

Wearable Simulator for Enhanced Realism

BME 301

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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 a graphical user interface 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. The final design involves five speakers, four for the lungs and one for the heart, controlled by a Raspberry Pi and soundboards. Currently, speakers controlled by an Arduino are able to produce sounds. The next step is to convert the controller to a Raspberry Pi and to integrate the circuitry into the Condor vest. 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 can wear to create a more realistic interpretation of these events. The vest will be equipped with audible heart and lung sounds able to be manipulated and detected for different scenarios similar to mannequin simulators. The vest wearer will 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 vest 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 the design 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. Angioplasty is 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 EMTs, to the nurses and physicians waiting at the emergency room entrance, as it will be easily mobile. In addition, since the design 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 ambulance 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 Laderal (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].

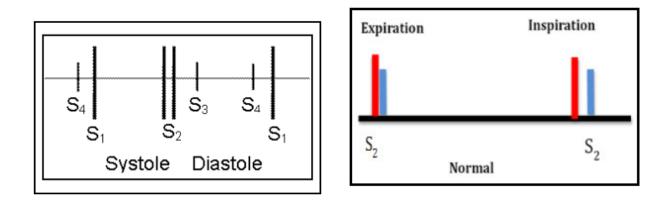


Figure 2: Normal Heart Sound. This is a visual representation of the four heart sounds detectable through a stethoscope [12]. The left shows systole and diastole sounds, and the right demonstrates the intervals between expiration and inspiration.

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. 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. Vest Designs

1. The Condor

The Condor Modular vest is an adjustable MOLLE vest intended to hold tactical gear, most often used by the military and paintballers [15]. Therefore, the Condor is intended to withstand rugged conditions with a tough canvas exterior while maintaining comfort with a mesh padded interior. This vest has adjustable straps at the shoulders and waist which allows the vest to fit many people and body types. The vest is marketed as a one-size-fits-all and should fit a size medium to x-large. This vest also includes a zipper in the front for easy on and off, and the MOLLE design provides additional points of access and storage for the circuitry integration.



Figure 3: The Condor Vest. A tactical, MOLLE vest with a durable canvas outside [15].

2. The Hyper Vest

The Hyper vest is a durable, light-weight vest made for weight training [16]. The vest materials are a cotton, canvas blend as well as cordura fabric, a very durable and lightweight material. The sides are open and have bungee cords that connect the back and front parts of the vest to allow for adjustability, free movement, and ventilation. Since the vest is intended for weight training, it contains many small pockets along the front and back to hold the desired weights. For the project purposes, the weights would be removed and replaced by the circuitry. The zipper allows for easy on and off, and the tight fitting design would allow for optimal movement and comfort. However, the vest is marketed in standard small, medium, and large sizes, so it would provide less adjustability to different body types.



Figure 4: The Hyper Vest. A weight vest with many small pockets and adjustable, bungee cord sides [16].

3. Hand Sewn

The hand sewn vest is a handmade vest which allows for maximum customizability for the design. This design would take the most materials and time to construct. However, the adjustability would be very high due to the simplistic life jacket design. The vest would be easily worn by sliding over the wearer's head and secured with a long, adjustable band around the waist. The design would be made of a waterproof canvas material for optimum durability and sterilizability with a padded inside for comfort.

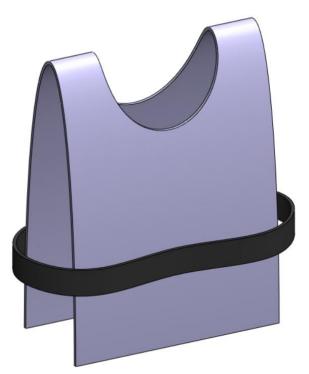


Figure 5: Hand Sewn. This design would be made of a waterproof material and be fully adjustable. It would be modeled after a lifejacket with an adjustable strap and padding.

b. Electronics Design

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.

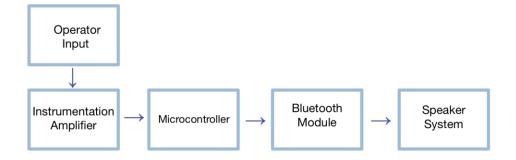


Figure 6: Wireless speaker block diagram. The wireless speaker system would be run by an external operator. The operator's commands would go through an amplifier, interpreted by a microcontroller, read through a bluetooth module, and emitted through a speaker system.

This wireless speaker design, along with other electronics designs, were evaluated in the previous BME

design semester. The wireless speaker was the design chosen and is currently in the process of fabrication.

IV. Preliminary Design Evaluation

a. Design Matrix

Criteria	Weight	The Condor	Hand Sewn	The Hyper Vest
Ease of Manufacturing	25	3	1	4
Durability	20	5	1	4
Comfort	20	3	2	5
Adjustability	15	4	5	2
Sterilizability	10	4	5	1
Cost	10	5	4	1
Weighted Total	100	77	50	66

Table 1: Vest design matrix.

b. Justification of Criteria

Ease of Manufacturing: The ease of manufacturing for the garment is the perceived ability to be able to add electronic components to it. This was weighted the highest as the electronic components need to be able to be incorporated into the vest or else that design would be unusable. The Hyper Vest scored the highest in this category, as it comes with built in pockets where the electronic parts would ideally be inserted into. The Condor came in second as it also contains pockets for the electronic components to be inserted within.

Durability: The durability of the vest is based on the ability of the vest to withstand multiple years of use during simulations. This was weighted as the second highest category because mannikins are currently used for multiple years; therefore it is important for the design to also be able to be used for multiple years in order to be an effective replacement. The Condor scored the highest in this category as it is a tactile vest made out of durable canvas material.

Comfort: The comfort of the garment product is determined based on how comfortable the user is while wearing and moving around in it. This is important because any discomfort will decrease the likelihood of someone wanting to wear the design. Due to the lightweight, thin fabric material and elastic on the sides to adjust the size, the Hyper Vest scored the highest in this category.

Adjustability: The adjustability of the vest is determined by the ability to change the sizing of the vest to fit the wearer. The vest should be able to be worn by a range of people of varying heights and weights. Based on the perceived ability to fabricate the vest as something that could be put on over one's head like a rain poncho and secured with a belt, the hand sewn design scored the highest in this category.

Sterilizability: The sterilizability of the garment 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 and the fact that it will be used in a clinical setting. The hand sewn design scored the highest in this category because it could be fabricated to have a waterproof outer layer, which would be relatively easy to sanitize.

Cost: The cost of the design is the overall cost of the vest. A lower cost would be ideal since it would make the device more marketable to consumers. The Condor scored the highest as it was the cheapest vest to purchase and would not have to be designed completely from scratch.

c. Proposed Final Design

The proposed final design will be the Condor vest design with the wireless speakers electronic design. The Condor will provide lots of adjustability in the shoulders and girth to fit many body types and sizes. It will also be very durable and comfortable due to the canvas exterior and padded interior. 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 being generated based on how the person wearing the vest is being treated during the given situation. Additionally, it may be 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 Condor Modular Vest is a premade vest on the market that is sold as a one-size-fits-all. The outside of the vest is made with cordura 600d canvas which is extremely durable and water resistant. The inside is made of a mesh padding. The vest is ordered in an olive green color. In order to integrate the electronics, this premade vest will need to be taken apart at the seams using a seam ripper and resewn using a matching thread.

The electronics within the vest will be controlled with a Raspberry Pi Zero W. The Raspberry Pi will be the microcontroller that allows for user input and will interact with the sound boards to decide what sounds are played at any given time. The Adafruit FX Soundboards will store the audio files. Each sound board can hold up to eleven sounds files. There will be three soundboards: one for the left lung, one for the right lung, and one for the heart. Each soundboard will have a corresponding Adafruit Amplifier that is then connected to the speakers. For the lungs, there are a total of four speakers to accommodate front, back, left, and right lung sounds. For the heart there will be only one speaker.

Additionally, there will need to be wires to run throughout the vest to connect the major circuitry items, solder to make all of the connections, and battery packs to power everything. There will be three separate battery packs to accommodate the three soundboards. This will make the batteries last longer and make it easier to identify which batteries need replacing. A full list of materials and their links can be found in Appendix B.

b. Methods

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

1. Build circuitry and develop code.

- a. Troubleshoot any challenges that may arise.
- b. Reevaluate design if necessary.
- 2. Finalize and purchase a vest.
- 3. Integrate the circuitry and vest.
 - a. Make any necessary adjustments to seamlessly integrate.
- 4. Test the prototype for functionality and comfort.
 - a. Modify as necessary.
- 5. Create a graphical user interface for the controller to manipulate the outputs.
 - a. Troubleshoot and get feedback from client
- 6. In the future: add pulses, electrical waves, and wireless modalities to design.

c. Final Prototype

The final design will be made up of six main components: a vest, a Raspberry Pi, soundboards, amplifiers, speakers, and battery packs. The vest has many pockets along its front and back sides which will give the team options when figuring out exact placement of the electronic components since the vest is going to contain all of the components within these pockets. By cutting holes into the pockets components could be inserted inside, and then secured by sewing the fabric back together.

The Raspberry Pi is going to be placed near the bottom in the back side of the vest in order to be able to run the wires from the Raspberry Pi to the three soundboards without having to worry about the zipper down the front of the vest. However, if it was discovered that it is uncomfortable for the wearer to have the Raspberry Pi on the back, then moving the Raspberry Pi to the front of the vest would be considered. The Raspberry Pi is going to be connected to the three soundboards, which are powered by their individual battery packs. The soundboards will then be connected to amplifiers which will be connected to the speakers. The speaker in the middle on the front of the vest will produce the heart sounds, and the other four speakers will produce the lung sounds. The person acting out the given situation will be the one who wears the vest containing the electronic components. The wires used to connect all of the components will be run between the layers of the vest. Dangling and loose wires will need to be avoided as they could become a safety hazard. The team also had the idea to 3D print plastic cases that the electronic components could be placed inside in order to help protect them from damage during the simulations.

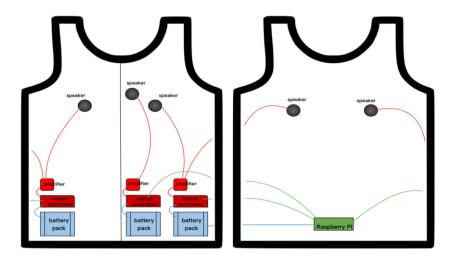


Figure 7: This is an illustration of the placement of the electronic components in the vest including the speakers, amplifiers, sound boards, battery packs, Raspberry Pi, and communication via connection wires. The left represents the front of the vest and the right represents the back of the vest.

d. Testing

Preliminary testing of the electronics have been conducted to ensure the speakers are controllable via a microcontroller-soundboard circuit. This testing was conducted to determine whether an operator could play, pause, stop, and start up to 11¹ different sounds by entering commands into a microcontroller. Sounds selected for testing included an elephant noise, a sample of House of Pain's *Jump Around*, and a heart sound. All sound files were open source and were obtained free of charge from various websites. The results of this testing were only qualitative. The goal was simply to prove if the speaker could produce the desired sounds or not. No measurements were taken during the course of the testing. This preliminary

¹ 11 is simply the maximum number of audio files the soundboard can hold. For testing purposes, only 2 audio files are needed to prove the ability to switch between sounds.

testing utilized an Arduino Uno microcontroller instead of the planned Raspberry Pi. This choice was made because the team is more familiar with the Arduino interface, which made troubleshooting much simpler. A fritzing diagram along with a photo of the circuit can be seen in Figure 10.

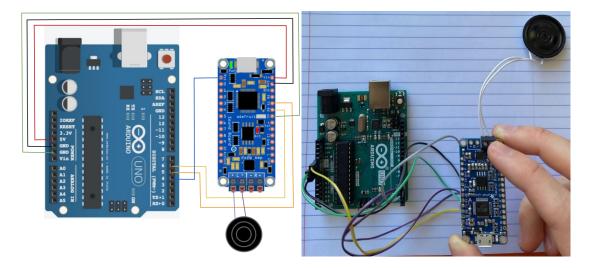


Figure 8: Fritzing diagram (left) with photo (right) of the Arduino Uno, Adafruit FX Soundboard, and speaker circuit. This was used to produce an elephant sound, a *Jump Around* sample, and a heart sound during testing.

Once a final prototype is fabricated, testing will be conducted in four stages. First, the circuitry will need to be tested. This will include running the code through the Raspberry Pi without errors and ensuring the interactions between all the components are hooked up correctly. The speakers will need to be verified by making sure the correct sounds are outputted at the right time and correct location.

Second, the sound accuracy from those speakers will need to be tested. This will be accomplished by using a stethoscope and listening through the vest to each speaker. In order to pass the test, the listener must be able to locate each speaker, be able to differentiate between the sounds coming from each speaker, and correctly identify which heart and lung sound is being played in each speaker. Ideally, this would be performed by our client to establish realistic amplitudes and frequencies. Statistical analyses will also be conducted using a multimeter to determine if the amplitudes are similar to what a physician would typically detect. The null hypothesis will be that there is no difference between the typical detected amplitude and the vest's outputted amplitude. The alternative hypothesis stating there is a difference between real-life detection and the simulated sounds. These values will be analyzed using a 1-sample T-test to determine if there is a statistically significant difference.

The next component to test will be the graphical user interface or controller. This test is crucial to the ability to manipulate and interact with the vest while a simulation is in progress. The instructor, or controller, must be able to change the sounds coming from each speaker to respond to an intervention applied during the scenario. Once the ability to manipulate is accomplished, the team will need to quantify the amount of time it takes for the controller to apply an intervention.

The final component to analyze and test will be the vest. The vest needs to be comfortable and adjustable. It is crucial that the person wearing the vest is able to have full range of motion and be able to comfortably wear the vest for a couple hours at a time. Additionally, people of all body sizes and types will need to be able to wear the vest. Therefore, the team proposes that the vest be worn by at least ten people for a minimum of 30 minutes. After, the subjects will fill out a survey judging the vest on its wearability for long periods of time.

VI. Results

Initial electronics testing was ultimately successful: all sound files chosen were able to be uploaded to the soundboard, selected by an Arduino, and played through the speaker. As previously mentioned, this initial test was largely qualitative. Demonstrations of the circuit can be found in the preliminary presentation and the design notebook.

Once a final prototype is constructed, the additional qualitative and quantitative testing will be conducted. For the first stage of testing, the design will pass once it is able to run code through the Raspberry Pi without throwing any errors and can play the different audio file through different speakers simultaneously. For stage two, the client will provide feedback on whether the sounds are clear and differentiable. The statistical analysis on the amplitude will result in a p value. If that p value is less than 0.05, the team will find significance in the readings and be able to accept the null hypothesis. If the p value is above 0.05, the team will not find significance and the null hypothesis will be rejected. For stage three, the graphical user interface will be tested and the amount of time from input to output will be calculated. This time should be less than five seconds to be considered successful. Lastly, for stage four, the surveys from the people wearing the vest will be added up. Any complaints of suggestions will be marked as qualitative observations and addressed to make the vest as comfortable as possible.

VII. Discussion

a. Results

The results of the electronics tests are promising; they demonstrated that an operator can manipulate the speaker sounds using a microcontroller. While the preliminary testing used an Arduino, the final design will incorporate a Raspberry Pi in its place. This is because the Arduino does not have easy wireless capabilities, while the Raspberry Pi does. Further testing will need to be completed to ensure the Raspberry Pi can successfully control the speakers similar to how the Arduino can.

Once results are obtained for the remaining tests, they will be used to troubleshoot and further improve the design. The results from stage one will receive pass or fail. The results from stage two will have two sets of results. The first set will have the qualitative observations made by the client and could involve needing to increase volume or obtain higher quality audio files. The second set will come from the statistical analysis to determine if the amplitude is significantly different than those typically observed in a living human. This will be a quantitative result to reject or accept the null hypothesis. Stage three results will once again have qualitative observations on the ease of use for the graphical user interface. It will also include quantitative data on the amount of time it takes from input to output. The standard has been placed at five seconds, but the results could vary and will be measured on a gradient rather than a pass/fail criteria. Stage four results will be based on the survey which will include qualitative suggestions and concerns as well as numerical grading on the comfort and adaptability of the vest. Similar to stage three, it is expected that the results will vary, thus they will be measured on a gradient rather than a pass/fail criteria.

b. Sources of Error

Currently, the preliminary speaker setup is able to produce sound and satisfy its testing requirements. However, it is not fully constructed and will need to be switched to a Raspberry Pi microcontroller. The only source of error at the moment is that the wires are not soldered yet which creates static and unreliable communication between the parts. The team anticipates that there will be additional errors once fabrication is completed and testing is conducted. The most likely sources of error will arise in the code and in the sound quality. It is expected that multiple iterations of code will need to be written for both the circuitry and for the graphical user interface. The largest concern is that the sound output will not be of a high enough quality to be identified and is not realistic in volume and quality to what would be heard on a living person. This could occur due to low resolution audio files and speakers. If this becomes a source of error, better audio files may need to be purchased or recorded, and the team may need to invest in higher quality speakers. Additionally, the wiring and soldering could create potential errors if they are not fully connected or become disconnected as the vest moves.

VIII. Conclusions

a. Overview

The 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 decided on an integrated vest and wireless speaker design. The vest will be constructed from the Condor vest and will contain all of the circuitry items between the inside and outside panels of fabric. The circuitry will be controlled with a Raspberry Pi microcontroller. The microcontroller will in turn interact with soundboards that store the audio files. The audio files will be transmitted from the soundboards, thru amplifiers, and out of the speakers. In total, there will be five speakers within the vest: front right lung, front left lung, back right lung, back left lung, and the heart. Preliminary testing of the speakers has been conducted using an Arduino Uno and have proved very successful. The next stages of fabrication will involve replacing the Arduino with a Raspberry Pi and integrating the circuitry into the Condor vest.

b. Future Work

The proof-of-concept speaker system currently fabricated needs to be fully constructed using a Raspberry Pi microcontroller. Once the circuitry is fully operational, it will be sewn into the Condor vest. Additionally, an app or other graphical user interface will need to be created to interact with the simulation. After fabrication, the design will need to be validated using the testing methods described previously. This will most likely result in troubleshooting and modifications to the design to account for unforeseen challenges.

Once the prototype is fabricated and tested, additional design elements can be added to enhance the simulations. These could entail more complex breathing and heart mechanisms, pulse points, and circuitry that could interact with an EKG machine to measure actual electrical signals within the circuitry of the vest. To more accurately simulate where a physician would need to hear all the heart and lung sounds, additional speakers may be added to the design since the current design is a simplification of all the possible listening points. In reality, there are about fifteen different points on the front and back of a person that a typical physician would utilize to diagnose and listen to the heart and lungs. Pulse points would add another diagnostic tool so that the physician could quickly calculate heart rate. Lastly, introducing electrical signals to imitate an EKG output would provide a more complete picture of a given scenario and could increase the number of scenarios the instructors could conduct using the vest. Additionally, the client also may want to upgrade the circuitry within the original design to accommodate more sounds, improve speaker quality, and vest comfort.

IX. References

- 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: <u>10.1080/01421590500046924</u>
- [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
- [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.penn medicine.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] "Simulaids SMART STAT Basic with IPad." Universal Medical, www.universalmedicalinc.
 com/simulaids-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/documentserver/?cfp=INACSL/assets/File/public/standards/SOBPEnglishCombo.pdf.
- [15] "Condor Modular Style Vest" Condor Outdoor, https://condoroutdoor.com/mv-modular-vest.html
- [16] "Hyper Vest Pro Weight Vest" Hyper Wear, [Accessed: 3-3-2021]
 https://www.hyperwear.com/product/weight vest/?attribute_size=Small&attribute_weight=10+LBS&gclid=Cj0KCQiAhP2BBhDdARIsAJEz
 XIHM-Lz2CgKv84Y8JTMN6iiFB-IvJFLS_u1kTpEdkMfxS_Q-BUozWCYaArn5EALw_wcB

Appendix

A: Product Design Specifications

Wearable Simulator for Enhanced Realism

Updated:	2/11/2021
Client:	Dr. Michael Lohmeier mtlohmei@medicine.wisc.edu
Advisor:	Dr. Ed Bersu etbersu@wisc.edu
Team:	Emma Neumann <u>ekneumann@wisc.edu</u> (Leader)
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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

[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: 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.

B: Materials

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Tota l	Link
Audio FX Sound Board	WAV/OGG Trigger w/ 16 MB Flash	Adafruit	2220	11/12/2020	3	24.95	74.85	<u>link</u>
Audio Amplifier	Mono 2.5W Class D PAM8302	Adafruit	2130	11/12/2020	3	3.95	11.85	<u>link</u>
Mini Metal Speaker	8 Ohm 0.5W	Adafruit	1890	11/12/2020	5	1.95	9.75	<u>link</u>
Raspberry Pi	Zero W	Adafruit	3400	11/12/2020	1	10	10	<u>link</u>
Battery Pack	MicroUSB Battery Holder, 3xAA	DFRRobot	FIT0362	11/12/2020	4	1.6	6.4	<u>link</u>
AA Batteries	Duracell CopperTop AA Alkaline Batteries, 24 ct	Duracell	AA-CTx24	11/12/2020	1	16.21	16.21	<u>link</u>
Condor Modular Vest	600D Cordura, Size M-XL	Condor	MV-001	2/25/2021	1	44.95	44.95	<u>link</u>
TOTAL:	\$174.01							