BME Design Courses
The Product Design Specification (PDS)

Arterial Line Simulator:

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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. Our 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 our 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 our 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 our 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].

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]