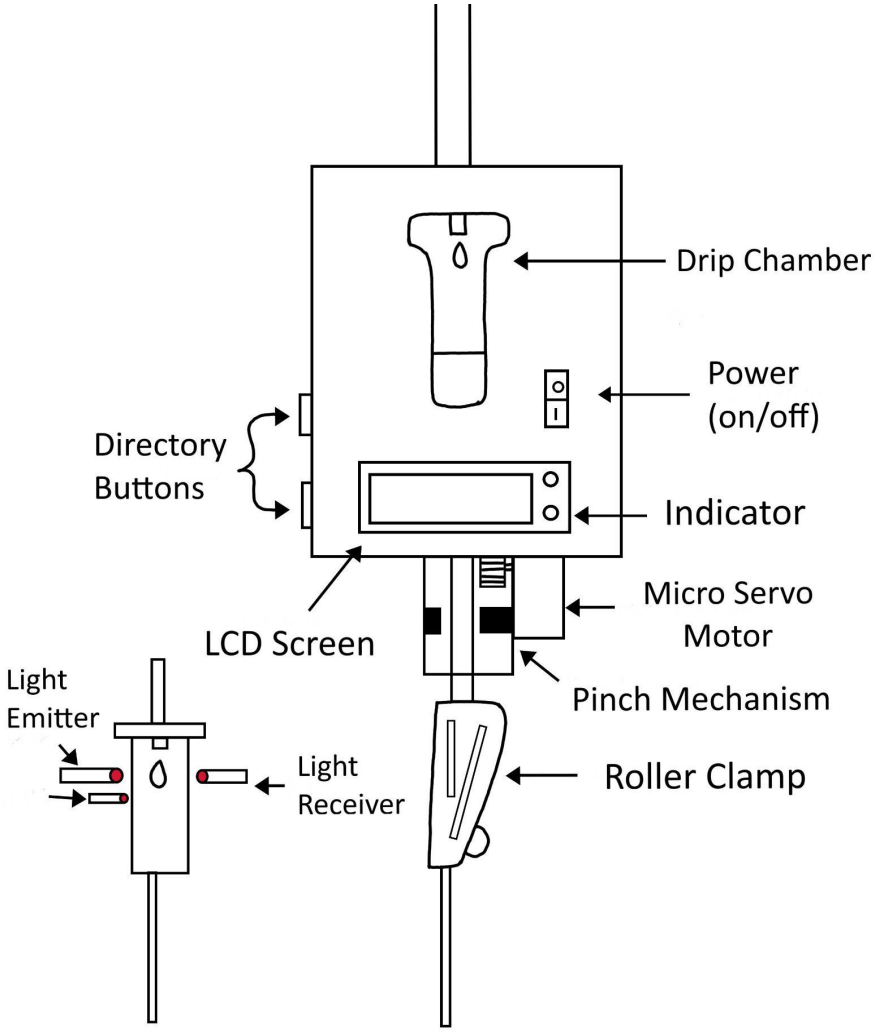


Figure 11. Overview illustration of Design 1

The design consists of a photoresistor and laser diode integrated in the device to calculate the drip rate produced by the drip chamber, which can be converted into flow rate using C++ coding. A microservor motor will be responsible for shutting off the liquid supply once the correct amount of liquid is administered. The microservor motor functions by pinching the IV tubing to prevent any excess liquid from being fed to the infant. An enclosure will be placed around the drip chamber, which will host the entire circuit board, liquid crystal display (LCD), and power source. The schematics of this design is shown in Figure 11 above. The tables below represent the main specifications in this design:

Table 6. Design 1 mechanical and electrical design specifications

Performance Specifications	
Administer desired nutrition	Deliver the necessary volume to the infant
Affordable cost for low-to-middle-income countries	Cost under $100
Flexible flow rate input	Clinician input interface
Administration accuracy and precision	Correctly dispense the input amount of liquid into the baby
Functional Specifications	
Resource availability	Materials available in Ghana
Enable display of volume being dispensed	Visible drip
Power source	Battery powered with light indicator when low

Table 7. Design 1 specifications

Performance Specifications	
Portability	Easy access to place on/off the IV bag and hand held
Functional Specifications	
User-interface/user-friendly	- Liquid crystal display (LCD) board to display live information - LED indicator (feeding complete, battery low, priming, clogging)
Easy to disinfect	Device made of plastic and has no opening to contaminate system

4.2.2 Design 2 - Peristaltic Pump

This design is similar to Design 1 stated in section 4.2.1, however it integrates a peristaltic pump in order to control the flow rate. This design also will utilize the IV bag as the recipient that stores the liquid. The goal for this design is to allow the device to attach onto a drip chamber where the drips are measured and the information is displayed right below. This will make it easy for clinicians to take the device on and off the IV bag and stand whenever needed. The device is functioned by an Arduino board using C++ coding and a battery source.

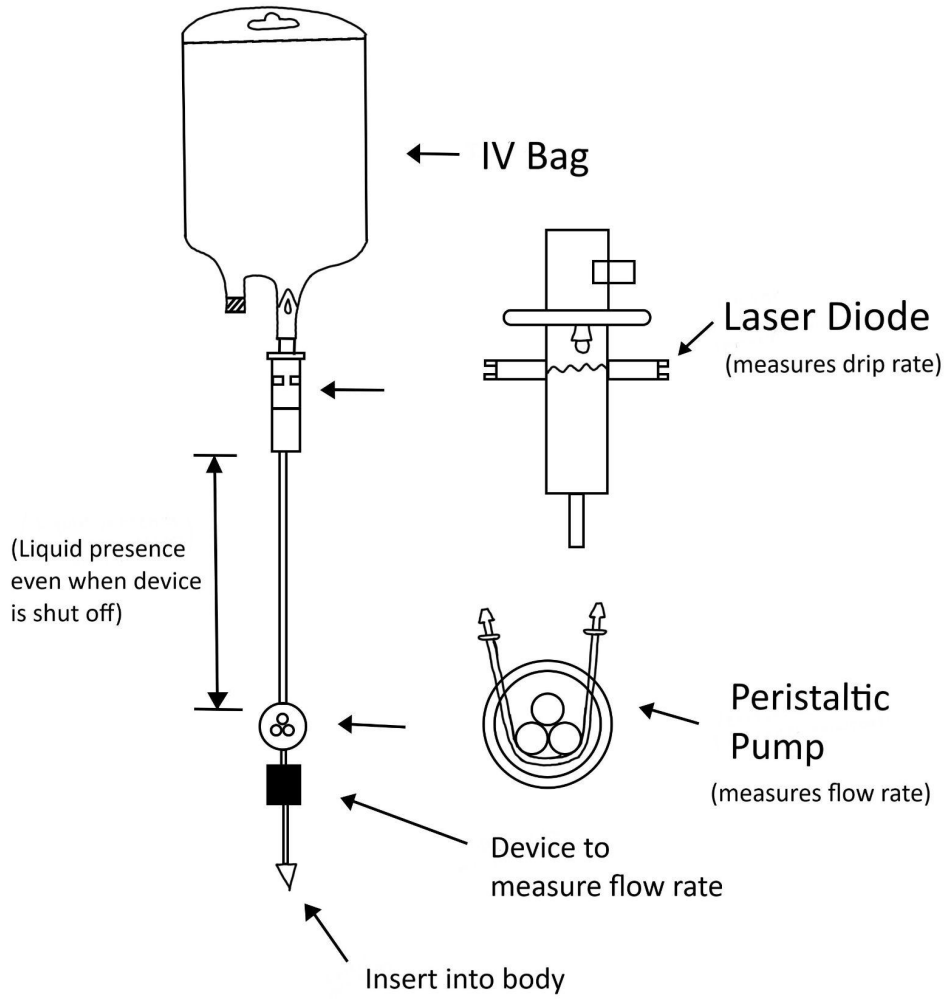


Figure 12. Overview illustration of Design 2

The internal design functionality of measuring drip rate and converting it into flow rate is the same layout used in Design 1 in section 4.2.1. The peristaltic pump allows for a more

consistent and accurate administration of liquid entering the infant than Design 1. An enclosure will be placed around the drip chamber, encompassing the entire circuit board, LCD, and power source. The schematics of this design is shown in Figure 12 above. The tables below represent the main specifications in this design:

Table 8. Design 2 mechanical and electrical design specifications

Performance Specifications	
Administer desired nutrition	Deliver the necessary volume to the baby
Affordable cost for low-to-middle-income countries	Cost under $100
Flexibility flow rate input	Clinician input interface
Administration accuracy and precision	Correctly dispense the input amount of liquid into the baby
Functional Specifications	
Resource availability	Materials available for clinicians/Ghana
Enable display of volume being dispense	Visible drip
Power source	Battery powered with light indicator when low

Table 9. Design 2 Specifications

Performance Specifications	
Portability	Easy access to place on/off the IV bag and is hand held available
Functional Specifications	
User-interface/user-friendly	- Liquid crystal display (LCD) board to broadcast live information - LED indicator (feeding complete, battery low, priming, clogging)

4.2.3 Design 3 - Motorized Hand Pump

The intention of this design is to provide clinicians accurate information efficiently during the process of feeding the infant. This design does not utilize any of the standard issued

IV bag itself, however it does utilize the roller clamp. The goal for this design is to be able to eliminate the IV bag and replace it with a whole new system that provides a reservoir to store the clinic's liquid, motorized hand pump to dispense the liquid, and relay information similar to Design 1 and 2.

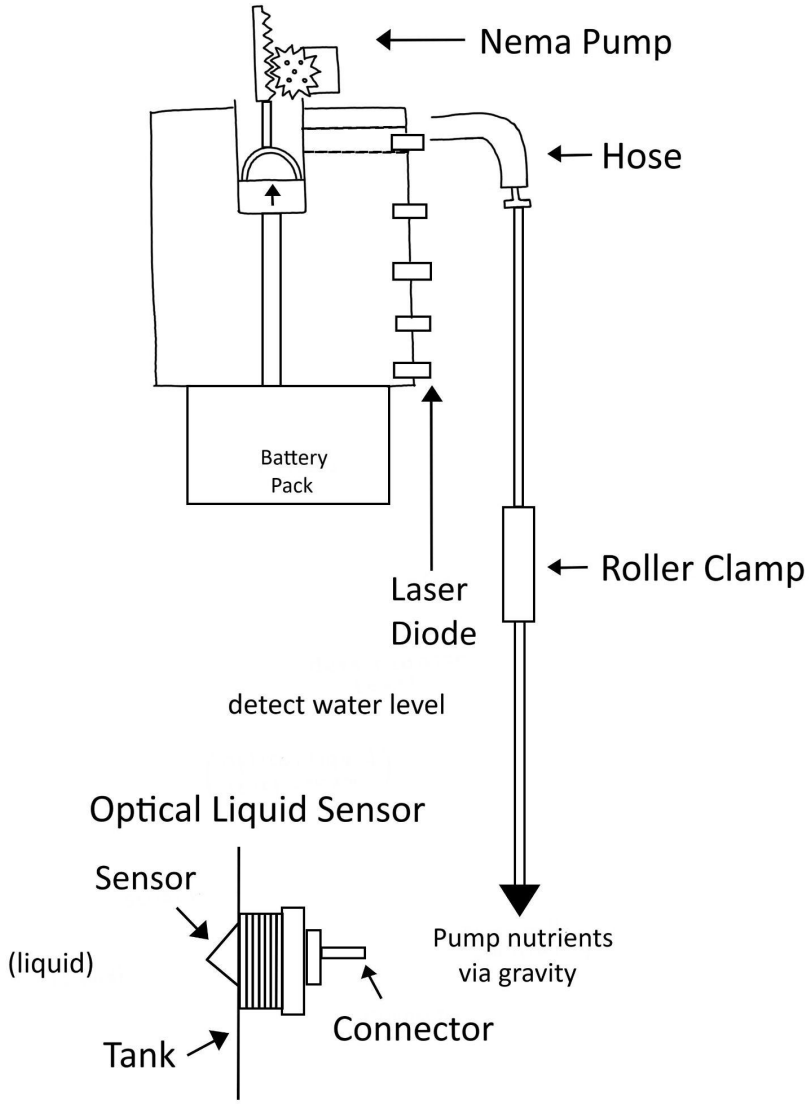


Figure 13. Overview illustration of Design 3

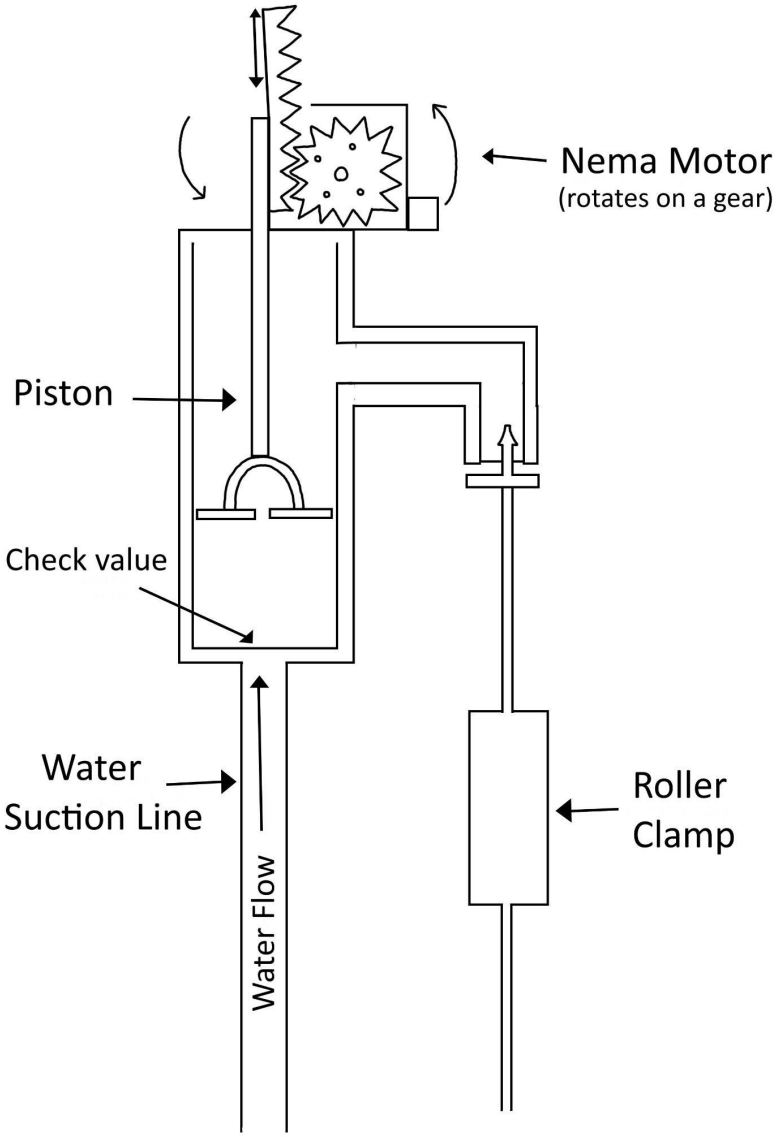


Figure 14. Closer inspection illustration of Design 3

This system does not contain a drip chamber, therefore optical liquid sensors are placed within the reservoir to detect liquid level which can then be converted into valuable information through C++ coding. The system operates through a motorized hand pump which can be further inspected in Figure 13 and 14 shown above. The hand pump is powered by a NEMA stepper motor through gear trains which cause the pump to constantly move a piston in a vertical direction. The hand pump action allows liquid to be filled in the designated tube and dispensed into the infant. The device is functioned by an Arduino board with C++ coding and a battery

source. An enclosure reservoir which will host the entire circuit board, LCD, and power source. The tables below represent the main specifications in this design:

Table 10. Design 3 mechanical and electrical design specifications

Performance Specifications	
Administer desired drug/nutrition	Deliver the necessary volume to the baby
Administration accuracy and precision	Correctly dispense the input amount of liquid into the baby
Functional Specifications	
Enable display of volume being dispense	Optical liquid sensors
Power source	Wall source/solar power

Table 11. Design 3 design Specifications

Performance Specifications	
Portability	Easy access to place on/off the IV bag and is hand held available
Functional Specifications	
User-interface/user-friendly	- Liquid crystal display (LCD) board to broadcast live information - LED indicator (feeding complete, battery low, priming, clogging)

4.2.4 Design 4 - Relay Switch Pump

This design is a combination of Design 2 and 3 shown in section 4.2.2 and 4.2.3. The team came up with a design using a relay switch which is operated through coding. This design completely eliminates the need of a standard issue IV bag and replaces it with a new system of feeding pumps. The design has a similar reservoir to design 3, which holds liquid and includes optical liquid sensors alongside the inside of the container. These optical liquid sensors are used to indicate the liquid presence level which can be converted into volume dispensed through C++ coding. The relay switch, which is connected to a peristaltic pump, allows the intervals of power (voltage) to act as a switch to turn on and off during a period of time. This will allow the device to pump liquid from the reservoir into the infant at a steady rate. The flow rate of the device is

determined by the rotation per minute (RPM) of the peristaltic pump while it dispenses a certain amount of liquid over time. The clinicians will input a set volume during a desired time and that will determine the relay switch's speed. That speed will be converted to flow rate by using C++ coding. The device uses an Arduino board and a battery source. An enclosure reservoir will host the entire circuit board, LCD, and power source. The schematics of this design is shown in Figure 15 below. The tables below represent the main specifications in this design:

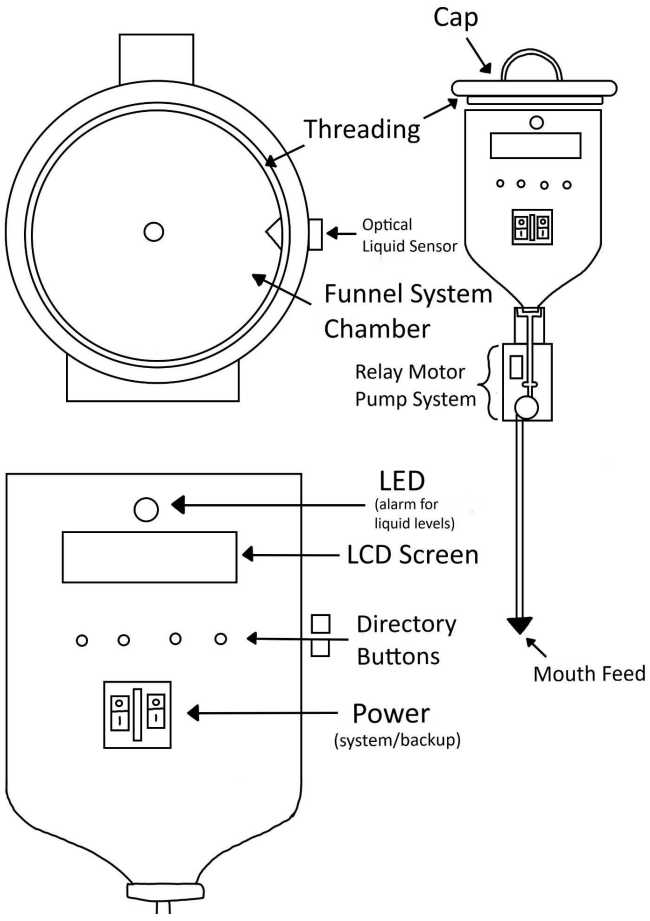


Figure 15. Overview illustration of Design 4

Table 12. Design 4 mechanical and electrical design specifications

Performance Specifications	
Administer desired drug/nutrition	Deliver the necessary volume to the baby
Affordable cost for low-middle-income countries	Cost under $100
Flexibility flow rate input	Clinician input interface
Functional Specifications	
Enable display of volume being dispense	Optical liquid sensors
Power source	Wall source/solar panels

Table 13. Design 4 design Specifications

Performance Specifications	
Portability	Easy access to place on/off the IV bag and is hand held available
Functional Specifications	
User-interface/user-friendly	- Liquid crystal display (LCD) board to broadcast live information - LED indicator (feeding complete, battery low, priming, clogging)

4.3 Alternative Design

During the team's development process of the preliminary design process, two initial concepts were considered into manufacturing; A gravity fed device and a peristaltic delivery pump device. Both designs were applicable to the client's statement, and for that reason, both concepts were considered for the initial prototyping process. At the start of manufacturing in SolidWorks CAD, both designs were initially developed and constructed. However, the team concluded overall that the gravity fed device would be the final design selection, due to multiple factors such as affordability and ergonomics. The peristaltic pump design was not selected to be a final design due to the complexity of parts as well for developing a system in the time frame

given. The concept of the peristaltic pump is designed with various systems that integrate with each other to deliver the desired liquid from a IV system. The following are listed below:

- Flow Rate System
- Delivery System
- Informatic System

Each of the systems that intertwine with each other help produce a product similar to the delivery machines in the market, such as the Kangaroo Joey. The flow rate system is a system that uses a laser diode and a photocell that captures drips from the IV drip chamber and with the Arduino IDE software that uses C++, the flow rate can be calculated. However, the drip rate is controlled by the next system, the delivery system. The delivery system uses a stepper motor that will rotate at various speeds depending on the flow rate desired. The peristaltic pump is a tube pump that uses positive displacement in which fluid is fed through rollers that grind on the tube, essentially squeezing certain areas of the tube creating a vacuum for liquid to enter. The rotating rollers are attached to the stepper motor which sets flow rate and allows the delivery of liquid. Both the flow rate and delivery system are conveyed by an informatic system consisting of an Arduino as center of the system and C++ to display values and calculations of the feeding system.

However, this system was not chosen as the final design of our project due to the complexity of calculating flow rate and vacuum of the tube when the delivery system is in action. The team came to the conclusion that due to time this device was not feasible since coding would consume most of the timeline of the project but manufacturing and testing were necessary parts that required time as well. There are multiple factors to consider in calculating flow rate from peristaltic pumps, it was potentially too difficult to translate in C++ onto Arduino. Overall, the peristaltic pump also decreases the affordability of the device as the stepper motor is a key aspect of the device and the price range can vary greatly. Considering a high end stepper motor will not only increase cost, but also require more features such as special driver boards and a larger power supply.

4.4 Final Design Selection

After reviewing the Pairwise Comparison created by the team, located in chapter 4.2, we then created a Pugh Analysis to help narrow down our choices. A Pugh Analysis is a decision matrix that has weighted specifications listed on the row (X) axis and the design concepts on the column (Y) axis. A baseline, which consists of the existing method for neonatal feeding in Ghana, is used and all other design concepts are compared to it. A design concept receives a score of 0 if it meets the baseline. A score of 1 is received if the design concept exceeds the baseline, and a score of -1 is received if the design concept does not meet the baseline. Our team had 4 design concepts that were included in the analysis. These consisted of Via Gravity, Via Pump, Via Relay Switch, and Via Motorized Hand Pump. Table 14 shown below illustrates the Pugh Analysis and the results we got. This displays how we chose the Via Gravity as our final design to later start prototyping.

Table 14. Pugh Analysis of Four Initial Designs

Designs	Affordable (Under $100) (6)	Administers nutrition accurately (5)	Reliable power source (4)	User-friendly (3)	Regulates flow rate (2)	Ability to measure drip rate (1)	*Total Score (Weighted)*	*Total Score (Non-weighted)*
Via Gravity	0	0	1	1	1	1	10	4
Via Pump	0	0	0	1	1	1	6	3
Via Relay Switch Pump	0	-1	1	1	1	0	-4	2
Via Motorized Hand Pump	-1	-1	1	1	0	0	-4	0

4.5 First Iteration of Prototype

With the evaluation process using the Pairwise Comparison Chart, Pugh Analysis and brainstorming more Design 2 that integrates the peristaltic pump, Design 1 which is via gravity pump was the design chosen for the prototyping process. The first prototype consisted of a case enclosing the drip chamber, a drip sensor, a LCD screen and a micro servo motor for a pinching system to cut off fluid.

The casing of the device was designed in Solidworks and 3D printed using PLA plastic, represented in Figure 16. It consists of two major parts, the front being removable and acting as a lid for the case while the body is one solid structure that does not come apart. The front has two holes, one to guarantee that the drip sensor is visible to the user as well as one to fit a 16x2 LCD screen that will show information to the clinician, shown in Figure 17. That entire part is removable and gives access to the inside of the case, where the drip sensor and micro servo motor are planned to be located as well as all the wiring of the device, shown in more detail in Figure 18. The back side of the casing was made with a slit so that the tubing could be placed and removed easily every time it needed to be switched from patient to patient.

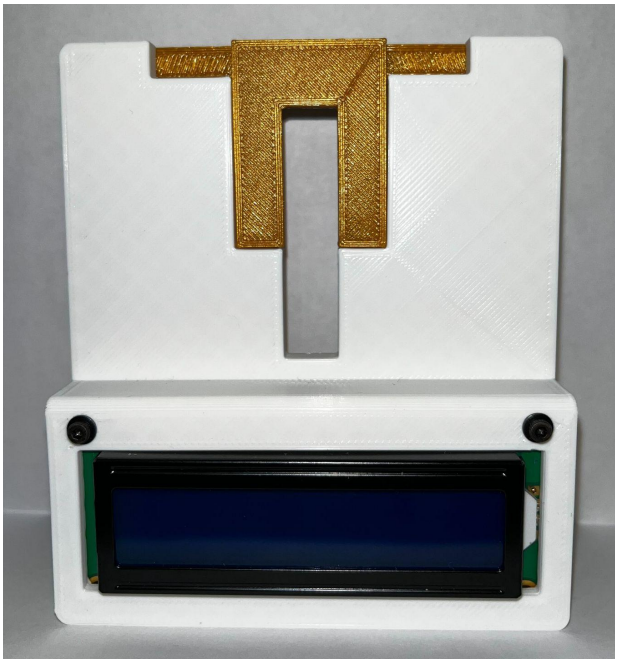


Figure 16. First iteration of the prototype with front and back parts combined

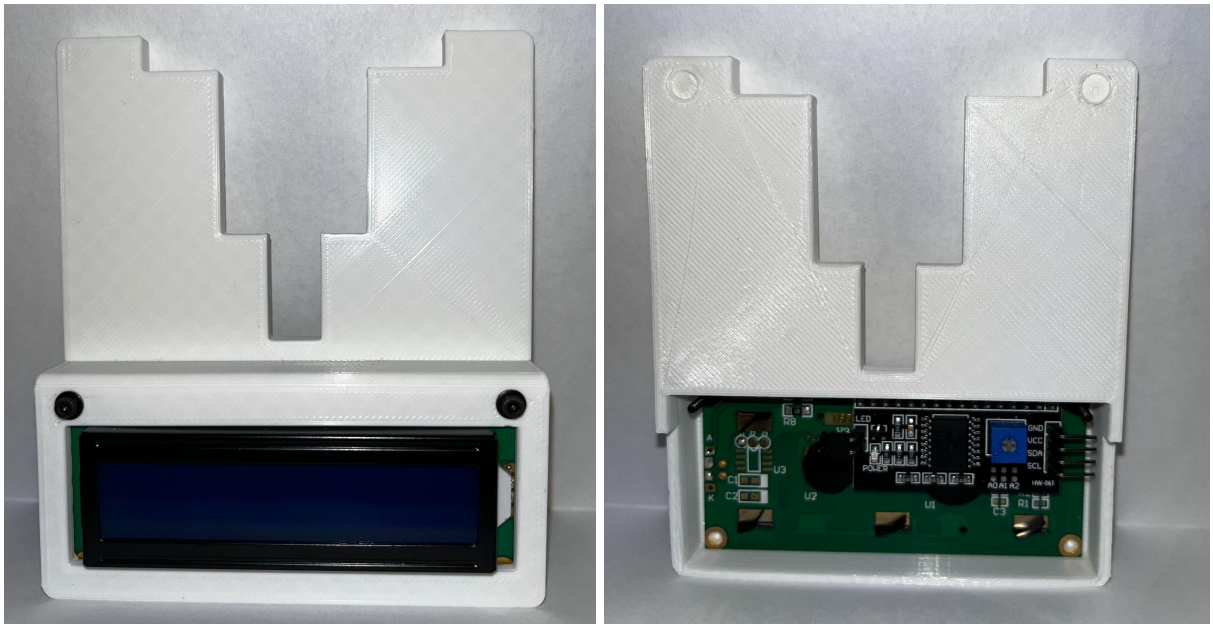


Figure 17. Front part of casing from the first iteration of the prototype. On the left it shows the front which is what would be visible for the clinicians and on the right it shows the inside

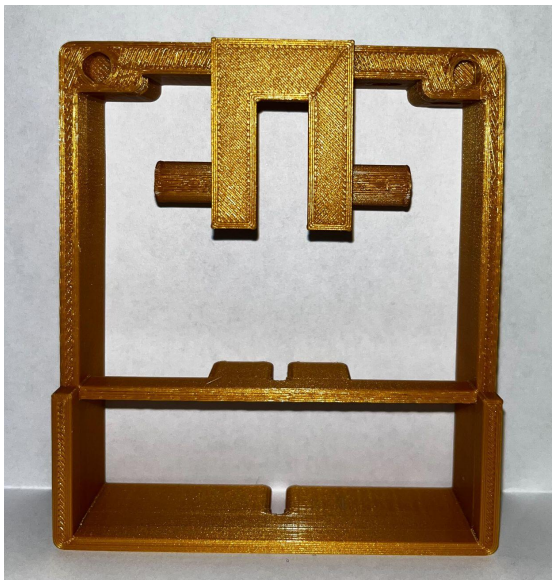


Figure 18. Back part of casing from the first iteration of the prototype. In the image it is possible to see the slit in the back of the casing for the tubing and the cavities for the drip sensor around the drip chamber

In order to determine the amount of liquid administered and flow rate, the team decided to integrate a drip sensor. The inspiration of this component of the project came from the previous MQP work (Deshpande et al., 2021) and it consists of a combination of a photoresistor

with a laser diode. A photoresistor is also known as a light-dependent resistor and has an inverse relationship between resistance and light, meaning its resistance increases as lighting increases (Haraoubia, 2018). The photoresistor was paired with a red laser diode and these two elements were set up to be constantly pointing at each other, creating a steady stream of red light towards the photoresistor through the drip chamber of the IV bag. The way the drops are detected is having that beam of light broken by the liquid. Once that occurs, the system detects a drop and adds that to the volume being administered. For the volume each drip represents, the team used what was indicated in the standard tubing bag, which is that 1 drip equals 0.05 mL. The LCD screen was connected to the system and for this first iteration, it showed only the total volume administered and that value would go up as more drops were detected.

4.6 Components' Designs

In this section, the different components of the device will be touched on, as well as going into detail for each component and the different iterations they had. Our different ideas and why we chose them are explained.

4.6.1 Pinching Mechanism

The team's design concept for the pinching mechanism has two objectives. The first objective is to design a system that will pinch the choice of tubing to cease the flow of fluid from the drip chamber. The second objective is to unpinch to restart the flow of liquid. The primary goal for the device pinching mechanism is to repeatedly perform both objectives and to cease cracking in any given medical tubing for feeding. For these objectives to be met the team designed multiple pinching iteration designs until a system satisfied both objectives.

The first iteration (Design 1) of the pinching mechanism the team designed consisted of a 180 degree micro servo motor mounted to a 3D printed chassis with an attached arm directly to the motor. The micro servo motor was programmed to turn 90 degrees in which rotates squishing the IV tube against a wall thus pinching the tube and preventing liquid from flowing through, this can be seen in Figure 19.

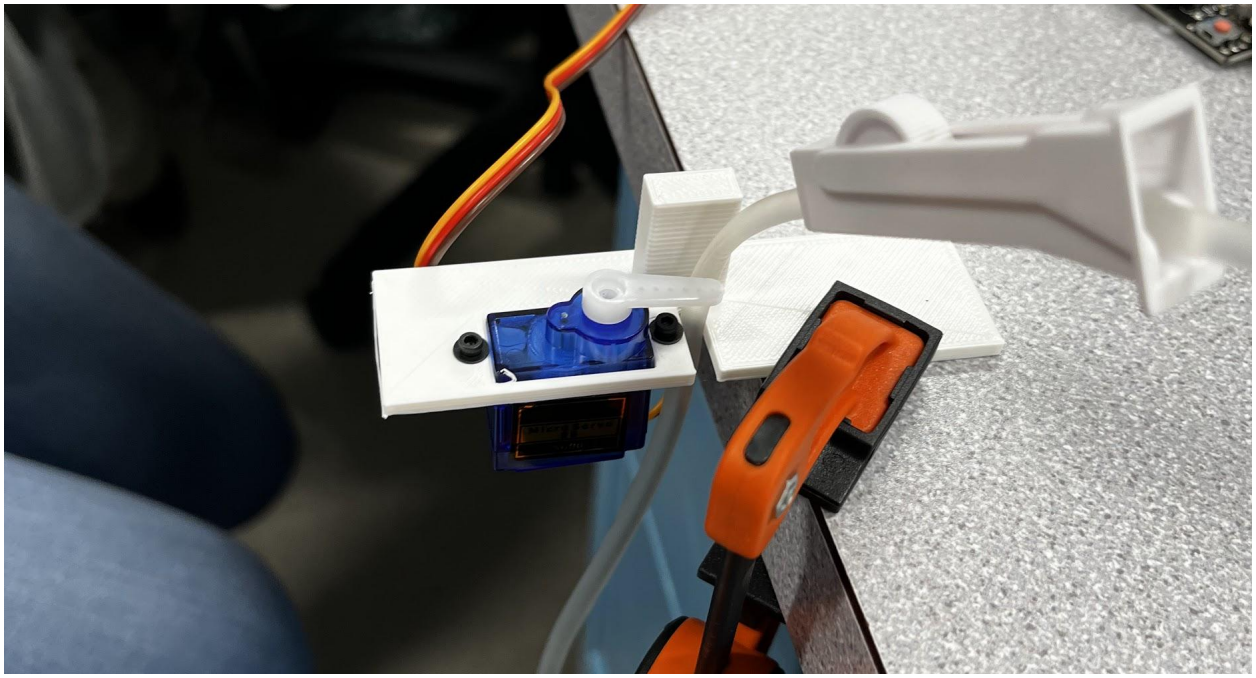


Figure 19. Design 1 iteration rough testing which consist using a micro servo motor to squeeze IV tubing

The team performed preliminary tests for this pinching mechanism iteration by clamping the back wall of a 3D printed mount seen in Figure 19 above. To test the system, the arm was screwed into the motor and was programmed to swing in a motion that would collide with the tube, pressing itself on a flat surface. This system, however, did not successfully pinch the tube and the drip chamber was continuously dripping fluid. For this outcome, no further rigorous testing was performed at this stage. The team concluded there were multiple problems related to the micro servo motor. One of the main issues that was encountered from this design was related to the usage of a micro servo and the positioning of the arm attached to it. With servo motors, there are initial positions that define its location, this allows the motor to know what degree to turn based on the code. Another main issue encountered during the team experience was during testing. The design using the micro servo motor provided an insufficient amount of torque to pinch the tube, resulting in dissatisfaction in both of the team's pinching mechanism objectives. The team concluded that this iteration design of the pinching mechanism was not suitable for the project. With power being the main issue the team then proceeded to resolve the issue by using a 5 volt stepper motor.

The next pinching mechanism iteration (Design 2) consisted of a stepper motor that provided more power and torque compared to the micro servo motor. However, with a new

motor in place the design was changed from an angular motion to a screw mechanism motion to pinch tubing. A screw mechanism is the conversion of rotational motion into linear motion. The team integrated both screw mechanism and 5 volt stepper motor to develop a linear motion design that will push forward a section into a tube pressing against an enclosure. The design consists of a limit switch that will provide a stopping point for the motor as well for the section that will pinch the tubing. However, there were challenges that were encountered while designing in SolidWorks (CAD) due to the objectives of the team's project goal of the device, listed below in Table 15:

Table 15. List of challenges that the team needs to consider during the design process

Design Challenges	**Reasoning**
Capacity (Spacing)	The goal is to minimize spacing to provide portability and accessibility for clinicians, as well maximize functionality of the device
Easy Accessibility	The design will need to low-maintenance as well easily accessible for clinic engineers to provide maintenance if needed
Functionality	The design will need to perform efficiently and fulfill the two objectives of a pinching mechanism of the team's device

The team developed the first iteration design using SolidWorks (CAD) consisting of the 5 volt stepper motor using a 1:3 gear ratio to drive gears to rotate a M3 screw. Attached to the screw is a 3D printed piece that motion is linear and the direction of the piece is determined by the rotation (counter/clockwise) of the gears. The 3D printed pincher piece is positioned to hit the limit switch which with software aspects the system will stop once pressed. A SolidWorks visualization is seen below in Figure 20.

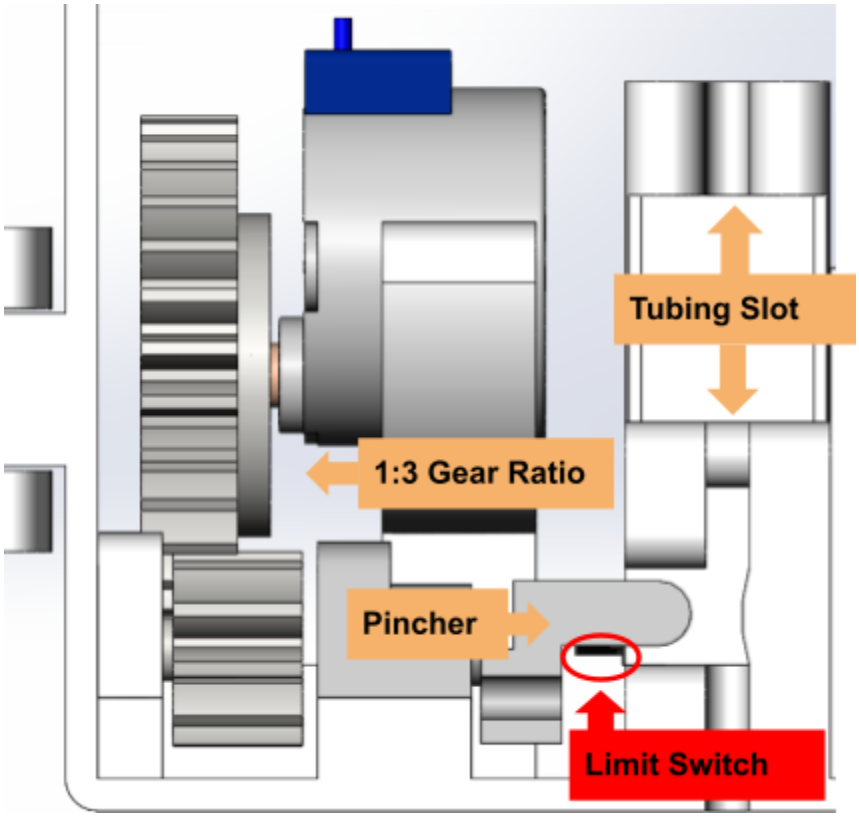


Figure 20. A front view and schematic of a SolidWorks assembly of iteration 2 consisting a 1:3 gear ratio (3 = driver gear and 1 = driven gear)

The team manufactured the pinching iteration and evaluated the performance of the design through various testing consisting of pinching of the tube. It was then experienced that there were issues from the mechanical aspect of the design system, listed in Table 16 below:

Table 16. This table shows the design issues and the reasoning for addressing the issues.

Design Issues	Reasoning
Improper Gear Ratio	The iteration design consists of a gear ratio of 1:3, however the larger gear was placed as the driver gear as for the small gear was placed as the driven gear for the linear motion system. The gear ratio reduced speed as well the teeth of the gears were not perfectly aligned causing stalling in the motor.

Mechanical Complications	The pincher on the system is a mechanical failure due to the imbalance of stress added towards the tubing. Essentially the threaded rod that holds the pincher piece on the device is being applied all the force at that location. However, the part that touches the tubing is not aligned with the screw, therefore not applying the equal amount of force to the tube. See Figure 21 below. The linear motion design also did not provide stability for the screw as well for the smooth rods supporting the pincher, this can be seen in Figure 21 below.

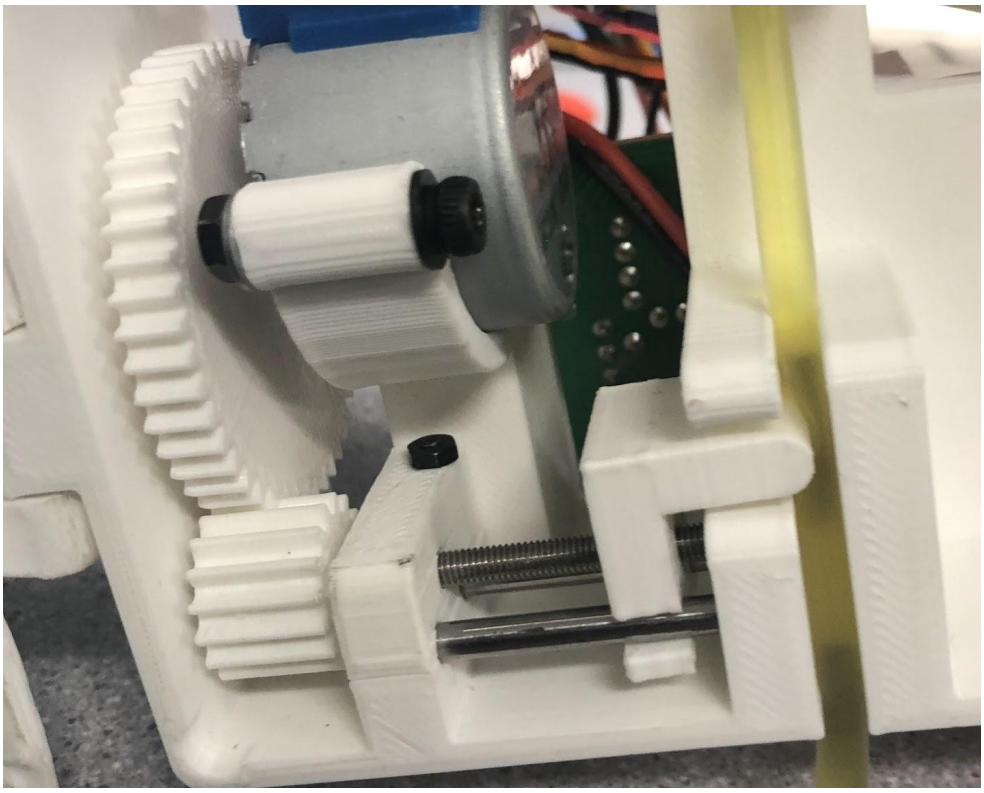


Figure 21. Design 2 iteration assembled consisting a 1:3 gear ratio (screw mechanism powered by stepper motor)

The team manufactured multiple parts and chassis for the pinching mechanism for this iteration to see if there were any issues that may follow upon 3D printing, assembling, or coding. However, none of the following reasons were the issue, but the ones stated in Table 16 above. The team concluded this iteration design of integrating the stepper motor and the screw mechanism was at a mechanical failure due to SolidWorks design as well not providing the

necessary torque and force to pinch the tube. This led the team to redesign the pinching mechanism so that both objectives are complete. A new iteration (Design 3) was designed, making major changes to both structure and mechanical functionality. The new iteration of the pinching mechanism reuses the idea of integrating a stepper motor and a screw mechanism to develop a linear motion to force a piece into a tube in an enclosure. The team decided to use a 12 volt stepper motor (same model as the previous iteration, but has more coiling meaning higher torque) to provide the necessary force to pinch the tubing. The structure design for the pinching mechanism chassis was changed into an open layout to provide easier maintenance and mechanical advantage. Mechanical advantage consists of using a 1:1 gear ratio for the stepper motor and the screw mechanism system. The team manufactured the iteration which can be seen below in Figure 22.

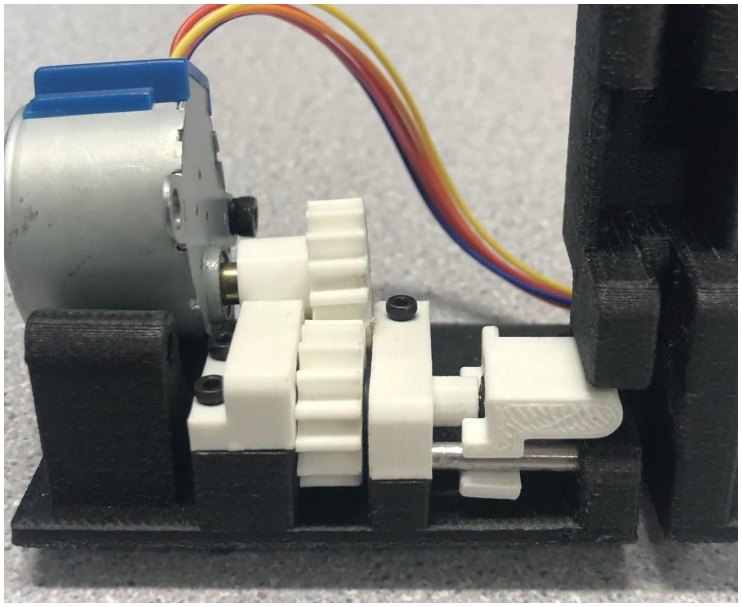


Figure 22. Design 3 iteration using revision ger ratio and 12 volt stepper motor with carbon fiber mount

A limit switch was still utilized to provide a stopping point for when the pinching mechanism applied force to the tube and caused a blocking of flow rate. Additionally, a ball-bearing is used to provide more stability in the mechanical structure of the design. Testing of the new iteration consisting of the new gear ratio, displayed success in pinching the tube with enough force to stop the flow of fluid from dripping in the drip chamber of the IV tube. With this the team was able to complete both objectives of pinching and unpinching through coding in Arduino. There were no visible signs of any issue of the gears not turning correctly as well for an

insufficient force and torque to the system. However, a design issue was encountered consisting of the design of the chassis that the pinching mechanism was mounted in. The essential design of the chassis was intended to provide housing for other components such as buttons and the drip sensor that will be later discussed in section 4.6.2. The new pinching mechanism design that requires a 1:1 gear ratio caused the main chassis of the whole device to enlarge itself by 1 inch. This made the design visually bulky and defeated the purpose of the team's project goal of keeping it a compact device, seen below in Figure 23. These constraints would also affect other parts of the device such as the front and back cover due to dimensioning changes. It was also due to SolidWorks constraints that kept causing issues for dimensioning iterations.

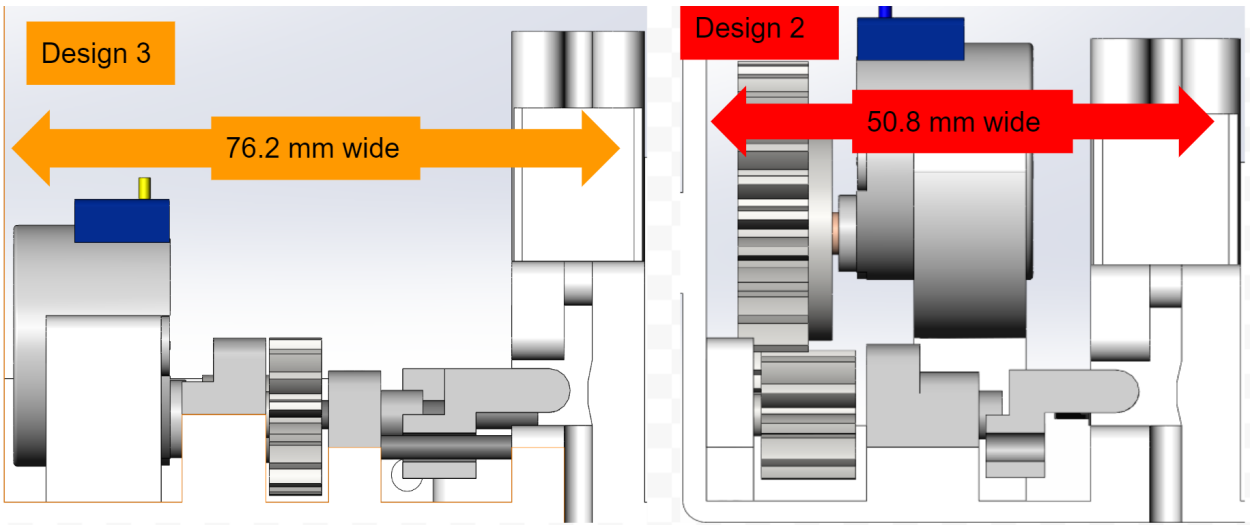


Figure 23. Design gear comparison of iteration 2 and iteration 3 mounting lengths

Therefore, the team continued to redesign using Design 2 chassis design, but reconfiguring spacing to fit every component needed for the pinching mechanism. However, this ended up as a challenge, the team continued using the 1:1 gear ratio causing spacing between the 12 volt stepper motor and the screw mechanism to be nearly colliding. The team developed a new iteration (Design 4) which consists of using the space provided by Design 2 chassis incorporating both the new gear ratio and screw mechanism, seen below in Figure 24 and 25.

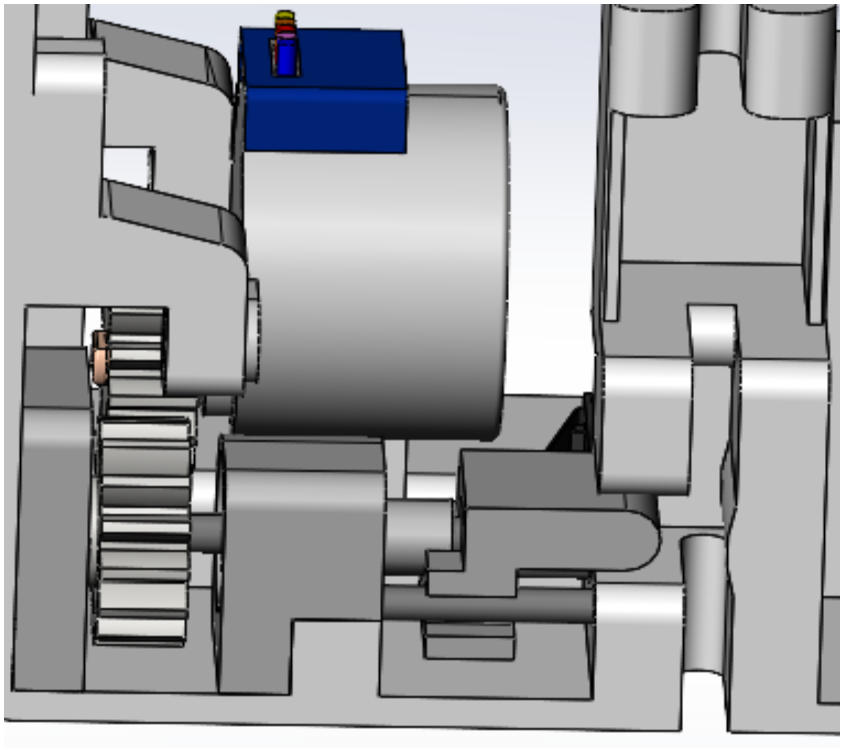


Figure 24. SolidWorks drawing of iteration 4 of design reconfigurement

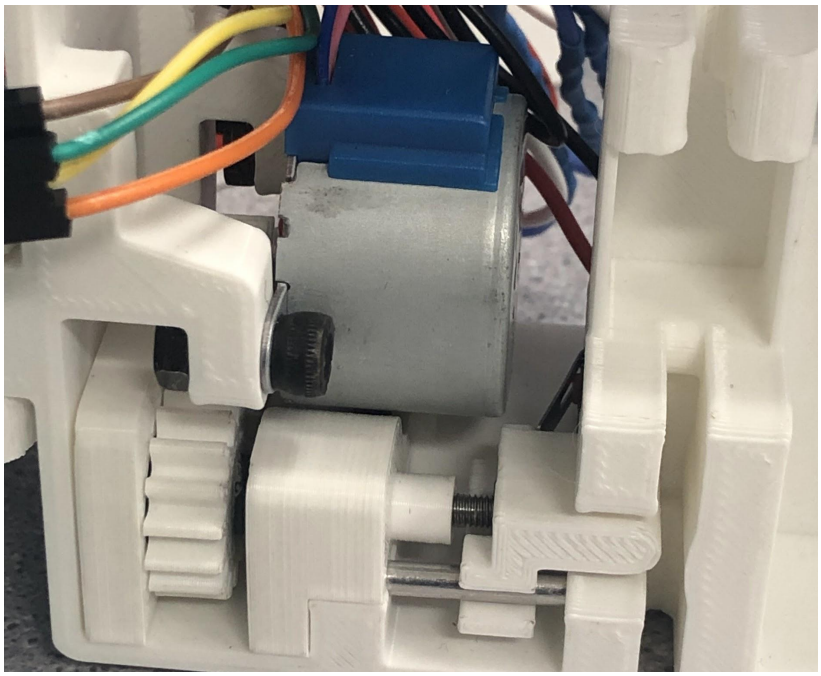


Figure 25. Manufacture prototype of iteration 4 using the same gear ratio and motor as iteration 3

Design 4 iteration seen in Figure 25 comprises two ball-bearings to provide stability to the screw mechanism system as the 1:1 gear ratio is also utilized for pinching tubes. The design is compact, but satisfies the objectives of the pinching mechanism and provides a way to easily access all components of the system. Testing was performed to observe the possibility of failure, however the gears correlate perfectly with each other as well for the linear motion of the pincher piece design in SolidWorks. The limit switch does also successfully perform simultaneously with the whole system in action. Even though design 4 is still an iteration, due to the time frame of the project, the team concluded that this design was the most suitable design to go forward with for validation of testing. Overall, the design process of the pinching mechanism took many trials, it validated the team's objective of have a system to go forward in the project goals of having flow rate regulations and being able to complete a goal of the client statement, which is to automate a fluid value from simple mechanics and engine unity.

4.6.2 LCD Screen

With the 16x2 screen from the first iteration of the prototype, an issue our team ran into when displaying multiple variables for the nurses on the LCD screen was the limitation to two lines, each with 16 characters. At first, the team displayed two variables: total volume administered and flow rate. Due to the number of characters restriction, abbreviations were made to fit the numbers on the lines given. For example, "VolAdmin" was used instead of "Total Volume Administered".

After further discussion throughout the project about the variables needed for the nurses, our team decided on three: flow rate, total volume administered, and battery life percentage. In addition, during an interview conducted by the team with a clinician working in Ghana, she suggested that the team add a line to the screen that would indicate whether the feeding is being done with breast milk or formula. In order for this to be accomplished, a larger LCD needed to be incorporated into the device. Instead of the 2x16 screen, a 4x20 was purchased and implemented into the device. With this larger screen, it was possible to accommodate all the variables desired and introduce more description of what is being shown, as the units. As shown in Figure 26 below, the first row shows the volume administered, which is represented in mL. The second row shows the flow rate, calculated in mL/min. The third row represents the battery

life shown in percentage while the fourth row was left open to incorporate any variable desired by the clinicians using the device.

Figure 26. 4x20 LCD screen incorporated into the device which shows volume administered, flow rate and battery life percentage

4.6.3 Drip Sensor

The overall design of the drip sensor is to have a transmitter on one side of the chamber and receiver on the other. In the case of a laser diode and photoresistor, the laser is the transmitter and photoresistor is the receiver. This can also correspond to an infrared (IR) beam sensor. Initially, the team decided to use the laser diode and photoresistor, as the team before had used. With only minor knowledge of the components, challenges occurred, so the IR beam was tested as an alternative design.

An infrared beam sensor has an emitter side that sends out infrared light and a receiver across from it which can detect that light. When something passes in between the emitter and receiver the beam is broken and the receiver will detect that. Our team made a rough layout of the IR beam by taping each component to one end of a popsicle stick and running our fingers in the middle. When our finger was in between both sides of the sensor, the receiver side detected that the infrared light beam was broken, and so the sensor's output read "Broken". When our

fingers were not in between the sensors the serial monitor outputted the words “Unbroken” indicating that there was nothing in between the receiver and emitter. The next step was to test our setup with liquid droplets, and unfortunately this did not work. Although the reasoning behind this setup not working was unclear because it could just be the droplets being too small or going by too fast, the team moved forward with the laser diode and photoresistor again.

To set up this type of sensor, the team made use of a 3D printed case that had inserts for the laser and photoresistor, allowing the laser to shine directly across to the photoresistor, and a drip chamber inserted right between the two. This allowed the team to get more accurate results on whether or not we could use these components to read the flow rate using a drip chamber. This was then connected to Arduino Uno, which was used to gather and display data on a team member’s computer. Although preliminary testing resulted in drops not being counted, a delay was found in the code that delayed the Arduino from reading the sensor quickly. Removing this delay showed great promise on Arudino’s serial plotter, as its graph showed spikes whenever a drop went by. Figure 27 shows an example of what this looks like.

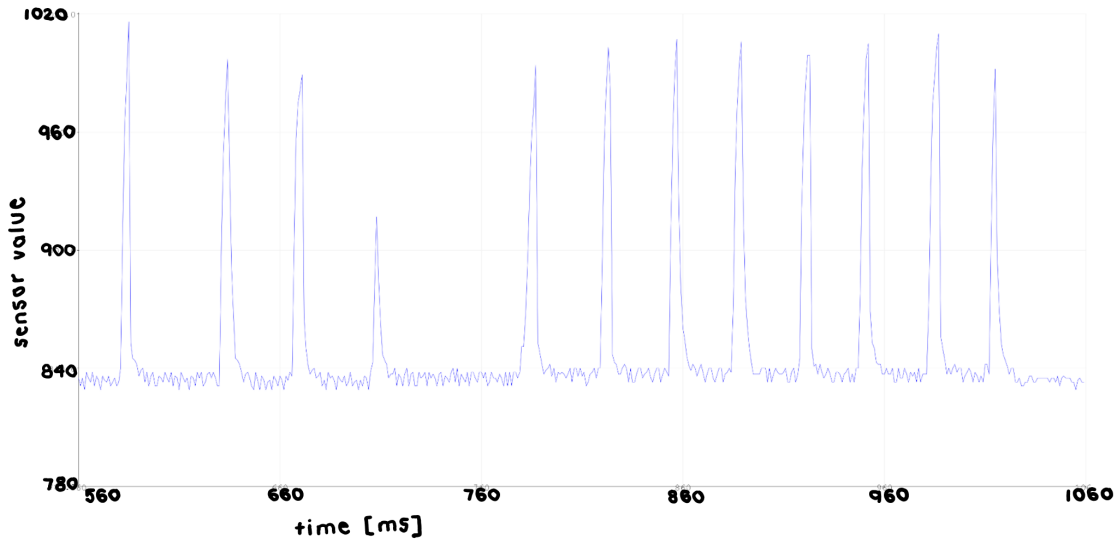


Figure 27. Plot of Sensor Readings with Low Pass Filter

Once it was established that this method of sensing drops could possibly work for our device, more code was written to count the number of drops that went by. Each drop was registered by a resulting sensor value of more than 900. Based on what our eyes saw and what was seen on the monitor, it appeared that the computer counted each drop twice, instead of once.

A 0.02 second delay in the code was found to be the shortest delay to stop the sensor from counting each drop twice, while still counting every drop, assuming a single droplet takes approximately 0.02 seconds to pass the sensor.

After accounting for the time it takes for a droplet to pass, flow rate and volume were both calculated within the Arduino code. As shown in Figure 27, the baseline of the sensor is unstable and would also change with the ambient lighting in the room, so the sensor value that would register a drop passing by would have to be manually changed in the code after looking at its resulting plot. The team did not think this would be user-friendly, so a calibration code was written to account for these discrepancies. The code would read the first 500 values of the sensor before drops would pass and create a baseline using the average of the values. A drop would then be recognized as 60 value units above that baseline. During this time, a filter was also added to the circuit it hopes of canceling out some noise that would interfere with the readings, although unfortunately it did not function well in doing so. Later results showed that the team was using a low-pass filter instead of a high-pass filter. The results from the high-pass filter using a 1.5kΩ resistor, 2.2kΩ resistor, and 1 µF capacitor showed a relatively steady baseline of around 0-2 sensor values with an increase of about 8 values when a drop passed. These components were added to the device to further smooth out any discrepancies in ambient light or noise affecting the sensor.

4.6.4 Case Iterations

The case design of the team's device is a crucial step in the design process. The case design for the device hosts all the mechanical and electrical components. The case of the team's device consists of a front cover, chassis, and a back cover, each fulfilling a certain purpose to satisfy the team's design and manufacturing objectives. The team iterations of the device case needs to satisfy the objectives in Table 17 below.

Table 17. Objectives of the Project

Objectives	Reasoning
Compatibility	Be able to house all components
Accessibility	Easily accessible for clinicians and engineers for maintenance or installation.

The front cover of the device hosts both a 20x4 LCD screen and I2C module that assist in displaying information of the device. The design of the front cover purpose is to allow the clinicians or engineers to access the inside of the device without having to take apart the device itself. Allowing easy access to inserting the IV tube as well for maintenance. The chassis has a purpose of hosting many of the components of the device such as the Arduino Nano and the various components that are the functionality of the device, such as the drip sensor and the pinching mechanism. As for the back cover, it is designed to allow engineers or clinicians to access for maintenance in case of a mechanical and electrical malfunction. The back case is also designed to host the power source. These three components for the case design are important to consider the functionality and creativity of aesthetics. The team used SolidWorks to develop many iterations of the case due to the changes of our pinching mechanism. The team's first iteration of a case was small and compacted which held a micro servo motor. Seen in Figure 28 below.

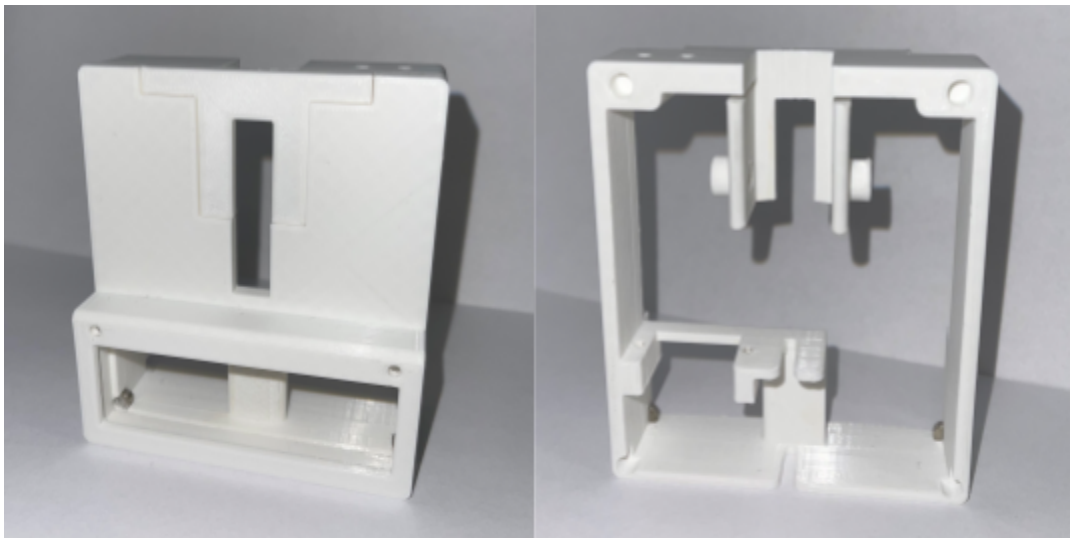


Figure 28. Case design for iteration 1 consist of using a micro servo motor

Due to new iterations from the pinching mechanism, the team redesigned and manufactured a new case that will house all the new components such as the stepper motor and a larger LCD screen. Seen below in Figure 29. Case iterations for the back and front cover where not establish due to the constant change of components in the team’s design process, but with these current iterations and prototypes that the team developed the team was able to pinpoint certain features to improve in SolidWorks, such as the front cover being accessible through a door hinge system.

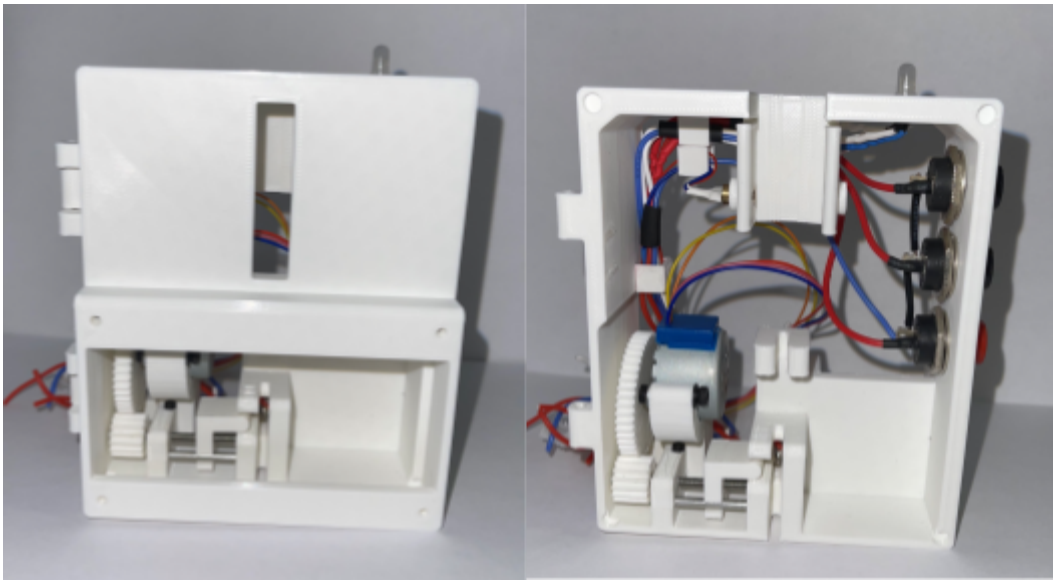


Figure 29. Case design for iteration 2 using the screw mechanism translating rotational motion into linear motion

The team developed a final iteration of the case which satisfies and succeeds with many of the device functionality. After deciding all the individual components' final design, the team finalized the design of the case for all front, chassis, and back covers of the device. The case is compact which allows wire management to be easily maintained as well for certain parts such as the pinching mechanism components. The final design of the case consists of most of the components to be in the main chassis of the device; however, the back cover of the device is designed to host the buck converters, the stepper motor driver board, and rocker switch that enables the empowerment of the device. The back cover is designed to be screwed on and off for maintenance and is able to detach wires itself from the main chassis of the device for further inspection. The front cover hosts the LCD screen that displays information and is easily attached to the main chassis by a door hinge system held shut by magnets. Below in Figure 30 and 31 is seen the final case design.

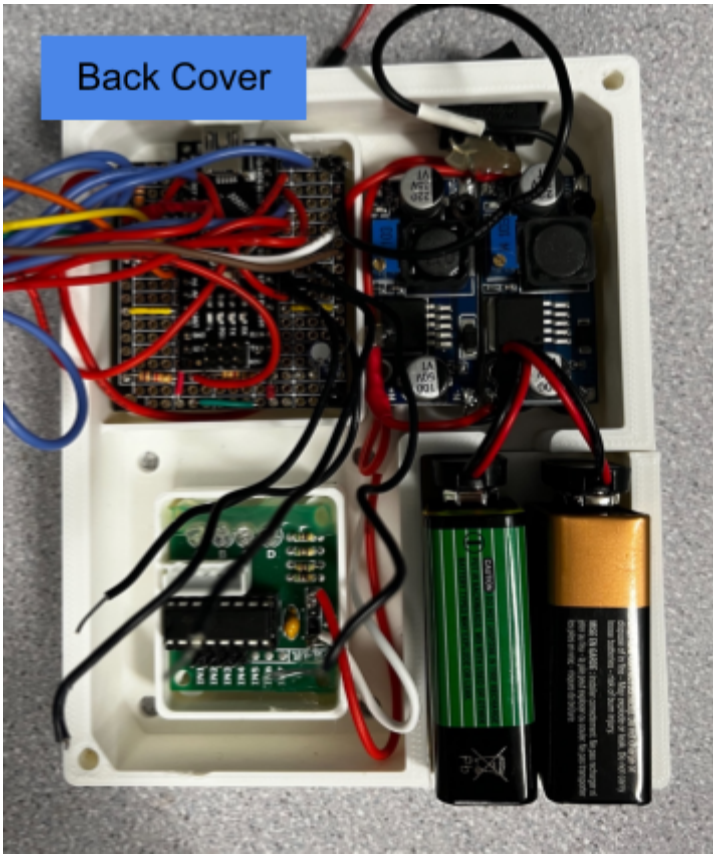


Figure 30. Manufactured back cover consisting the board, motor driver board, and the buck converters

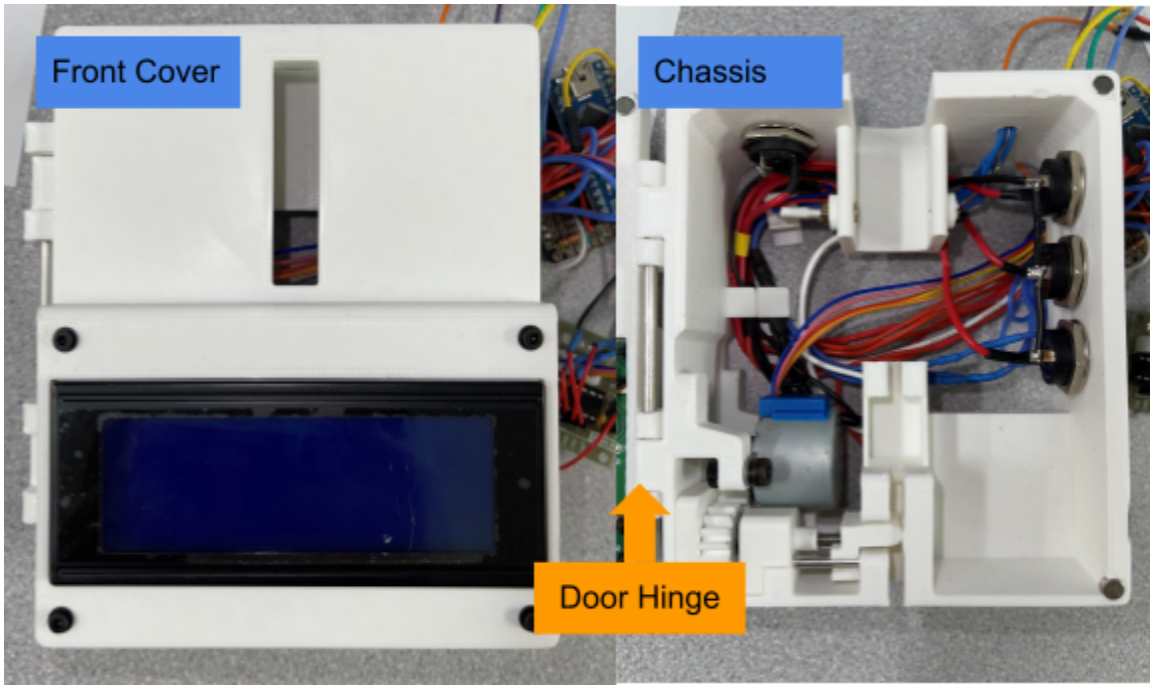


Figure 31. Manufactured chassis and front cover with iteration 4 in place for the pinching mechanism

4.7 Final Prototype Design

4.7.1 Circuit Design

One of the main parts of this device is the circuit, which incorporates all the individual components of the prototype. The components' design are explained in detail in Chapter 4.6, they being a stepper motor, a 4x20 LCD screen, a limit switch, four push buttons, a RGB LED, 18V battery with power switch and buck converters and a laser diode and photoresistor. A small protoboard was made for this device to make sure it does not take up too much room and allow it to easily fit inside the casing. This protoboard contains 19 columns and 17 rows. In Figure 32 below, there is the schematic of the entire circuit integrating all these parts, made in Fritzing. The circuit drawing was made using a larger breadboard in order to better represent the wiring without crowding.

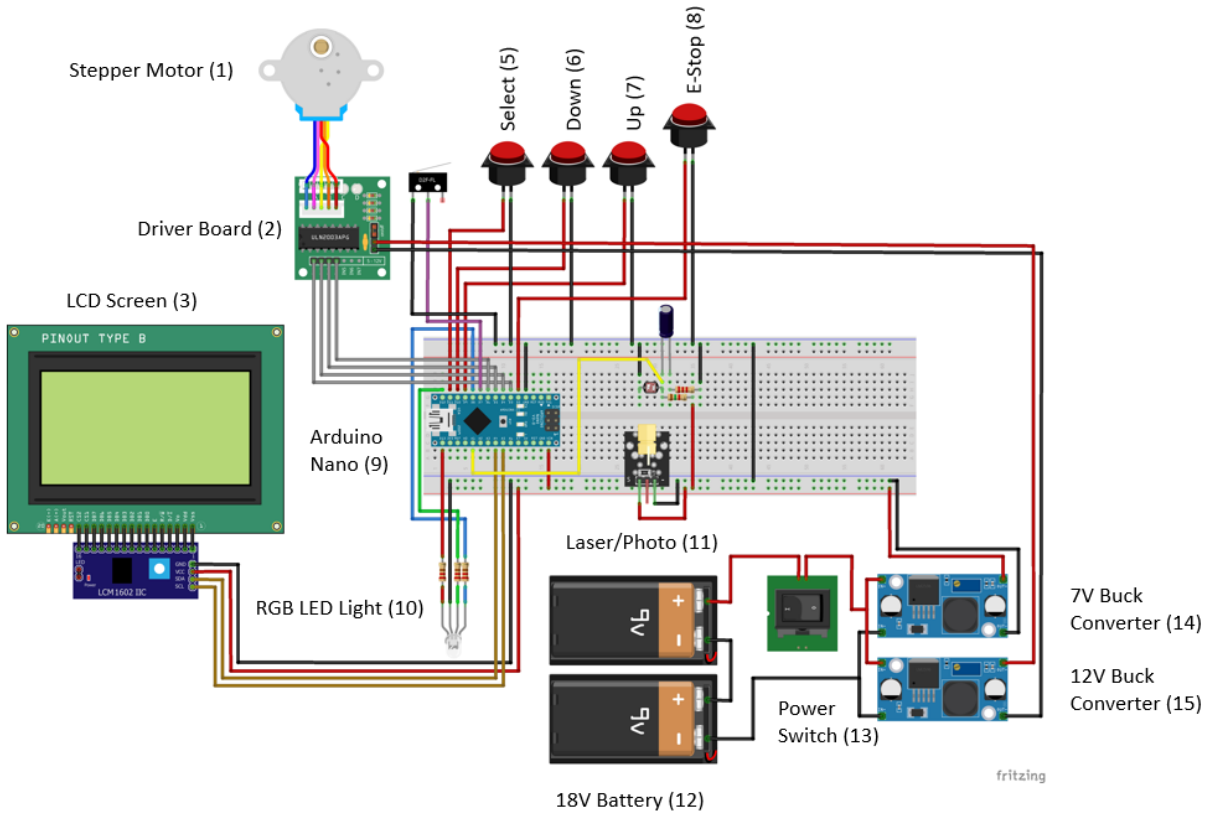


Figure 32. Final Circuitry of the Device

For the power of the board, the team used two 9V batteries, labeled as 12 in the image, which total to 18V. These batteries are connected to a power switch, labeled as 13, which turns the device on and off, and to two different buck converters. The first buck converter converts the voltage from the batteries to a 7V output, labeled as 14, which then powers the entire protoboard, except the motor. With the ground and power wires from those, a ground and power strip are made in the circuit, which power almost all the individual components. The Arduino was placed on the edge of the board, as shown in the Figure and around the middle, allowing space for wiring on both sides of it. It is powered through the Vin pin while the ground connects to the GND. The second buck converter, labeled as 15, converts the voltage from the batteries to a 12V output, which is responsible for powering the motor, the first component of the circuit.

The stepper motor, labeled as 1, is a 28BYJ-48 4-phase 12V stepper motor, which is connected to a ULN2003 drive board, labeled as 2. From this driver board there are two different main connections, the first one being from the 1N1, 1N2, 1N3 and 1N4 pins to the digital pins 3, 4, 5 and 6, respectively, on the Arduino Nano. The second connection is made from the side pins of the driver board, the negative pin going to the negative side of the 12V buck converter and the positive going to the positive side of the buck converter. The second component, labeled as 3 in the image, is the 4x20 LCD screen, which contains an I2C module connected to the back side. From that part, there are four different wires with connections. The SDA and SCL ports connect to pins 4 and 5 on the analog side of the Arduino, respectively. The GND port connects to the ground strip of our protoboard while VCC connects to power. The third component is the limit switch, labeled as 4, which has one wire connecting to the ground strip of our board and another to the digital pin 7 of the Arduino. The fourth components are the four push buttons, labeled as 5, 6, 7, 8, those being select, down, up and emergency stop, respectively. The four buttons are connected to digital pins 9, 10, 11 and 2 of the Arduino, respectively, and all the ground wires are connected to the ground strip of the protoboard. The next component is the RGB LED, labeled as 10 in the image, and the red, green and blue pins from the light are connected to 220 Ω resistors. The blue and green pins are connected to digital pins 8 and 12, while the red pin is connected to analog pin 13. The anode pin of the light is connected to the ground strip of the board. The final components are the laser diode and photoresistor. The laser diode is powered by connecting to the power and ground strips of the protoboard. The photoresistor is wired alongside a high pass filter, which was created with a 1.5 kΩ and 2.2 kΩ resistors and a 1 μF capacitor.

4.7.2 Code Structure

The coding structure of this device can be seen in Figure 33 below. When turning the device on, a volume selection process occurs. This starts at 0 mL and uses the three buttons on the side of the device to go up or down in volume. The lowest, green button allows the user to select the volume displayed on the screen, and the code uses the selected volume as the desired volume to be reached. After this, a calibration process occurs that reads the first 500 values of the sensor, and uses the average to obtain a baseline for the ambient lighting of the room. During this time, no drops should be going by the sensor, and the writing on the display reads, “Calibrating… Please wait…”.

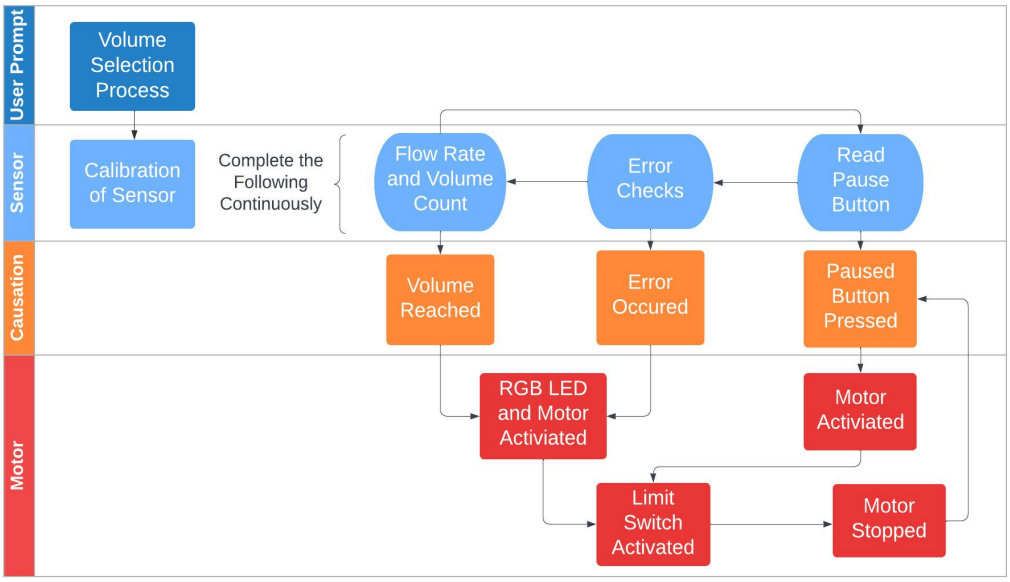


Figure 33. Coding flowchart

After this, the roller clamp can be set to the desired position, and drops will go by. To recognize the drops passing by the laser and photoresistor, the sensor value reads at least eight units above the baseline. This signals that a drop was detected and adds 0.0585 mL to the total volume. If a drop goes by, the total volume is updated and flow rate is calculated using the change in volume, which is the same as the volume of one drop, and is divided by the time between the current drop and last drop. This provides an instantaneous flow rate. These calculations are then displayed on the screen for the user. If the desired volume is reached, it triggers the motor to run until the limit switch is hit, signaling that the tube is now pinched shut.

The tube will remain pinched until the pause button is pressed again. When this happens, the motor is activated to run backwards until the tube is unpinched. The device then continues to

monitor flow rate and volume, check for errors, and read the pause button until the device is turned off.

4.7.3 Device Construction

The final device consists of three main 3D printed structures and all individual components are contained within them; those being the front cover, the case and the back cover. The front cover is able to open and close and is what allows the drip chamber to be placed in the main case. The dimensions of the front cover are 104.1 mm (length) x 127 mm (width) and there are two different depths. As shown in Figure 34 below, the top half of the case is 10.2 mm in depth, while the bottom half is larger for the LCD screen placement, with a depth of 17.1 mm. There is an extruded cut on the top half for the drip chamber as well one on the bottom half for screen to allow for them to be viewed. The entire cover is integrated to the main case using a door hinge system with a metal rod.

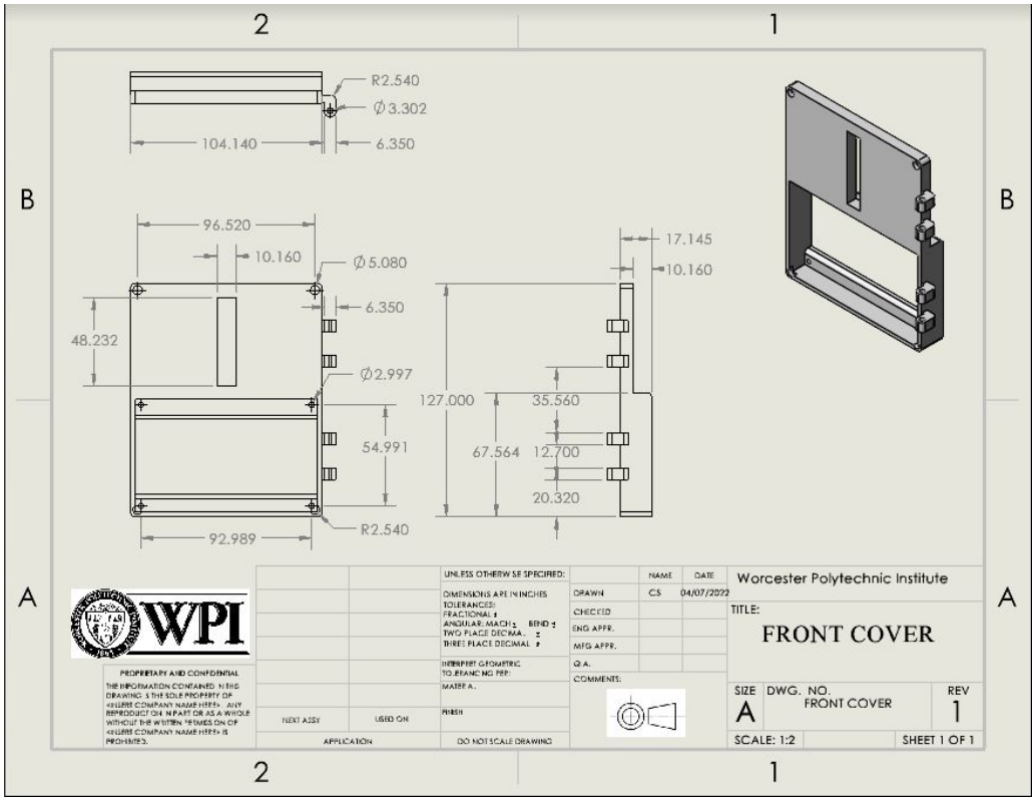


Figure 34. eDrawing (Using SolidWorks) of the Front Cover that host the LCD screen

The case is the largest and most elaborate structure of the device. As shown in Figure 35 below, there are many extrusions and cuts included. The dimensions of the exterior are 104.1 mm (length) x 127 mm (width) x 43.2 mm (depth).

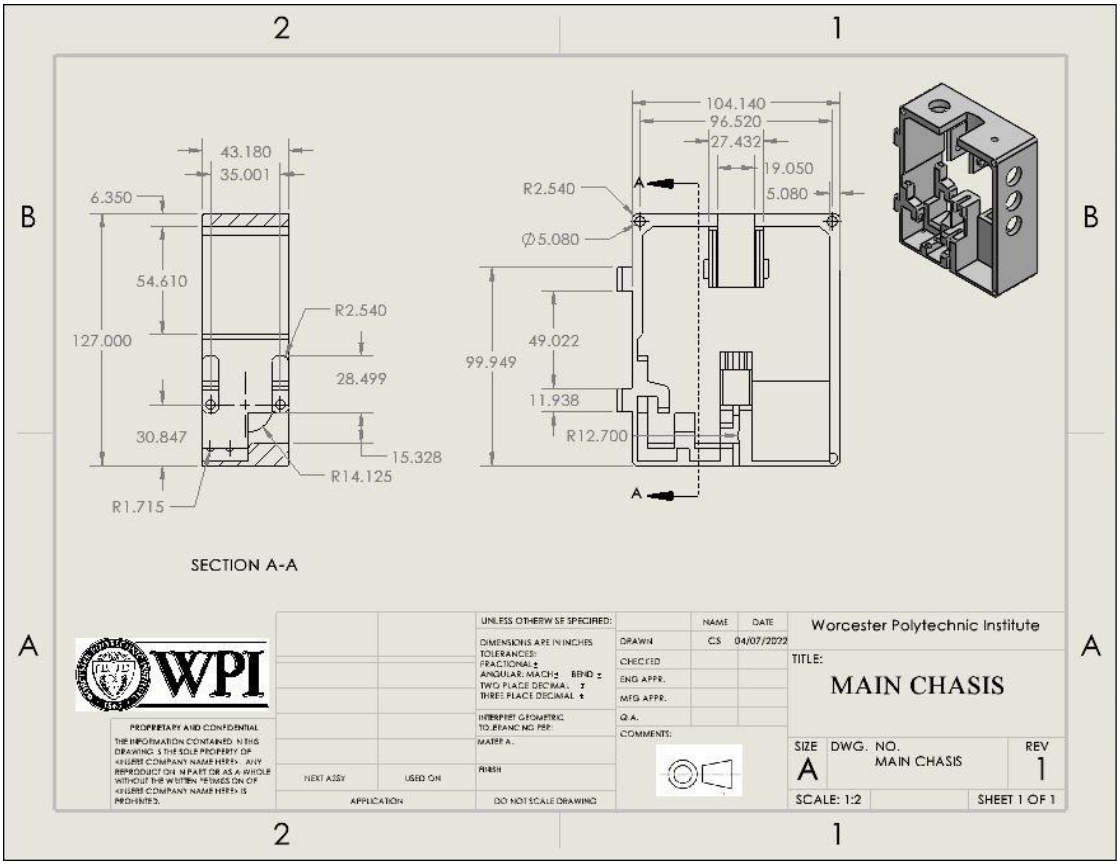


Figure 35. eDrawing (Using SolidWorks) of the Main Chassis that host the drip sensor and the pinching mechanism

To accommodate the buttons, the case has 4 extruded cuts, three being on the right side for the up, down and select button and one on the top for the E-stop button. On the top as well, there is an extrude cut to expose the RGB LED. On the left side edge, there are two hinges to connect to the front cover. Directly in the middle of the case is where the drip chamber is placed as well as the drip sensor which includes the photoresistor and laser diode. There are extruded cuts from top to bottom of the case to accommodate for tubing and a larger cut to place the drip chamber. On the sides of this larger extrude, there are two holes, the one on the left accommodating the photoresistor and the one on the right, the laser diode. The pinching mechanism is also located in this case and it is the most elaborate part of the system. There are two main parts to this mechanism, the screw mechanism and the structural stability. The

structural ability consists of two ball bearings that are hosted by 3D printed mounts for a M3 thread that is attached to a 3D printed gear as a driven transmission. The screw mechanism itself consists of two smooth rods that are supported for the pincher piece of the device and the thread rod is the actuator for the system that pinches the tubing close. The whole system itself is using a 12 volt motor that is mounted with a 3D printer gear that drives the whole pinching mechanism system. The last major structure is the back cover. This cover accommodates the driver board as well as the batteries and buck converters. The main structure dimensions are 104.1 mm (length) x 127 mm (width) x 21.6 mm (depth). The back case has an “L” shape and on the top there is an extruded cut for the power switch. On the bottom left corner of this cover, the driver board for the motor is placed. Above that, there is a space left to accommodate the protoboard and the Arduino which are screwed on to the main case. On the top right corner, the buck converters are placed and on the bottom right corner, the batteries are accommodated.

5. Design Verification

Testing of the individual components were done to make sure it worked how we intended it to. The testing we executed included verification of the buck converter, volume accuracy, and the pinching mechanism..

5.1 Buck Converter Verification

The team's original design concept for the buck converters was to split the voltage from the two 9V batteries and put them in series to create an 18V system, powering the Arduino nano and the 12V stepper motor. The team chose to power the nano through the Vin pin instead of the 5V pin so that the buck converters did not need to be set to exactly 5V because it can be difficult to set an exact value. The minimum voltage needed to power the stepper motor to pinch the tube is 10 volts. The minimum power needed to power the Arduino nano is 5V but since the team used the Vin pin to power the nano, the team needed to supply this with a voltage range between 7V and 12V. The team adjusted the buck converters and measured the voltage at each buck converter to verify the voltages. The voltage reading for the nano buck converter was 7V and the reading at the stepper motor buck converter was 11V. To further verify that the buck converters were working properly, the team connected the battery pack and buck converters to the rest of the circuit and turned on the device. A trial was then run and it was verified that the nano and the stepper motor received a sufficient amount of power to fully pinch the tube. Figure 36 below shows the wiring diagram of the buck converters and batteries.

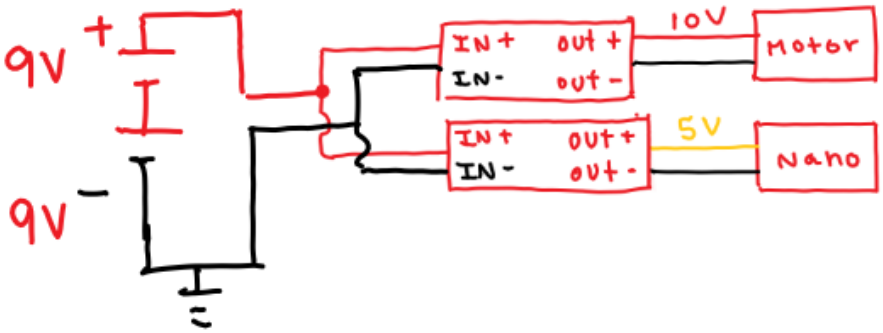


Figure 36. Wiring Diagram of Buck Converters and Batteries

5.2 Volume Measurement Accuracy and Drip Sensor Verification

To make sure the device monitored the volume correctly, the team completed a series of tests. This included setting the desired volume to 5 mL on the device and setting different flow rates using the roller clamp. The set up of this can be found in Figure 37.

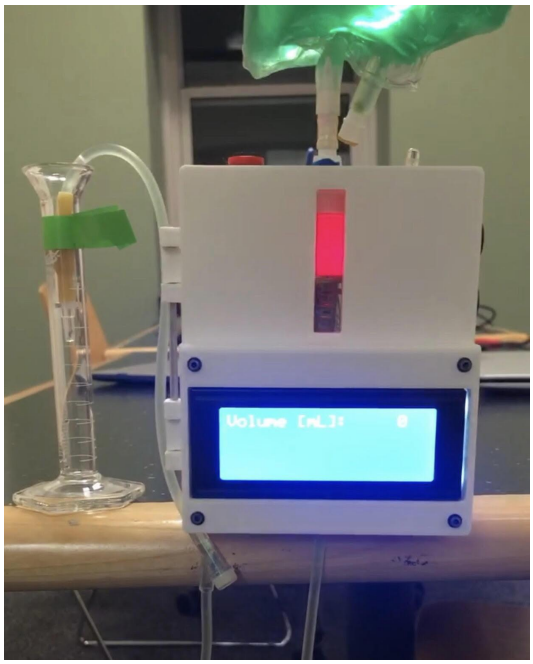


Figure 37. Volume Measurement Accuracy Testing Set-Up

This was set to include slow flow rates, which ranged from 0.7 mL/min to 1.1 mL/min, medium flow rates which ranged from 1.9 mL/min to 2.5 mL/min, and high flow rates which ranged from 4.3 mL/min to 5.5 mL/min. These flow rates were set due to premature infants starting to feed around 0.5 mL/min until they can eventually breastfeed, which starts at around 5 mL/min (Pados, 2015). When the device measured the 5 mL, which signaled the device's LED to signal green, the volume in the cylinder was recorded to ensure the device was monitoring volume properly. This is when the device would activate the motor to start pinching the tube. At slow flow rates, the average volume in the graduated cylinder measured 5.02 mL, 5.09 mL at medium flow rates, and 5.385 mL at high flow rates. These flow rates were calculated using the volume on the screen and dividing that by the time taken to obtain that volume. For example, if the 5 mL took 5 minutes to obtain that volume, it would be calculated as 1 mL/min. Because the graduated cylinder only measured up to 10 mL with 0.1 mL increments, one must note that the uncertainty of the measured volumes are ± 0.1 mL. 10 trials were completed at each speed to get

a range of flow rate values, which can be seen in Appendix B. This data is also shown in the graphical display in Figure 38.

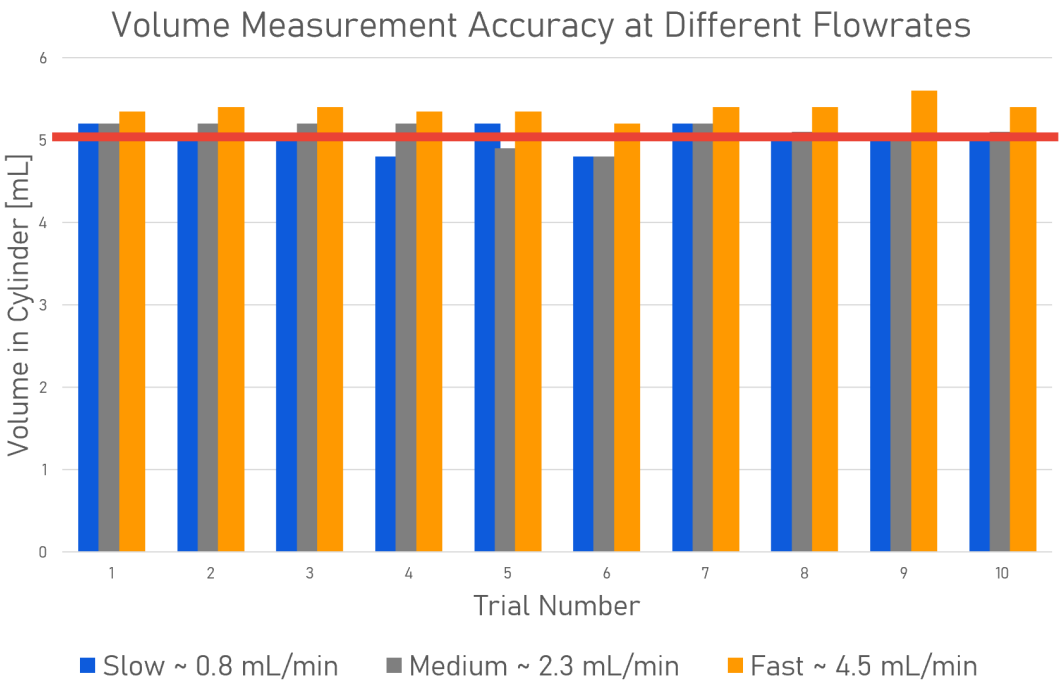


Figure 38. Graphical Display of Data for Volume Measurement Accuracy Testing

Based on the 10 trials for each range of flow rates, the percent error for slow, medium, and high flow rates was found to be 2%, 3%, and 8%, respectively. These percentage errors were calculated using the following equation:

$$\%\ error\ =\ \frac{|accepted\ value - experimental\ value|}{accepted\ value} \times 100$$ [7]

These percentages represent the average of how close each flow rate's yielded volume was to the desired volume. As shown directly from the graph and assuming the sensor correctly sensed every drop passing by, one can assume that drop size changes with flow rate. Future work could account for this inconsistency. These measurements were taken before the tube was pinched to see if the drip sensor measured volume accurately, so more tests had to be completed to measure the volume administered once the motor fully pinched the tube.

[7] *Anne Marie Helmenstine. (2020). https://www.thoughtco.com/how-to-calculate-percent-error-609584*

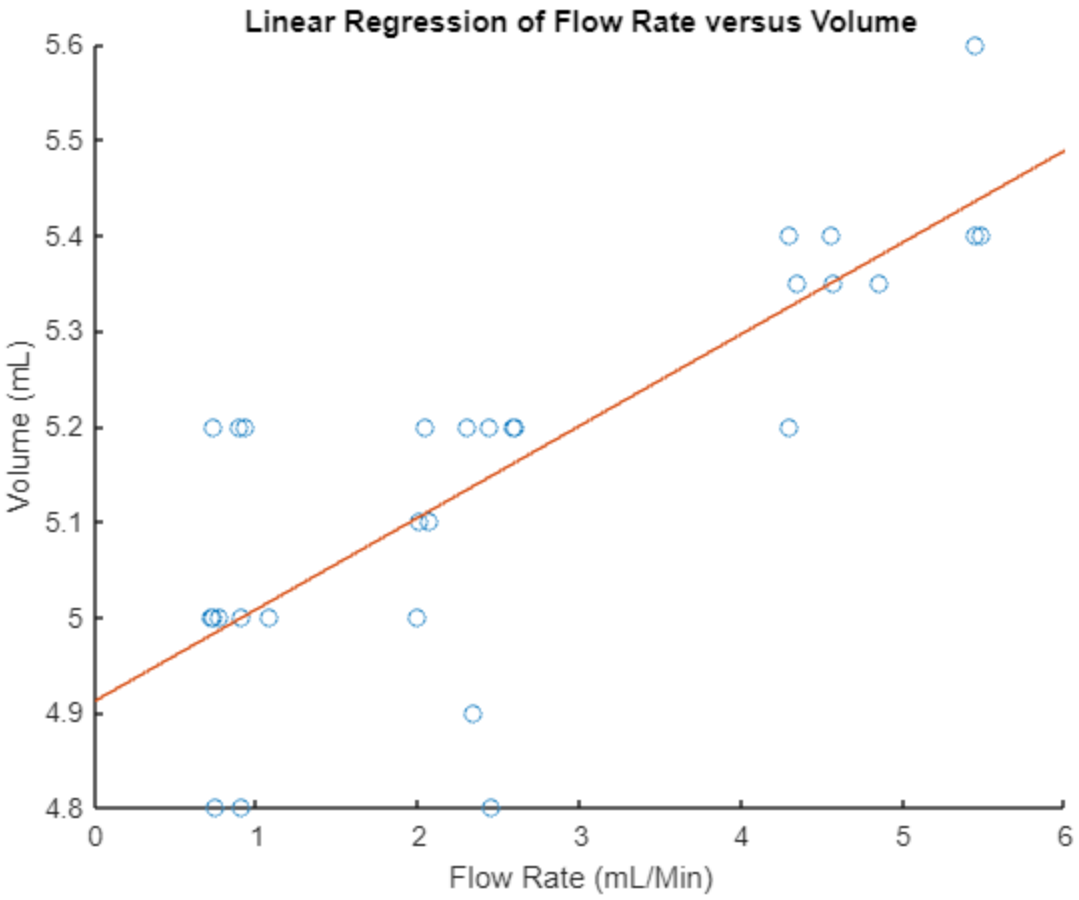


Figure 39. Linear Regression graph of drip sensor measurement of flow rate versus actual volume delivered

The team used Matlab to perform statistical analysis, such as a linear regression seen in Figure 39 above, to see if the device drip sensor was measuring flow rate and volume correctly. The two variables, “Flow Rate (mL/Min)” and “Volume (mL)” are correlated with each other as the P-value is 0.000 which proves that the two variables are dependent on each other (probability of null hypothesis that they are NOT correlated is 0). The R-square value is 0.6160 which depicts that values recorded from testing are fitting the model and the regression line. The R-square is not an ideal value that the team expected, however this could be countered with improving the light settings in the drip sensor or the high pass filter that the team developed.

5.3 Pinching Mechanism and Excess Volume Administered Testing

Pinching the tube to force the flow to completely stop is an important aspect of our device, so it was necessary to test it and make sure it worked properly. To test the pinching mechanism, the team set a stopwatch to measure the time it took for the motor to pinch the tube, while also noting if it was able to completely stop the flow of liquid from running through the tube. There were 15 trials, which yielded an average pinching time of 26.08 seconds. The data obtained from these trials can be seen in Appendix C. It was also shown that the motor provided enough torque to fully pinch the tube shut every trial.

Once the team ensured that the motor could stop fluid flow, we had to measure the excess volume being administered while the motor was running to pinch the tube. To complete this testing, 15 more trials were set: 5 at slow rates, 5 at medium rates and 5 at high rates. The desired volume was set to 2 mL on the device, although this was only used to get the device running. Much like the volume accuracy testing, the flow rates were similar. Slow flow rates ranged from 0.5 - 0.9 mL/min, medium ranged from 1 - 1.8 mL/min, and high ranged from 2 - 2.7 mL/min. Right after the green LED turned on, signaling the motor to pinch the tube, the end of the tube, where the liquid came out, was placed in the graduated cylinder and the stopwatch was started. While the time was being recorded, the volume in the graduated cylinder was also recorded to see the excess volume being administered after the desired volume had been reached, and while the motor was running to pinch the tube. The average excess volume above the desired volume at slow, medium, and high rates was about 0.71 mL, 1.36 mL, and 2.22 mL, respectively. The exact volumes for each trial can be seen in Appendix C.

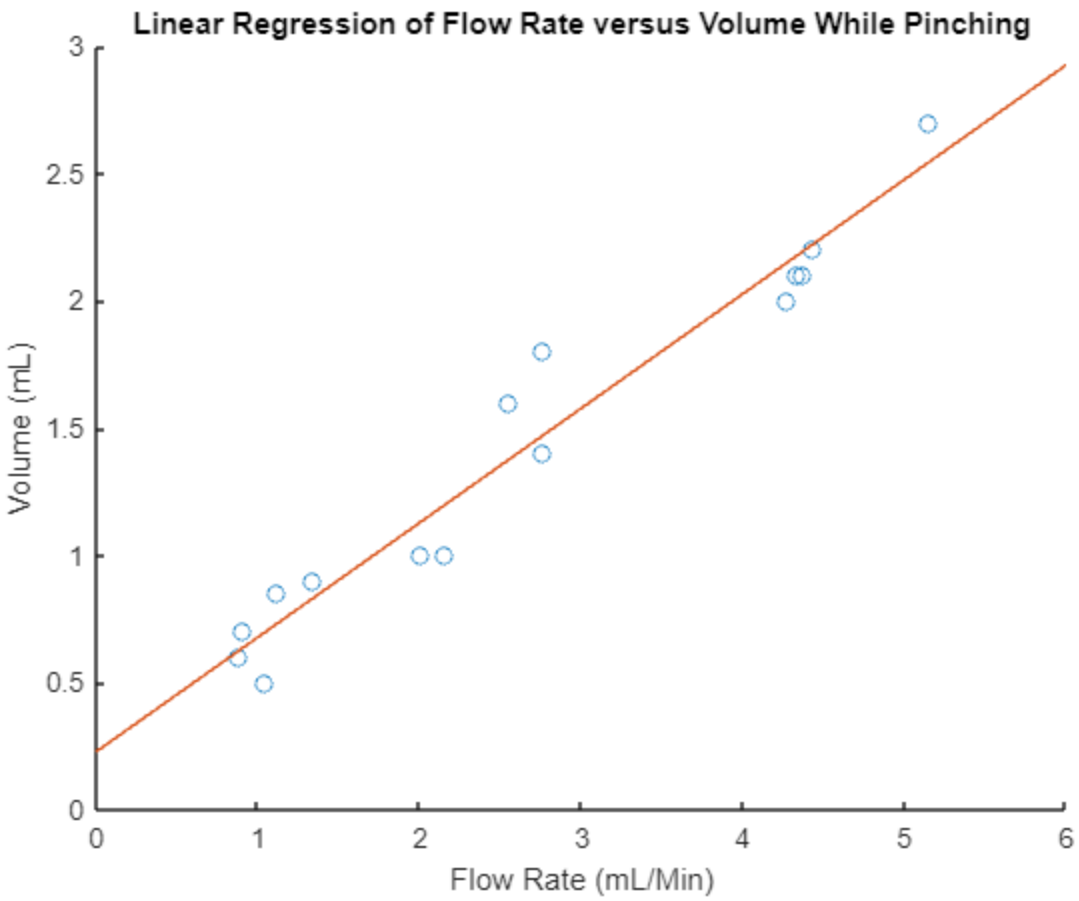


Figure 40. Linear Regression graph of flow rate versus actual volume delivered while the device is pinching

The team used Matlab to perform statistical analysis, such as a linear regression seen in Figure 40 above, to see if the device pinching mechanism pinched the tubing closed while measuring flow rate and volume correctly. The two variables, “Flow Rate (mL/Min)” and “Volume (mL)” are correlated with each other as the P-value is 0.000 which proves that the two variables are dependent on each other (probability of null hypothesis that they are NOT correlated is 0). The R-square value is 0.9480 which depicts that values recorded from testing are fitting the model and the regression line. This R-squared value shows promise that the design works and potentially can be tuned by improving the code that activates the motor to pinch the tube.

6. Design Validation

Our team took many factors the user wanted into consideration when creating this device, so it was important that the final design would be able to meet the customer's needs perfectly. The specifications we considered and our explanations of each are given below.

6.1 Specifications Validation

6.1.1 Administers Volume Accurately

As stated before, one of our main goals for this device was for it to administer the same amount of fluid as the desired amount. From volume measurement accuracy tests that were completed, along with the pinching mechanism testing, the team was able to get data on how accurate the total administered volume was to the desired volume. In Table 18 below, the final volume delivered is represented as well as the percent error. For the data in this table, the average volume measured for slow, medium and fast flow rates was added to the average excess volume administered while the tube is being pinched. As the flow rate increases, the amount of liquid above the desired volume increases as well, increasing the percent error. The flow rates are based on the researched feeding flow rates range for premature infants.

Table 18. Total Volume Administered Data Based on Flow Rate for 5 mL testing

Flow Rate [mL/min]	Slow ~ 0.5	Medium ~ 2.0	Fast ~ 4.5
Total Volume Administered [mL]	5.73	6.45	7.605
Percent Error [%]	14.6	29	52.1

The scenario done during the team's tests is not a likely scenario to occur in the clinic. From the interview done with Dr. Eunice at the Regional Eastern Hospital in Ghana (more information in Appendix D), the feeding regimen for premature infant feeding starts at 30 mL and increases daily from there. The team then used the excess volumes achieved from the experiments run, and calculated the percent error that would cause in 30 mL feeding, which is the lowest feeding administered in the clinic. This information is shown in Table 19 below, where the highest percent error achieved with 30 mL is at the fast flow rate, that being 8.68%.

These percent errors would only decrease as the feeding increases, as the excess volume administered as the tube is pinching would not change if the volume of feed changes and the error from the volume measurement accuracy does not change as well.

Table 19. Total Volume Administered Data Based on Flow Rate for 30 mL testing

Flow Rate [mL/min]	Slow ~ 0.5	Medium ~ 2.0	Fast ~ 4.5
Total Volume Administered [mL]	30.73	31.45	32.605
Percent Error [%]	2.43	4.83	8.68

Although the most used flow rates would likely be slow for premature infants, which yields higher accuracy, improvements could still be made. The code could be edited to account for the volume administered while the tube is being pinched by incorporating the known time it takes to pinch the tube and the already calculated flow rate. This would lead to the motor being activated earlier, pinching the tube at the exact time the desired volume is reached.

6.1.2 Affordability

Another specification our team considered was the affordability of the final device. Our goal was to keep the cost of the device under 100 USD to make sure clinics in LMICs would be able to buy this device. In the end, the cost of the device came out to 65 USD which meets and even exceeds our initial specification. When thinking about this device in a professional setting and manufacturing, mold injection will likely be used to create the device. This will cause the price of the device to increase slightly, but we hypothesize the price will still be under 100 USD. The prices we used in our cost analysis came from amazon. When manufacturing the devices in the future, we would likely buy components in bulk from the manufacturer, minimizing the cost of the device.

6.1.3 Reliable Power Source

Through interviews conducted with clinicians, our team found that power outages are very common in clinics in Ghana, so one of our specifications was to have our device include a reliable power source. From testing that was done, the battery was successfully able to power the device without any problems. Although our team was not able to test how long the battery would

last, from the information we gathered, we hypothesize the device will be able to last two full days only using the battery to power it. In the future, formal testing should be done to make sure this information is accurate by running the device non-stop and observing how long it is able to last.

6.1.4 User-Friendly

Our team wanted to make sure the final device was easy for clinicians to use after some basic training on how to use it. Although we were not able to test the user-friendliness during the scope of our project, our team did come up with a testing plan that can be implemented in the future. The device will be taken to clinicians and a basic training session will be given. Once that is completed, we will ask the clinicians to set random volumes and run the device. A survey will then be given to find out how simple they thought the device was to use and any comments they have on what can be improved. From there, we can understand how user-friendly the device actually is and figure out ways to improve it.

6.1.5 Regulates Flow Rate

Another specification the team initially had was to create a device that regulates flow rate. Due to time constraints, the team did not get to address this specification. Currently, the device monitors the flow rate but does not automatically regulate it. To regulate the flow rate in the device's current state, the roller clamp must be manually adjusted to either decrease or increase the fluid flow. The team suggests this specification be focused on in future project teams. More details about this specification can be found in section 8.2.1 Motor Programming.

6.1.6 Ability to Measure Drip Rate

The final specification the team had for the device was ensuring the device had the ability to measure the drip rate in order to monitor the flow rate of the liquid. The team used a laser diode, photoresistor, and high pass filter to count the number of drops that passed through the laser beam and monitor how quickly the drops passed. The team ran multiple tests to verify that the drip sensor was monitoring the flow rate correctly. The testing data for the drip sensor can be found in section 5.2. As shown by the data, the device does have the ability to measure the drip rate accurately.

6.2 Economics

One of the main goals of the project was to build a device that costs under 100 USD. While ordering components the team considered the costs and the availability in Ghana. The price of each component of the device is based on the costs from the parts ordered from Amazon. Many components were ordered in bulk or in packs with multiple components. For these components the price was divided to get the individual component price then multiplied by the quantity needed for our prototype. These estimated prices are reflected in the "Cost (USD)" column. For the smooth metal rod and threaded metal rod, the price is calculated based on the price per mm of rod length and multiplied by the length needed for the prototype. Another material of note is the polylactic acid (PLA). PLA was the main source of prototyping and manufacturing and the cost is estimated based on filament diameter, the length of filament used, and the cost of a 1 kg filament spool. The team used Omni Calculator to determine the final cost of 3D printing.

Table 20. Cost analysis taken from purchases the team made from Amazon Market

Part Name	Quantity	Cost (USD)
LCD 124x64 Screen & I2C Module	1	12.99
12 Volt Stepper Motor	1	2.83
5v-50v Buck Converter	2	3.14
Momentary Push Buttons	4	5.33
RGB LED (4 pins)	1	0.1
Laser Diode	1	0.63
Photoresistor	1	0.17
Stepper Motor Driver Board	1	2.8
Rocker Switch	1	1.2
Arduino Nano	1	9
Proto-Board	1	2.5

9 Volt Battery Clip	2	1.75
220 Ohm Resistor	3	0.18
1.5k Ohm Resistor	1	0.06
2.2k Ohm Resistor	1	0.06
Limit Switch	1	0.58
9 Volt Batteries	2	3.52
Smooth Metal Rod	20.32mm (0.03 per mm length)	0.61
Threaded Metal Rod	38.1mm (0.06 per mm length)	2.29
Jumper Wires	30	1.5
PLA	71.61m (1.75 Diameter & 24 USD/1kg Spool)	9.57
Magnets	7	0.69
Total Prototype Cost		65.5

Along with a low cost, our device is also able to pinch standard IV tubing as well as other tubings that might be used during feeding.

6.3 Environmental Impact

The environmental impact of this device would mainly come from gathering the materials to build this device and manufacturing it. The transportation to ship these materials to the location it is being built as well as having a factory to assemble the device will definitely have an impact on the environment. Electricity is also used to run the device when it is available, which is another aspect that could impact the environment. In addition, this device utilizes plastic feeding bags and feeding tubes, which are essential to achieve the design goal. Lastly, the device uses two 9V batteries which would be thrown away once the batteries have died. Disposal of the batteries would have an effect on the environment.

6.4 Societal Influence

Another important factor our team considered was the societal influence this device would have in LMICs. Currently, in LMICs, it takes a significant amount of time to feed a premature infant, because it is done by hand. There are also not enough clinicians to the amount of infants in these clinics, meaning not all infants are getting the attention needed to be successfully fed. With this device, it allows clinicians to leave an infant while feeding and care for another in the time it would have taken to feed an infant by hand. The health and wellbeing of premature infants in LMICs will be greatly improved and clinicians will be able to care for more infants at once.

6.5 Political Ramifications

The political ramifications of this device would be very minor. Based on our interviews with the engineers and clinicians from the hospitals in Ghana, they were all excited about the device and its functions. One concern related to this topic our team considered was Ghana's FDA approval process. However, if all the stages of the approval process are followed adequately and the proper testing is conducted, there should be no negative political or governmental issues. Beginning Ghana's FDA approval process is one of the team's recommendations for future work.

6.6 Ethical Concerns

LMICs do not have the resources that developed countries have when it comes to medical devices and healthcare. Any individual should be allowed access to whatever medical care needed, and that is the main reason this device was built. This device will be a low cost and easy to use solution when it comes to external feeding in LMICs and will allow for more premature infants to get the help they need.

It will also allow clinicians to care for the infant's instead of having the mother's step in because constant clinician input will not be needed with the device. Mother's do not have the knowledge or experience to deal with issues that can go wrong during feeding because they do not have formal training. With this device, mother's will not have to feed their infants anymore because clinicians will be able to take care of many infants at once.

6.7 Health and Safety Issues

Due to the nature of the device, health and safety issues were a top priority which the team heavily considered throughout the design process. One main potential safety issue that can occur when tube feeding premature infants is the formula can get clogged in the tube, the flowrate can become too fast, or the infant's bodily reaction can cause the flow of formula to become disrupted. These are all potentially very serious issues to be aware of and can occur during any standard tube feeding process. To help alert clinicians of an issue and make the issue more visible sooner the team incorporated an LED light system. In the case of an error, the LED on the team's prototype would turn red. The programming for this alert is based on the flowrate so if the flow rate becomes higher than a certain rate which could be dangerous for a premature infant then the LED turns red. While the device is working properly the LED is blue and once the feeding has been successfully completed then the LED is green. The goal of the LED is to allow clinicians to quickly assess the state of the device and infant by quickly looking at the color of the light. Future iterations could be done to this LED feature so that the LED would turn red for more dangerous problems that could occur in addition to a fast flow rate. The team ran tests to ensure that the LED did in fact turn red once the flow rate exceeded a certain flow rate and also made sure that the green and blue colors appeared at the appropriate time.

6.8 Manufacturability

The team used 3D printing as the main source of manufacturing for prototyping and testing during the design process. 3D printing is developing physical models or objects from three-dimensional coordinates and digital modeling. This process is later translated to using hardware and a machine to lay out layers of material, such as polylactic acid (PLA). Each layer is laid on top of each other and forms into the desired object by the user. The team used both SolidWorks (CAD) to create digital models of the device which was translated into a G-code file using a slice software, CURA, to allow the 3D printer machine, Creality Ender 3, to understand the coordinates needed in the three-dimensional plane to perform. The team were able to use 3D printing successfully to manufacture all of the necessary parts needed for the project without any major issues. 3D printing was a suitable and efficient method for manufacturing due to the availability of having a personal 3D printer as well for time efforts of continuous prototyping.

Using 3D printers for manufacturability was justified from discussing with the Ghana University Biomedical Engineer team that was also working on solving the project goal of making an affordable automated feeding device. The Ghana team's main source of manufacturing was also 3D printing at the current moment as the team was also in the prototyping phase. It was difficult to justify other options of manufacturability due to time constraints and the early phases of prototyping.

6.9 Sustainability

When looking at the sustainability of the device, we can first look at the power source. The device will be able to run on electricity as well as batteries. According to our advisor, Professor Mensah, there are many power outages in LMICs that occur at random times, meaning there needs to be some way the device can work without electricity. This is why our team decided to add batteries to the device, allowing it to run for up to two days on them. The device is also reusable, cutting down on the amount of plastic that needs to be used. We also made sure to use materials that are accessible in LMICs, making it easy for individuals to create this device in their own country without the materials costing a fortune. In the future, we would like to use recyclable materials to build the device, allowing it to be better for the environment. For certain components it is easy to get replacements online or in stores, however for more complex parts they will be less accessible.

7. Discussion

After testing the device, comparisons to the current methods were made and are written in the section below. The chapter will also go more into depth of the issues encountered throughout the scope of the project, including software and manufacturing issues.

7.1 Comparison to Current Methods

The feeding methods to provide the needed nutrition to premature infants vary from country to country. The current methods used in Ghana to feed premature infants require mothers to hold a syringe or cup for long amounts of time while gravity transports the formula to the infant. In the United States a Kangaroo Joey device is used to flow the liquid to the baby. For low to middle income countries the current methods used in both countries have negative aspects. For example, the current method used in Ghana requires mothers to complete the feeding by holding a syringe. This feeding process needs to be repeated multiple times a day and each feed is a slow and time consuming process. In addition to taking up a lot of the mothers' time the current method has no alert system if an error occurs. Even though the current method used in Ghana has some problems associated with it, the method used in the United States cannot be implemented into low to middle income countries as a quick solution. The kangaroo joey device used in the United States is an expensive device that costs from $500-$2,500. In addition to the high initial costs, expensive proprietary tubing is also required for the kangaroo joey system. In other words, a very specific type of tubing is needed for the kangaroo joey system and purchasing that type of tubing would be another added cost which many hospitals can not afford in low to middle income countries. The team recognized the negative aspects of both current methods to develop a prototype that addressed all the issues. The team created a device that monitors the flow rate, delivers a selected volume of liquid, and has an LED light alert system. The LED light system allows clinicians to quickly look over at the color of the light on the device and assess the state of the device and infant. The LED is programmed to be red when there is an error, such as flow rate being too fast or clogging in the tube, both of which are dangerous for the baby. The LED is blue when the device is functioning properly and green once the feeding is completed and the selected volume has been reached. The LED light system addresses the no alarm or alert system used in the Ghanian current feeding method and can

potentially help clinicians detect a problem earlier. The team was also mindful of the cost of the device and set a project goal of creating a device that is under $100. The team successfully met the goal by carefully choosing the materials and setting the design specifications so that the overall device created by the team cost $65 to build. The low cost of our device allows it to be a feasible solution for low to middle income countries. Additionally, our device works with multiple different types of tubing, including the tubing used in Ghana, which is unlike the standard kangaroo joey system which requires expensive proprietary tubing.

7.2 Issues Encountered

7.2.1 Software

When programming the device, multiple issues came up. One issue the team encountered was related to the needed bootloaders. Switching between different types of Arduino nanos requires different types of bootloaders and drivers than the Arduino Unos the team practiced on before assembling the entire device. If the correct bootloader is not selected in the Arduino IDE software, then the code will not upload to the board. This issue is similar to the drivers, where a specific driver had to be selected, downloaded and used for different Arduino processors. To resolve the issue, the team had to research the required driver, and then download the driver to the computers used to upload the code.

Another issue encountered related to the coding portion of the project was the specific Arduino libraries. Arduino IDE contains different libraries that contain built-in functions to help read components' values or program them to complete different tasks or actions. Unfortunately, the team was not aware of libraries that can be "blocking" or "not blocking". When programming the motor to run, the stepper library called 'myStepper' was used. During the time the motor was running, the sensor could not read drops falling through the drip chamber. The team later learned that blocking libraries, such as 'myStepper', blocked the code from completing other tasks simultaneously. Other libraries then had to be explored, causing the code to be mostly rewritten using a non-blocking library.

Lastly, another issue that the team faced was that occasionally the computer port could not be found on the Arduino IDE program, that is selecting the right port to upload the code to (eg. COM13). This was later found that the battery cannot be turned on when plugging the nano

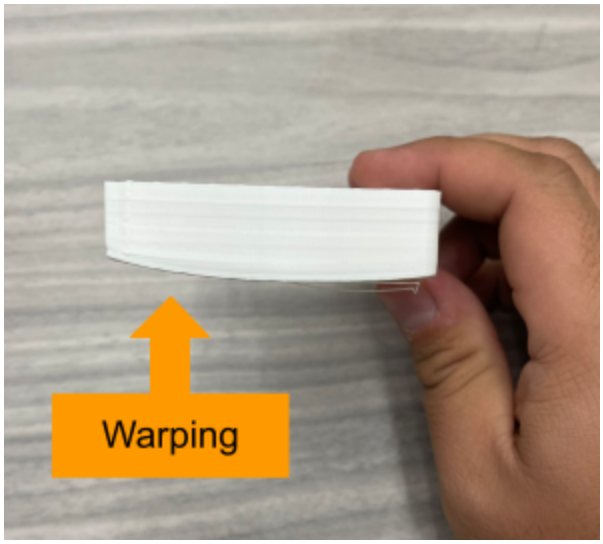
into a laptop, as the computer sees the power as a threat. Another reason behind this issue was also found to be shortages within our circuit. For example, one of our LCD screens had an internal issue that connected its power and ground ports, shorting the circuit. Although the team faced multiple issues when trying to program the device, we learned a lot about how this software works and ways of debugging that we may not have learned before. These issues also helped the team learn of ways to further improve the device's code for future teams, such as exploring more non-blocking libraries and ways to alert the user when specific errors occur, such as a circuit shortage or specific component error.

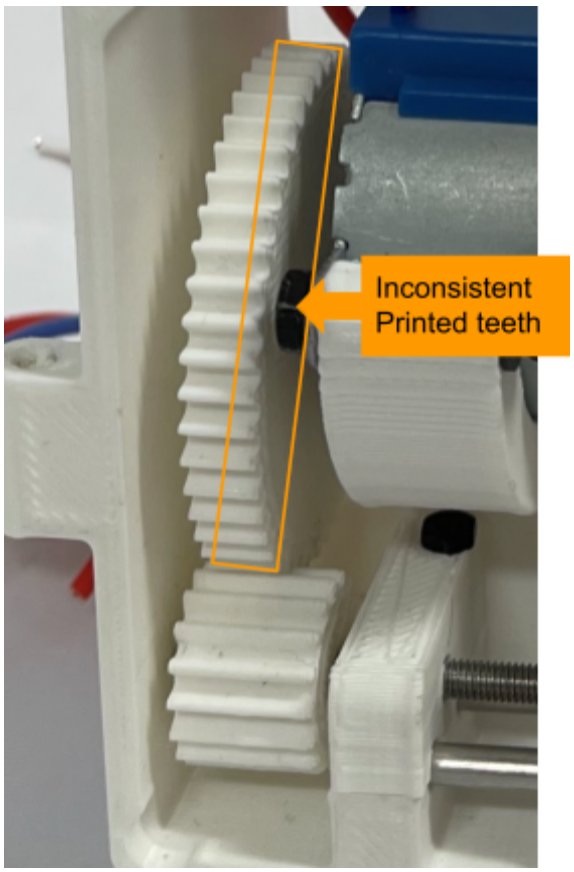
7.2.2 Manufacturing

The team encountered multiple complications during the design process of manufacturing prototypes. These complications consist of additive manufacturing processes as well for the diagnostics of the prototypes. Issues encountered with manufacturing were resolved, but noted here in this section. During the design process the team came to a conclusion that the design will need to be redesigned for manufacturability in certain components of the device such as the pinching mechanism. Overall, 3D printing satisfied the needs of the team and provided a general foundation for the design process. However, there were complications of manufacturing through 3D printing, shown in Table 21 below.

Table 21. A list of complications that the team encountered during the design process

Complications	Explanation
Warping	3D printers have a consistency of prints being warped or twisted out of shape from the bedding of the machine as seen in the picture below. This causes certain parts of our design, such as the back cover to not flush flat for embedded screws. An example is shown below:

	
Inconsistent Definement	In digital modeling, it is necessary to consider if 3D printers' performance can handle defining details. If not it will cause either parts not meshing together or complications of print failures. For example: The limit switch in the device needs to be at a certain distance from the pincher piece and the only thing securing the limit switch is two tiny prongs that are in 2mm diameter. Another example is the gear teeth being undefined as the 3D printer was not capable of detailing in large teeth quantities. An example is shown below:

	
Incorrect Tolerance	In digital modeling, it is also considered tolerance as 3D printing causes a fluctuation of sizing in perspective of what 3D printers are used. It is essentially the acceptance of deviation for parts interlocking each other.
Material Selection	Certain 3D printers can only print certain material due to nozzle performance. However, various materials have specific modulus yield and can provide the necessary strength and durability. The project used PLA as the main base but would like to go with PETG filament or basis.

These constraints kept the team to continuously print and readjust the sizing of the design during the peak of manufacturing in C-term. Even though the team used a 3D printer as its main source of manufacturing there are always improvements in making quality better. For instance, mold injection is the primary source of manufacturing for most companies when dealing with

polymers plastics as a basis for products. However, mold injections require a metal casing of the object or model. This requires extensive detail as the finest mark on the metal casting can cause issues in the manufacturing process. Mold injection was considered however, there were design constraints that prevented mold injection casing to occur. This was also considered near the end of the project timeline, therefore was not suitable to perform any advancements in the new objective.

One of the major components of this project are wires. In the initial state of the project, when the team was still creating the circuit of the device, one of the major issues encountered was wiring and keeping the wiring stable long term, since the team made use of breadboard and loose jumper wires. Once the final circuit was decided and the project moved on to a breadboard with soldered wires, some issues were still encountered. For some of the parts, like the LCD screen, it was not possible to solder all the wires on, since they connected to the I2C module. There was a clutter of wires that the team experienced difficulty to manage as well for maintenance when testing turned into failure. The wires were constrained due to the position and location of components in the device such as the limit switch in a confined small area. This issue potential may have been solved by redesigning the case and chassis of the device however, due to time it was not complete. Below is Figure 41 that displays 3D models and printed pieces that were used to organize wiring to a confined area, this allows available areas to be easily accessed such as the pinching mechanism, however, maintenance on the wires were difficult to take out. Wires were needed to be completely removed or extended due to complications in diagnostics and manufacturing capabilities.

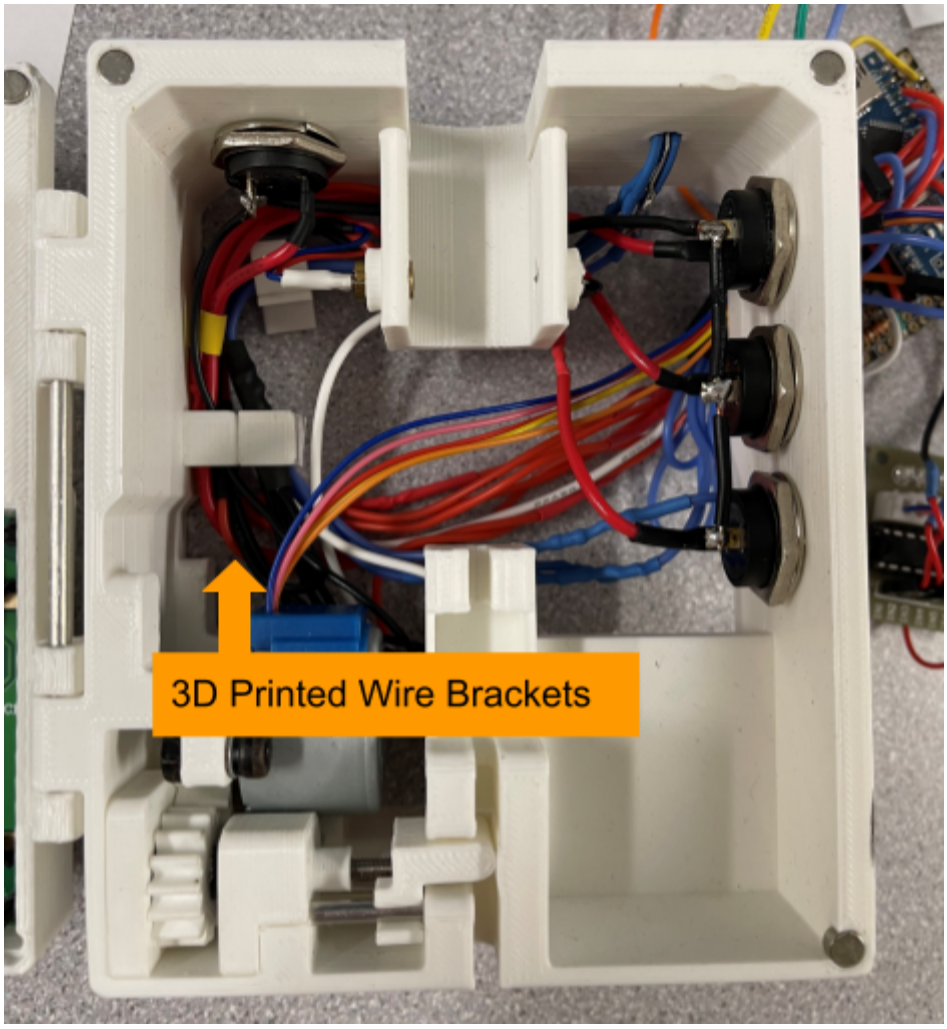


Figure 41. Front view of a manufactured prototype consisting 3D printed brackets for wires to organize

8. Conclusion and Recommendations

8.1 Conclusion

The goal of this project was to create a low-cost feeding device for low to middle income countries that was user-friendly and accurately monitored flow rate and volume being administered. The team accomplished this by creating a device that only cost around 65 USD and has a simple design that is user-friendly, such as color coded buttons and a user interface LCD screen. Based on our testing results, the volume delivery accuracy yielded great results, only having a 2% error at slower flow rates, which are more likely to be used than higher flow rates. When it comes to the volume accuracy, additional testing on larger volumes should be done. With the information collected from these trials, we can change the code to allow for a better volume accuracy. We could code the device to pinch sooner to minimize the amount of nutrients that go to the infant after the desired volume is reached and we could also adjust the drops per mL of fluid based on the flowrate. Through the course of this project, the team learned a lot about the design process and the research that goes into manufacturing a medical device, along with the time and effort it takes to fully understand the customer needs. After interviewing and messaging clinicians and engineers from Ghana, the team was able to get valuable feedback that was partially included in the device and in future recommendations for future teams. Overall, the team was highly satisfied with the outcome with the project.

8.2 Recommendations

Although our team had many advances throughout the project and created a successful device, there are some things that could be worked on in the future. At the time the team had created many iterations for each component, but there are still things that could be refined when it comes to the sensor, motor, wire management, nutrition reservoir, and Food and Drug Administration (FDA) regulations in Ghana. This section will talk about all of those aspects and how exactly they can be improved.

8.2.1 Motor Programming

Adjusting the motor to control the flow rate of the liquid could add another positive aspect to the device, because the flow rate is already monitored and calculated, this could be used to set the position of the stepper motor to set a desired flow rate. A process of motor calibration could be completed when the device is first turned on to obtain the initial position of the motor, and use tested calculations to move the motor to a set location that would control the flow rate of the liquid flowing through the tube. The live flow rate measurement would be used and then adjusted to maintain the desired flow rate. The partial pinch position would be determined by the current location vs a chosen setpoint which could be the location of the limit switch. Changing the code for the motor to these aspects will provide more options for nurses to easily change and set up flow rate. This will reduce time for clinicians to set up feeding for babies, but also reduce the time to transfer feeding from station to station. Another improvement that could be added to the motor is speeding up the pinching process to improve the volume delivery accuracy.

8.2.2 Wire Management

Wire management is an aspect of the device that can be improved upon. There are many wires in our design that connect to various parts which can lead to a cluttered and unappealing prototype. The wires could be improved by color coding each component so that it is easily noticeable by which wires to focus on when maintenance is done. This can also be expanded to having wires with labeling such as “Ground Wire” or for the power line to the stepper motor driver board, “SM-Power” to allow engineers to locate and manage wires to the correct ports or circuitry. In addition to redefining the designs of the device to be more aesthetically appealing, wire manager parts can be made to be able to run lines of wire through without blocking any sort of major PCB panel or tangle into anything major. This can be directed into two parts of having wires that are in the main chassis be directly soldered onto the Arduino Nano as for the wires that are attached on the back cover can be detached. The team attempted this concept, but would still need some future work on how to run wires properly due to the respected areas of boards and components. This will eliminate the need for cutting wires as engineers will be able to have the ability to easily check circuits for any shortages or mistakes made in the process of manufacturing. This will also provide more available space for any upgrades in the future such as a new and more efficient motor.

8.2.3 Reservoir

One recommendation for a future improvement to the design would be to design a reusable formula or breast milk reservoir with an openable cap that could also be securely closed. This type of reservoir would allow clinicians to open the reservoir and pour in the formula or breastmilk, and then close the reservoir again. Currently, the nutrition reservoir on the device is an IV bag. This type of reservoir does not have any easily accessible opening so that nutrition can be poured in. A reusable reservoir would be more cost effective for the hospitals, more convenient for the clinicians, and more environmentally friendly.

8.2.4 Food and Drug Administration (FDA) Research

In order for this device to reach the market, it is necessary that it meets all FDA regulations relevant to this scenario. Since the context of this project is in Ghana, the team recommends filling out the application for that country and performing clinical trials there. In the initial stages of this project, that process was researched and some key requirements should be kept in mind. First, the timeline of this process is an important factor and was the major reason the current team was not able to move forward with the application. Once the clinical trial application is sent in, the approval process itself takes 60 working days. However, before reaching the state of filing for approval, there is a lot of additional paperwork that needs to be gathered to do so, which is also very time consuming. Some of these forms needed include external committees, such as an Institutional Review Board (IRB) and a Good Manufacturing Practice (GMP) certificate. Following the policies of Ghana and filling out this application in order to allow this device to reach the targeted population would be extremely beneficial for this project.

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Appendices

Appendix A - Interview notes from previous MQP group

Ridge Hospital Interview conducted by Audrey Tetteh on October 2, 2020 with Head of NICU, Dr. Abrakwa.

- Feeding Methods

Feeding is manual and they use the NG tube to do that, so what happens is that the tube is inside the body of the baby then they use a syringe filled with the volume of formulae or breast milk by via of gravity to push the formula through the tube into the body, during this whole process the nurse has to hold the syringe and this can be stressful at times. Now pertaining to feeding as well there were other alternatives which were available in the hospital and that is using a perfusor, so this one is kind of automated. For this you put the syringe into a certain area, the syringe is then pushed and based on the amount you set and all that the baby would receive its food however with this one there are few in the hospitals.

- Feedback

Speaking to him pertaining to what our project entails and asking about qualities of the expected device, he said 4 major things they would like to see are something that is easy to use by the health professionals, easy to maintain, low cost and easy to sterilize and reuse.

Ridge Hospital Interview conducted by Nathaniel Adibuer and Audrey Tetteh on October 7, 2020. Interviewees included Dr. Abrakwa (head of department – responsible for ward checks of NICU) and nurses from the NICU.

FEEDING MODE IN RIDGE HOSPITAL

According to the nurses in Ridge hospital, preterms are fed by the following method due to the inability of them to suck on their own. Most of these preterms face conditions such as respiratory distress syndrome and birth asphyxiation. The method used is based on how critical the condition of the preterm baby is.

1. If the case is very critical, such as birth asphyxiation, the NG tube together with the

perfusor is used and feeding is done continuously.

2. If the case is not that critical such as respiratory distress syndrome then the OG tube together with the syringe pump is used and feeding is done intermittently.
3. If the preterm's condition improves and it is able to have some kind of sucking abilities, then the calibrated cup is used.

According to the doctor in charge at Ridge Hospital, he says the syringe pump is the feeding instrument recommended by WHO for preterms. The perfusor is only used if the baby would need continuous feeding. Upon our observation at Ridge hospital, critical cases are far less than less critical cases.

1. OG TUBE/NG TUBE WITH A SYRINGE PUMP (Majority are fed using the OG tube)

The OG/NG tube together with a syringe pump is used in feeding the preterm babies. The syringe mainly consists of the calibrated container, the plunger and the kink. The calibrated container contains the breast milk, the kink prevents the backflow of the breastmilk and the plunger is used to pull in breastmilk into the container and also pump breast milk into the OG tube. The calibration ranges from 2 ml to 50 ml.

- PROCESS

The breast milk is expressed into the feeding bottle and kept in the fridge to be used whenever the baby is ready to be fed. The breastmilk in the feeding bottle is warmed to an optimum temperature and pulled into the syringe with the help of the plunger when it's time for the baby to feed. The end of the syringe is connected to the OG/NG tube and the breast milk moves into the preterm's stomach with the help of gravity. It takes about 5-10 mins for all the breastmilk to move into the baby's stomach. When the breast milk gets stagnant in the tube probably because of fats in the breast milk blocking the tube, the plunger is used in pushing down the rest of the breast milk into the preterm's stomach.

- PROBLEMS ASSOCIATED WITH THIS METHOD ACCORDING TO THE NURSES INTERVIEWED

1. Tubes can be blocked by fats in the breast milk.
2. Growth of microorganisms in the tube.
3. Infections may be introduced into the preterm's system because of how the syringe pump is handled.

2. CALIBRATED CUP

The warmed breastmilk is just poured into the calibrated cup and the breastmilk is passed into the preterm's mouth bit by bit till everything gets finished in the cup.

- PROBLEMS ASSOCIATED WITH THIS METHOD ACCORDING TO NURSES INTERVIEWED.

1. The baby might be aggressive in swallowing the food so the baby might end up aspirating.
2. The baby might vomit.
3. The baby might be aggressive and spill the breast milk.
4. It requires a skilled nurse to feed the preterm.

3. PERFUSER

It is used with the NG tube. Perfuser is not ideally used for feeding but the nurses in ridge use it as a substitute for feeding for preterms who will need continuous feeding. (We can read more on it)

- PROBLEMS ASSOCIATED WITH THIS METHOD ACCORDING TO NURSES INTERVIEWED.

1. The breast milk gets cold because the feeding is done continuously.

- THESE WERE THE CLIENTS (DOCTOR AND NURSES) SUGGESTIONS ON THE DEVICE

1. Devices should be calibrated.
2. Devices should not be big.
3. It should be simple to use.
4. It should be affordable.
5. It should have a reliable power source.
6. It should have some form of mechanical power aside from electrical.
7. Easy to maintain.
8. Easy to sterilize.

According to the nurses, female preterms survive more than male preterms.

- PATIENT RATIO

Nurses in the unit usually care for up to 6 infants at once. In other places like rural hospitals there can be as many as 15 infants to one nurse because of fewer personnel in those areas.

Appendix B - Volume Measurement Accuracy and Drip Sensor Verification

Slowest Flowrate - 0.5ml/min				
Trial	**Displayed Flow Rate on Screen at green light [mL/min]**	**Displayed Screen Volume at green light [mL]**	**Actual Cylinder Volume at green light [mL]**	**Volume Percent Error [%]**
1	0.935	4.98	5.2	4.417670683
2	0.91	4.98	5	0.4016064257
3	1.088	4.98	5	0.4016064257
4	0.75	4.98	4.8	3.614457831
5	0.735	4.98	5.2	4.417670683
6	0.913	4.98	4.8	3.614457831
7	0.898	4.98	5.2	4.417670683
8	0.735	4.98	5	0.4016064257
9	0.777	4.98	5	0.4016064257
10	0.728	4.98	5	0.4016064257
Average	0.8469	4.98	5.02	2.248995984

Medium Flowrate - 2.0ml/min				
Trial	**Displayed Flow Rate on Screen at green light [mL/min]**	**Displayed Screen Volume at green light [mL]**	**Actual Cylinder Volume at green light [mL]**	**Volume Percent Error [%]**
1	2.595	4.98	5.2	4.417670683
2	2.61	4.98	5.2	4.417670683
3	2.445	4.98	5.2	4.417670683
4	2.31	4.98	5.2	4.417670683
5	2.345	4.98	4.9	1.606425703
6	2.45	4.98	4.8	3.614457831
7	2.05	4.98	5.2	4.417670683
8	2.01	4.98	5.1	2.409638554
9	1.993	4.98	5	0.4016064257
10	2.07	4.98	5.1	2.409638554
Average	2.2878	4.98	5.09	3.253012048

Fastest Flowrate - 4-6ml/min				
Trial	Displayed Flow Rate on Screen at green light [mL/min]	Displayed Screen Volume at green light [mL]	Actual Cylinder Volume at green light [mL]	Volume Percent Error [%]
1	4.57	4.98	5.35	7.429718876
2	4.555	4.98	5.4	8.43373494
3	4.3	4.98	5.4	8.43373494
4	4.854	4.98	5.35	7.429718876
5	4.348	4.98	5.35	7.429718876
6	4.304	4.98	5.2	4.417670683
7	4.3	4.98	5.4	8.43373494
8	5.49	4.98	5.4	8.43373494
9	5.45	4.98	5.6	12.4497992
10	5.45	4.98	5.4	8.43373494
Average	4.4885	4.98	5.385	8.13253012

Appendix C - Pinching Mechanism and Excess Volume Administered Testing

Slowest Flowrate - 0.5ml/min			
Trial	Pinching time [s]	Volume while pinch [mL]	Flow rate [mL/min]
1	26	0.6	0.89
2	27.8	0.7	0.91
3	26.37	0.9	1.34
4	25.01	0.5	1.04
5	25.98	0.85	1.12
Average	26.232	0.71	1.06
Medium Flowrate - 2ml/min			
Trial	Pinching time [s]	Volume while pinch [mL]	Flow rate [mL/min]
1	25.27	1	2.016
2	25.98	1.6	2.55
3	24.69	1.4	2.76
4	26.19	1	2.16
5	27.23	1.8	2.76
Average	25.872	1.36	2.4492
Fastest Flowrate - 4-6ml/min			
Trial	Pinching time [s]	Volume while pinch [mL]	Flow rate [mL/min]
1	24.95	2	4.271
2	26.44	2.2	4.43
3	25.46	2.1	4.37
4	26.78	2.1	4.34
5	27.05	2.7	5.15
Average	26.136	2.22	4.5122

Appendix D - Dr. Eunice Interview Notes

1. Could you tell us a little more about yourself and your background?
    a. Currently medical officer - can do anything
2. Can you walk us through each step of how you feed the babies and what tools you use to do it?
    a. Recommend breastfeed 6 months exclusive after introduce introduce complementary feeds
    b. Premature babies are given formula through a syringe, 30 mL day 1, then 60, 90, 150, and 180 mL of formula
    c. Given breast milk if the mother can produce it
    d. Calculate the mL then put in syringe then connect to ng tube, pump it slowly, do not know the rate
    e. Premature is considered before 38 weeks, above 38 is full term
3. Are all formulas the same for each baby or do babies have different nutritional liquids?
    a. Each mother brings formula for their child, which is put into a stock area. This is then used for all babies
4. Would it be useful to have a reservoir that you could detach and place on different tubes?
    a. Ex. Then you could detach the feeding tube from the baby and move the large reservoir from baby to baby. Is this possible to do this or would it be useful?
5. Can the milk sit in the reservoir all day?
    a. No cannot sit overnight
6. Do you only pour single servings of milk for each feed?
7. Do you use your tubing on different patients or are they single use? Meaning do you clean them and reuse them or just throw them out?
    a. Single use
8. How many times do you feed the infants per day and what are the time intervals between the feeds?
    a. Preterm: 12 times per day (full 24 hours, not just at night)
    b. Full-term: 8 times per day
9. What is your method of feeding the baby? Do you use a syringe to hold the milk and have it be gravity fed or do you use a syringe with a plunger and gently press out the milk or do you do both? Do you use a different type of reservoir besides a syringe or is it always a syringe?
    a. Open-ended syringes are used and held by the mother. This uses gravity to feed the baby
10. How many times a day would you use this device?
11. Explain how our device works and how we think it could be used and then ask how you would use this device to make it most useful to you?
    a. It would be useful to have a reservoir that holds maybe 200 mL
    b. Big reservoir to feed multiple babies
12. How do the different feeding tubes connect?
13. What type of power source do you think would be better? Batteries that can be replaced or plugged into the wall?
    a. Batteries because there are lots of power outages
    b. Would like it to be possible to be connected to the wall and batteries
14. What kind of batteries are common in Ghana?

    a. Good ones: energizer
        i. Any type
        ii. Use aaa batteries
    b. Our batteries are available there too
    c. Double aa batteries are very available we should use those

- Formula goes mostly to preterms
    - Formula comes in powder form
    - Cannot keep formula overnight
    - Feeding Amount
        - Day 1: 30 mL per day
- How many babies are in one hospital room?
    - 30 babies
    - 2-3 clinicians
    - The mothers feed the babies - the ones who use the syringe
- Puts exactly the about of formula in the syringe, the baby cannot give give more than the amount they're supposed to
- Mothers also bring other supplies for cleaning purposes
- Hospitals do not provide the formula
    - Lactogen formula
    - Naan?spelling? Formula
- A bigger reservoir is more useful than a syringe
- After the feeding the syringe is thrown away
- The drip chamber and tubing can be sterilized at the hospital
- Breast milk device is exclusive for each baby
- Formula could be shared with one device with one large reservoir
- Best to have one device per baby
- Device display should be in english
- There are ring stands there also
- They have a three way valve so we could use one device to feed multiple babies
    - This is used for blood transfusions
- Tubes are run through the nose

Appendix E - Links to External Folders

Coding:

https://drive.google.com/drive/folders/1hSMI8uUG5EKZSiMuC8LPvkV5OPD8UVor?usp=sharing

SolidWorks:

https://drive.google.com/drive/folders/114HyjsaOsuDQsT5IyiKR0zWEzLWQL9Sb?usp=sharing

Images and Videos:

https://drive.google.com/drive/folders/17GlCDflBahkPxOZH_YCxMDP0TCXhc4d8?usp=sharing

Appendix F - User Manual

Turning the Device On and Off

Use the switch on the top of the device to turn the device on and off. If a new specific volume must be delivered, restart the device and reselect the volume needed.

Selecting the Volume

Use the three buttons on the side of the device to select the volume to be administered. The top black button will increase the volume, the middle black button will decrease the volume, and the bottom green button will select the volume displayed on the screen as the volume to be administered.

Pausing the Device

The red button on the device will pinch the tube closed to stop any liquid from flowing through the tubing. Simply push the button again to un-pinch the tube, which will allow liquid to flow through the tubing again. Using the pause button will allow the device to remain on and store the value of the administered volume.

Calibrating the Device

This device auto-calibrates itself when turned on. If the lighting in the room is to change, such as a power outage, the device will not read the volume administered correctly. The device will also

not read the volume correctly if the ambient light is not shown during the calibration process. Make sure the device is started in the position and lighting it will be used in, and step back after turning the device on to allow it to register the ambient light correctly. To recalibrate the device, turn the device off and back on. After, the user can select the remaining volume to be administered.

Changing the Batteries

The screws on the back cover can be removed using a screwdriver. Two new batteries can then be inserted, and the cover can be put back on.