



Wearable Simulator for Enhanced Realism

BME 200/300

October 7th, 2020

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Abstract

Simulations are an incredibly useful tool for training medical personnel on high-risk and infrequent scenarios [1]. Although there are many high fidelity simulations on the market, all of them are based around plastic mannequins that lack the ability to interact and move the way a real human could thus breaking a sense of realism for the medical personnel [2]. Therefore, the team proposes a wearable simulation vest that can be worn by an actor or instructor. This will enhance the authenticity of the experience between the medical personnel trainee and the patient by allowing the trainee to interact with someone that can talk, act, and move the way a real patient would. The vest will include speakers that emit heart and lung sounds that are hearable through a stethoscope. The vest will be controlled remotely through an app that will allow either the user or an instructor in a nearby room to control the vest and adjust the sounds to create different scenarios and respond to interventions applied. Ultimately, the goal is to have a functional simulation vest that has heart and lung sounds, and can be used to assist doctors, residents, and nurses in training by providing the most realistic interpretation of any given scenario.

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I. Introduction

a. Problem Statement

Simulations have become a prominent tool in the medical industry to train students and staff in a safe environment on infrequent and risky scenarios [1]. 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 heart and lung sounds 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.

b. Impact

The current market for mid-fidelity healthcare simulators is limited due to high prices and limited functionality for purposes of training with an actual patient. For instance, many of the models in the current market are focused on providing training with mannequins that, though designed to be very accurate humanoids, do not provide the needed comprehension when working with a real life being. The idea behind the team's design is to allow actual people to put on the simulation and see how healthcare professionals orient themselves in those scenarios, since working with mannequins rarely allows emotional constructs that are present in real life situations. In addition, the model designed by the team is fairly inexpensive and mobile, compared to many of the available simulators in the market. For example, the SimMan 3G, a high fidelity simulator, costs over \$66,000 for a non-upgraded model, compared to the

team's model which has a budget of \$500 [3]. This design is especially important as the simulation market has generated over 2.5 billion dollars in revenue throughout the world [4]. In addition, the model designed by the team will be wearable and simulate many different conditions and ailments a patient may be affected with, thus allowing for a plethora of different scenarios for a healthcare provider to learn from. The individual wearing it can also convey symptoms from a certain condition through acting. For instance, if a patient is suffering from a heart attack, the individual wearing the device can visually display the feelings of pain they would be going through if they were experiencing such a condition.

Practicing on a simulation can improve reaction time and technique for physicians [5]. For example, when an individual suffers from a heart attack they have only 90 minutes from Door-to-Balloon time which is the amount of time after symptoms of a heart attack come up to the time it takes for an angioplasty to take place, a surgical intervention where a balloon is placed into an artery to move aside the cholesterol [6]. As soon as an individual experiences myocardial infarction, the timer starts on how fast they can be saved. The team's simulator will allow for the optimal timing for the transfer of a patient in an ambulance, with the ambulatory team, to the nurses and physicians waiting at the emergency room entrance, as it will be easily mobile. In addition, since it will be worn by an individual, it will allow for the most optimal setting to learn how to deal with the situation at hand. For instance, the ambulatory team will learn how to properly place a person into a stretcher without causing further discomfort and will learn how to properly analyze the situation and act accordingly in a high pressure situation.

c. Existing Devices

There are currently a large number of medical mannequins with a variety of fidelities on the market. Some of the most popular mannequins that excel in medical simulation include: "Medical Manekin," "Simulaids," and the "SimMan 3G" by Lateral (Figure 1) [7-9]. The common goal of all the medical mannequins/patient simulators is to mimic life-like and real patient scenarios to train healthcare

professionals. They are designed to have medical specialists bring and test their knowledge from inside and outside the classroom, to earn valuable "real-life experiences" so that they are better adapted for the situations they trained for in their specified fields [5]. Healthcare professionals come in contact with the sim-mannequins to comprehend more about certain real life situations and learn from potential errors that can be fixed before interacting with real patients.



Figure 1: The SimMan 3G, a high fidelity mannequin intended to accurately represent a human being's symptoms and presentation [9].

The fidelity of these mannequins depend on different models, but most mid- to high-fidelity mannequins are capable of breathing, producing life-like sounds, heart tones, and palpable pulses. They may also connect to an EKG or oscilloscope monitor, pulse oximeter, arterial waveform, pulmonary artery waveform, and anesthetic gases monitor [4]. Many of these mannequins are touch sensitive and provide immediate feedback depending on different interactions from individuals testing with them. Each mannequin has different internal programmable settings depending on the situation they are placed into and are tailored to a specific area of medical expertise for the health professional's comprehension.

The SimMan 3G is the most comprehensive mannequin of the three listed above and is an advanced patient simulator that can display neurological symptoms as well as physiological (Figure 1). It is simple to operate and features innovative technology such as automatic drug recognition, POC ultrasound, advanced ventilation management and patient monitoring. It is controlled via a software called LLEAP, which unifies the operation of all PC operated Laerdal simulators by providing a shared user interface, interchangeable hardware options, and a cohesive simulation experience. It is also remotely

controlled, wireless and self-contained, and includes rechargeable batteries which last about four hours. The mannequin's features are extensive in that it has a controllable open/closed airway; automatically or manually controlled, a transtracheal jet ventilation, need/surgical cricothyrotomy, four settings for variable lung and airway compliance and/or resistance, simulated spontaneous breathing, bilateral and unilateral chest rise and fall, oxygen saturation with carbon dioxide exhalation, and lastly normal and abnormal breathing sounds through five anterior auscultation sites and six posterior auscultation sites [9].

II. Background

a. Research

The medical mannequin currently used in the UW Hospital Simulation lab is designed by a company called Laerdal. This product includes a silicone skin, air compressors for pulse points, wire hookups to connect to EKG machines, and ultrasound capabilities. The mannequin has the ability to be wireless, but is usually used while plugged in. The mannequin has the ability to produce a pulse at several points, including the neck/throat, hip, wrist, upper arm, and heart. There are pre-programmed noises and phrases that the mannequin can make and say, along with the ability to connect to a microphone where an outside party can relay information. Other major features include crying, bowel sounds (normal, gurgling, constipation), IV setup and injection, Ultrasound probe, EKG hookup, and defibrillator hookup.

Lung and heart sounds are one of first things a medical professional will evaluate during a physical examination. Techniques for listening and diagnosing lung noises include auscultation, which is the process of listening to breathing sounds with a stethoscope; percussion, which involves tapping on the chest to analyze bodily structures; and tactile fremitus, which assesses the vibrations traveling through the chest [10]. Internal breathing sounds are produced in the vocal cords, whereas external signals are results of the chest percussion and airway insonification. Some internal breathing sounds to listen for include, crackles, wheezes, squawks, rhonchus, stridors, and bronchioles [11]. Crackles are short high pitched noises caused by air passing through fluid in the lungs. Wheezes are high pitched whistling noises correlated with asthma or chronic obstructive pulmonary disease. Rhoncus is a low pitched wheeze when breathing out, caused by mucus in the bronchial tubes. Stridors are harsh squeaking noises caused by a blockage in the airway. Lastly, bronchioles are hollow sounding breaths caused by mucus build up in the airways.

Heart sounds can also be extremely useful diagnostically to recognize different problems in the heart. The heart has four distinct sounds that are spaced in a predictable pattern as shown in Figure 2 [12]. Deviation from the norm could signify an abnormality such as a murmur, block, stenosis, or hypertension [12]. Additional heart sounds a doctor could hear and diagnose are bradycardia, the heart beats too slow; tachycardia, heart beats too fast; fibrillation, heart quivers; and premature contraction, an early heartbeat [13].

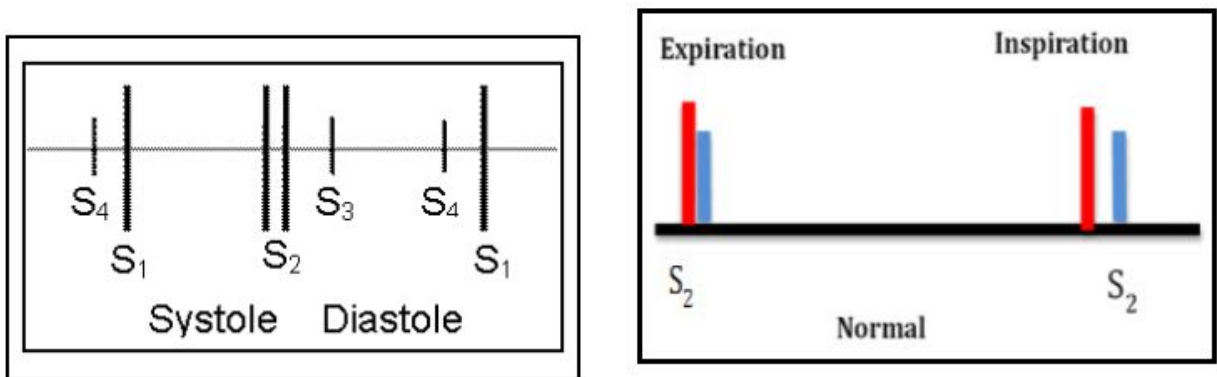


Figure 2: Normal Heart Sound. This is a visual representation of the four heart sounds detectable through a stethoscope [12].

To guide the simulation design process, the International Nursing Association for Clinical Simulation and Learning Simulation (INACSL) has implemented standards for medical simulations. These standards include design requirements for foundational evidence, measurable objectives, purpose, theory modality, scenarios, cases, modality, fidelity, prebriefing, debriefing, and pilot test simulation. These design requirements under the INACSL standards ensure that all medical simulators uphold professional integrity, are ethical, and provide valuable learning opportunities [14].

b. Client Information

The client, Dr. Michael Lohmeier is an emergency medicine doctor for the University of Wisconsin School of Medicine and Public Health. His responsibilities include EMS, prehospital care,

mass casualty preparedness, fireground rehab, and resident education. He plays a large role in teaching and assisting students and medical professionals in the University of Wisconsin Simulation Lab. Therefore, he has tasked the team with creating a wearable vest with Sim Man features, including pulse rates and heart sounds while he or another professional can act out situations and communicate with the patients for a more comprehensive learning experience.

c. Design Specification

The simulation vest design should be a wearable and functional item to be used by the University of Wisconsin-Madison Hospital Simulation Lab and Emergency Department. The vest should be adjustable so that it can be worn by an average sized male. For the most part it will be used by a 6ft 180 lb male, so it should be the length of an average male torso. The vest will have a wearable component as well as an electronic component. Imbedded in the vest there will be a speaker system, which can simulate breathing and heart sounds. The heart sound, pulses, and breathing features should have multiple leads. Pulse sounds should be found on the arms, heart and neck. Breathing should be able to be heard on the front of the vest as well as the back. The vest will be lightweight so that it can be worn for extended periods of time during educational training. For this design, there will be a bluetooth component embedded which will control the speaker and the state of the heart and lungs. The bluetooth component will be connected to an app which can simulate different conditions such as cardiac arrest and murmurs. The sim-vest will be controlled by a second operator at a separate workstation who could manipulate the heart and lung sounds. The vest material will also be made of a cleanable cloth, so that it can be sanitized easily between uses. The vest should be sturdy and withstand years of use when used approximately 8-12 hours a week.

III. Preliminary Designs

a. Garment Designs

1. The Breast Plate

The breast plate design is the smallest garment design. The breast plate will be a plastic capsule that houses all of the electronics (Figure 3). It will be secured to the actor with adjustable criss cross elastic straps wrapping around the front and back of the actor. This design is the most lightweight and will be easy to sterilize. However, its small size hinders the design's ability to add additional elements in the future and would be restricted to a single touch point.

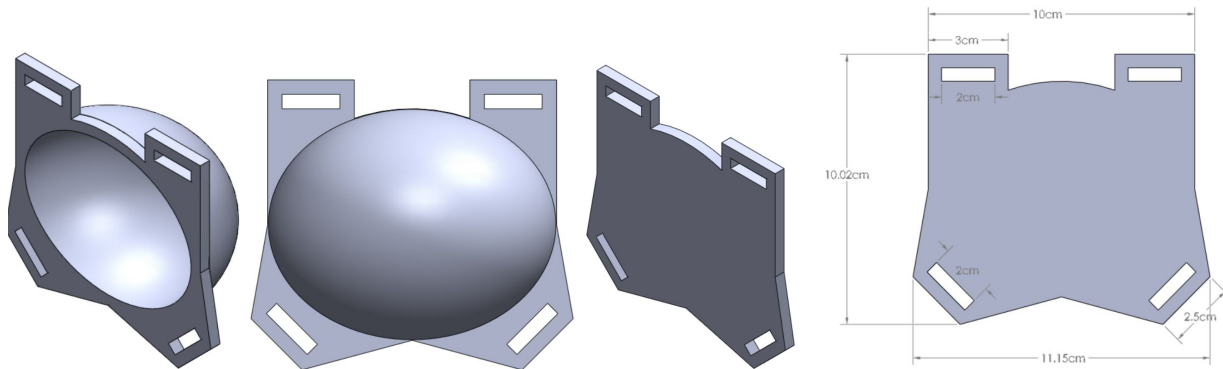


Figure 3: The Breast Plate. The first two images depict the front of the capsule. The last two images depict the back of the capsule. The two parts would be joined with fabric straps through the four attachment points in the corners.

2. Long Sleeves

The long sleeves design is a full upper body suit. This suit will have a similar form to a vest combined with a turtleneck sweater (Figure 4). The suit will have a zipper in the front which will allow actors to easily put it on. The full upper body design allows for wires to be run to the arms and neck for additional pulse points and speakers. The extra space is also good for the adaptability of the product.



Figure 4: Long Sleeves. The long sleeves design would consist of a slim fitting vest and long sleeve, turtle neck. The images depicted are inspiration from which the design would be created from [15,16].

3. The Vest

The vest design is the middle ground between the two previous designs. This design has a form similar to life jackets and kevlar vests (Figure 5). The vest will feature a side mesh to allow for better airflow and buckles in the front to allow for adjustability. The vest will be more adaptable than the breastplate and will be easier to sanitize than the long sleeve design.



Figure 5: The Vest. This design would be made of a waterproof material and be fully adjustable. It would be modeled after a lifejacket similar to the one depicted in this image with pockets, adjustable straps, adjustable waistline, and a zipper [17].

b. Electronics Designs

1. Wireless Speakers

This design will use a programmable app, which will connect via bluetooth, to control the speakers on the vest. This design will eliminate loose wires and allow the vest wearer to move freely. The app increases the functionality of the product, as it could be programmed to run additional scenarios. One drawback of this design will be that it cannot produce electrical waves to simulate heart or lung signals.

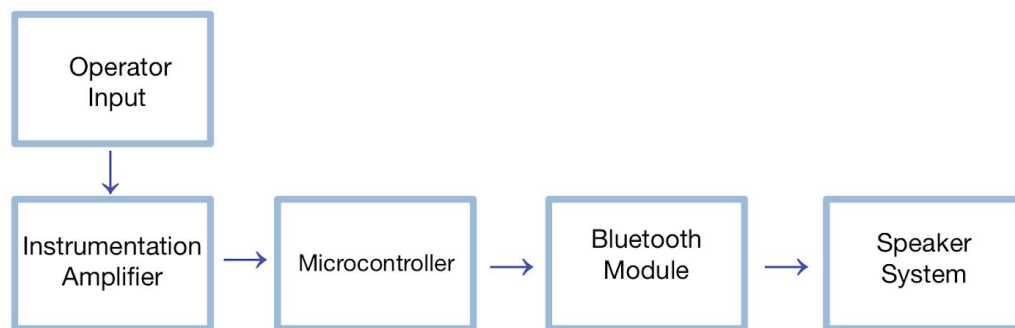


Figure 6: Wireless speaker block diagram. The wireless speaker system would be run by an external operator. The operator's commands would go through an amplifier, interpreted by a microcontroller, read through a bluetooth module, and emitted through a speaker system.

2. Dial-Controlled Speakers

This design will utilize a remote controller connected to the vest that will be accessible by the vest wearer. The remote will be able to flip through pre-programmed scenarios and sounds. Since the vest is controlled by the actor, this cuts out the need for additional people needed for training, which in turn reduces confusion and hassle.



Figure 7: Dial-controlled speaker block diagram. This system is a simple three step process where a dial would be directly connected to the microcontroller which would then emit signals to turn the speaker system on and off.

3. AC Generator

The AC generator design looks to implement an AC wave generator into the vest in order to produce sounds and electrical signals to mimic the heart and lungs. The drawback of this design is the expense of AC generators and the reduced mobility of the design.

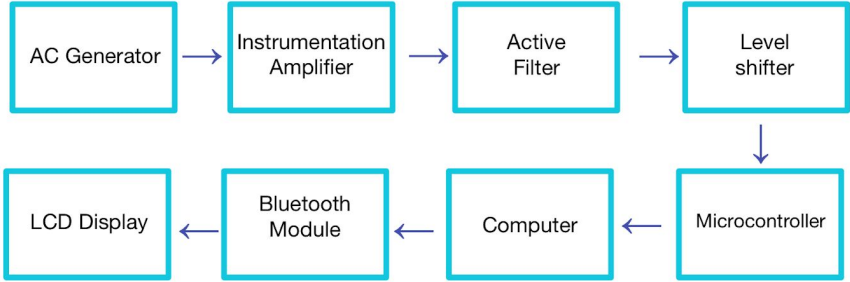


Figure 8: AC generator block diagram. This design would require an AC plug-in to the wall. This would be attached to an amplifier which would need to be filtered and shifted to the microcontroller. The microcontroller would be able to interact with the AC wave and would be modulated by the computer and would communicate with the user through a bluetooth and computer connection.

IV. Preliminary Design Evaluation

a. Design Matrices

Table 1: The wearable garment design matrix.

Criteria	Weight	Breast Plate	Long Sleeves	The Vest
Adaptability/Fidelity	30	1	5	4
Ease of Manufacturing	20	5	1	3
Comfort	15	4	3	4
Sterilizability	15	4	1	4
Cost	15	5	2	3
Safety	5	5	5	5
Total	100	70	57	74

Table 2: Electronic component design matrix.

Criteria	Weight	Wireless Speakers	Dial-Controlled Speakers	AC Generator
Ease of Manufacturing	25	2	4	1
Safety	20	5	4	2
Accuracy of Output	15	4	4	5
Adaptability	15	4	2	3
Motility	15	5	3	1
Cost	10	4	3	1
Total	100	77	69	42

b. Justification of Criteria

Adaptability/Fidelity: The adaptability/fidelity of both products is determined by the ability to add more components to it and for it to produce more data. This weighed the highest (30%) for the

garment design because a goal for this design would be for it to be used instead of a manikin during simulations. “Long Sleeves” scored the highest, with “The Vest” very close because both of these designs have a larger total area of fabric, meaning there is more area for additional components to be attached. For the electronic design this category weighted 15%, as it is important for the electronic component to be able to produce multiple different types of data (ie sounds, pulses). “Wireless Speakers” scored the highest in this category as the use of an app or bluetooth device would allow multiple data components to be incorporated into the design.

Ease of Manufacturing: The ease of manufacturing for both the garment and electronic designs is based on the perceived fabrication ability of the team and the ability to use various resources on campus. The ability of the team to produce effective prototypes is important to determine the effectiveness of the design and ability for the design to be used in live simulations. This received the second highest weight for the garment design (20%) and the highest weight for the electronics design (25%) because if the components cannot be properly fabricated by the team, the overall design will be flawed and unable to be used.

Comfort: The comfort of the garment product is determined based on how comfortable the user is while wearing it. This is important because any discomfort will decrease the likelihood of someone wanting to wear the design. Due to the lightweight plastic chest component and the use of thin stretch straps the “Breast Plate” scored the highest in this category.

Sterilizability: The sterilizability of the garment design is based on ability for the design to be properly sterilized between each use. This is important, especially given the increase in sanitization protocols due to COVID-19, because this design will be used in clinical settings many different people will be practicing with the device. Both the “Breast Plate” and “The Vest” scored the highest in this category because both designs have an outer layer of some type of plastic coating, making them easy to sanitize.

Cost: The cost of both product designs includes the price of the individual components of each design and the total cost of production. A lower cost would be ideal since it would help make the device more marketable to consumers. “Breast Plate” scored the highest and the main component of this design could be 3D printed, which usually has a low fabrication cost. “Wireless Speakers” scored the highest on the electronic side as the creation of an app would be at a zero or very low cost.

Safety: If users do not feel safe or are putting themselves in danger while using this product, they will not want to use it, and there could be a high risk of injury. Safety was ranked the lowest in the garment design matrix as all designs were developed to be safe for one to wear. However, safety was ranked second highest (20%) for the electronics components as the likelihood of being electrocuted should be determined for each design. “AC Generator” scored the lowest in this category because, if the wiring is off, there would be a chance the user could be electrocuted while using the device.

Accuracy of Output: Accuracy of output of the electronics designs is based on how well the output of the signal corresponds to an individual experiencing similar conditions. This is important because the electronics must generate accurate sounds and pulses during the given scenario or else the entire design would be useless. Since the purpose of the product would be to simulate certain medical situations, if the design cannot accurately produce data for the certain situation, then the person practicing on the design would not benefit or learn how to accurately assess and treat the situation. “AC Generator” scored the highest, by one point, in this category because it would not rely on multiple equations to generate the output data like the “Wireless Speakers” and “Dial Controlled Speakers” would require.

Motility: Motility of the electronics designs refers to the ability to remove the circuitry from the garment design, move the circuitry to different positions on the garment, and whether it can be remotely controlled. This is important because the ability to have all of the electronic components fit within the garment design, the easier it would be for the user to wear during simulations. “AC generator” scored the worst in this category because this design would require the user to carry around an AC generator to plug

into the wall during use. “Wireless Speakers” scored the highest in this category as all the electronic circuitry components would be able to be stored within the garment. The wirelessness would allow for a second person to control the output data during use, which is something that the client would like to see in the design.

c. Proposed Final Design

The proposed final design will be “The Vest” garment design with the “Wireless Speakers” electronic design. The garment part will have side mesh to allow for breathability and buckles around the midsection to allow for size adjustments. The vest will have an outer layer made of some type of plastic material in order to allow for the design to be easily sterilized in between uses. There will be additional padding used around the shoulder area and other potential areas to provide additional support and comfort for the wearer. Speakers will be placed within both the front and back sides of the vest in order for the design to generate more consistent sounds throughout. These speakers will be used to generate both heart and lung sounds which will correspond to each other and to what one would hear from a living person based on the situation being simulated. These speakers will ideally also be able to be controlled remotely via a bluetooth module, allowing for a second person to make changes to the heart and lungs sounds be generated based on how the person wearing the vest is being treated during the given situation. However, it may be more beneficial for the vest wearer to be able to change the output sounds throughout the scenario as it would eliminate the need for an additional person to be present during the practice of the scenario.

V. Fabrication/Development Process

a. Materials

The vest will need to be made of a fabric material that is waterproof, functional, and comfortable. To ensure that the vest is waterproof to protect the electronics and allow for sterilizability, the fabric will need to be coated in a plastic-based film or be chemically treated. The outside of the vest needs to allow for sound to travel through it easily without being overly muffled and needs to be relatively quiet to reduce external noise. The inside of the vest should be made of polyester, cotton, nylon, or a combination of the three to make it comfortable for the wearer while also being durable. The electronics within the vest will comprise of speakers, a microcontroller such as a Raspberry Pi or Arduino, and any additional circuitry required to enable communication between the speakers, microcontroller, and user.

b. Methods

The team will execute the following tasks to create the final design:

1. Finalize circuit design for internal electronics and order parts.
2. Build circuitry and develop code.
 - a. Troubleshoot any challenges that may arise.
 - b. Reevaluate design if necessary.
3. Finalize vest design.
4. Either build a complete vest or modify a vest off the market.
5. Integrate the circuitry and vest.
 - a. Make any necessary adjustments to seamlessly integrate.

6. Test the prototype for functionality and comfort.
 - a. Modify as necessary.
7. If time, or in the future, add pulses, electrical waves, and wireless modalities to design.

c. Final Prototype

To be completed later in the semester.

d. Testing

To be completed later in the semester.

VI. Results

To be completed later in the semester.

VII. Discussion

a. Sources of Error

To be completed later in the semester.

VIII. Conclusions

a. Overview

Our team has been tasked with creating a wearable, simulation vest for training medical staff. Current simulations have many complex functions and abilities, but lack realism since they are simply mannequins. By creating a vest that an actor or instructor can wear, the simulation becomes much more realistic and beneficial. Upon analyzing different garment and electronic designs, the team has decided on a vest and wireless speaker design. This vest will feature a comfortable, waterproof design with speakers that will play heart and lung sounds. These speakers will be controlled wirelessly via bluetooth.

This section will be expanded upon as the design process and semester progresses.

b. Future Work

Our future work includes finalizing our design, and moving forward into fabrication. This will involve additional research on circuitry and wireless adaptability to create a circuit that will be safe and effective. For the vest, we need to decide whether we are going to adapt a pre-made vest or create one ourselves.

After fabrication, we will move to integration and testing which will combine the garment and electronic designs and evaluate the functionality, validity, and efficacy of the final prototype. This may lead to alteration in the fabrication process.

Future work design elements could entail more complex breathing and heart mechanisms, motion sensor modeling, and circuitry that could interact with an EKG machine to measure actual electrical signals within the circuitry of the vest.

IX. References

- [1] S. Barry Issenberg, William C. Mcgaghie, Emil R. Petrusa, David Lee Gordon & Ross J. Scalese (2005) Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review, *Medical Teacher*, 27:1, 10-28, DOI: [10.1080/01421590500046924](https://doi.org/10.1080/01421590500046924)
- [2] Zoë Paskins & Ed Peile (2010) Final year medical students' views on simulation-based teaching: A comparison with the Best Evidence Medical Education Systematic Review, *Medical Teacher*, 32:7, 569-577, DOI: [10.3109/01421590903544710](https://doi.org/10.3109/01421590903544710)
- [3] Laerdal Medical Corp. July 29 2014. Pricelist Update PC62203. https://www.ogs.state.ny.us/purchase/spg/pdfdocs/3823219745PL_Laerdal.pdf
- [4] High Fidelity Simulation: Healthcare Simulation. (2019, March 21). Retrieved September 24, 2020, from <http://www.healthysimulation.com/high-fidelity-simulation/>
- [5] Yasuharu Okuda, et al. (2009) The Utility of Simulation in Medical Education: What is the Evidence? *Mount Sinai Journal Of Medicine*, V76:I4, <https://doi.org/10.1002/msj.20127>
- [6] What is Door-to-Balloon Time? – Penn Medicine. (n.d.). Retrieved from <https://www.pennmedicine.orgupdates/blogs/heart-and-vascular-blog/2017/january/door-to-balloon>
- [7] “Medical Manikin: Healthcare Simulation.” *HealthySimulation.com*, 1 Oct. 2019, www.healthysimulation.com/medical-manikin/.
- [8] “Simulaid SMART STAT Basic with iPad.” *Universal Medical*, www.universalmedicalinc.com/simulaid-smart-stat-basic-with-ipad.html?campaignid=1049828359.
- [9] SimMan® 3G. (n.d.). Retrieved October 06, 2020, from <https://www.laerdal.com/us/doc/85/SimMan-3G>
- [10] A. Rao, E. Huynh, T. J. Royston, A. Kornblith, and S. Roy, “Acoustic Methods for Pulmonary

- Diagnosis,” *NCBI*, 2019. [Online]. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6874908/>. [Accessed: 23-Sep-2020].
- [11] Kahn, A. (2019, September 18). Breath Sounds: Types, Causes, and Treatments. Retrieved from <https://www.healthline.com/health/breath-sounds>
- [12] “Pediatric Cardiology.” (2020) Cardiac Cycle, www.utmb.edu/Pedi_Ed/CoreV2/cardiology/Cardiology3.html.
- [13] "Abnormal Heart Rhythms & Arrhythmia | MemorialCare", *Memorialcare.org*, 2020. [Online]. <https://www.memorialcare.org/services/heart-vascular-care/abnormal-heart-rhythms-arrhythmias>. [Accessed: 17- Sep- 2020].
- [14] INACSL Standards Committee (2016, December). INACSL standards of best practice: SimulationSM. *Clinical Simulation in Nursing*, 12(S), S5-S47. <https://www.inacsl.org/INACSL/document-server/?cfp=INACSL/assets/File/public/standards/SOBPEnglishCombo.pdf>.
- [15] “2021 Ronix Supreme Athletic Cut Comp Vest.” *WakeMAKERS Wakeboard Ballast and Wakesurf Store*, www.wakemakers.com/ronix-supreme-athletic-cut-comp-vest.html.
- [16] Sharon, et al. “KOGMO - KOGMO Womens Long Sleeve Solid Basic Fitted Turtleneck Shirt.” *Walmart.com*, 11 Sept. 2020, www.walmart.com/ip/KOGMO-Womens-Long-Sleeve-Solid-Basic-Fitted-Turtleneck-Shirt/715973613.
- [17] “NRS Chinook OS Fishing Lifejacket (PFD).” *OutdoorPlay*, www.outdoorplay.com/nrs-fishing-lifejacket-pfd.

Appendix

A: Product Design Specifications

Wearable Simulator for Enhanced Realism

Updated: 10/7/2020

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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 about 8-12 hours a week, 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].

PDS References:

- [1] US Department of Health and Human Services (1997, February). Good Guidance Practices: Labeling Regulatory Requirements for Medical Devices. *HHS Publication FDA 89-4203*. <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, [nij.ojp.gov:https://nij.ojp.gov/topics/articles/current-and-future-research-body-armor](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-overt-lighter-smaller>
- [5] INACSL Standards Committee (2016, December). INACSL standards of best practice: SimulationSM. *Clinical Simulation in Nursing, 12(S), S5-S47*. <https://www.inacsl.org/INACSL/document-server/?cfp=INACSL/assets/File/public/standards/SOBPEnglishCombo.pdf>.
- [6] "Simulaids SMART STAT Basic with iPad." *Universal Medical*, www.universalmedicalinc.com/simulaids-smart-stat-basic-with-ipad.html?campaignid=1049828359.
- [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.