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ARTERIAL LINE SIMULATOR PRELIMINARY REPORT

BME 200/300 10/20/21

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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 he is currently doing this manually using his hand. By applying pulses of pressure to a syringe plunger attached to a transducer he simulates the different waveforms for his 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. The team brainstormed and evaluated three design variations for a potential arterial line simulator. These consist of a cam design, a piston design, and a bolt design. The cam design was chosen to move forward with, as this rotating wheel, with an arterial line waveform mapped onto its surface in the form of elevations, could spin to strategically push the syringe with varying rates and pressures. The other designs were not chosen for reasons of complexity, consistency, ease of fabrication, and range of use. The team plans to conduct testing to determine the ideal shape of the three interchangeable cams and then begin fabricating the device.

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I. Introduction

A. Motivation/Global Impact

Arterial lines are vital healthcare devices that are used to obtain accurate information about the cardiovascular system of a patient. Therefore, it is important for healthcare professionals to receive adequate training that will prepare them well 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

Several other methods for creating arterial line simulators currently exist on the market, however it is composed of 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



Figure 1: Manikin with Arterial Line Capabilities [1]

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. Problem Statement

In order to simulate arterial line waveforms in teaching labs, 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. To pracing the process of placing and reading an arterial line, ideally, 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].

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 [5]. The monitor often displays the ECG as well, however the

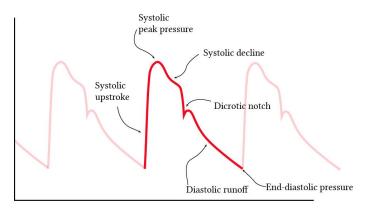


Figure 2: The Normal Arterial Pulse Waveform [5]

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].

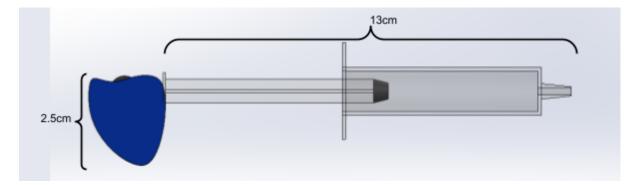
B. Client Information

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. <u>Design Specifications</u>

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 75 cm cube 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. Given the device's proximity to saline, any electrical components or wiring showing would be a safety hazard. Finally, the device must be low cost compared to the MedSim manikin simulator, with an absolute maximum fabrication cost of \$1000.



Preliminary Designs

III.

A. Design 1 - The Cam:

Figure 3: Cam Preliminary Design

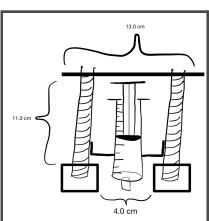
The cam design relies on a custom shaped cam that depresses the syringe plunger as it rotates (Fig. 3). The shape of the cam directly influences the pressure waveform that is created. Therefore, it will be necessary to manufacture three different cam shapes, one for each waveform that is desired. The 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. <u>Design 2 - The Piston:</u>

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 in parallel to the syringe (**Fig. 5**). Attached to the top of both bolts is a metal plate applying uniform pressure 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.

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

IV. Preliminary Design Evaluation

A. Design Matrix

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.

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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. <u>Materials</u>

Specific material choices have not yet been determined. The cams will either be 3D printed or laser cut, whichever is determined to be more conducive to the required shapes. The other materials will be chosen over the coming weeks.

B. <u>Methods</u>

The fabrication methods of the device have yet to be determined.

C. Final Prototype

The final prototype has not been assembled at this time.

D. Testing

At this time, no testing has been conducted. However, the team plans to use software to test cams of different shapes in order to determine the waveforms that they produce.

Additionally, the team will work with the client's equipment to perform testing of the fabricated device and observe the waveforms on the monitor.

VI. Results

Since there has been no testing at this point, there are no results to discuss. However the team plans to use the results of the cam testing to make any necessary adjustments to the shape of the cams. These adjustments will provide more accurate results for the three desired waveforms.

VII. Discussion

The device will need to produce accurate waveforms so that healthcare professionals using the device can receive proper training. This is necessary because those being trained will need to be able to accurately read the blood pressure of patients. In order for the design to be ethical the team must ensure that the waveform readings are consistent, accurate, and precise.

VIII. Conclusions

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, if successful, the design has the possibility to be used beyond Mr. Mitchel Reuter's teaching lab and could be used in many healthcare training programs.

The proposed final design is the cam design which incorporates three different interchangeable cams. Each cam will be designed specifically to create one of the three desired waveforms. Additionally, the cams will be motorized to rotate at a specific speed in order to apply the correct amount of pressure to the syringe plunger.

In the upcoming weeks the team will begin using computer software to determine the ideal shape of the cams. The team will make adjustments to the cam shapes and then begin

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fabricating the device. After fabrication is complete, the team will work with the client to perform testing using the client's equipment. This testing will allow the team to determine the success of the device and make changes if needed. Potential areas of challenge include determining the cam shapes, rotation speed, and pressure needed to create the desired waveforms.

IX. References

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X. 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 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:

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