Product Design Specification

Wearable Simulator for Enhanced Realism

BME 200/300 Lab Section: 307

Updated: 09/23/2021

Team Members and Contacts:
Client: Dr. Michael Lohmeier (mtlohmei@medicine.wisc.edu)
Advisor: Dr. Krishanu Saha (ksaha@wisc.edu)
Team Leader: Francisco O'Neill Rodriguez (fgoneill@wisc.edu)
Communicator: Sierra Reschke (sgreschke@wisc.edu)
BWIG: Jessie Hunt (jjhunt2@wisc.edu)
BSAC & BPAG: Sami Matloub (smatloub2@wisc.edu)

Function

Modern medicine relies heavily on the teaching of new and upcoming physicians. Simulations have become a prominent way of teaching that allows individuals to be trained in a safe and controlled environment, allowing them to learn and hone their skills before they are actually in the field. Even though the simulations and mannequins that exist today are able to mock human injuries in impressive and accurate ways, they are unable to simulate an actual human. The proposed simulation vest would allow for training that includes human interaction and more realistic symptoms. The vest would be equipped with audible and electrical body function simulators able to be manipulated and detected for different scenarios similar to mannequin simulators. This would allow for the medical condition to be better portrayed, allowing for a more in-depth and accurate training of medical students and staff.

Client requirements:

- No more than $500
- Must be a wearable simulator of reasonable weight and size to fit the average person
- Can be used 4-5 times a month
- Outputs can be modified during simulation to respond to interventions
- Simulates heart sounds and pulses
- Simulates lung sounds

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The design should be made so that the vest can be worn in a comfortable manner on the upper body of a person, and should produce a variation of heart sounds and pulses.

b. *Safety:* The vest will contain electrical components that will be properly enclosed, grounded, and will have a kill switch. To prevent any injury, the edges of the vest will be made soft and rounded, while still keeping as full of a range of motion as possible. Anyone who wears the vest should receive training on how to properly utilize it. Proper labeling on the vest will warn users of the electrical components present and the thermal risk of wearing the vest for extended periods of time to avoid overheating. A disclaimer will be added advising users that the vest will simulate medical conditions, but does not perfectly mimic all these conditions nor all aspects of them. The labels utilized will adhere to FDA Labeling Regulatory Requirements for Medical Devices [1].

c. *Accuracy and Reliability:* The vest will consist of two components, the wearable vest component and the electronic components. It will be built with strong materials so that it is reliable, durable, accurate, and will not tear or break when worn by an actor of the appropriate size. The electronic portion will be based on current simulator technology. The vest should be able to produce reliable results in every occasion that it is used, as it will be equipped with high quality technology.

d. *Life in Service:* The simulator will be made of sturdy materials similar to those in a kevlar vest, which uses sail cloth and polyethylene fibers [2]. The vest should be able to be worn for multiple years in a medical education setting without it needing to be replaced or repaired, assuming it is used about 8-12 hours a week depending on the medical training. The electronic components in the vest will function to be able to simulate heart sounds, and pulse. A speaker system should also be powered by these components. These features will be similar to the technology used for current simulators and mannequins, which have been used in medical practice for many years, and have proven to be durable and provide accurate information.

e. *Shelf Life:* The vest will be made from polyethylene fibers, which has an indefinite longevity [3]. The batteries utilized for the electronics, that will be needed to simulate heart and breathing sounds, will need to be changed or charged once every few months depending on its usage, which is the only potential corrosive aspect of the device.

f. *Operating Environment:* This device will primarily be used in special environments dedicated to training medical students and staff. This environment must be well-maintained, kept clean, and remain at room temperature with no contact with any aqueous solutions or extreme humidity. Furthermore, there must be access to power outlets and a table to place the device upon, and the

environment must be safe and relatively undisturbed so that individuals such as EMTs and medical school residents can properly learn.

g. *Ergonomics:* Without the electronic kits, the vest itself will be easily portable, easy to carry, and easy to store. The electronic kits will also be easy to store and transport by means of permanent attachment to the vest or a separate, organized toolkit box. In addition, the vest and additions will be made such that the actor wearing the vest will not experience any inhibition of motion, allowing them to properly simulate the scenario.

h. *Size:* The design for this product should be created to be comfortably worn by a 6ft, 185lb male, but will be able to adjust to fit similarly-sized individuals. It should not be overly heavy and bulky or restrict movement of the waist, shoulders, and neck. It will also be small enough to be easily transported and stored.

i. *Weight:* As the actor could potentially be wearing this vest for long periods of time, it will be designed to maintain their comfort and capabilities. To maximize functionality and minimize discomfort, the vest, including all of its electrical components, will weigh no more than 5-6 pounds. This weight is similar to that of a kevlar vest, and with the weight distributed over the actor's chest, it won't feel unreasonably heavy [4].

j. *Materials:* For a balance between strength, weight, comfort, and affordability, the vest will be made out of canvas and strong fibers such as polyethylene and sail cloth [3]. This vest has been obtained from the previous group.

k. *Aesthetics, Appearance, and Finish:* It is important that there are no sharp edges on the design and that the material chosen does not cause excess irritation or pain to the skin. There should be no loose wires or anything sticking out. The device should be pleasing to look at and all parts should be attached cleanly and be easily accessible. The vest shouldn't distract from medical care in a way that makes the simulation unrealistic.

2. Production Characteristics

   a. *Quantity:* A single prototype vest will be created. Ideally, more vests would be created and at a lower cost in the future.

   b. *Target Product Cost:* The initial budget is no more than $500, however, Dr. Lohmeier can be contacted about receiving more funding if it is necessary for an important addition to the project. The vest, as well as some electronic material components, have already been obtained.

3. Miscellaneous

   a. *Standards and Specifications:* INACSL Standards of Best Practice: Simulation SM outlines eleven design criteria, two outcomes and objectives, five facilitation, five debriefing, four participant evaluation, four professional integrity, four simulation interprofessional education, and six operations criteria that will need to

be satisfied for the vest to be used in an educational/training setting [5]. The vest, like all other medical devices, must be approved by the FDA before any mass distribution takes place. The device will be classified as a Class 1 medical device [6].

b. *Customer:* Our client, Dr. Lohmeier, would like a wearable device with speakers to mimic heart and lung sounds. This device would be in the form of a vest and would ultimately carry out all the medical functions that Dr. Lohmeier is anticipating. He would like the vest to be comfortable, manipulatable, customizable, and be sturdy enough to last over time.
c. *Patient-related Concerns:* The primary concern for this vest is the comfort and durability factor. We want the patients to be relieved of any discomfort or pain when wearing the medical device. The vest will also be sterilized after each use in order to prevent the spread of COVID-19 during the pandemic. Finally, any data collected while the patient is wearing the medical device will be shared with no outside parties; only immediate doctors and nurses may access this information.
d. *Competition:* While there are many simulators that can perform the same functions as this medical device, our team has not found any competitors on the market who use a vest to execute these medical simulations. Every simulator on the market utilizes a mannequin; however, it can be difficult for the students to understand the real-life process of working directly with a patient. The vest is being designed as an educational tool for students who are new to the medical world, but also the vest will provide a more accurate representation of how to read palpable pulses.
    i. *SimMan 3G Plus by Laerdal Medical*: SimMan is a full-sized adult man mannequin that can be used in several different environments and has a battery life of up to four hours. The mannequin is rechargeable and completely wireless. The device can store an extensive ECG library, produces normal or abnormal breathing sounds, and has realistic compression depth and resistance [7].
    ii. *Simulaids Smart STAT Basic with iPad*: Includes advanced airway management, emergent lung sounds, emergent heart sounds, pulse points, bilateral chest decompressions, bilateral chest tube insertion, and virtual capnography and oximetry. It costs $13,365 [8].

References:

[1] US Department of Health and Human Services (1997, February). Good Guidance

Practices: Labeling Regulatory Requirements for Medical Devices. HHS Publication FDA89-4203.https://www.fda.gov/files/medical%20devices/published/Labeling---Regulatory-Requirements-for-Medical-Devices-%28FDA-89-4203%29.pdf

[2] National Institute of Justice, "Current and Future Research on Body Armor," January 1, 2010, https://nij.ojp.gov/topics/articles/current-and-future-research-body-armor

[3] Bally Ribbon Mills. n.d. Polyethylene | Bally Ribbon Mills https://www.ballyribbon.com/fibers/ polyethylene

[4] Total Security Solutions. 2016. Today's Police Body Armor: Overt, Lighter, Smaller. - Total Security Solutions https://www.tssbulletproof.com/blog/todays-police-body-armor-overtlighter-smaller

[5] INACSL Standards Committee (2016, December). INACSL standards of best practice: Simulation SM. Clinical Simulation in Nursing, 12(S), S5-S47. https://www.inacsl.org/INACSL/ document-server/?cfp=INACSL/assets/File/public/standards/SOBPEnglishCombo.pdf.

[6] Center for Devices and Radiological Health. (n.d.). *Classify your medical device*. U.S. Food and Drug Administration. Retrieved September 23, 2021, from https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

[7] *Simman 3G Plus - immersive training for emergency care procedures*. Laerdal Medical. (n.d.). Retrieved September 23, 2021, from https://laerdal.com/us/products/simulation-training/emergency-care-trauma/simman-3g/.

[8] “Simulaids SMART STAT Basic with IPad.” Universal Medical, www.universalmedicalinc.com/simulaids-smart-stat-basic-with-ipad.html?campaignid=1049828359.