

Product Design Specifications

Wearable Simulator for Enhanced Realism

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Function:

Simulations have become a prominent tool in the medical industry to train students and staff in a safe environment on infrequent and risky scenarios. However, mannequins remain inanimate objects that can be hard to interact with in a realistic way. This project aims to create a wearable simulation vest that a human could wear to create a more realistic interpretation of these events. 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. The vest wearer would then be able to more accurately act out scenarios and interact with the medical students and staff to better portray specific medical conditions, emotions, and body positions.

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:* This design should be something that can be worn comfortably on the upper body of a person and can produce varied heart sounds and pulses. It should be able to be used about four to five times a month and able withstand the force exerted by the user each time. The device should also be adjustable to fit the various builds of the user.
 - b. *Safety:* This product will contain electrical equipment that will be properly enclosed, grounded, and equipped with a kill switch. The edges of the vest will be soft and rounded

to prevent injury, and it will be designed to keep as full of a range of motion as possible. Anyone wearing the vest, will need to be trained on how to properly use 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. There will also be a disclaimer reminding users that the vest is a simulation of medical conditions, but does not perfectly mimic all conditions or all aspects of those conditions. All labeling will adhere to FDA Labeling Regulatory Requirements for Medical Devices [1].

- c. *Accuracy and Reliability*: This product will have two components, the wearable vest component and the electronic components. The vest will be built with strong materials so that it is reliable, accurate, and will not rip or break when worn by an actor of the correct size. The electronic portion will be based on current simulator technology. With high quality technology installed in the vest, it should be able to produce reliable results almost every time.
- d. *Life in Service*: This product will be made of sturdy materials similar to those in a kevlar vest, which uses sail cloth and polyethylene fibers [2]. With these strong materials and the vest being used only 4-5 times per month the vest should be able to be worn for multiple years in a medical education setting before needing to be replaced or repaired. The vest simulator will also have an electronic component for measurements including heart sounds, pulse, and a speaker system, These features will be similar to the technology used in the 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 itself will mostly be made from polyethylene fibers, which has an indefinite longevity [3]. The batteries for the electronics, that will be needed to moderate the heart and breathing sounds, will need to be changed/charged once every few months depending on usage, which is the only potential corrosive aspect of the device.
- f. *Operating Environment*: The device will mostly be used by EMTs and medical students as a training model for real-life patients. The training with the device will mostly occur in special simulator training areas. The device will need outlets and a table for the electronic kits included with the vest and will require an environment that has no contact with any aqueous solutions.
- g. *Ergonomics*: The vest itself will be easily portable with the various electronic kits that will be sized into a well balanced tool kit. The vest itself will be reasonably weighted and sized to avoid weighing down the user and to maintain as much range of motion as possible.
- h. *Size*: The design for this product should be created to be comfortably worn by a 6ft, 185lb male. It should not be overly heavy and bulky or restrict movement of the waist, shoulders, and neck.
- i. *Weight*: This product will be worn by actors for potentially long periods of time; therefore, to maximize comfort and functionality, the vest, including the electrical components, will be a maximum of 5-6 pounds, similar to the weight of a kevlar vest [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].

- 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.

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*: There is an initial budget of no more than \$500, but if more money is needed Dr. Lohmeier can be contacted about receiving more funding.

3. Miscellaneous

- a. *Standards and Specifications*: INACSL Standards of Best Practice: SimulationSM 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].
- b. *Customer*: The client, Dr. Lohmeier, would like a wearable device with speakers to mimic heart and lung sounds. He would like it to be comfortable, manipulatable, customizable, and be sturdy enough to last over time.
- c. *Patient-Related Concerns*: Since a person will be wearing the vest, we need to make sure the inside of the vest is comfortable enough to be worn without discomfort. The device will need to be sterilized between uses if different people intend to use the vest, especially in the current pandemic, sterilization will be necessary. All materials will need to be safe for human use.
- d. *Competition*: There is currently no competition for this exact product on the market. Components from the present medical simulators will be used as a part of our design. This product is being created to make a more real and educational experience for students when working in medical simulation. The current medical mannequins make it hard for students to get a real feel for what patient to medical worker interaction is actually like. This product will add to the learning experience and hopefully be used and implemented into hospitals and sim labs.
 - i. *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 [6].
 - ii. *Gaumard Gaumard Scientific Co. Inc.*: A full size adult mannequin with movable joints as well as soft fingers and toes for training of important basic nursing skills such as surgical draping, bathing and bandaging, oral and denture hygiene (movable jaw with removable dentures), ophthalmic exercises, ear irrigation and application of otic drops, and I.M. injection (arm and buttock). It costs \$695 [7].

References:

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- [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-overt-lighter-smaller>
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- [7] "Simple Simon Patient Care Manikin, Medium Skin." *1005807 - W45070 - Gaumard Scientific Co. Inc. - S205.M - Adult Patient Care - 3B Scientific*, www.a3bs.com/simple-simon-patient-care-manikin-medium-skin-1005807-w45070-gaumard-scientific-co-inc-s205m,p_153_5293.html?utm_source=google.