Low-Cost Infusion Pump

Engineering World Health

Design Competition, 2019

University of Minnesota Twin Cities Chapter

Problem Definition

Pediatric IV delivery systems are virtually non-existent in third world hospitals. Due to being a separate cost, adult-sized equipment is often deemed more valuable and adapted to pediatric use, to the best of the hospital's ability. Nonetheless, pediatric patients often receive damaged IV lines and inconsistent medication delivery due to the infusion pumps' large size. Therefore, pediatric patients are susceptible to infections that are treatable with basic fluids, such as pneumonia. According to UNICEF, pediatric pneumonia kills 3 million children worldwide each year. Of those 3 million children, it has been found to contribute to 750,000 and 1.2 million neonatal deaths.[1] In addition to pneumonia, an appropriately sized infusion pump can assist in the prevention of dehydration, which is the second most prominent cause of death for five-year-olds and under.[2] Overhydration can also occur if pumps are not regulated, which is why a programmable pump that ensures a consistent rate of delivery is ideal.

Adult infusion pumps either deliver medications at a rate that a pediatric patient cannot tolerate or damage IV lines beyond further usage. In addition, usable pumps may not be on hand due to the hospital not having access to repair or supply services. With a low-cost infusion pump that is built from accessible local materials, a hospital could see significant improvement in pediatric patients. An infusion pump that is battery-powered, adaptable to medications with various viscosities, and programmable by staff would alter these outcomes for the better.

Impact on Global Healthcare

Our Solution

We propose a low-cost, battery-powered infusion pump that delivers a set amount of fluid at a constant rate that is chosen through a user interface. The idea is to produce an infusion pump that is equal in accuracy to the pumps produced by manufacturers while significantly decreasing overall cost and need for specialized parts. During the 2018 EWH Summer Institute in Guatemala, participants were presented with two inoperable infusion pumps, and in both cases, the problem came from the power supply. When interviewed, the hospital staff said the specific batteries needed for the pumps were hard to come by and it was too expensive to buy a new infusion pump altogether. That is why our design focuses on minimizing cost and maximizing

the ability to find parts. Our design will be powered by rechargeable batteries which can be easily found in most convenience stores. Moreover, the device is designed to be user friendly to minimize technical errors and misuse. The user simply needs to input the amount and rate.

The proposed infusion pump will be sized appropriately for adaptable use in pediatric patients in a third-world hospital. Specifically, this technology will assist pediatric patients because the technology will be appropriately sized as not to rupture IV lines and will provide medication to prevent easily treatable infections, such as pneumonia.[3] Current low-cost technologies include spring-force and stepper motor pumps. To improve this technology, we propose to improve low-cost infusion pumps by increasing adaptability to medications with varying properties, improving the user-friendliness to physicians, and refining the accuracy of speed and volume delivery.

Competitors

Current low cost infusion pumps include syringe pumps using Stepper motors and microcontroller pumps. The disadvantage to the Stepper motor designs is the usage of acrylic sheets, which use a laser cutter that third-world hospitals would not have access to. Current microcontroller pumps are not only difficult to program for medical staff but also deliver with a flow error of up to ~5%.[4] Though our design will also utilize a microcontroller, it will be easier for medical staff to operate due it being programmed to adapt to different fluid viscosities based on simple calculations.

Technical Description

Mechanical: Our design was inspired by Michigan Tech's Sustainability Technology Lab[11]. The original design consisted of 3D printed components including a Motor End, a Carriage, a Plunger Holder Base, a Plunger Holder Tab, two Body Holders and an Idler End. We also prepared assembling materials including M3 socket head cap screws of various sizes (10mm, 20mm, 40mm), LM6UU linear bearings, 625z ball bearings, a 0.2m M5 threaded rod, a 5mm x 5mm shaft coupling, M3 hex nuts, M5 hex nuts and two 6mm A2 tool steel 0.2m.

The motor was mounted onto the Motor End. We used a coupler to connect the threaded rod and the motor. We hollowed out the two ends of the Carriage and placed a linear bearing on each end, then we attached the Carriage with the Plunger Holder Base with two M3 nuts and M3 x 10mm screws. We slid the two steel rods through the linear bearings into the two ends of the Motor End. We adjusted the position of the Carriage so it was placed in the middle of the rod. We inserted two ball bearings into the Idler End, then slid it onto the three rods and secured the connection with two M5 nuts. We placed the two Body Holders on the steel rods, right next to the Idler End. The syringe plunger flange was inserted into the Plunger Holder Base, while the barrel flange was held in between the two Body Holder pieces.

We modified the pieces through SolidWorks and manufactured using a Monoprice Select Mini 3D Printer V1. We removed the top half of the circle of the two Body Holder pieces to make it easier for syringe change without affecting its function. We removed the Plunger Holder Tab, which inserted into the Plunger Holder Base in order to hold the syringe in place, because the tab imposed limitations on the syringe size and it was hard to fit or secure perfectly. We moved the position of the motor hole on the Motor End piece so the screw was connected horizontally across pieces and would not rotate in an ellipse when the motor spinned. We moved the screw holes positions on the Motor End Piece to fit our motor type. We also secured the attachment of the two Body Holders and the Idler End with two rubber bands.

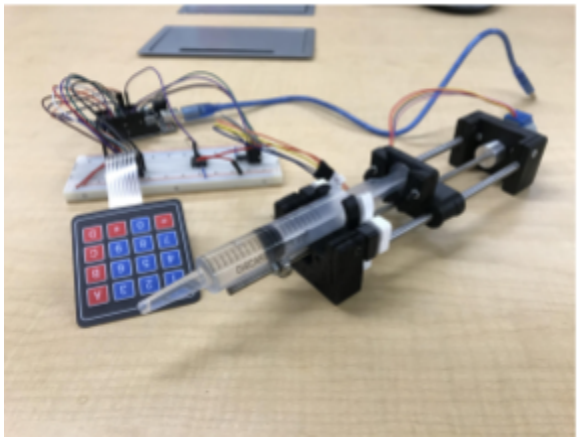
When injecting fluids, the motor spinned and the threaded rod rotated, causing the Carriage to move towards the Idler End. The Plunger Holder Base attached to the Carriage would then push the plunger flange of the syringe, while the Body Holder would hold the other parts of the syringe in place. Therefore, fluids would come out from the syringe. When refilling the syringe, either the motor spinned and cause the Carriage to move backward to draw liquid, or the syringe was directly taken out and refilled manually.

Electrical: The code for the device was written in an Arduino sketch and implements the Stepper motor library. An instance from the Stepper class was created with the name myStepper to initialize the motor. The four motor pins are connected to the Arduino Uno's digital pins 10-13. The steps per revolution for the motor was set to 200 in correspondence with the specifications from the motor's datasheet. The setSpeed function takes a parameter called

motorSpeed which is an integer value between 0 and 100. The motor used was a 5VDC unipolar stepper motor by Adafruit with product ID 858. The ULN2003 Darlington array by STMicroelectronics was also used in the hardware.

Operation

Before using the device, the necessary syringe size must be chosen as this will dictate the starting position of the motor. The end of the syringe plunger must be pulled out to maximum length and the motor is spun backwards such that the device can release the maximum volume. The barrel flange and plunger end are inserted into their appropriate holder in the movable center unit. To spin the motor, the desired speed is set via a keypad. The syringe will continue to be emptied until the end of the track is reached. By reversing the direction of the motor, the same syringe can be used again or can be changed out for a different size.



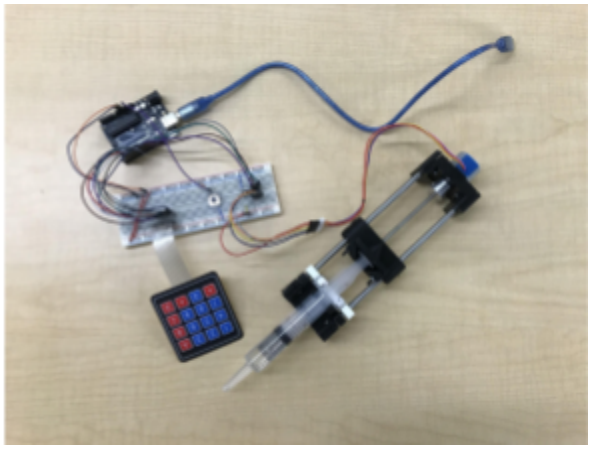


Figure 1: and 2 Front and top views of assembled device

Cost of Device

Component	Cost
3D printed parts	$3.95
fasteners	$10.03
bearings	$15.38
coupler	$6.91
rods	$12.71
stepper motor	$4.95
20 mL syringe	$2.25

wires	$8.99 (Arduino Starter Kit)
arduino	
breadboard	
number pad	$2.50
TOTAL	$58.68

Currently, the power source comes from a laptop which the Arduino is plugged into. In addition, the size of the syringe will vary and the price will vary based upon it.

Proof of Performance

The goal of this test was to verify that the flow of fluid from the infusion pump was consistent over time. In addition, these tests served to show whether or not the rate of the motor changed the consistency of flow delivered over time. Together, these tests determined whether or not this device is consistent enough with fluid delivered over time for its use as an infusion pump. Commonly, infusion pumps report a range of $\pm$5% for their fluid flow rates. Therefore, if the values deviate in a range larger than this changes will need to be made to ensure accuracy. To verify this device for more broad conditions an additional trial must be run for a more viscous fluid, another common practice for infusion pump verification.[5]

Experiment 1: Increasing Flow Rates

1. Fill the syringe of the infusion pump with water, it should be filled halfway
2. Place a graduated cylinder under the outflow of the syringe pump
3. Turn on the pump, starting with setting the infusion pump to a low setting
4. Let the pump run for 30 seconds, recording the amount of water in the graduated cylinder 5. Repeat steps 1-4 a total of five times at the same speed setting
6. Increase the speed twice each time repeating steps 1-5

Important: If the speed increase causes the syringe to empty too fast, make sure to fill it more at the start and note the increase. Do not let the syringe run out of fluid air could be damaging to the motor or pump assembly. If the speed remains a problem even with more fluid, then test with less time.

Experiment 2: Viscosity

1. Select a separate more viscous liquid and fill the syringe with it. To push the limit of this system and verify it operates consistently even at high viscosities vegetable oil can be used
2. If using a standard soybean vegetable oil, record the viscosity as approximately 54.3 cP assuming room temperature (6). This value far exceeds likely substances to be added but serves as a testing of the upper bounds of this model
3. Repeat steps 1-4 from Experiment 1 with this new liquid. Again measure to verify it fails within $\pm$5%.

Results

The aim of the first experiment was to test the pump over a range of flow rates while the second experiment tested the pump with a new viscosity. For both experiments the required range to fall under for acceptable use was $\pm$5 %. This condition was met in the varying of flow rates with constant viscosity, but this condition failed during the high viscosity testing. The failure was likely due to the extremely high viscosity of the testing fluid, which was grape seed oil. The table below shows the results as well as the highest percent error from the average for each testing condition.

Table 1: Testing Results for Experiments 1 and 2

Trial	High Speed	Medium Speed	Low Speed	Oil
1	4.4	3.5	2.6	1
2	4.7	3.6	2.5	0.8
3	4.7	3.6	2.4	0.8
4	4.7	3.5	2.5	NA
Avg	4.625	3.55	2.5	0.866
Largest % Error	4.86	1.41	4	15.47

Voice of Customer

In testimonials from physicians who have worked in low-resource hospitals extensively, the chief issue in attaining pediatric equipment was weighing its value against adult equipment. Due to limited funds in these situations, the syringe pump will be low-cost, but also assembled from materials that are accessible in these countries. The primary engineering problem that this project poses is consistent drug delivery at a speed that a pediatric patient can withstand. In order to guarantee consistent delivery, the infusion pump will be adaptable to delivery medications of varying viscosities with a reprogrammable microcontroller that uses rechargeable batteries for power.

Feedback from two physicians and a DNP, all experienced in medical device design, highlighted the importance of minimization of exposed parts (ex. rods, circuitry) to reduce contamination and better securement of the plunger end. Minimization can be improved by enclosing the circuitry in a 3-D printed box and covering the two rods that move with the syringe. To secure the syringe end, a three-point system would be employed that would be able to adapt to various syringe sizes. Additionally, the stabilizing apparatus for the anterior handle of the syringe would have a hinged lever that would secure the anterior handle and also allow for interchangeability of various syringes.

Business Plan

Since this product was made with the intention of affordability for developing countries, the low cost device will be purchased by hospitals in developing nations. Since infusion pumps are expensive as stated previously, this lower cost one would be a more reliable and cost effective option for customers. While it would be beneficial for a non profit organization to buy the medical equipment to distribute to countries, most medical equipment is donated to these organizations and not sold. Therefore, our primary customers would need to be the hospitals or health organizations within the country as opposed to a non profit organization. By using materials easily replaceable and durable, the infusion pump created would be a worthwhile investment without actually costing the hospital a significant amount of money.

According to the World Health Organization, the Pharmaceutical Food and Supply Agency is responsible for the regulation of medical device products in Ethiopia.[9] Therefore, if the device was distributed beyond the St. Paul Hospital in Ethiopia, it must meet approval standards through this organization. In addition, recent government legislation has increased the country's desire for modern medical technology, according to the United States International Trade Administration.[10] Therefore, partnering with the government's public health sector would produce the most probable successful distribution of the product. If we no longer wished to produce the product due to demand or other reasons, the intellectual product could be sold to the Pharmaceutical Food and Supply Agency, who could distribute it at either low to no cost.

It will be crucial to gain funding for our infusion pump in the first stages of production. To get the product up and running and for production to start as intended, we will need a few initial investments by outside sources. We will try to gain these initial investments several different ways including funding through grants, crowdfunding, and other online websites that help fund startup companies. The devices will be assembled by members of our EWH design team on a volunteer basis which will help lower the cost of production. The goal for the first initial investments will be to find a source that is interested in our product and believes that our product will be able to fund itself on its own. The key is that we will need enough funding to produce several devices which will help get our product up and running. Some of the initial funding will help us advertise our device so that more people know about it and can purchase it. Once the device starts creating a profit, we will use the money to buy several of the parts in bulk in order to keep the cost of the device down and minimize the need for additional funding in the future. The long term goal for our infusion pump is that it creates enough profit that all of the production and raw material costs are covered and outside funding is no longer needed.

Regulatory

The FDA regulates medical devices for the purpose of ensuring consumer safety and high quality treatment, and the FDA's legal authority to regulate medical devices comes from the Federal Food Drug & C (FD&C) Act. Under this act, any product that qualifies as a medical device must meet the regulatory requirements found in the Code of Federal Regulations (CFR)

before it can be marketed in the U.S. However, our device is marketed primarily towards resource-poor nations. The World Health Organization has a mandate, as outlined in the World Health Assembly (WHA) Resolution 60.29 "to encourage member states to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and, where appropriate, to participate in international harmonization". While there is no worldwide regulating authority, individual nations should have their own policies regarding medical device regulation. For example, if we wanted to market our device in Ethiopia, we would have to comply with the regulations from the Food, Medicine and Health Care Administration and Control Authority of Ethiopia.

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