Wearable Simulator for Enhanced Realism

FINAL REPORT

BME 200/300

Clients: Dr. Michael Lohmeier[1]

Advisor: Dr. Krishanu Saha[2]

Team Members:

Francisco O'Neill Rodríguez, Team Leader[2]

Sierra Reschke, Communicator[2]

Sami Matloub, BSAC[2] & BPAG[2]

Jessie Hunt, BWIG[2]

[1]Department of Emergency Medicine, UW School of Medicine and Public Health, WI 53726

[2]Department of Biomedical Engineering, University of Wisconsin-Madison, WI 53706

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Abstract

Medical simulation mannequins are useful prototypes that are able to emulate a wide range of physiological features in order to provide the most optimal experience for medical residency and EMT trainees to learn from. Although many of these prototypes are currently available in the market, very few of them introduce the element of human interaction. The team was tasked to create a wearable simulation prototype that shall be worn by an actor in order to enhance the realism of a routine medical assessment of a patient to create a more in-depth and interpersonal experience. The wearable simulation prototype needed to be in the form of a vest and be able to simulate vitals such as heart pulses and respiration noises. Included in these sounds were abnormalities in normal heart pulses and respiration noises which would allow medical trainees to practice diagnosing conditions and assessing them once identified. The team's research focused on the normal and abnormal sounds produced by the cardiovascular and respiratory systems, the optimal vest for the storage of the electrical hardware, and the most efficient electrical design for the accurate representation of the sounds. The final vest design combined the Condor Ballistic Vest, wireless with Bluetooth electronics design, and silicone fake skin obtained from a past simulator mannequin. The final prototype was tested based on the accuracy of the sounds displayed and comfortability and will also be judged by our client. The test results concluded that there was not a significant difference between the sounds produced by the speakers on their own compared to through the fake skin. Furthermore, the testing concluded that the vest design is comfortable enough to be worn for at least 2 hours. In the future, further components could be incorporated into the vest to allow for an even more immersive and realistic experience.

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I. Introduction

A. Motivation

In the market today, there are numerous simulators that are being sold to hospitals and medical clinics. These simulators are adult full-sized mannequins that are capable of playing accurate heart and lung sounds of certain conditions, including tachycardia, bradycardia, arrhythmia, rales, and many others. They allow these trainees to experience the high pressure environment of being in the ICU, ER, or OR by performing various procedures on these mannequins. While they are beneficial in the different functionalities and features that each of them have, they lack one main component: the element of human interaction. Our team intends on taking all the advantages that these simulators have and creating a wearable simulation device, where the incoming medical workers can feel the presence of a real human being. From the perspective of a doctor, not being able to experience a living patient in your midst and instead having a mechanical simulator with built-in audio quotes can be difficult as they begin to transition into the life of medicine. Our vest simulator is one of many theoretical ways these students can execute procedures to simulate a condition or severe accident and also keeping the touch of human interaction.

B. Existing Devices/Current Methods

A medical simulator is nothing new to the market; however, these simulators take the form of highly complex adult-sized mannequins instead of our team's wearable simulator. These mannequins are capable of simulating hundreds of different conditions, whether it be in the heart, in the lungs, or in other organs of the body. The companies that have mass distributed these devices are stacked with highly educated engineers, ranging from software engineers to biomedical engineers. Some of these companies include Laerdal Medical, TruCorp, and Universal Medical, and their success in the medical simulation field will be discussed in this portion of the report.

One important simulator currently on the market is the SimMan [7]. The SimMan is an adult full-sized mannequin engineered by Laerdal Medical. They officially released the SimMan in 2010, where they began distributing them to hospitals or medical clinics around the globe. These simulators were made to prepare incoming medical staff how to perform simple procedures, including measuring blood pressure, reading EKGs, and monitoring oxygen flow. UW Health University Hospital has several SimMan models in the Clinical Simulation Center for students who hope to perfect these procedures. There are various settings that the doctors and individuals who are in charge of operating these mannequins can experiment with. For example, they have the ability to adjust how loud the heart and lung sounds are, how often the device will blink, and how fast the heart can beat. However, this simply scratches the surface of what the SimMan can do.

Another major competitor in the medical Simulation market is the Simulaids Smart STAT Basic with IPAD [8]. The company behind the production of this full-sized mannequin is Universal Medical. They wanted to find a way for students to learn in a high-pressure environment without taking the risk of severely injuring an individual but also preparing them for future scenarios. With that in mind, they introduced the Simulaids Smart STAT Basic. The cost of buying one of these mannequins is around $14,800, which is much higher than our cost of $500. Some of the major features of this mannequin include the following: Advanced Airway

Management System, Emergent Heart and Lung Sounds, Bilateral Chest Tube Insertion, and Pulse Points located around the mannequin.

A third important simulation device in the market is the HAL S3201 Advanced Multipurpose Patient Simulator [9]. The company responsible for making this mannequin is Gaumard Scientific. Their motivation for creating this medical simulator was simulating life-like cases where medical trainees can practice various procedures pre-hospital, in the ICU, ER, PACU, and in surgery. By placing themselves in certain situations, whether it be a cardiac arrest, heart attack, or lack of oxygen flow, they are preparing for future cases where you have no time to think and everything is based on reaction. The main components of the device are Drug Recognition System, Neural Responses, Vital Signs Monitor, and Articulation Movement. The mannequin also has some pre-recorded speech, to keep the interaction between the medical trainees more interactive.

The fourth and final competitor that will be discussed in our report is the TruMan Trauma X [10]. This device, along with many other variations of this mannequin, was introduced by TruCorp. They, like the other companies discussed before, wanted to find a safe way for medical students just finishing school or any new medical workers to function in an educational environment. While they have numerous mannequins being listed on the market, the focus will be placed on one in particular called the TruMan Trauma X. It has cost-effective & easily replaceable consumables (neck skin, larynx inserts, needle decompression inserts & chest drain inserts), AirSim X Airway System with 5 nasal passages, and user feedback with visible chest rise. The difference between this simulator from the other ones on the market is that it does not need to be plugged in for it to function properly. It has a battery life of six hours, allowing medical procedures to take place almost anywhere you desire.

C. Problem Statement

Preparing for a heart attack, cardiac arrests, or difficulty breathing is difficult for incoming medical staff. For this reason, simulators are being used in hospitals and clinics to help evaluate what they learned from the books, and that knowledge is being put into action. Simulations and mannequins that exist today are able to mock human injuries in impressive and accurate ways, however they are unable to simulate an actual human. There is no room for true human interaction between an incoming medical worker and his/her patient. Our team is attempting to find a way for students to simulate medical procedures done on those highly complex mannequins, without losing the touch of human interaction through a wearable simulator.

II. Background

A. Physiological and Biological Research

During a routine and initial physical examination, a medical professional will interact with a patient and carry out an assessment of the patient's current physiological status. Lung and heart sounds are one of the first things a medical professional will evaluate during a physical examination. These sounds are crucial indicators for the diagnosis of various cardiothoracic conditions and illnesses. Correct diagnoses are dependent on the accuracy and knowledge of the indicator being perceived, which is why it is important to understand the physiological background behind the outputs being simulated by the wearable simulator vest.

Techniques for listening and diagnosing abnormal lung noises include auscultation, the process of listening to breathing sounds with a stethoscope; percussion, the tapping of the chest to analyze bodily structures; and tactile fremitus, which assesses the vibrations traveling through the chest [11]. Internal breathing sounds are produced in the vocal cords, whereas external signals are results of the chest percussion and airway insonification. Normal breathing sounds in healthy patients can be identified based on the intensity and pitch of the sound made. A normal breathing sound can differ depending on the location where the stethoscope is placed in the torso. Auscultation assessments are performed in three different areas. These are the tracheal, bronchial and vesicular areas as seen in **Figure 1.** A normal breathing pattern in the tracheal area can be described as a very large and high pitched sound with equal inspiratory and expiratory breathing times. Normal bronchial breathing patterns are described by loud, relatively high pitched sounds with the inspiratory breathing time being shorter than the expiratory breathing time. Normal vesicular breathing sounds are described by a soft, relatively low pitch with the inspiratory breathing time being longer than the expiratory breathing time [12].

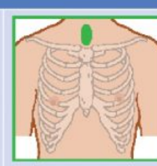
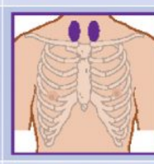
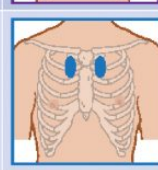
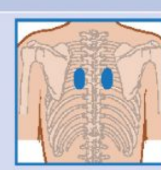
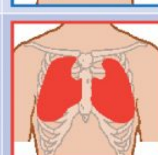
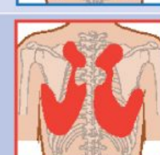
Breath sound	Intensity and pitch	Inspiratory: expiratory ratio	Positions to hear sounds	
Tracheal 	Very loud, high pitch	Inspiratory and expiratory sounds equal	Over the trachea (above the subclavicular notch)	
Bronchial 	Loud, relatively high pitch	Inspiratory sound shorter than expiratory	Over the manubrium (just above the clavicles)	
Bronchovesicular 	Medium loudness, intermediate pitch	Inspiratory and expiratory sounds equal	First and second intercostal spaces next to the sternum and between the scapula	 
Vesicular 	Soft, relatively low pitch	Inspiratory sound longer than expiratory	Most of the lung field	 

Figure 1. Normal Breath Sounds and Areas. Normal breath sound descriptions and respective areas of detection [12].

Abnormal breathing sounds are those that do not concur with any of the normal breathing sounds that can be detected in the three main areas of auscultation assessments. Some abnormal sounds include rales, wheezes, squawks, rhoncus, stridors and bronchioles. Rales are short high pitched noises that occur during inspiration and are caused by airflow through fluid filled alveoli. Wheezes are high whistling sounds in the lungs mainly during expiration that are caused by asthma or obstructive pulmonary diseases. Squawks are short wheezes that occur in late inspiration and are associated with pneumonia, lung fibrosis and bronchiolitis obliterans. Rhonchi are described as low-pitched wheezing sounds during expiration that are caused by obstruction or mucus build-up in large airways. Stridors are harsh high-pitched noises that are heard mostly in inspiration and typically loudest over the neck. It is primarily produced by blockage in the upper airways. Lastly, bronchioles are hollow sounding breaths caused by mucus build-up in the airways [13].

Abnormal breath noises can also be characterized by unilateral or absent breathing sounds that can be perceived as a non-symmetric respiration pattern. A condition that might produce this breathing pattern is pneumothorax, which is the entry of air into the potential space between the parietal and visceral pleura. The parietal pleura is a serous membrane that attaches to the chest wall, and the visceral pleura is a membrane from the same serum that attaches and covers the surface of the lungs. Air can enter the chest cavity from a disruption in lung tissue or pleural trauma as seen in **Figures 2 & 3** [14].

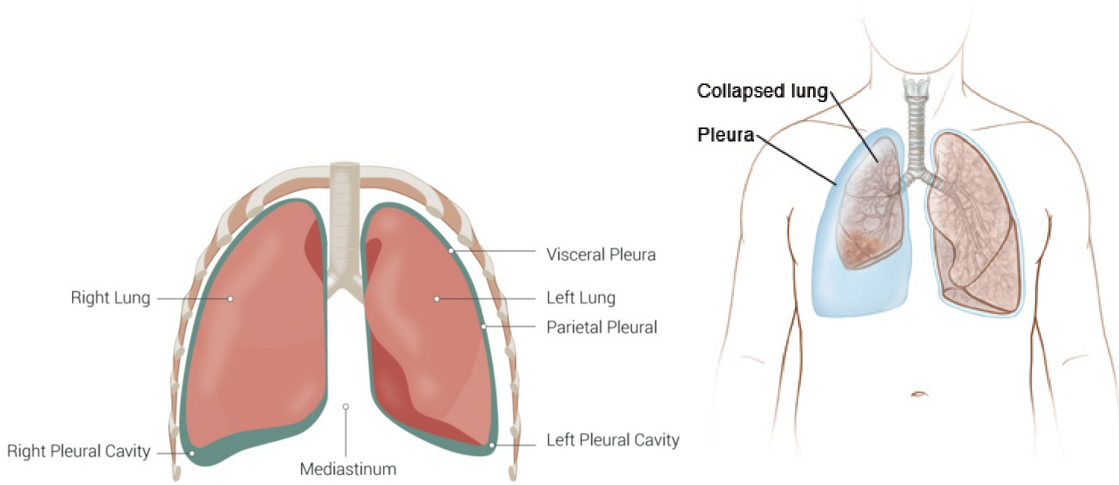


Figure 2. Healthy Lungs vs Lungs with Pneumothorax. Healthy lungs pictured on the right and lungs with pneumothorax pictured on the right [14].

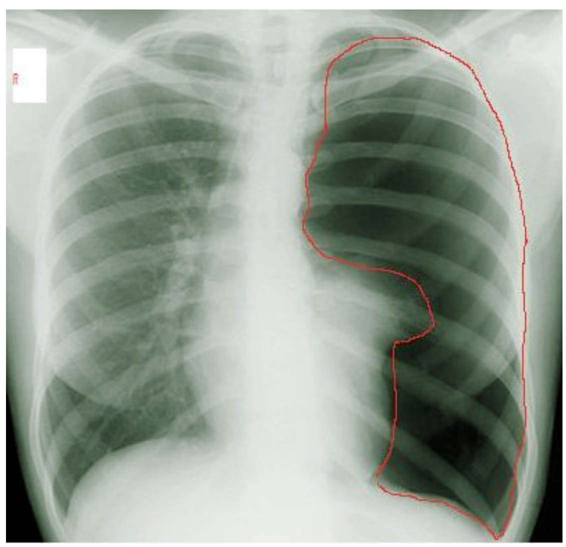


Figure 3. Pneumothorax X-ray. Right lung suffered apparent pneumothorax with black area indicating empty space where lung tissue should be located [14].

Patients with pneumothorax generally present acute onset shortness of breath and unilateral pleuritic chest pains. The most common sign of pneumothorax which typically confirms its diagnosis is the presence of unilateral decreased breath sounds. Also, other signs of pneumothorax include dyspnea, unilateral chest rise and jugular venous distention.

Heart sounds can also be extremely useful diagnostically to recognize different problems in the heart. There are four types of heart sounds that can be appreciated when an auscultation assessment is carried out. In a healthy heart, there are two normal sounds that can be heard. These are the S_1 and S_2 heart sounds. They both resonate in a pattern when the heart undergoes systole and diastole contractions repeatedly to circulate blood throughout the vascular system. The S_1 heart sound is produced during systolic contraction when the left and right ventricles contract and pump blood out of the heart through the aorta and pulmonary arteries. The tricuspid and mitral valves close to prevent the flow of blood back in the heart. Vibrations of the valves closing is what causes this specific noise. The S_2 heart sound is produced during diastolic contraction when the ventricles relax to receive incoming blood. The valves again close and produce the sound due to vibrations. In a healthy heart, the aortic valve and pulmonic valves close at different times. Due to this closing at different intervals, split S_2 sounds might be produced as seen in **Figure 4**. However, increasing or narrowing S_2 splitting might be due to underlying heart conditions. The third and fourth sounds that are produced are due to existing or underlying heart conditions. The S_3 heart sound is a low-pitched that is audible with a rapid rush of blood in the atrium into the ventricle as the heart undergoes relaxation. In some people, this can be a normal sound, but in people with existing heart conditions it could mean heart failure. The S_4 heart sound is low-intensity and can be heard just before the S_1 heart sound in a normal cardiac rhythm. It is caused by a sudden slowing of blood flow by the ventricle as the atrium contracts. This sound is an indicator for potential heart disease [15][16].

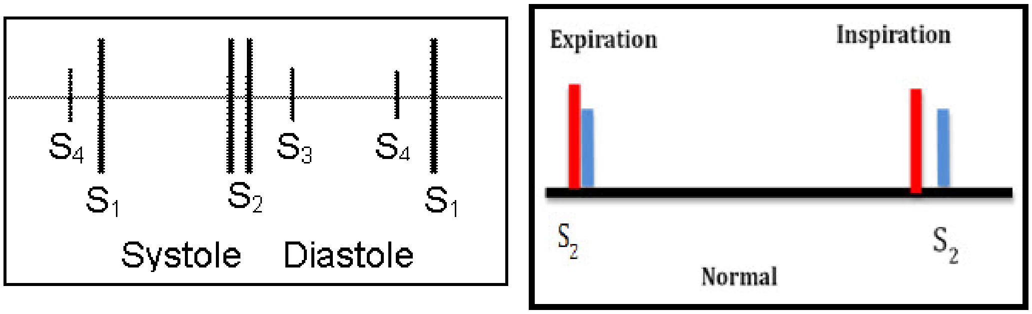


Figure 4. Heart Sound Rhythm and Sounds. Normal and abnormal heart sound intervals are pictured on the left. Normal S_2 splitting intervals are pictured on the right [17].

Aside from the main four types of heart sounds, other kinds of heart sounds exist and can either hold no physiological consequence or be the cause of an underlying heart disease. These sounds are often called heart murmurs and are produced by the turbulent flow of blood across the heart valves and the vibration of cardiac structures. They can be characterized as soft sounds that occur during systolic contraction and do not propagate well. Trained medical professionals often refer to these sounds as “innocent murmurs” as they are not necessarily caused by a disease. The murmurs can be just characteristic blood flow of a specific person. Some known examples of murmurs are Still’s murmur, venous hum, and pulmonic flow murmur [18].

In routine cardiac auscultations, medical professionals not only listen to the types of cardiac sounds being outputted, but they also listen to the cardiac rhythm to verify if any kind of irregularity in the cardiac cycle is present. The most common types of arrhythmias are tachycardia, bradycardia, fibrillations and premature contractions [19]. Bradycardia is a slow paced arrhythmic pulse. A resting heart rate that is less than 60bpm (beats per minute) is considered bradycardic. An exception is when athletic individuals have a resting heart rate of 60bpm, which is still considered healthy. It is caused by damage in electrical impulses in the heart and risk factors include aging, hypothermia, heart attack, and heart disease. Tachycardia is a fast paced arrhythmic pulse. A resting heart rate that is above 100bpm is considered a tachycardic pulse. It is mainly caused by damage in electrical impulses and risk factors include heart attacks, congenital heart disease, high blood pressure and smoking. Fibrillations, also known as heart quivers, are fast trembling or shaking movements produced by the heart due to damaged electrical impulses. There are two types of fibrillations: atrial fibrillation and ventricular fibrillation. Atrial fibrillation produces an abnormal rhythm and it originates from affected electrical impulses in the atriums. It is often a manageable condition and sometimes even harmless. Ventricular fibrillations however, are life threatening rhythmic patterns that originate from affected electrical impulses in the ventricles. These fibrillations limit adequate contraction of the ventricles, preventing them from restoring adequate blood flow throughout the body. Lastly, premature contractions are early heartbeats that occur just before systolic contractions and cause the pumping of blood before the filling of fluid in the ventricles. These are usually not life threatening, are more common and are not continuous [20][21]. Normal and arrhythmic heart patterns for these conditions can be seen in **Figure 5.**

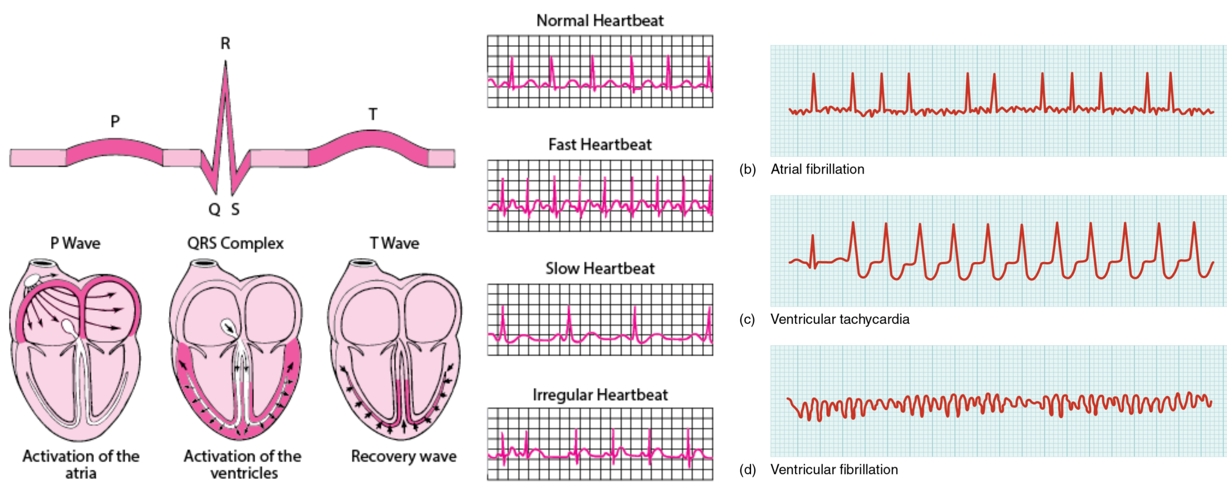


Figure 5. Normal and Arrhythmic Heart Rhythms. Left figure pictures the EKG segment of the electrical cardiac cycle along with sections of electrical stimulation. Heart EKG rhythms for the normal and arrhythmics patterns are also pictured [20][21].

B. Prototyping Research

The medical simulation mannequin that is currently in use in the UW Hospital Simulation lab is the SimMan 3G mannequin by Laderal. 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.

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 [22].

C. Client Information

Our client for this project is Dr. Michael Lohmeier, an emergency medicine doctor for the University of Wisconsin School of Medicine and Public Health. Along with resident education, his responsibilities include Emergency Medical Services, prehospital care, mass casualty preparedness, and fireground rehab. His role in teaching students and medical professionals in the University of Wisconsin Simulation lab was the main inspiration for this project.

D. Design Specifications

The proposed simulation vest will allow for training that includes human interaction and more realistic symptoms. Simulators will be embedded into the vest and will be able to be manipulated and detected for different scenarios similar to mannequin simulators. Specifically, heart sounds of tachycardia, bradycardia, and heart murmurs and lung sounds such as rales, fluid in the lungs, and different sounds from right versus left lungs will be able to be produced. These audio files will be played through the vest via separate Bluetooth speakers which will allow for accurate audio output as well as the ability for another staff member to manipulate the sounds during the simulation. Furthermore, per the client's requirements, the design will cost no more than $500 and will be a wearable simulator of reasonable size and weight to fit the average adult male. The vest will be comfortable, durable, and easy to use for incoming medical staff. Finally, the vest will be made of materials that are not only safe to the user and easy to clean, but also durable and able to withstand 8-12 hours of use per week over multiple years.

III. Preliminary Designs

A. Vest Designs

1. The Condor Ballistic Vest

The Condor Ballistic vest is an adjustable MOLLE (Modular Light-weight Load-carrying Equipment)vest intended to hold tactical gear, most often used by the military and paintballers [23]. 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 6. The Condor Ballistic Vest. A tactical, MOLLE vest with a durable canvas outside [23].

2. Long Sleeve Vest

The long sleeve vest design is a full upper body suit. This suit will have a similar form to a vest combined with a turtleneck sweater as seen in **Figure 7**. 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 7. Long Sleeve Vest Design. The long sleeves vest design would consist of a slim fitting vest and long sleeve, turtle neck. The images depicted are representative of the components in which the design would be created from [24][25].

3. Add-On Vest

The Add-On vest design is a separate malay system vest that functions as an additional exterior compartment that is meant to be combined with another vest. The component that will be used to serve as the exterior malay system would be the GAM Groin Armor Module by URAM [25]. This malay system is ergonomically designed to distribute component weight throughout the vest and is made of a tactical mesh which provides comfort and long-lasting durability. The Add-On vest design is both very modular and mobile as the exterior component can be removed to display interior components. The design also has various compartments which provides adaptability to a wide range of add-ons making it easy to customize and improve for future application of electrical components. It is also very spacious inside, which is an advantage when it comes to extensive wiring.

Figure 8. Add-On Vest Design. The GAM Groin Armor Module which will serve as the Add-On vest design malay system [26].

B. Electrical Designs

1. Dial Controlled Speakers

This design planned to take advantage of an arduino, by wiring the speakers to the arduino and then connecting the arduino to a remote. The controller of the remote would be able to turn the sounds up and down as well as change what was being played. The advantage to this is that the individual actor could control their own simulation if another person couldn't be present. However, it would take advanced knowledge of programming to accomplish and the wires make it harder to fix if it broke. Additionally it would take a bit of training for each person running the simulator as due to the small size of the remote it could not be intuitive.

2. Wireless with Bluetooth

The wireless with bluetooth idea is to use a sound library that connects to multiple sets of speakers as well as a vibrating pulse. In the preliminary design multiple devices may be used for the multiple different speakers. As the project progresses the goal would be to integrate everything into one program with an easy to use interface, similar to the one seen in Laerdal's SimMan3G [5]. The advantage to this design is that the initial idea is very simple and feasible. The opportunity to have bluetooth speakers also gives the electronics more flexibility to be changed. Additionally, most people have worked with bluetooth before so fixing it wouldn't be too difficult. One of the disadvantages is that bluetooth is a little bit more expensive than wired speakers. The initial design will be simpler than the others making it less likely to compete with the more complex designs. However, it has room for growth and improvement in the future and has the largest potential.

3. Wired to Computer

The wired to computer design is the most basic of our designs. The idea being that the speakers in our device would be connected directly to a computer. This computer would then be programmed to control the sounds out of each individual speaker. The advantages to this are that the design would be very cost effective and accurate without much room for random problems. However, having a wire produces a safety hazard and also makes the device less mobile. The other issue with wires is that if something goes wrong it may be harder to identify the issue and fix it. The client specified that durability was very important to him and with wires this device is significantly less durable since it has many moving parts.

IV. Preliminary Design Evaluation

A. Preliminary Vest Design Evaluation

Ensuring that the requirements of the client are met and that the wearable simulation vest is designed as efficiently as possible, several designs were considered. The preliminary designs were subjected to an evaluation in a design matrix as seen in **Table 1**, in which each design was compared based on chosen relevant criteria. Finally, a sole design was chosen based on the evaluation, which will be used for the final design.

Design Criteria	Weight	Condor Ballistic Vest		Long Sleeve Vest		Add-On Version	
Durability	30	5/5	30	3/5	18	4/5	24
Output potential	15	4/5	12	4/5	12	5/5	15
Adaptability	15	3/5	9	2/5	6	5/5	15
Feasibility	10	5/5	10	2/5	4	3/5	6
Safety	10	5/5	10	4/5	8	4/5	8
Comfort	5	3/5	3	3/5	3	2/5	2
Aesthetics	5	2/5	2	4/5	4	3/5	3
Sterilizability	5	5/5	5	2/5	2	3/5	3
Cost	5	5/5	5	2/5	3	2/5	2
Total	100		86		60		78

Table 1. Vest Design Matrix. Preliminary Designs are compared based on the given design criteria.

The design matrix shown in **Table 1** evaluates each preliminary design based on chosen relevant criteria for the project. Each criteria was given a percentage value depending on how relevant and important it was when evaluating each preliminary design. The criteria for design matrix are durability weighing 30%, output potential weighing 15%, adaptability weighing 15%, feasibility weighing 10%, safety weighing 10%, comfort weighing 5%, aesthetics weighing 5%, sterilizability weighing 5%, and cost weighing 5%. Durability is the most heavily weighted category at 30%, because it is the most important criteria for our client. The final design should be able to withstand heavy use as it is intended to be utilized between 4-5 times a month. It will also be exposed to a wide range of environments as medical residency students will learn to assess patient diagnoses in different places. Output potential and adaptability are the next most heavily weighted at 15%, because it is crucial that the wearable simulation vest accurately reflect vitals, heart sounds and respiration sounds to ensure that medical trainees that use it obtain the most educational experience. The wearable simulation vest should also be easily adaptable to any further electrical components or features added for its improvement. Feasibility and safety are the third heavily weighted criteria as it is important that the final design chosen is easy to fabricate due to time constraints, COVID-19 restrictions and availability. The final design should be safe for the actor to use as they will be using it for an extended duration of time while potentially exposed to interior electrical components. Lastly, comfort, aesthetics, sterilizability and cost were the least weighted criteria as they are not as important as the previous components. The vest should be comfortable for the actor to wear, it should be easily sterilizable as it will be used by different trainees on various occasions, it should be simple, easy to use, and should be within the budget range of our client, which is a maximum of $500.

When evaluating each preliminary design in the design matrix based on the criteria, all the weights were taken into consideration. The Condor Ballistic Vest received the highest score in durability as its exterior material is made of a tough rubber canvas, which is stronger than the materials used in the other designs. The Long Sleeve Vest obtained the lowest score in this criteria as it is made of a less durable material in comparison to the other designs. The sweater component of the Long Sleeve Vest design is made of cotton, giving it an increased risk of tear during extended periods of use. When considering output potential and adaptability, the add-On Vest design scored the highest as it can be easily adaptable to include more electrical components to simulate even more physiological functions other than the ones that our team will be simulating. Its ability to be more adaptable and have more spacing for wire extendibility increases the output potential of this design. The long sleeve vest design scored the lowest as it has less space to add more components as it has fewer pockets than the other two vest designs, decreasing its output potential. For feasibility and safety, the Condor Ballistic Vest scored the highest as it is the vest the previous team that worked on this project utilized and it was passed down to our team. It is also easy to work with and adapt as it has various pockets and easy access points which aid in the installation of the electrical components. It was the safest among all the designs as the pockets efficiently hide all the electrical components in the interior, limiting direct exposure of the actor to the components. For comfort, the Condor Ballistic Vest and the Long Sleeve Vest both scored the same and the highest as they are both made with a comfortable interior material. The Condor Vest being made from a comfortable mesh and the Long Sleeve Vest sweater component being made from cotton. For aesthetics, the Long Sleeve Vest scored the highest as it is a simple design and it does not have lots of bulky components that hang from the vest. For sterilizability and cost, the Condor Ballistic Vest scored the highest as it can be easily sterilized due to its exterior rubber material and it comes with no charge as the team already owns the design.

After considering all of the given criteria, the Condor Ballistic Vest received the highest score with a total score of 86, compared to the other materials which had lower overall scores as seen in **Table 1**. After carrying out the design evaluation, it was agreed that the Condor Ballistic Vest would be used as the main design for simulating vitals, heart sounds and respiration sounds in the final product.

B. Preliminary Electrical Design Evaluation

Design Criteria	Weight	Dial Controlled Speakers		Wireless/Bluetooth		Wired to Computer	
Ease of Use	25	3/5	15	5/5	25	3/5	15
Output Accuracy	20	4/5	16	4/5	16	4/5	16
Durability	15	3/5	9	4/5	12	3/5	9
Feasability	15	2/5	6	4/5	12	3/5	9
Adaptability	10	3/5	6	3/5	6	3/5	6
Cost	5	3/5	3	3/5	3	4/5	4
Motility	5	4/5	4	5/5	5	2/5	2
Safety	5	3/5	3	4/5	4	2/5	2
Total	100		62		83		63

Table 2. Electrical Design Matrix. Preliminary Designs are compared based on the given design criteria.

The first criteria in the electronics matrix is ease of use. The client specified that this was the most important aspect because the device will need to be used by many different people. Limiting the amount of training needed to use it is ideal because it will open the population of people who will be able to train with the device. Additionally, in the hospital at UW Madison, the SimMan3G was chosen because the interface was the easiest to work with and highly adjustable. The group felt that the wireless device would be the easiest to use because there is less that can go wrong. Additionally the group will be able to make it with less programming and so the individual running the simulation will not have to know code either.

The next most important criteria was the accuracy of the output. Future doctors and EMT's will be using the information they learn through the simulation in order to save lives. Therefore, the device must be accurate to prevent poor training. Additionally, an accurate simulation is much more time efficient than an inaccurate one. Doctors are in a world of people who are pressed for time and so this is of utmost importance. The group felt that all 3 designs have the potential to be accurate because once the code or sound library is designed it will not need to be changed.

The third most important criteria is durability. The client specified that the device will need to be used 4-5 times a month. Since it is a wearable device it will be thrown into different situations such as those that EMT's will run into out in the field. If something is constantly breaking it will defeat the purpose of running a more lifelike simulation. Therefore, having it be able to withstand a variety of conditions is important. After evaluating the three designs to this criteria the group felt that the bluetooth design has the least ability to be messed up as it doesn't have wires that could suddenly become unconnected.

The feasibility of the design was also important in the group's evaluation. When choosing a design the group needed to take into consideration the strengths and weaknesses of the group members. None of the group has coding experience and so it may be difficult to do one of the wired options connected to an arduino or coding a computer. The group felt that the bluetooth option would be the most feasible option since everyone has experience with bluetooth and there are multiple ways to go about creating the sounds. On one end, an app could be created, but on the other side, multiple devices could be used. This will allow the group to get an actual working prototype that can be built upon in the future.

Adaptability was defined as the design to be updated and changed depending on the circumstance. It was the group's plan to give all three designs the same sound playing capabilities and so the group felt that all designs deserved the same adaptability score.

Cost was weighted relatively low because the group has a fairly large budget of 500 dollars. From the previous group, the group did obtain some wires that made the wired to computer design slightly cheaper.

Motility referred to the ability of the electronic components to be removed from the vest at any time. The wireless speaker had the least moving parts and connections and so it would be easiest to change out certain components quickly.

The last criteria in the design matrix was safety, the bluetooth design with less wires scored the highest. While all designs were relatively safe, should a rainstorm or another unexpected event occur during a simulation it would be safer to have less exposed components and wires.

Overall, the bluetooth design greatly outweighed the competitors. This was mostly due to it's high scores in ease of use, durability and feasibility. It received a score of 83 in the design matrix which was well above the other designs considered in **Table 2.** After careful consideration the group feels that this design will lead to the most successful and easy to use wearable simulator vest.

V. Fabrication and 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 obtained from the previous group is 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 to place the speakers inside. Holes will be left for charging cables. The seam that was ripped will be resealed using a zipper in order to provide easy access to it in the future.

The other category of materials being used is electronics. We plan to use the Bluetooth V5.0 Replacement Module for Sleep Headphones. These are small flat speakers in pairs of two that have the ability to connect to any smartphone or tablet. They are encased in foam which increases their durability and are able to be heard through fabric. Their best quality compared to the competition is they have a battery life of 12 hours which will allow our simulation vest to be fully functional for longer simulations without worrying about an electronics malfunction. There will be 2 sets of two speakers for the lungs, one for each side. Additionally the heart will have one set of two speakers.

The pulse will be played off of a SoundBrenner Metronome which is a haptic feedback device typically used for musicians [27]. This device has the ability to vibrate at whatever frequency desired and will be able to simulate a pulse very well. The strengths of the pulse may be adjusted as well which allows for more variation in the simulation.

For the heart and lung sounds we plan to use the audio files from thesimtech.org, run on a laptop that is connected to the pillow speakers.

B. Methods

The methods that we will employ will be to first purchase the pillow speakers as well as the SoundBrenner metronome from Amazon. From there the group will seam rip the vest in order to place the speakers inside. This will be when the first test is run. As long as you are able to hear the speakers and feel the vibrations through the vest the group will move on with designing.

The next step after this will be to create the sound library. This will be created using the audio files from thesimtech.org. The sounds will need to be integrated together and linked to their respective bluetooth speakers. This process will involve troubleshooting any problems that arise and reevaluating the design if necessary.

From there, once the speakers are functioning properly they will be sewn into the vest and the zipper attached to close off the electronics. The prototype will be tested for comfort and functionality. Next the group will adjust any components that didn't pass their respective tests and then test again until all components are functional.

The client will then be brought in at this time to ensure that the vest is functioning as he hoped and any adjustments will be made.

In the future the group hopes to create an interactive interface that allows for all the speakers to be controlled off of one device. This will most likely require the creation of an app or computer software that is connected to all of the speakers.

C. Final Prototype

Based upon observations that arose during testing, we decided to use only the front piece fake skin and attach it to the vest. The overall design incorporates velcro straps and hooks to allow for adjustability and comfortability (**Figure 9**).

Furthermore, the bluetooth speakers are connected via velcro strips to the inside of the fake skin to allow for easy external identification as well as stability (**Figure 10**). Each speaker has the ability to connect via bluetooth to a device, allowing the respective sounds to be played. Finally, the palpable pulse simulates the patient's pulse, which can be detected and read by the medical student or EMT trainee.

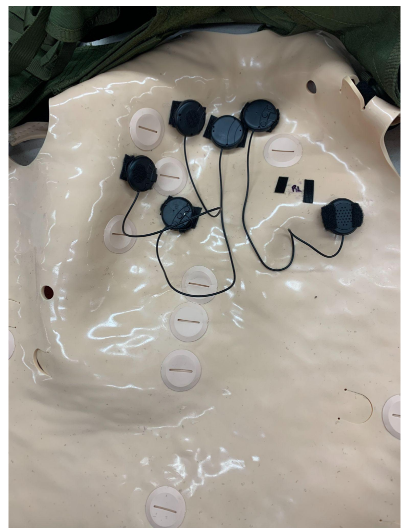


Figure 9 (left). Final Prototype. Final Prototype being worn with pulse monitor and adjustable clips.
Figure 10 (right). Close-up of electronics. Bluetooth Speakers integrated on the inside.

D. Testing

Preliminary testing of the bluetooth speakers will first need to be conducted to ensure that they are adequate for our purposes. For this we will have a group of 10 people ensure that through the vest, using a stethoscope they are able to hear sounds being played. If this isn't the case we will look for a different speaker option. Additionally, the battery life has to be at least 5 hours. All 4 sets of speakers need to pass these tests. The preliminary testing of the SoundBrenner device will need to be able to be felt through the vest as well as also have a battery life of at least 5 hours. Once a final prototype is fabricated, testing will be conducted in four stages.

First, the electronics will need to be tested. This will begin by running the sounds on the different speakers and haptic feedback device and making sure the interactions between all the components run smoothly. The speakers will need to be playing the correct sounds at the correct time in the correct location. This test will be conducted by the team as a group, the purpose of the test is to ensure that the device is in minimum working condition. As long as the sounds are being played completely accurately, the test will be considered a pass.

The next test that we will run is to ensure that the sounds are being played accurately from the speakers. This will be accomplished by using a stethoscope and listening through the fake skin to each speaker. In order to pass the test, our test subjects must be able to locate each speaker, differentiate between the sounds coming from each speaker, and correctly identify which heart and lung sound is being played in each speaker. This will be tested through the fake skin as well as with the speaker alone. The null hypothesis will be that there is no difference between the test through the skin and without the skin. The alternative hypothesis will state that there is a difference between the sounds through the skin and without the skin. These values will be analyzed using a 2-proportion z-test to determine if there is a statistically significant difference.

The next component to test will be the use of our sound library. This test is critical as it tests the ability to manipulate and interact with the vest while a simulation is in progress. Through our meeting with the current technology expert in the SimLab at UW hospital, the ease of use is what differentiates a good simulator from a bad one. 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. We will have 10 test subjects, who we will brief on the interface prior to the test. The average time that it takes for an individual to apply the short intervention will need to be less than 2 minutes.

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 wearing the vest, the subjects will fill out a survey judging the vest on its wearability for long periods of time. The simulations will typically last longer than an hour and so in order to pass this test we need 80% of our test participants to say they could wear the vest for more than at least 2 hours.

VI. Results

To begin our testing process we tested all of our electronics to ensure that they were adequate for our purposes. For the first test we ran sounds on the different speakers and haptic feedback device, and made sure the interactions between all the components ran smoothly. To pass this initial test, the speakers needed to play the correct sounds at the correct time in the correct location and the haptic feedback device needed to play at the correct pace. This test was considered a pass.

One of the biggest criteria of our client was that the device was required to work for a long period of time. To fit his needs the speakers needed to be able to function for 5 hours. The speakers were each left on for a period of 8 hours playing music, and all 3 successfully stayed charged and played music during the whole duration of the test. The sound brenner was plugged into a computer and played through the night without dying. This test was considered a pass.

Another important criteria for our client was that the vest had to be comfortable but also realistic. Upon initial evaluation, the vest didn't look very realistic. Therefore, we got fake skin to put over the vest. With the skin over the vest it was very hard to wear for an extended period of time, so we decided to only put skin on the front. We proposed that 10 people should wear the vest for 30 minutes and then take a survey assessing it's comfort level. We had 11 individuals wear it and 90.9% of them felt that it was comfortable enough to wear for at least 2 hours, shown below in **Figure 11**. The survey participants also gave the group tips on how to increase the vests' comfort level. In the future we would like to implement these changes and then retest to ensure we are creating the best product possible.

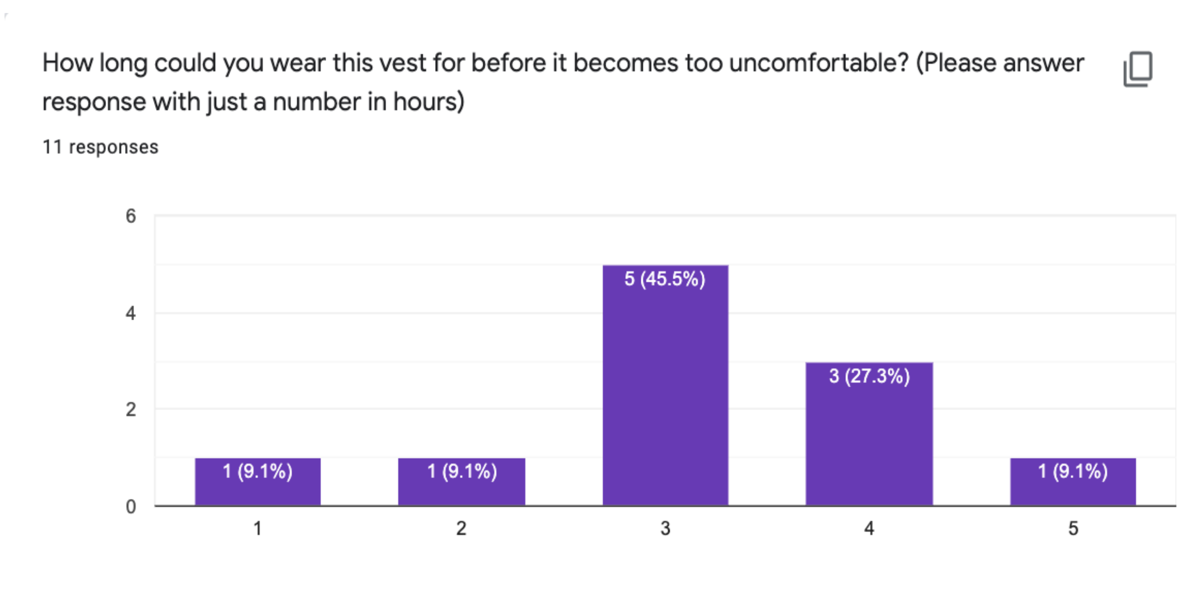


Figure 11: Data from 11 survey participants who wore the vest for 30 minutes. The criteria was that the vest needs to be able to be worn for at least 2 hours so this data is promising.

The next test performed was to ensure the sounds were being played accurately from the speakers through the fake skin. We ran a two part test where the participants, who were Madison students found in the engineering building, listened to two different heart sounds from the speaker, then one of the two sounds would be played again. To be a successful trial, the participant would have to identify the sound correctly. We tried this test without any fake skin covering the speaker and then again with the fake skin covering it. Initially, we had the speakers attached to the vest and it was extremely difficult to hear so we switched to attaching the speakers straight to the skin. Each of our 5 random participants participated in 4 trials both with and without the skin. We then conducted a two proportion z-test to compare the speaker quality with and without the skin. The data is shown in Test Data Table 1 and Test Data Table 2 show a portion of the data from our test.

Person (average, our group and found in discovery building)	Sound 1	Sound 2	Sound played	Distinguished?
1	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes
1	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes
1	Heart - S3	Heart - S4	Heart - S3	Yes
1	Lung - normal vesicular	Lung - pleural friction	Lung - pleural fiction	Yes (with difficulty)
2	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes
2	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes
2	Heart - S3	Heart - S4	Heart - S3	Yes
2	Lung - normal vesicular	Lung - pleural friction	Lung - pleural fiction	No
3	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes
3	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes
3	Heart - S3	Heart - S4	Heart - S3	No

Test Data Table 1 This chart shows a portion of the test data for sounds just through the speaker with the stethoscope. Two sounds were played and the test subject listened and then one of them was repeated and the subject was asked to identify which sound was repeated.

Person (average, our group and found in discovery building)	Sound 1	Sound 2	Sound played	Distinguished?
1	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes (much quieter)
1	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes (with a question mark)
1	Heart - S3	Heart - S4	Heart - S3	Yes
1	Lung - normal vesicular	Lung - pleural friction	Lung - pleural fiction	Yes
2	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes
2	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes
2	Heart - S3	Heart - S4	Heart - S3	No
2	Lung - normal vesicular	Lung - pleural friction	Lung - pleural fiction	No
3	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	Yes
3	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	Yes
3	Heart - S3	Heart - S4	Heart - S3	No
3	Lung - normal vesicular	Lung - pleural friction	Lung - pleural fiction	Yes
4	Heart opening snap	Heart pansystolic murmur	Heart pansystolic	No
4	Heart diastolic rumble	Heart early systolic murmur	Heart early systolic murmur	No

Test Data Table 2: This chart shows a portion of the test data for sounds through the fake skin with the stethoscope. Two sounds were played and the test subject listened and then one of them was repeated and the subject was asked to identify which one was played again.

The findings of our two proportion z-test at a significance level of 0.05 was that there is not a significant difference. The proportion of tests that were wrong without the fake skin was

2/20, and with the skin it was 6/20. This produced a one tailed p-value of .0575. Which is not significant at the .05 level of significance, but it is very close. This is shown in **Figure 12** below.

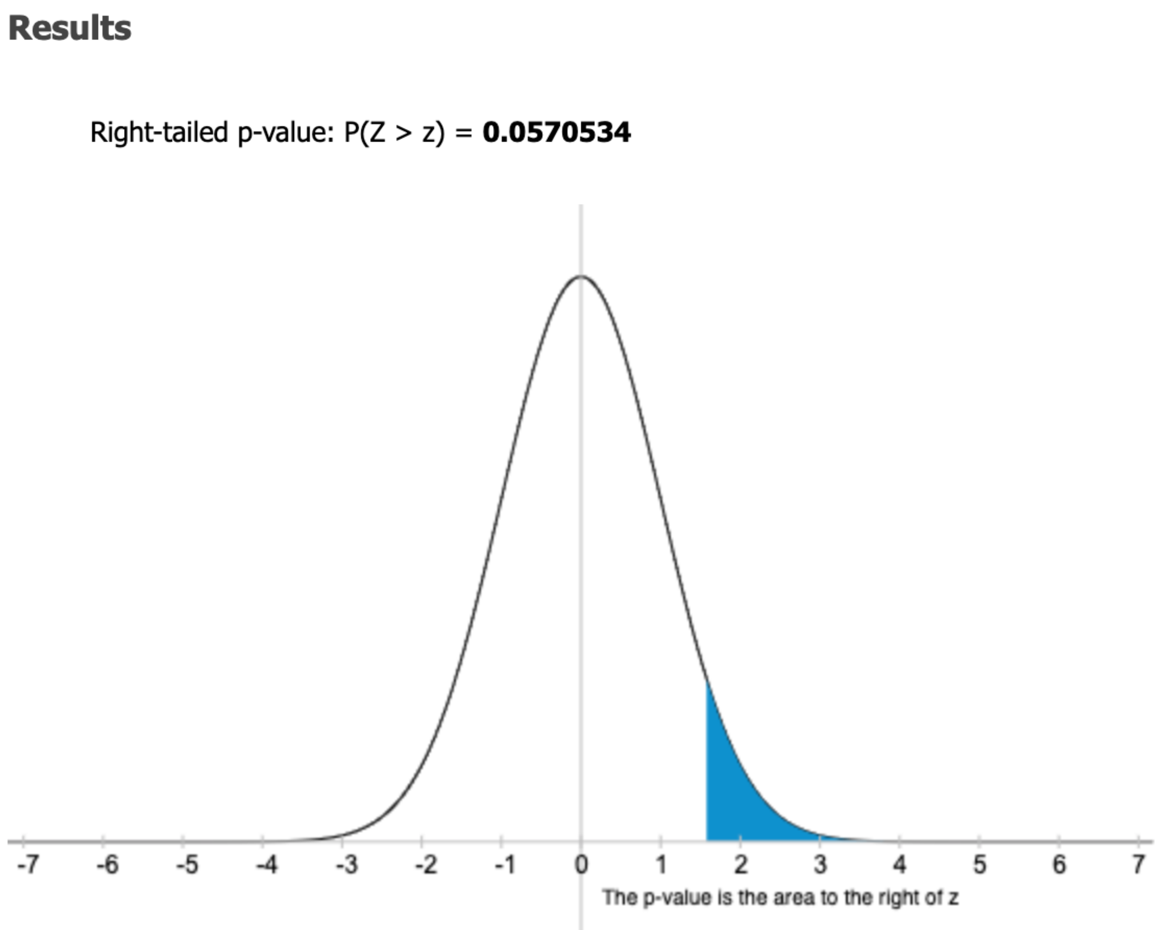


Figure 12: P-value of 0.05705 from the 2-proportion Z-test differentiating between skin and no skin.

One explanation for this is that since the test subjects do not have medical knowledge it was difficult for them to decipher the difference between the two sounds. In the future we would like to rerun this test with medical students to make sure there is not a significant difference for those with more knowledge on the sounds.

The final test that we plan to perform pertains to the ease of use of our product. This test is critical as it will test the ability to manipulate and interact with the vest while a simulation is in progress. Through our meeting with the current technology expert in the SimLab at UW hospital, the ease of use is what differentiates a good simulator from a bad one. The instructor, or controller, must have been able to change the sounds coming from each speaker to respond to an intervention applied during the scenario. The ability to manipulate a slideshow with different conditions has been accomplished and future plans involve testing the database with experts. Ten test subjects will be briefed on the interface prior to the test. The average time that it takes for an individual to apply the short intervention should be less than 1 minute.

VII. Discussion

A. Implication of Results

Upon successful completion of both the bluetooth speaker quality test and vest comfortability test, the team evaluated the results and carried out interpretations of the possible reasons for them. It was determined that based on the statistical analysis of the bluetooth speaker qualitative data utilizing a two-proportion t-test that there was no evident significant difference in identifying types of conditions based on auditory observations between playing sounds without the silicone fake skin and with the silicone fake skin. Under statistical analysis, the team decided that a benchmark of 0.05 was the determinant value in comparing for significance. After evaluation of the results, the calculated p-value was **0.05**. This value signifies that the data was trending or approaching significance but under the team's specifications, this was not considered a significant finding. Thus, the null hypothesis was accepted and it was concluded that determining the sounds through the silicone fake skin is no different than determining them without the skin. The analysis suggests that the quality of the speakers is adequate for the purposes of our design, and should prove to be efficient for the training of medical students and other subjects who practice on the prototype. However, because the data did approach significance as provided by the analysis ($p = 0.05$), the team assumed that there is the possibility of a difference between both, as it is evident that listening through speakers through the skin is not absolutely identical to listening to the speakers without the skin. The volume of the sounds displayed by the speakers might be perceived with a different volume intensity in each of the situations (fake skin vs. no fake skin), which gives rise to a possible difference between the two. For this reason, it is recommended that the simulation of the prototype be carried out utilizing a stethoscope pressed against the fake skin to fully observe the auditory effects of the speakers and maximize the prototype's efficiency. Use of the stethoscope is intended for the design, which is why the results were demonstrative of the purpose of our design.

The survey conducted by the team with the purpose of assessing comfortability was answered by 11 subjects after wearing the vest for 30 minutes. After collating the responses containing feedback for our vest, the team saw that 90.9% of respondents answered that the prototype was comfortable enough to be worn for longer than 30 minutes. This helped the team determine that the criteria for comfortability and durability was met and it suggested that the ergonomics that were taken into consideration were more than adequate for the body types of several actors and test subjects. Further advice on how to improve the vest was accepted and was implemented in our final design. In addition to comfortability, during the wearing of the vest on volunteers, none of the electrical components were displaced or affected, which proved to be promising for the structural integrity of the design.

In the future, the team plans on reevaluating the prototype with the purpose of improving the functionality of the design, and continue implementing additional components and features to enhance the realism of the simulator. Some additional components and features that shall be included are an IV arm sleeve, more sounds to assess more conditions that can be identified from auscultation, a pressure simulating system, and gravity liquid system that would irrigate throughout the vest. Also, further tests shall be conducted with more parameters and test subjects in order to increase the confidence of our design. The team plans to continue meeting with the UW School of Medicine and Public Health SimMan Simulation Lab to retrieve preliminary information on the functionality of our simulation and work on improvements to introduce the prototype in other smaller clinics for primary care and education centers.

B. Ethical Considerations

The principal purpose of simulations in a professional environment and in healthcare is to expose trainees to a situation that resembles the logistics of an actual protocol in order to educate them and assist them in the completion of specific learning objectives. Simulations like this one aim to enhance the realism of a situation with the expectation of improving the quality of a learning process. However, it is evident that simulations never fully resemble these situations in an accurate manner, which introduces a design process with a wide range of considerations regarding the improvement of said design. In addition, simulations typically involve human test subjects which signifies that ethical considerations must be thoroughly evaluated when constructing a design.

Because our final prototype involves the participation of medical trainees and shall serve as an important instrument for the improvement of healthcare quality, our team considered several questions that address the ethicality of our product. Some questions were: "how closely does our prototype simulate auscultation?", "if any issue with our prototype arises, can this affect the learning experience of the trainees, which in turn can pose a risk to patients' healths?", “Does our prototype constitute any type of danger to the trainees or does it invade their privacy?”. These questions were all accounted for as part of our design process. In the scenario where an inconvenience happens that is related to our prototype the team will collect any feedback from the client to solve the problem with the design and the team shall assume responsibility. Sometimes flaws in the design or in the practice of trainees are helpful as they serve as learning experiences. Training is critical for the preparation of clinicians before their first “real” experience and patients, which supports the fact that it is needed and the learning process is not perfect. It is also a way to learn and practice collaboration through team training, interpersonal, interprofessional and decision making skills and not incidentally an opportunity for training in the ethics of the various healthcare professions [28].

The team implemented the ethical considerations to the addressed questions in the final design and testing protocol. The team researched and thoroughly revised the final design in order to provide the enhanced realism the prototype promises in order to guarantee the best learning experience. The physiological components such as heart and lung sounds were tested based on accuracy and the locations of the sound displays were positioned accordingly. This ensures better simulation realism to avoid indirect threats to patients in the future and successful training of students. Also, as part of the integration and fabrication of the prototype, any minor dangers were accounted for. This included any dangers regarding the electrical components and vest ergonomics. Lastly, as part of our testing process, the surveys conducted for collecting feedback for vest comfortability were written in a manner that could not disclose by any means any subject’s information and respected their privacy.

C. Mid-Fabrication Changes

Our team initially planned on using the Condor ballistic vest and attaching pillow speakers underneath the vest using velcro adhesive tape. We also planned on connecting a Peterson Metronome device as part of our interactive simulation prototype, not only for the medical trainees, but also for the actor/actress. However, the team decided to make some adjustments to the design as we started the fabrication process. Some of these adjustments include changes to the vest materials, placement of the bluetooth speakers, and the simulated heart and lung sounds.

The first major change was the vest design. After visiting the Clinical Simulation Center at the UW-Madison Hospital, we were told by the head technician of the SimMan mannequins that a group before us had utilized the outer skin of the SimMan and implemented it into their design. We initially decided to stay with our current condor vest, but we soon realized that the fake skin could add a more human interactive element to the product. We acquired the fake skin from the same simulation center and implemented it to our design. We did this by removing the back part of the skin and placing the anterior portion over the condor vest. Four velcro straps assisted in keeping the fake skin connected to the vest. These straps are located on the four corners of the prototype and can be easily adjusted to different body types.

The second adjustment was positioning of the bluetooth speakers. This change resulted due to the drastic modification in the vest design. The speakers were going to be placed underneath the condor vest to hide all the wiring and to prevent damage to the electrical components. However, due to the addition of the fake skin, the speakers were positioned in between the skin and vest. This was done by the use of velcro tape with adhesive. We attached small adhesive strips of velcro to the interior portion of the skin and to the front part of the bluetooth speakers. Then, the vest will keep the speakers compact, allowing for minimal to no movement of the electronic devices. The group also labeled where the speakers are located on the front of the skin, so medical trainees can easily navigate their way around the simulator.

Finally, our team chose different heart and lung sounds to be played in live simulations. We initially wanted to play bradycardia and tachycardia for the heart sounds, and rales for the lung sounds. After doing further research on various heart and lung conditions, we found that we can accurately simulate more advanced conditions like pulmonary edema and a collapsed lung. In order to simulate pulmonary edema, a faster tempo heartbeat was played through one of the speakers to indicate tachycardia. If someone were to listen to the speakers in the left lung, they would hear rales, and in the right lung they would hear rapid breathing. In addition to these conditions, tachycardia and bradycardia were also simulated as a warmup test for the medical trainees.

D. Sources of Error

While there were minimal sources of error in our testing, we have identified a few that may cause future issues in the prototype: accuracy of sounds from the bluetooth speakers and comfortability of the vest.

The major source of error is the accuracy and consistency of the heart and lung sounds being emitted from the speakers. One way that the accuracy could be affected is the velcro tape that was implemented into the vest. As previously mentioned, we cut small strips of velcro adhesive tape and placed them on the inside of the vest and on the front side of the speakers. The velcro strips cover a small portion of the speakers, which may affect the volume and exactness of the sounds being simulated. Since the application of the velcro was recent, sufficient testing was not performed to verify that the sounds could be heard just as clearly as without the velcro.

Another source of error involved in the precision of the heart and lung sounds is the fake skin covering the speakers. Since the skin is extremely thick, it could create issues for medical trainees during simulations. One way this could be solved is by cutting out holes where the speakers are located in the fake skin to maximize their performance.

The second source of error that may be encountered is the comfortability of the wearable simulator. Unfortunately, due to time constraints, we were unable to allow more individuals to take our survey to ensure the vest is comfortable to wear for at least one to two hours. We would also intend on widening the range of body types to test the adaptability of the simulator. This would help determine how well our wearable simulator can adjust with the newly implemented velcro straps.

VIII. Conclusion

Modern medicine relies heavily on the teaching of new and upcoming physicians. Simulations have become a prominent way of teaching that allows individuals to be trained in a safe and controlled environment, allowing them to learn and hone their skills before they are actually in the field. Even though the simulations and mannequins that exist today are able to mock human injuries in impressive and accurate ways, they are unable to simulate an actual human. The simulation vest allows for training that includes human interaction and more realistic symptoms. The vest is equipped with embedded simulators that are able to be manipulated and detected for different scenarios similar to mannequin simulators. The vest is a ballistic condor vest with the front patch of fake skin attached. The heart and lung sounds are produced through Bluetooth speakers that are controlled by separate devices loaded with audio files. The palpable pulse is connected to a computer and is capable of producing a measurable pulse. Overall, this design allows for the medical condition to be better portrayed, creating a more in-depth and accurate training of medical students and staff. Based on the results of our testing, we found the vest to be comfortable and able to adequately produce the necessary heart and lung sounds. Our tests were able to quantifiably measure our design's performance, and gave us promising results. However, if these tests were performed again, a larger sample size could be used to ensure that the widespread functionality of the vest design is accurately tested.

In terms of future work, further development of this prototype could be conducted to increase its applicability and enhance the realism of the simulation. For example, additional components could be included in the design such as wrist/neck pulses or an IV arm sleeve, additional sounds could be added to the sound library, and a pressure simulating system and a liquid irrigation system could be integrated. Furthermore, if UW-Health ends up purchasing the Avtone Simulator by Avkin, we would be able to test our design against this existing product and analyze the results. Finally, our team plans to remain in communication with the UW School of Medicine and Public Health in order to receive information and results from the design's use in their simulation center.

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X. Appendix

Appendix A - Product Design Specifications

Product Design Specification

Wearable Simulator for Enhanced Realism

BME 200/300 Lab Section: 307

Updated: 09/23/2021

Team Members and Contacts:

Client: Dr. Michael Lohmeier (mtlohmei@medicine.wisc.edu)
Advisor: Dr. Krishanu Saha (ksaha@wisc.edu)
Team Leader: Francisco O'Neill Rodriguez (fgoneill@wisc.edu)
Communicator: Sierra Reschke (sgreschke@wisc.edu)
BWIG: Jessie Hunt (jjhunt2@wisc.edu)

BSAC & BPAG: Sami Matloub (smatloub2@wisc.edu)

Function

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

Client requirements:

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

Design requirements:

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

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

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

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

f. *Operating Environment:* This device will primarily be used in special environments dedicated to training medical students and staff. This environment must be well-maintained, kept clean, and remain at room temperature with no contact with any aqueous solutions or extreme humidity. Furthermore, there must be access to power outlets and a table to place the device upon, and the environment must be safe and relatively undisturbed so that individuals such as EMTs and medical school residents can properly learn.

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

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

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

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

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

2. Production Characteristics
    a. *Quantity:* A single prototype vest will be created. Ideally, more vests would be created and at a lower cost in the future.
    b. *Target Product Cost:* The initial budget is no more than $500, however, Dr. Lohmeier can be contacted about receiving more funding if it is necessary for an important addition to the project. The vest, as well as some electronic material components, have already been obtained.
3. Miscellaneous
    a. *Standards and Specifications:* INACSL Standards of Best Practice: Simulation SM outlines eleven design criteria, two outcomes and objectives, five facilitation, five debriefing, four participant evaluation, four professional integrity, four simulation interprofessional education, and six operations criteria that will need to be satisfied for the vest to be used in an educational/training setting [5]. The vest, like all other medical devices, must be approved by the FDA before any mass distribution takes place. The device will be classified as a Class 1 medical device [6].
    b. *Customer:* Our client, Dr. Lohmeier, would like a wearable device with speakers to mimic heart and lung sounds. This device would be in the form of a vest and would ultimately carry out all the medical functions that Dr. Lohmeier is anticipating. He would like the vest to be comfortable, manipulatable, customizable, and be sturdy enough to last over time.
    c. *Patient-related Concerns:* The primary concern for this vest is the comfort and durability factor. We want the patients to be relieved of any discomfort or pain when wearing the medical device. The vest will also be sterilized after each use in order to prevent the spread of COVID-19 during the pandemic. Finally, any data

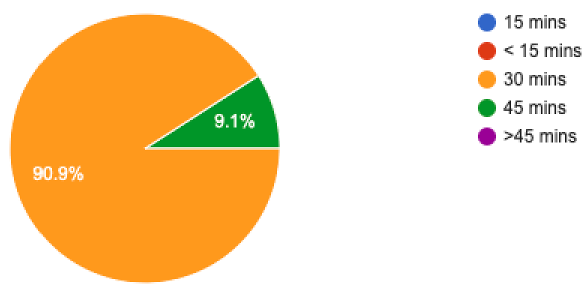
collected while the patient is wearing the medical device will be shared with no outside parties; only immediate doctors and nurses may access this information.

d. *Competition:* While there are many simulators that can perform the same functions as this medical device, our team has not found any competitors on the market who use a vest to execute these medical simulations. Every simulator on the market utilizes a mannequin; however, it can be difficult for the students to understand the real-life process of working directly with a patient. The vest is being designed as an educational tool for students who are new to the medical world, but also the vest will provide a more accurate representation of how to read palpable pulses.
    i. *SimMan 3G Plus by Laerdal Medical*: SimMan is a full-sized adult man mannequin that can be used in several different environments and has a battery life of up to four hours. The mannequin is rechargeable and completely wireless. The device can store an extensive ECG library, produces normal or abnormal breathing sounds, and has realistic compression depth and resistance [7].
    ii. *Simulaids Smart STAT Basic with iPad*: Includes advanced airway management, emergent lung sounds, emergent heart sounds, pulse points, bilateral chest decompressions, bilateral chest tube insertion, and virtual capnography and oximetry. It costs $13,365 [8].

Survey Results:

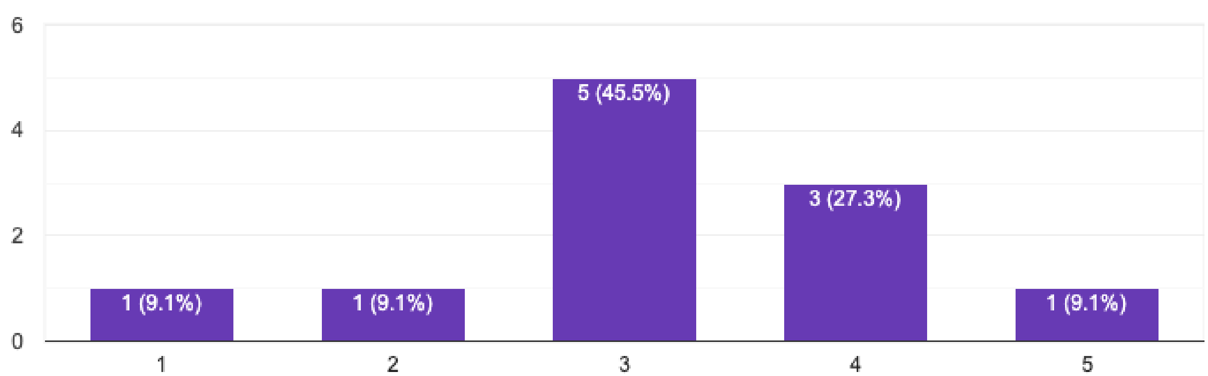
How long were you wearing the vest?

11 responses



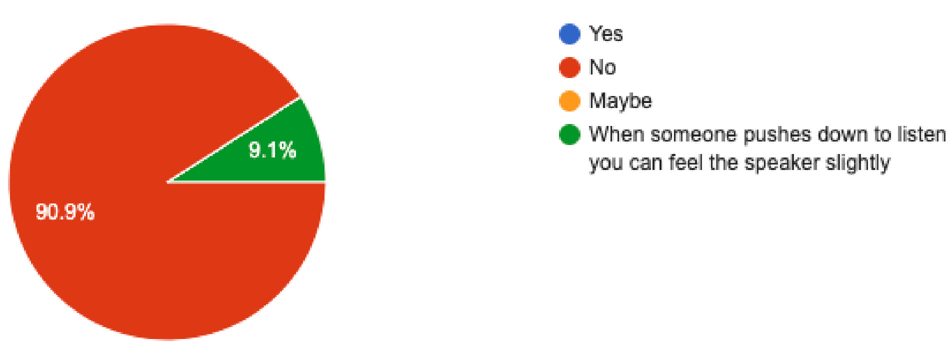
How long could you wear this vest for before it becomes too uncomfortable? (Please answer response with just a number in hours)

11 responses



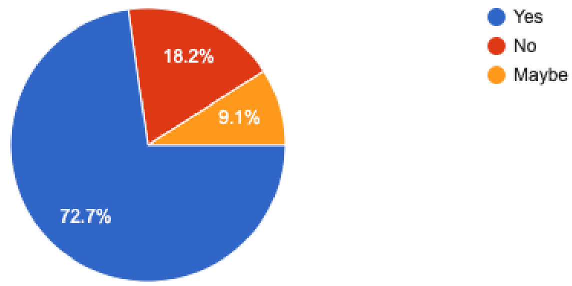
Could you feel the inner components of the vest?

11 responses



Was the vest able to be adjusted to your body type?

11 responses



Do you have any recommendations for increasing the comfortability or adjustability of the vest?

6 responses

Make more skin tone types

Maybe try and make it a little lighter?

I liked the vest a lot

Use a few more straps so that it is more form fitting

straps all over could make it a lot more form fitting

The vest is a little bit heavy and there are parts that poke into you but it is not problematic! If you are going to redo it I would just add a little bit more padding

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