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ARTERIAL LINE SIMULATOR
FINAL REPORT
BME 200/300
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Abstract

Arterial line simulators are a vital component of the education of healthcare professionals. Arterial lines are used to detect and communicate information about a patient's cardiovascular health through blood pressure waveforms. The team's client uses an arterial line simulator to educate his students, however this is currently being done manually. By applying pulses of pressure to a syringe plunger attached to a transducer, different waveforms are simulated for the students. The team was tasked with designing a device that can be attached to the syringe to replace the need for manually creating the waveforms. The device should be conveniently sized, compatible with a standard syringe, and capable of accurately reproducing various arterial waveforms. After evaluating three design variations for a potential arterial line simulator, the cam design was chosen as the final design. The cam design consists of interchangeable rotating wheels with arterial line waveforms mapped onto their surfaces in the form of elevations. As the cams spin, the syringed is strategically pushed in with varying rates and pressures. Fabrication of this device included circuitry to power the motor, 3D printing of components which hold the syringe and motor in place, a laser-cut baseboard, and two cam shapes laser-cut at two different sizes. Testing revealed that the device is most accurately able to produce a normal arterial pulse waveform with a maximum correlation of 84%, however there is much room for improvement. Future work includes adjusting the shapes of the cams, reducing vibrations caused by the motor, and increasing the pressure range of the output waveforms.

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I. Introduction

A. Motivation/Global Impact

Arterial lines are vital healthcare devices that are used to obtain accurate real-time information about the cardiovascular system of a patient. Therefore, it is important for healthcare professionals to receive adequate training that will prepare them for the reading and interpretation of arterial line waveforms. The current practice for doing so involves the manual manipulation of a syringe, which does not meet the standard that should be used for such a vital training process. Healthcare professionals in training may not get practice reading waveforms on a simulation that is consistently precise. The team's goal for this project is to provide an arterial line simulator that is both reasonably priced and capable of accurately replicating a variety of waveforms so that those in search of quality training may have access to it.

B. Existing Devices & Current Methods

Figure 1: This image shows a manikin used in healthcare training labs to teach students how to insert and read arterial lines. [1]

Several other methods for creating arterial line simulators currently exist on the market, however they are mostly costly manikin models. There are no current designs that can be retrofitted to a syringe inorder to produce arterial waveforms. The closest model that can achieve our client's requirements is the Blue Phantom™ gen II PICC W/IV & arterial line ultrasound training model arm **(Fig. 1)** [1]. This device is not only able to allow students to practice placing arterial line monitors but also peripheral IV placement and needle placement in a wide variety of veins and arteries. Unfortunately, these extra features, as well as the anatomical correctness of this device, bring the price up to $2,699.00 which is well out of the client's price range.

C. <u>Problem Statement</u>

In order to simulate arterial line waveforms in teaching labs, our client Mr. Mitchel Reuter currently must mimic them by manually pressing the plunger of a syringe. Arterial line monitoring is a method of yielding real-time feedback about a patient's cardiovascular system using an invasive technique, monitoring both heart rate and blood pressure. In order to practice placing and reading an arterial line, a product should accurately reproduce arterial line waveforms with each use and be simple for an instructor to utilize in a demonstration. Unfortunately, no such product currently exists aside from costly manikins that exceed our client's budget. Currently, our client reproduces such waveforms by manually pressing the plunger of a syringe. This process is neither efficient nor does it satisfy our client's need for precision and accuracy.

Mr. Mitchel Reuter has asked the team to design an arterial line similar that is more effective than his current method and more cost effective than competing products on the market, while maintaining a reasonable size and the ability to simulate a reasonable number of waveforms.

II. Background

A. <u>Physiology and Biology</u>

Arterial lines are catheters that are inserted into the lumen of an artery, most often the radial or femoral artery. Arterial lines are used for continuous monitoring of arterial blood pressure as well as to take frequent blood samples [2]. The arterial line itself contains a type of strain-gage called a transducer which allows blood pressure and heart rate waveforms to be monitored. Waveforms will vary based on the artery chosen for insertion, the patient, and the angle of insertion [3]. The line uses a hanging saline bag to obtain a baseline pressure, and it is important for the patient as well as for proper monitoring that there are no air bubbles, the line has been zeroed after exposure to atmospheric pressure, and that the transducer is positioned properly [3].

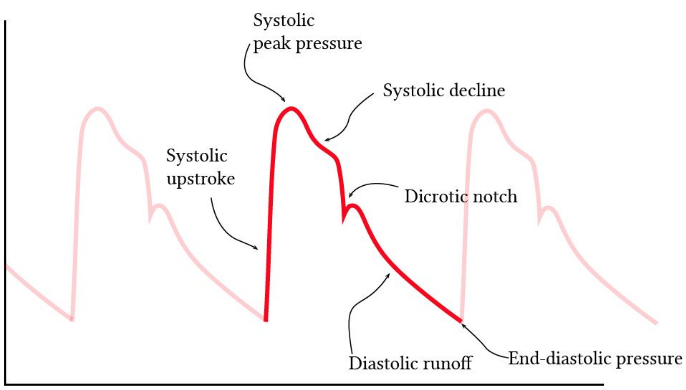


Figure 2: This figure shows the normal arterial pulse waveform. The peak pressure is known as the systolic pressure which is followed by the diastolic runoff. [5]

Once the arterial line has been inserted into the artery, the cardiac contractions will exert pressure within the catheter, which in turn transmits to the transducer. The transducer then converts the increase in pressure into an electrical signal that transmits to the monitor. These increases in pressure are represented on the monitor as the arterial pulse waveform [4]. The waveform consists of the systolic upstroke, systolic peak, systolic decline, dicrotic notch, diastolic runoff, and end-diastolic pressure. These components of the arterial pulse waveform correspond to the ventricular ejection, systolic ejection, ventricular contraction, aortic valve closure, pressure decline due to valve closure, and the pressure exerted by the vascular tree on the aortic valve, respectively (**Fig. 2**)[5]. The monitor often displays the ECG as well, however the arterial pulse waveform is delayed by 160-180 ms compared to the ECG. From these waveforms, a lot of information can be gathered such as the systolic, diastolic, and mean arterial pressures, as well as heart rate and pulse pressure **(Fig. 2)** [5]. Normal systolic pressure is the range of 90-120 mmHg, diastolic pressure is in the range of 50-80 mmHg, and mean arterial pressure can range from 70-100 mmHg [6].

Monitoring systems are prone to interference and resonance causing amplitude distortion. For this reason, damping is introduced in order to decrease the distortion [7]. However, insufficient and excessive damping is common, causing errors in pressure readings. Overdamping is associated with an incorrectly low systolic pressure and high diastolic pressure, along with an increased system response time [7]. This corresponds to a low systolic peak and a high end-diastolic pressure. On the other hand, underdamping is associated with incorrectly high systolic pressures and low diastolic pressures, corresponding to high systolic peaks and low end-diastolic pressures [5].

B. Client Information

The client for the project is Mr. Mitchel Reuter, who works in the Emergency Education Center as well as the Clinical Simulation Program for UW Hospital and Clinics associated with UW School of Medicine and Public Health. Mr. Reuter instructs medical students who need to learn many techniques such as arterial line monitoring. The client has provided the team with a standard arterial line and 10 mL syringe plungers which connect to a monitor, pressure transducer, and hanging saline bag.

C. Design Specifications

The device must be able to connect to the arterial line and 10 mL syringe plunger provided by the client and produce at least a normal arterial pulse waveform, however underdamped and overdamped waveforms are desired as well. Since the device is meant to minimize human error, accurate waveforms should be consistently produced and the setup should require minimal effort by the user. The operating environment of the device will most likely be a classroom, meaning the product should be able to function in bright lighting, varying noise levels, and varying vibration levels. A classroom environment will subject the device to a lot of operators and handling or transportation, so the device should be durable and transportable with a size no larger than a typical VHS tape and a weight less than 7 kg. The device should be functional for a full instructional period but ideally would last a few years to accommodate multiple student classes.

In order to withstand repeated amounts of pressure, a durable material should be used to fabricate the main component of the device. Although the product will be used in a teaching setting rather than a sterile medical setting, safety and sanitation should still be considered when selecting the material. Finally, the device must be low cost compared to the MedSim manikin simulator, with an absolute maximum fabrication cost of $1000.

III. Preliminary Designs

A. Design 1 - The Cam:

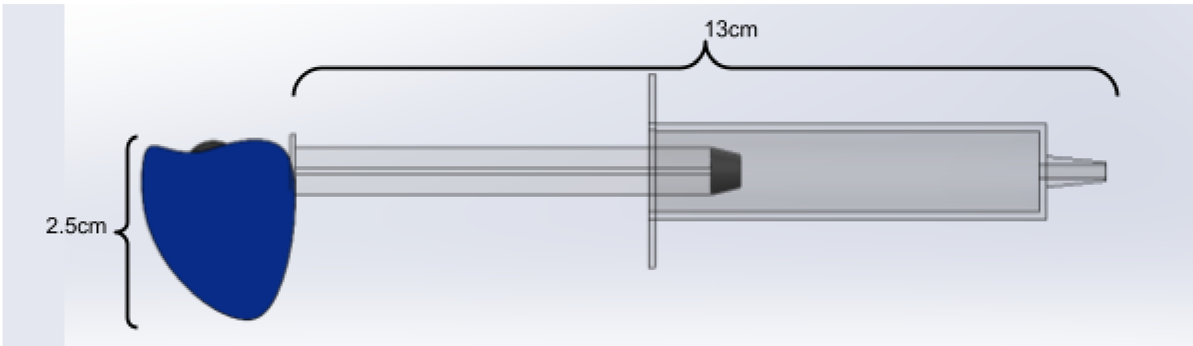


Figure 3: Cam Preliminary Design

The cam design relies on a custom shaped cam that depresses the syringe plunger as it rotates **(Fig. 3)**. The shape of the cam directly influences the pressure waveform that is created. Therefore, it will be necessary to manufacture three different cam shapes, one for each waveform that is desired. The simplicity of the cam design is one of its greatest strengths. It utilizes only one moving part, and therefore has fewer possible points of failure.

B. Design 2 - The Piston:

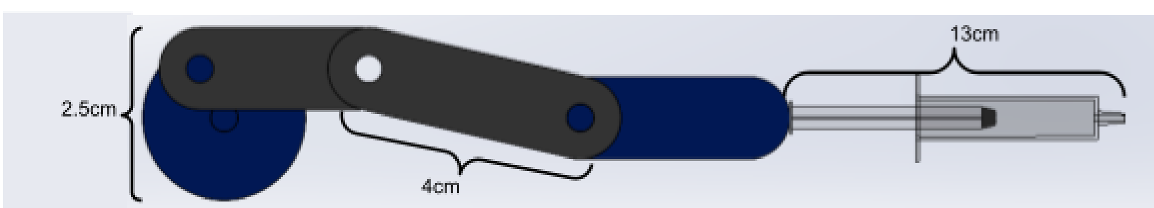


Figure 4: Piston Preliminary Design

The piston design utilizes a three-pin arm attached radially to a rotating axle **(Fig. 4)**. It functions similarly to any other piston, in that rotary movement is converted to linear motion. To create the desired waveform, the team would utilize servo or stepper motors. The software program would be vital in dictating the speed and direction of the piston arm for accurate waveform emulation.

C. <u>Design 3 - The Bolt:</u>

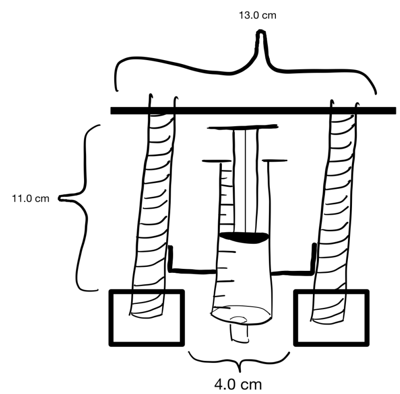
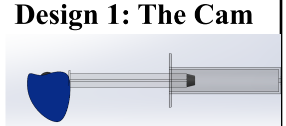
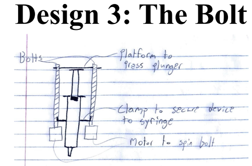


Figure 5: Bolt Preliminary Design

The bolt design utilizes two bolts positioned parallel to the syringe. One motor is attached to each bolt and enables smooth, uniform movement. Software and coding would be how the team establishes control over pressure and ultimately generates the desired waveforms. To keep the pressure changes smooth and controlled, the device would need to operate more slowly than the other designs.

IV. Preliminary Design Evaluation

A. <u>Design Matrix</u>

Criteria	**Design 1: The Cam** 	**Design 2: The Piston** 	**Design 3: The Bolt** 
Consistency (25)	5/5 * 25 = 25	5/5 * 25 = 25	4/5 * 25 = 20
Range of Use (25)	4/5 * 25 = 20	2/5 * 25 = 10	3/5 * 25 = 15
Ease of Use (20)	5/5 * 20 = 20	5/5 * 20 = 20	4/5 * 20 = 16

Ease of Fabrication (10)	3/5 * 10 = 6	2/5 * 10 = 4	2/5 * 10 = 4
Safety (10)	5/5 * 10 = 10	5/5 * 10 = 10	4/5 * 10 = 8
Durability (5)	3/5 * 5 = 3	3/5 * 5 = 3	4/5 * 5 = 4
Cost (5)	5/5 * 5 = 5	4/5 * 5 = 4	4/5 * 5 = 4
Total = 100	**89 / 100**	**76 / 100**	**71 / 100**

Table I. Design Matrix

This table shows the criteria used to evaluate the three preliminary designs. Each criterion was rated out of five, and then scaled accordingly.

The above design matrix was created by the team in order to thoroughly and fairly score and evaluate the three design ideas. The criteria were chosen and weighted based on the importance of each to the overall success of the product, with the most important being the consistency and the range of waveforms that it is able to produce.

The Cam design scored well in most categories, making it the team's highest score. The device scored a 5/5 in both consistency and ease of use because once the cam is in place on the motor all that is required is to turn the device on and a perfect identical waveform would be created every time. In addition, the cam scored a 3/5 in ease of fabrication, the highest among the designs, because it uses a single component which can be designed in CAD software that can then be printed or laser cut with ease.

The Piston design also scored a perfect 5/5 in both the consistency and ease of use categories. Once this device is fabricated, one would simply need to turn it on and the programming of the piston would form a perfect and consistent waveform based upon the movement of the piston. This device only scored a 2/5 in range of use because in order to create the various required waveforms the movement of the piston would have to change drastically which would be difficult given the largely linear movement of the piston. Finally, the Piston scored a 2/5 in ease of fabrication not only because of the various physical moving parts, but also because of the difficulty in writing the code that would be required to rapidly change the speed of the piston to produce the required waveforms.

The Bolt design scored a 3/5 in range of use because, although it could recreate the various waveforms that the client desires, it would be much more difficult to program the motors to spin the bolts perfectly. This would result in the device struggling in some areas, especially as the client increases the rpm to higher speeds. The design also scored a 2/5 in ease of fabrication because this would most likely be the hardest design to build. With the many moving parts and the required code to produce the waveforms, this design would require many challenging fabrication steps. Finally, the bolt design scored a 4/5 in durability because the solid metal bolts and simple movements would make this design stronger than the 3D printed alternatives.

B. Proposed Final Design

Based on the design matrix, the proposed final design was the Cam design. This design scored highest in the majority of the categories and was a clear front runner when compared to the other two designs. Given the simplicity of three cams to create three waveforms and the ease of fabrication, this design seemed to be the best balance of the clients expectations and the team's abilities.

V. Fabrication/Development Process

A. Materials

A few different materials were used throughout the project, given the different performance requirements of each component of the device. The base platform, cams, and support box were all made out of High Density Fiberboard (HDF). This material was chosen because it is very cheap, lightweight, durable, and easy to work with. The base platform and support box acted as the backbone of this device, so having a sturdy material was important. The

HDF was also ideal because it allowed the team to connect other device pieces using glue, screws, and bolts. Additionally, the HDF made it very easy to laser cut the various cam shapes and end up with 4 identical pieces which could then be stacked and glued to obtain the desired thickness. The cams also had relatively low friction with the syringe plunger, which was important for smooth circular motion while operating against the syringe. However, the team is still researching different materials which could provide even less friction with the syringe plunger. The only unforeseen drawback of the material was that the transducer system leaked a small amount of saline onto the material which slightly damaged the HDF.

The remainder of the parts fabricated by the team were 3D printed using polylactic acid or PLA. The remaining pieces included the motor mount and the syringe clamps. These pieces lent themselves well to 3D printing because they had complex geometries that 3D printers can easily produce. In addition, these components had to be extremely precise as they were responsible for securing the motor as it spun and securing the syringe as it was pressed by the cams. If either of these pieces was to be improperly sized it would lead to slipping and reduced functionality of the device.

Finally, it was decided that a stepper motor would be used in order to drive the cams. This choice was hard for the team to make without much collective experience with motors. The stepper motor was chosen over a DC motor because of its superior speed control and torque [9]. The chosen stepper motor was a Nema 14 motor that could easily fit within the required speed range (30-200 RPMs) and torque required to spin the cams.

B. Methods

Fabrication of the prototype primarily utilized the laser cutter, 3D printer, and basic fasteners. The pieces were created based on their respective fabrication method and were then brought together in order to form the final product.

The first pieces were made using the laser cutter which made it easy to convert from CAD drawings directly into the real world in a matter of minutes. After getting the laser cutter upgrade, the necessary Adobe Illustrator files from the team's CAD drawings were created. Then, after buying a sheet of HDF, the pieces were ready to be cut out. Super glue was used to put together the support box and the multiple layers of cams.

Next, the syringe clamps and motor mount were 3D printed because they could also be produced directly from the CAD files made while designing the device. These pieces were quickly printed and ready to be integrated with the laser cut portions.

Using simple bolts and nuts, the syringe clamps and motor mount were fixed to the laser cut portions of the device. This produced the skeleton of the device, but the circuitry needed to be added in order to make the electronics function as desired.

The circuitry was largely able to be plugged directly into a breadboard and connected using jumper wires. The team used a fritzing diagram that was an example circuit of driving a stepper motor. The circuit had to be adjusted slightly in order to power our arduino and motor with separate power sources [10]. Some minimal soldering was needed to add more secure wires to the stepper motor, as well as better connections for the potentiometer. With these few pieces soldered the electronics were complete and the breadboard was secured inside of the support box.

Finally, with the circuitry complete, the laser cut and 3D printed pieces were securely fastened to one another and the potentiometer and rubber feet were glued on, thus completing fabrication of the device.

C. <u>Final Prototype</u>

The final design consists of an interchangeable cam that depresses the syringe as it rotates. Two different cams were created, one to model the normal arterial waveform and one for the overdamped waveform. In order to align the cam with the syringe, the syringe is placed on a raised box and clamped into place using 3D printed clamps **(Appendix F)**. The entire prototype is powered using a 9V battery and 12V wall power.

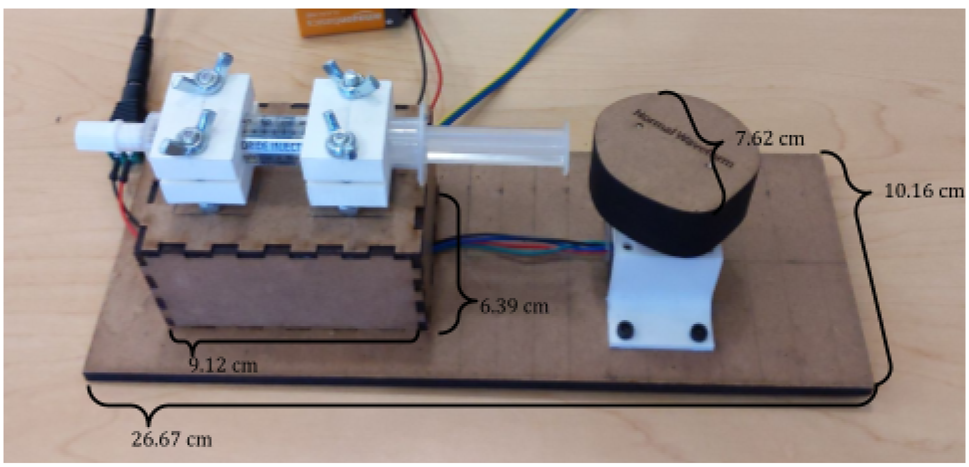


Figure 6: This image shows the final fabricated prototype. The syringe is stabilized on the left while the cam sits on the motor at the right.

In order to create a cam shape that would consistently and accurately generate the waveforms that were needed, a mathematical model to represent the cam was created. First, the shape of the cam was written as a parameterized equation in terms of t. The curvature of the shape, given by the equation $K(t) = \frac{|F'(t) \times F''(t)|}{|F'(t)|^3}$ where $K(t)$ is the curvature at point t and the $F(t)$ is the parameterized function, is then calculated. Finally the curvature of the shape is plotted against t. Because the curvature of the function is proportional to the pressure the cam would apply at a point, this graph is analogous to the waveform that would be created. This process is shown below for the overdamped cam model. The entirety of the Matlab code is available in appendix C. The shape of the normal waveform cam was based on a design from a research group also working with modeling arterial line waveforms [8].

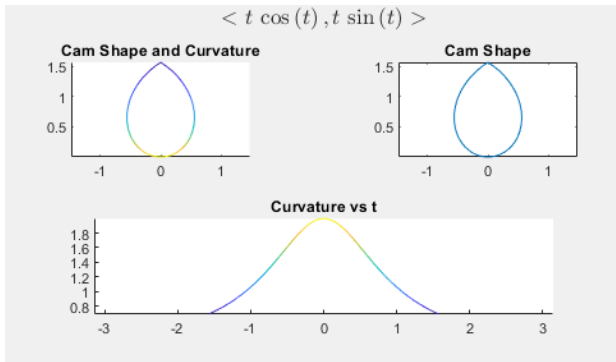


Figure 7: This image shows the MATLAB Cam Model that was used to determine the ideal shape of the cams for the overdamped waveform.

The electronics needed for the arterial line simulator are relatively simple, consisting of an Arduino Nano, a motor driver, and a stepper motor. As shown in the figure below **(Fig. 8)**, the motor and motor driver are powered using a 12V connection from the wall. A 9 volt battery is used to power the Arduino. The final design also features a potentiometer used to control the speed of the motor. The Arduino reads in the value of the potentiometer and sends it to the motor controller to change the speed.

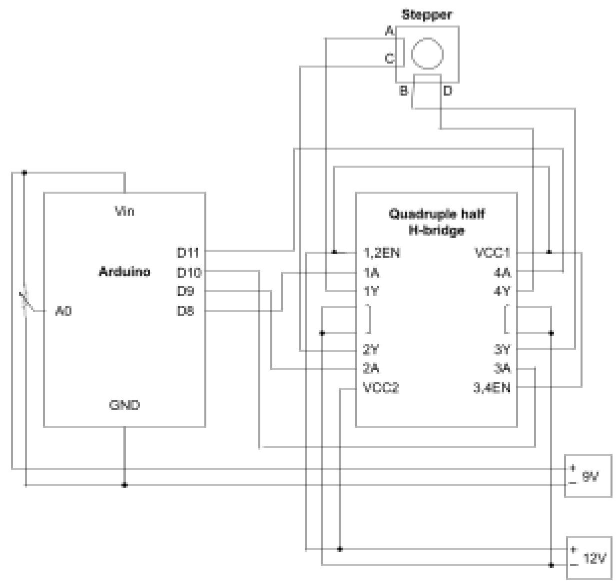


Figure 8. Electrical Diagram

D. <u>Testing</u>

The team evaluated the functionality of the device by testing both the circuit and the cams. This entailed testing voltages and currents at various circuit elements, as well as comparing the cam-generated waveforms to ideal arterial pulse waveforms.

After compiling and uploading the Arduino code (**Appendix E**), a multimeter was used to determine the voltages and currents going into the Arduino and the motor. The Arduino requires 5V operating power while the motor requires 12V power and 1A current. In the beginning, the device was powered solely from 12V wall power and the circuit consisted of a 22kOhm-47kOhm voltage divider in order to lower the voltage going into the Arduino. Though this did give 7.04V to the Arduino and 12.36V to the motor, it was found that only 0.34A of current reached the motor. Realizing that changing the resistances in the voltage divider still would not deliver enough current to the motor, the team decided to use a separate power source for the Arduino. After removing the voltage divider, the device was powered using a 9V battery for the Arduino and 12V wall power for the motor. Testing various components in the circuit using the multimeter showed the desired results of 9.13V going to the Arduino, with 12.07V and 1.98A going into the motor.

In order to determine the accuracy and precision of the device, qualitative and quantitative data was collected using an arterial line monitor provided by the client. All four final design cams were tested at varying motor speeds and distances from the syringe. First, the syringe was attached to the arterial line, secured on the clamps, and the transducer was connected to the monitor. After performing initial testing which gave poor results, it was determined that the rotating cams were producing excessive lateral pressure on the syringe. In order to reduce the lateral pressure, the team decided to decrease the length of the syringe plunger by lowering the amount of fluid from 10mL to 5mL. This significantly improved the results and allowed waveforms to be displayed on the monitor.

With 5mL of fluid in the syringe, the cams were tested at varying distances. However, it was found that viable results were only evident when the end of the syringe overlapped the outermost point on the cam by 2mm. Additionally, since the ideal arterial pulse rate is 80 BPM, each cam was tested at motor speeds between 60-100 RPM. When the generated waveform was shaped most similarly to the ideal waveform, the motor speed was recorded. At these assigned distances and speeds, three trials were performed for each cam. For each trial the average first and second peaks were recorded, representing the systolic peak pressure and the dicrotic notch, and pictures of the displayed waveforms were taken. Using the collected data and pictures, the team was able to recreate the normal cam waveforms in MATLAB and compare them to the ideal normal arterial pulse waveform using the MATLAB cross-correlation function **(Appendix D)**.

VII. Results

Cam	Motor Speed (RPM)	Trial 1 (Max) in mmHg	Trial 1 (Min) in mmHg	Trial 2 (Max) in mmHg	Trial 2 (Min) in mmHg	Trial 3 (Max) in mmHg	Trial 3 (Min) in mmHg	Avg. Peak 1 in mmHg	Avg. Peak 2 in mmHg
Small Normal	82	96	74	92	70	94	96	96	72
Large Normal	91	46	17	51	20	47	21	48	19
Small Overdamped	65	64	32	58	39	62	37	61	36
Large Overdamped	74	44	31	46	25	48	29	46	28

Table II. Results

This table compares the maximum and minimum pressure values recorded while running the prototype on the arterial line transducer

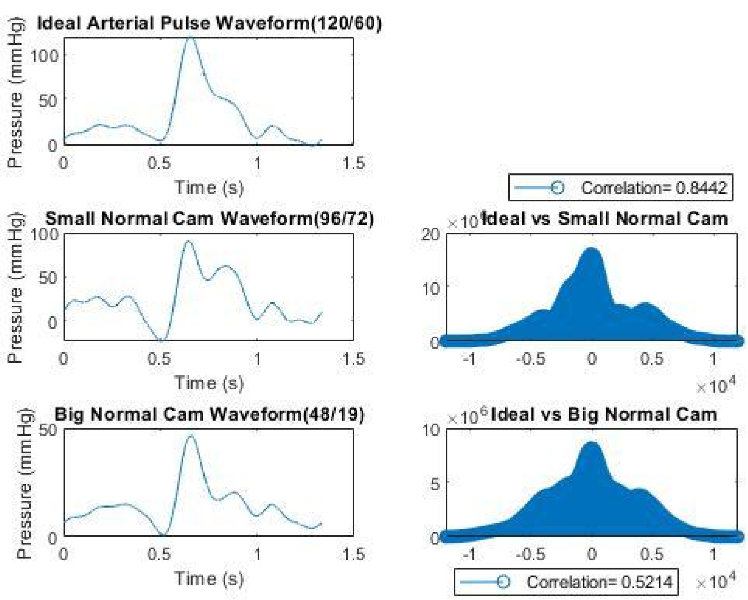


Figure 9: The ideal normal arterial pulse waveform and the waveforms generated by the cams are shown on the left. On the right are the cross-correlation plots comparing the generated waveforms to the ideal.

The results from the collected data and MATLAB plots are shown above (**Table II**). The team found that, due to high vibrations in the system while using the overdamped cams, the arterial transducer detected too much artifact. That artifact unfortunately prevented the team from comparing the generated overdamped waveforms to the ideal overdamped waveform. The ideal pressure values the team was trying to emulate are 120/60 mmHg. For the normal waveform, this is typically represented with a slight dip in pressure, followed by a large spike to that 120 mmHg peak. This represents the systolic portion of the heart rhythm. The peak will drop down to 60 mmHg briefly, representing the diastolic portion of the heart rhythm. The pressure will drop back to around 0 mmHg and the whole process will repeat around 80 times per minute.

Utilizing the cross-correlated data shown above (**Fig. 9**), the team was able to conclude an approximate 84% correlation between the ideal normal waveform and the waveform generated by the small normal cam. The team was also able to conclude a 52% correlation between the ideal and the large normal cam's generated waveform. This quantitative data shows that the small normal cam produced a waveform significantly closer to the ideal. The team found that the largest difference in that correlation is due to the better approximation of systolic and diastolic pressures, with the small normal cam achieving 96/72 mmHg. While this was only a 24-point change compared to the ideal 60-point change, the max pressure was found to have a slightly higher importance than the pressure range. Through testing, it was found that low max pressures produced weak spikes and dips on the transducer, making readings more difficult. For this reason, the team feels bringing pressure values closer to the ideal is one of the main takeaways from testing.

VIII. Discussion

The device was best able to create the normal waveform using a combination of the smaller waveform cam and the box being supported from only the back edge. In addition, the waveforms were achieved at a medium-high speed setting with stabilization on the base platform to reduce vibrations.

However, there were a few factors preventing the creation of accurate replicas of all the waves. The device did not produce enough of a pressure difference and future work will likely require using a stronger force to replicate all of the waves. The cam force also had lateral components rather than going straight in and out. The torque of the motor should be increased in order to, in turn, increase the force it puts on the syringe plunger to create the desired pressure difference. Work in the future should also include elongating the base platform to support the actual transducer sensor, adding a hinge to the back side of the box, and producing a better cam shape for the three different waveforms. Considerations for a better cam shape include larger height differences between peaks and troughs to induce a greater pressure difference. To reduce friction, and thus the vibrations caused by it, higher density plastic could be used for the cam material, and a cap may be added to the plunger of the syringe.

IX. Conclusion

The team's client, Mr. Mitchel Reuter, wants to eliminate the need for manually applying pressure to a syringe's plunger by fabricating a motorized device. The device will be used to train healthcare professionals on how to set up an arterial line and read the arterial pulse waveforms. However, the design has the potential for use beyond Mr. Mitchel Reuter's teaching lab and could be part of many healthcare training programs.

The team evaluated three designs and ultimately decided to proceed with the cam design. The final fabricated prototype consisted of interchangeable cams that rotated with a motor and applied pressure to the syringe. The shape of the cams were specifically designed to correlate with both the normal and overdamped waveforms. The team was able to successfully fabricate the device and test it using the client's monitor. After testing the team was able to identify areas of improvement. To modify the existing device, the team hopes to extend the base platform in order to stabilize the transducer which in turn will reduce vibrations and produce more accurate waveforms. Additionally, the best method to increase the pressure applied to the syringe in order to reach the desired 120/60 mmHg blood pressure should be identified. Future work will also include evaluating whether these changes should be made to the fabricated device, or if a complete redesign is necessary.

X. References

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XI. Appendices

A. Product Design Specifications

Function:

Medical students need to be able to practice a wide variety of different techniques and skills on representative models to improve their skills without putting a living patient at risk. One such technique is arterial line monitoring. This technique involves placing an arterial line in the patient's artery to monitor their blood pressure and arterial waveform. This device should be able to attach to a syringe of saline and replicate the waveforms expected from arterial line monitoring of a living patient. The device should be able to have adjustable heart rate, blood pressure, and ideally arterial line waveform. Finally, it should be affordable and allow for an experience that is comparable to the real world.

Client requirements (itemize what you have learned from the client about his / her needs):

A device that:

- Can replicate regular wave form for an artery
- Has variable speeds of 30 - 200 rpm
- Is about the size of a VHS tape
- Ideally can replicate both overdamped and underdamped wave forms
- Can be reused and attached to any 10mL syringe

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: This device should be able to withstand small but consistent amounts of pressure, repeatedly, and ideally on a daily basis. It should be compatible with the monitor and transistor that the client plans to pair with the device. It should replicate accurate results on demand.

b. *Safety*: This device is entirely for instructional purposes. Ease of sanitization is a plus, but is not required.

c. *Accuracy and Reliability*: Given that this device is meant to minimize human error in replicating waveforms, it must measure up to a high degree of accuracy. This degree of accuracy needs to be repeatable, so that accurate waveforms are replicated with every use.

d. *Life in Service*: This device should be functional for a full demonstration period. As we only plan to showcase about one to two waveforms, we anticipate that the demonstration periods will not be long -- likely less than an hour at a time. This device will likely not travel much, and remain in one location dedicated to the education that this device aids in providing.

e. *Shelf Life*: The shelf life of the device will depend on if the device is battery powered or electronically powered. If battery powered, a battery will have to be replaced or recharged between usage. If electronically powered, the device must be plugged in when in use. With either power method, the device must not lose any functionality in between usages throughout its life-span.

f. *Operating Environment*: The device may be subjected to sterile medical environments, classroom environments, and storage. Any wires or electrical components should be covered to prevent corrosion from fluids, dirt, and dust. Temperatures may range from 15-26 degrees Celcius with 40-60% humidity. The device will need to function under fluorescent lighting with varying noise and vibration levels. Durability should also be considered because the device will be transported and operated by multiple people.

g. *Ergonomics*: This product should require less interaction and force than manually simulating waveforms with a saline plunger. Ideally the device will only require minor setup and specification adjustments. No more than 80 N of force will need to be applied throughout the process [1]. The accessibility of the device will depend on where the operator chooses to set it up.

h. *Size*: The device should be easily portable, with dimensions no larger than 75 cm x 75 cm x 75 cm and weighing less than 7 kg. Space is not an issue, however the device should be accessible for maintenance and may require a power cord long enough to reach an electrical outlet. The device should be capable of operating on a flat surface at any height.

i. *Weight*: The device has no specific restrictions on weight, although ideally it will weigh under 7 kg. For ease of use, the device should weigh as little as possible. Because the product will not need to be transported long distances, weight is not a principal concern. Nevertheless, a lighter product will be more convenient to use.

j. *Materials*: The device has no restrictions on the materials used to construct it. Although the device will be used in a medical context, it is a teaching tool and will not need to be sterilized. Despite this, using a nonporous material would help with day to day disinfection, as needed.

k. *Aesthetics*, *Appearance, and Finish*: The final appearance and finish of the product will be solidified as we begin the design process. Throughout the process, we will be able to consult with the client and mentor to see if they have any suggestions on how to improve the aesthetics of the device.

2. Production Characteristics

a. *Quantity*: The client has requested one unit of the device. The quantity may increase if the client requests.
b. *Target Product Cost*: The client has set a flexible budget for the product at $500-$1000.

3. Miscellaneous

a. *Standards and Specifications*: The device is only for instructional purposes and will only be used in a simulation lab. The device will not need FDA approval for these reasons.

b. *Customer*: The client would like the design to be approximately the size of a VHS tape. If possible, they would like the design to be easy to wipe down. They also feel that a simpler design would be beneficial.

c. *Patient-related concerns*: The device will be used solely for educational purposes. As such, there will be no patient data to store or safeguard. Sterilization is not necessary, but would be appreciated.

d. *Competition*: In September 2000, David M. Feinstein, MD and Daniel B. Raemer, PhD designed an arterial-line monitoring simulator that utilized a stopcock, potentiometer and transducer. It was designed to emulate electrical mechanical delay, beat to beat amplitude variability, respiration variation, and realistic pulse pressure in high and low blood pressure. It was designed to be compatible with MedSim's manikin simulator [2].

PDS References:

[1] A. Vo, M. Doumit, and G. Rockwell, "The biomechanics and optimization of the NEEDLE-SYRINGE system for INJECTING Triamcinolone acetonide into Keloids," *Journal of medical engineering*, 2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5098087/. [Accessed: 22-Sep-2021].

[2] Feinstein, D. M., & Raemer, D. B. (2000). Arterial-line monitoring system simulation. *Journal of clinical monitoring and computing*, *16*(7), 547–552. https://doi.org/10.1023/a:1011434028338 [Accessed: 23-Sep-2021]

B. <u>Costs and Materials</u>

Table II. Costs and Materials

This table lists the materials used in the design and fabrication of our final prototype. Part numbers are given when available.

Part	Vendor	Part ID	Amount	Price per Part	Subtotal
Initial 3D printed cams	Makerspace	n/a	1	$5.00	$5.00
Hex adaptor	Mouser	713-114070065	2	$0.89	$1.78
Stepper Motor	Digikey	2183-1208-ND	1	$16.38	$16.38
10k ohm potentiometer	Makerspace	n/a	1	$0.25	$0.25
Stepper Driver SN754410NE	Texas Instruments	296-9911-5-ND	1	$3.09	$3.09
Jumper wires	Makerspace	n/a	1	$8.00	$8.00
Arduino Nano	Makerspace	n/a	1	$10.00	$10.00

Syringe clamp	Makerspace	n/a	1	$4.75	$0.00
Motor mount	Makerspace	n/a	1	$5.50	$0.00

C. MATLAB Code - Cam Design

```
syms t

genWaveform(t*cos(t),t*sin(t) , 50, -pi/2, pi/2); % Pear Shaped Cam

% Generates a cam waveform given a parameterized function
% representing the shape of the cam.
%
% @param x_param the x component of the parameterized function (e.g. 4*cos(t))
% @param y_param the y component of the parameterized function (e.g. 3*sin(t))
% @param d_param number of tangent vectors to use for approximated calculations.
% @param domain_start the beginning of the domain of the periodic function
% @param domain_end the end of the domain of the periodic function

function a = genWaveform(x_param, y_param, d_param, domain_start, domain_end)
    t_num = linspace(domain_start, domain_end, d_param);
    syms t;

    % r(t) = <4cos(t), 3sin(t)> = <x,y>
    x = x_param;
    y = y_param;
    r = [x;y];

    % r'(t) = <-4sin(t), 3cos(t)> = <dx, dy>
    dx = diff(x);
    dy = diff(y);
    dr = [dx;dy];

    % r''(t) = <ddx,ddy>
    ddx = diff(x,2);
    ddy = diff(y,2);
    ddr = [ddx;ddy];

    % curvature of function
    K = (norm(cross([dr;0],[ddr;0])))/((norm(dr).^3)+0.000001);

    % Plot cam shape and curvature
    figure;
    chart = tiledlayout(3,2);
    nexttile([1 1]);
```

```
    hold on;
    plot(subs(x,t,t_num),subs(y,t,t_num));
    surface([subs(x,t,t_num); subs(x,t,t_num)],[subs(y,t,t_num); subs(y,t,t_num)],
[zeros(size(subs(x,t,t_num))); zeros(size(subs(x,t,t_num)))], [subs(K,t,t_num); subs(K,t,t_num)],
"EdgeColor","interp");
    axis equal;
    title("Cam Shape and Curvature");

    % Plot cam shape alone
    hold off;
    nexttile([1 1]);
    plot(subs(x,t,t_num),subs(y,t,t_num));
    axis equal;
    title("Cam Shape");

    % Plot curvature over t
    nexttile([1 2]);
    surface([t_num; t_num],[subs(K,t,t_num); subs(K,t,t_num)], [zeros(size(subs(x,t,t_num)));
zeros(size(subs(x,t,t_num)))], [subs(K,t,t_num); subs(K,t,t_num)], "EdgeColor","interp");
    axis equal;
    title("Curvature vs t");
    title(chart,"$< "+latex(x_param)+ " , "+latex(y_param)+" >$",'interpreter', 'latex');

end

function b = genCam(waveform_function, d_param)

end
```

D. MATLAB Code - Testing Results

```
function [Sn] = arterialW(a,b,N,theta)
%arterial pulse waveform function
a0 = a(1)/2;
Sn = 0;
for n = 2:N
    Sn = Sn + (a(n).*cos((n-1)*theta)) + (b(n).*sin((n-1)*theta));
end
Sn = a0 + Sn;
end

beatsPerMin = 80;
dur = beatsPerMin/60; %80 beats per minute (80/60)
```

```
fs = 12000; %%sampling rate
t = linspace(0,dur,fs);
theta = linspace(-pi,pi,fs);

%%%%%% Ideal Normal Waveform

a = [0.9490, 0.5150, 0.2893, 0.2838, 0.1498, 0.1227, 0.1177, 0.0569, 0.0105, 0.0008, 0.0056];
b = [0, 0.05873, 0.1871, 0.0459, -0.0032, -0.1109, -0.0743, -0.0196, -0.0086, -0.043, -0.0007];
N = length(a);  %%number of fourier series coefficients
Sn = arterialW(a, b, N, theta);  %%arterial pulse waveform function
Sn = fft(Sn);
Tn = ifft(Sn,'symmetric');

figure  %%display arterial pulse waveform as function of time
hold on
plot(t,Tn*58); %%scale the waveform and plot against time
xlabel('Time (s)');
ylabel('Pressure (mmHg)');
title('Ideal Arterial Pulse Waveform');
hold off

%%%%%%Small Normal Cam Waveform

a2 = 0.96*[0.9490, 0.5150-.15, 0.289-0.08, 0.2838-0.075, 0.1498, 0.1227, 0.1177, 0.0569, 0.0105, 0.0008,
0.0056];
b2 = 2.1*[0, 0.05873, 0.1871, 0.0459, -0.0032, -0.1109, -0.0743, -0.0196, -0.0086, -0.043, -0.0007];
N = length(a2);  %%number of fourier series coefficients
Sn2 = arterialW(a2, b2, N, theta);  %%arterial pulse waveform function
Sn2 = fft(Sn2);
Tn2 = ifft(Sn2,'symmetric');

figure  %%display arterial pulse waveform as function of time
hold on
plot(t,Tn2*51);
xlabel('Time (s)');
ylabel('Pressure (mmHg)');
title('Small Normal Cam Waveform');
hold off

[r,c] = xcorr(Tn*58, Tn2*51);

figure
hold on
stem(c,r)
```

```
title('Ideal vs Small Normal Cam')
hold off

rmean = mean(r);
correlationW = rmean/4.543973457992685e+06

%%%%%%% Big Normal Cam Waveform

a3 = 0.48*[0.9490, 0.5150-.25, 0.289-0.18, 0.2838-0.075, 0.1498, 0.1227, 0.1177, 0.0569, 0.0105, 0.0008,
0.0056];
b3 = 0.34*[0, 0.05873, 0.1871, 0.0459, -0.0032, -0.1109, -0.0743, -0.0196, -0.0086, -0.043, -0.0007];
N = length(a2);  %%number of fourier series coefficients
Sn3 = arterialW(a3, b3, N, theta);  %%arterial pulse waveform function
Sn3 = fft(Sn3);
Tn3 = ifft(Sn3,'symmetric');

figure  %%display arterial pulse waveform as function of time
hold on
plot(t,Tn3*63);
xlabel('Time (s)');
ylabel('Pressure (mmHg)');
title('Big Normal Cam Waveform');
hold off

[r2,c2] = xcorr(Tn*58, Tn3*63);

figure
hold on
stem(c2,r2)
title('Ideal vs Big Normal Cam')
hold off

r2mean = mean(r2);
correlationW2 = r2mean/4.543973457992685e+06
```

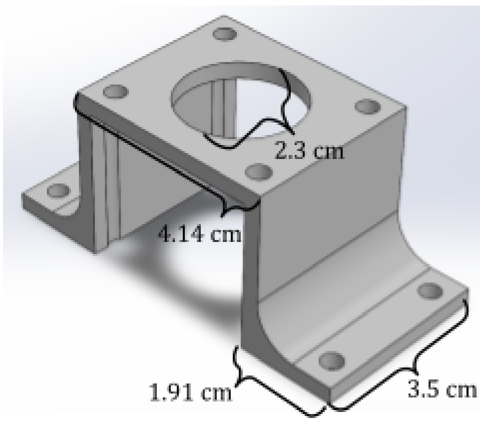
E. Arduino Code

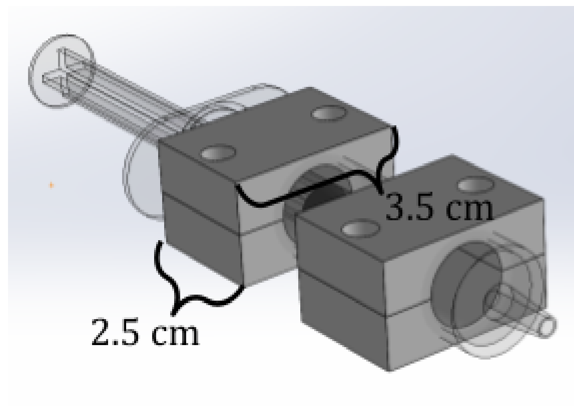
```
/*
 Stepper Motor Control - speed control

 This program drives a unipolar or bipolar stepper motor.
 The motor is attached to digital pins 8 - 11 of the Arduino.
```

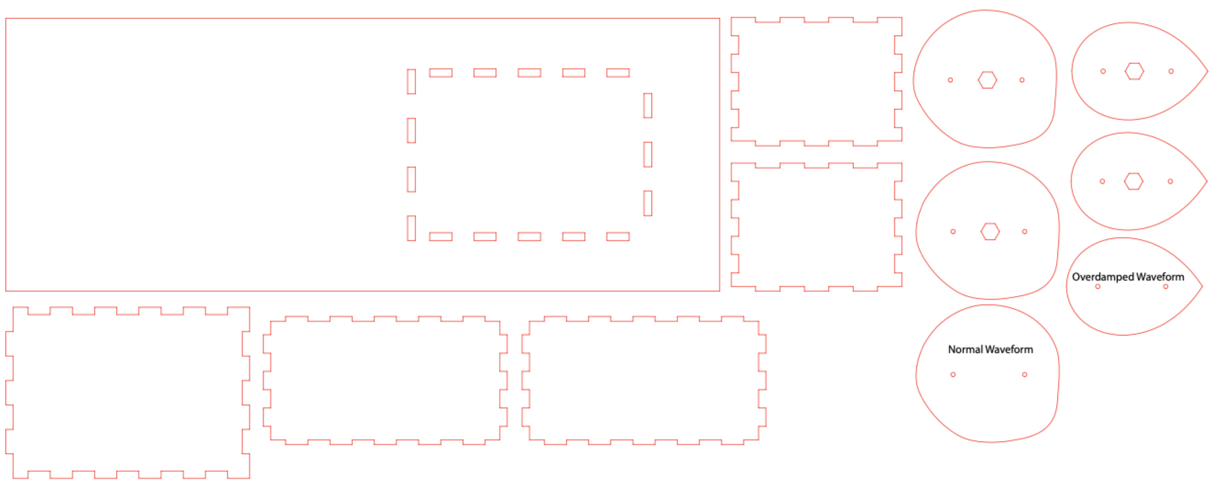
```
 A potentiometer is connected to analog input 0.

 The motor will rotate in a clockwise direction. The higher the potentiometer value,
 the faster the motor speed. Because setSpeed() sets the delay between steps,
 you may notice the motor is less responsive to changes in the sensor value at
 low speeds.

 Created 30 Nov. 2009
 Modified 28 Oct 2010
 by Tom Igoe

 Modified 27 Nov. 2021
 by Frankie Szatkowski

 */

#include <Stepper.h>

//sets the number of steps on specific motor:
const int stepsPerRevolution = 200;


// initialize the stepper library on pins 8 through 11:
Stepper myStepper(stepsPerRevolution, 8, 9, 10, 11);

int stepCount = 0;  // number of steps the motor has taken

void setup() {
  // Open Serial monitor for RPM values
  Serial.begin(9600);
}

void loop() {
  // read the sensor value from potentiometer:
  int sensorReading = analogRead(A0);
  // map it to a range from 0 to 150:
  int preSpeed = sensorReading * 1.5;
  int motorSpeed = map(preSpeed, 0, 1023, 0, 100);
  //Output motor speed to serial monitor
  Serial.print(motorSpeed);
  Serial.print("\n");
  // set the motor speed:
  if (motorSpeed > 0) {
    myStepper.setSpeed(motorSpeed);
```

```
    // step 1/100 of a revolution counter clockwise, then repeat loop:
    myStepper.step(-2);
  }
}
```

F. Additional Images







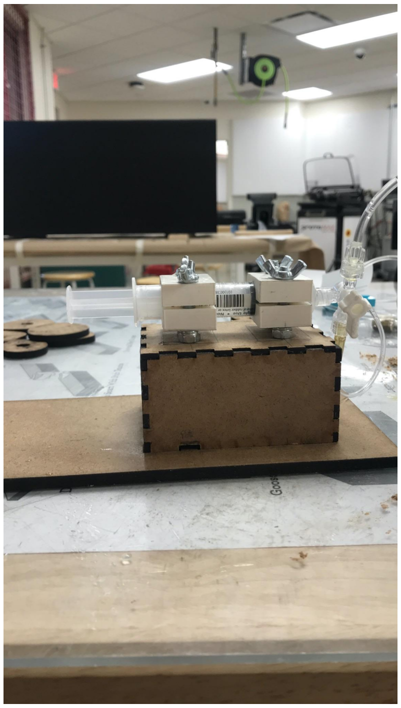


Figure depicting the support box with the syringe clamps installed.

Figure depicting the testing setup.