Force-Sensing Neonatal Ventilation Training Device

Final Report

ME 450 – Winter 2024

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

Positive Pressure Ventilation (PPV) is a type of mechanical ventilation used in medical settings to support or replace spontaneous breathing. Neonatal doctors are taught to conduct this treatment, but there is a glaring gap in the training procedure. 5-10% of newborns undergo PPV to aid their breathing upon birth. When a baby struggles to immediately breathe, it poses a significant risk to a baby's wellbeing. Specifically, there is a need to develop a training device that informs PPV providers on the range of force to apply to the neonate's face, as insufficient force can lead to air leakage, while excessive force may result in injury to the baby, potentially causing bradycardia or apnea.

Jacqueline Hannan, our sponsor, is a PhD student whose work centers around the amount of force applied to the face of training manikins during PPV. The goal of our study is to apply these limits of forces to the training sessions by creating a device that not only detects the limits of forces, but also provides live feedback to the user as to whether they are applying the correct amount of force. Live feedback will make the training session for PPV more effective, and therefore address the issues of applying too much or too little force.

It was found that while there was research addressing the minimum amount of force that can be applied during neonatal PPV, there is limited research on the maximum force. The training process itself, while it addresses the issues of providing too little force and air leakage, does not give the users any feedback on whether or not the amount of force they are applying could be detrimental.

Through concept generation and an extensive selection process, we developed our Alpha design. Based on our Alpha design, we came up with a series of design worries and associated design analysis procedures. Following the results of these analysis, and further research on the subject, we iterated our Alpha design to our Beta design. Minor issues were addressed to form our final ME 450 Build, or Gamma design. With a focus on accessibility and impact, our device is designed to integrate seamlessly with existing setups, allow nurses to emulate the real scenario, and provide live feedback. As our project progressed, our specifications guided our design decisions, resulting in a robust prototype that addressed the critical needs of stakeholders effectively.

When considering the Final Design past ME 450, our recommendations address key areas for improvement in the manufacturing process, the design of the mask, and the choice of sensors for our neonatal resuscitation device. Looking ahead, future work should focus on implementing these recommendations to enhance the functionality and effectiveness of our device, ultimately improving outcomes for newborns in need of respiratory support.

Abstract
Positive Pressure Ventilation (PPV) is a resuscitation method used to treat newborns who are struggling to breathe in the first minutes after birth. When nurses perform PPV, care must be taken as too much force applied from the ventilation mask to a newborn's face could result in injury or obstruction of the airway. Too little force could lead to an improper seal and air leakage. The goal of our team's project is to develop a training device that measures and provides live feedback on the force applied to a neonatal manikin's face.

PROJECT INTRODUCTION, BACKGROUND, AND INFORMATION SOURCES

The Stirling Research Group is an organization at the University of Michigan focused on advancing the use of wearable sensors for a variety of different applications. This project is supported by our other sponsor, PhD student Jacqueline Hannan, who is attempting to quantify the minimum and maximum amounts of force that can be applied to the neonate during the procedure. Our sponsors have asked us to design a training device that can accurately measure the force applied from a physician to a neonate manikin during a neonatal resuscitation process called Positive Pressure Ventilation (PPV).

Breathing after Birth and Complications

The first few minutes after birth represent a crucial window wherein vital oxygen is required for immediate survival and laying the groundwork for healthy development. This pivotal period, often referred to as the golden minute, encompasses the immediate moments following delivery when the newborn must initiate independent breathing[1]. During this time, the infant's ability to take in oxygen and expel carbon dioxide is paramount in establishing a successful transition to life outside the womb and ensuring overall well-being.

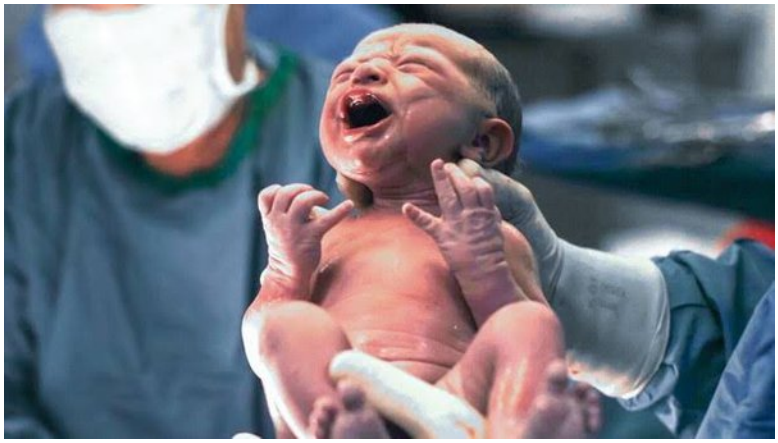


Figure 1: A newborn held by doctors immediately after birth *Getty Images*

When a baby is born, their lungs are initially filled with amniotic fluid, which needs to be cleared out to make way for air. That first breath triggers a series of events: the baby's chest expands,

creating a vacuum that pulls air into the lungs. As air rushes in, it pushes out the remaining fluid, allowing the tiny air sacs in the lungs to expand and start working. At the same time, the baby's brain sends signals to muscles around the chest to help them breathe in and out rhythmically. As the baby breathes in, oxygen from the air enters their bloodstream and travels all over their body, providing the energy they need to thrive. Meanwhile, carbon dioxide, a waste product, is expelled with each breath out. The resuscitation process continues, ensuring that the baby gets the oxygen they need and keeps their body running smoothly as they adjust to the world.

In some cases, newborns may encounter complications or struggles as they attempt to breathe independently, a condition commonly known as birth asphyxia[2]. Birth asphyxia occurs when the baby experiences difficulty breathing immediately after delivery, often due to factors such as prolonged labor, umbilical cord compression, or placental insufficiency. It accounts for an estimated 900,000 deaths each year and is one of the primary causes of early neonatal mortality. The lack of oxygen can result in a cascade of adverse effects on the newborn's health, including impaired cardiovascular function and compromised tissue perfusion.

As the baby struggles to breathe, two common challenges that may arise are bradycardia and apnea.[3] Bradycardia, characterized by a slower-than-normal heart rate, can occur if the baby's respiratory efforts are inadequate to maintain sufficient oxygen levels in the bloodstream. The diminished oxygen supply can lead to decreased blood flow to vital organs, potentially resulting in serious health consequences if not promptly addressed. Similarly, apnea, defined as a temporary interruption of breathing, may manifest as the newborn's respiratory system struggles to adapt to the transition from the womb to extrauterine life. In newborns, episodes of apnea lasting longer than 20 seconds are considered abnormal and may indicate underlying respiratory issues or neurological immaturity. Both bradycardia and apnea pose significant risks to the newborn's well-being, necessitating immediate intervention to restore normal respiratory function and prevent further complications. Therefore, prompt recognition and management of birth asphyxia and its associated complications are essential for ensuring optimal outcomes and safeguarding the health of the newborn.

Moreover, the first minutes after birth represent a critical window for intervention in cases of respiratory distress or failure to initiate breathing. Prompt identification and appropriate management of such conditions are vital to prevent hypoxia and mitigate the risk of adverse outcomes. Approximately 5-10% of newborns need life-saving Positive Pressure Ventilation.[4] Given the paramount importance of this period, ensuring effective support and assistance during neonatal resuscitation is imperative. Early recognition and management of these complications are essential for ensuring optimal outcomes and safeguarding the health of the newborn.

Positive Pressure Ventilation (PPV)

Roughly 10% of neonates need help to begin breathing after birth. When completing this life-saving resuscitation process, Positive Pressure Ventilation (PPV) is the most common method used.[5] Historically, ventilators were more invasive and more intrusive on patients[6]. Noninvasive resuscitation such as PPV is considered the best method for resuscitating neonates who cannot withstand invasive procedures. PPV allows for a direct manual reaction for the distribution of gas flow within the lungs. The goal of PPV is for the patient to achieve oxygenation in the lungs.[7]

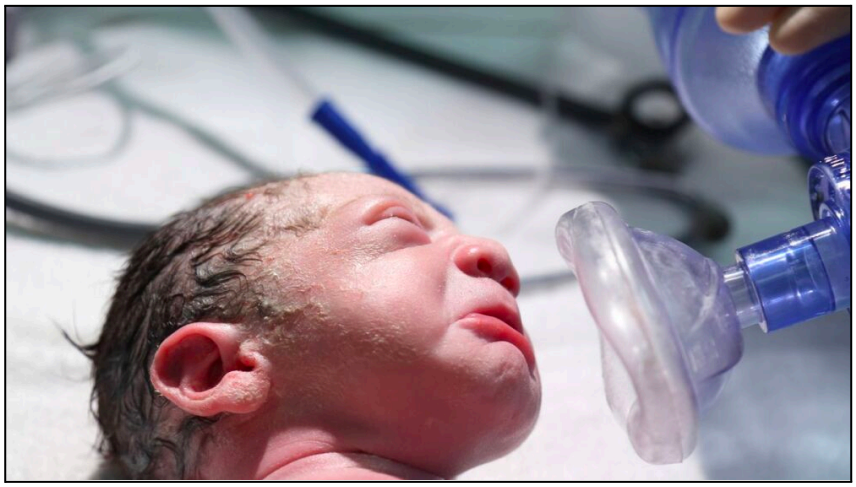


Figure 2: A newborn about to receive PPV after birth. *Getty Images*

Through PPV, air is delivered to the patient through a mask that covers the mouth and nose. When applying PPV there are limitations to providing a successful ventilation. If too little pressure is applied, then the seal between the mask is broken and the process becomes less effective. However, if too much pressure is applied, then the higher forces can cause an increased risk of an obstructed airway for the neonate. The conditions of an obstructed airway include both apnea and bradycardia, which are critical to neonates.[6]

Training

The current training methods address several key aspects of PPV in order for the provider to ensure the resuscitation process is working. These aspects include chest rise, health vital signs, amount of air received, and status of condition.[8] The current feedback that is provided during these sessions include information from breathing rate and leakage from the mask.

Figure 3: Current resuscitation training process using RQI cart. *Laerdal Medical*

The training sessions combine a lecture and hands on case-based simulation, some specifically use training videos to aid the physician. The training videos are used as a tool to increase the effectiveness of training sessions, and are stated to increase the effectiveness of the sessions by 10%. [9] The videos address the issues of applying too much pressure, but in vague terms. The issues of applying too little pressure are addressed in the sessions in terms of preventing leakages. Another current study in the training strategies show the training sessions decreasing the leakages by 60%, but seeing an increase of 5% three weeks later. The study identified that training in mask ventilation was focused on preventing mask leakages, and not airway obstructions that are caused by applying too much force.[10] The focus of the training sessions, as well as the limited effectiveness, demonstrates areas of improvement that are needed in the way training sessions are conducted. Our focus will be on these training sessions and our work will therefore only be relevant to the medical manikins used, not the babies themselves.

Manikins and Masks

When it comes to characterizing airway management, various manikin styles are utilized in professional fields, including the SimNewB, Newborn Anne, Premature Anne, Neonatal Intubation Trainer, and more [11]. The different high-fidelity manikins boast sophisticated systems that provide crucial feedback during training sessions. The manikins incorporate features such as chest rise simulation, simulation of vital signs, and respiratory monitoring capabilities. Our sponsor provides us with a SimNewB, which is one of the highest rating manikins, and one of the most commonly used manikins in PPV training sessions. However, it is worth noting that these advanced manikins often come with a significant price tag, with costs reaching upwards of $3,000 [11]. The high cost of the manikins may limit the flexibility to modify the manikin itself for pressure measurement purposes.

Figure 4: The high fidelity newborn manikin, SimNewB™ full-term manikin, produced by Laerdal Medical. *Laerdal Medical*

There are various masks designed to deliver positive pressure ventilation effectively for neonatal resuscitation, as seen in Figure 5. These masks typically come in two main types: round masks and anatomic masks. Round masks vary in diameter, offering options suitable for different neonatal sizes, while anatomic masks are shaped to conform to the contours of the infant's face, providing a more customized fit. There are several providers who offer these masks.[8]

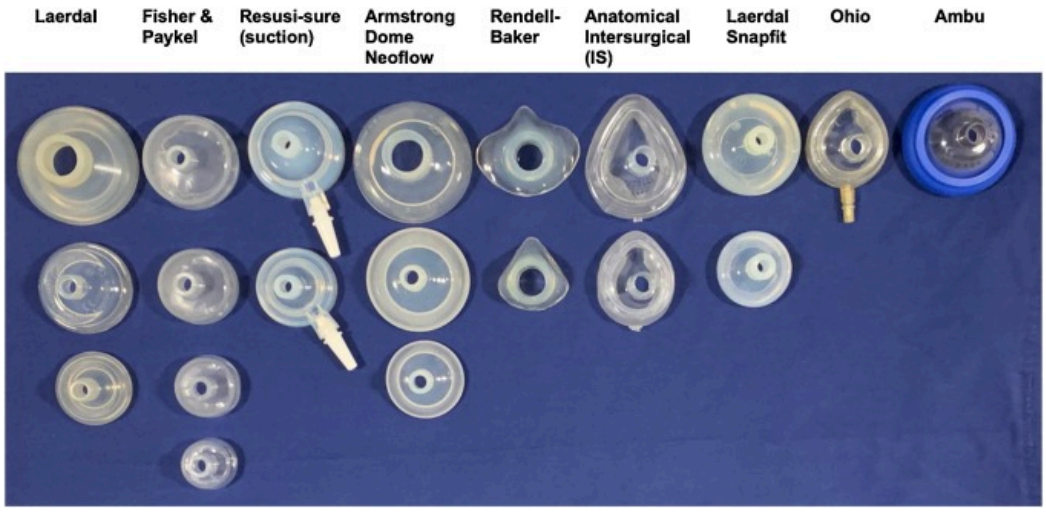


Figure 5: Variety of masks used for PPV consisting of different shapes, sizes, and providers. *University of Michigan*

For our project, we will primarily focus on utilizing 60 mm round masks, which are most commonly used in training scenarios due to the size of the manikin. However, to ensure versatility

and compatibility, our design optimally aims to accommodate a range of mask sizes, from 35 to 60 mm, thereby catering to various neonatal stages and clinical needs.

Live Feedback During Ventilation Training

Previous studies have demonstrated that providing live-feedback during training can significantly enhance post-training performance. For instance, a randomized controlled trial investigated the effectiveness of using a respiratory function monitor (RFM) during newborn facemask ventilation training, with results shown in Figure 6. The study found that participants who received real-time, objective feedback through the RFM during training exhibited reduced facemask leak compared to those without access to such feedback.[12] The ability to receive feedback in real-time allows nurses to immediately adjust their actions resulting in more effective outcomes, highlighting the practical utility of incorporating real-time feedback mechanisms into healthcare training protocols.

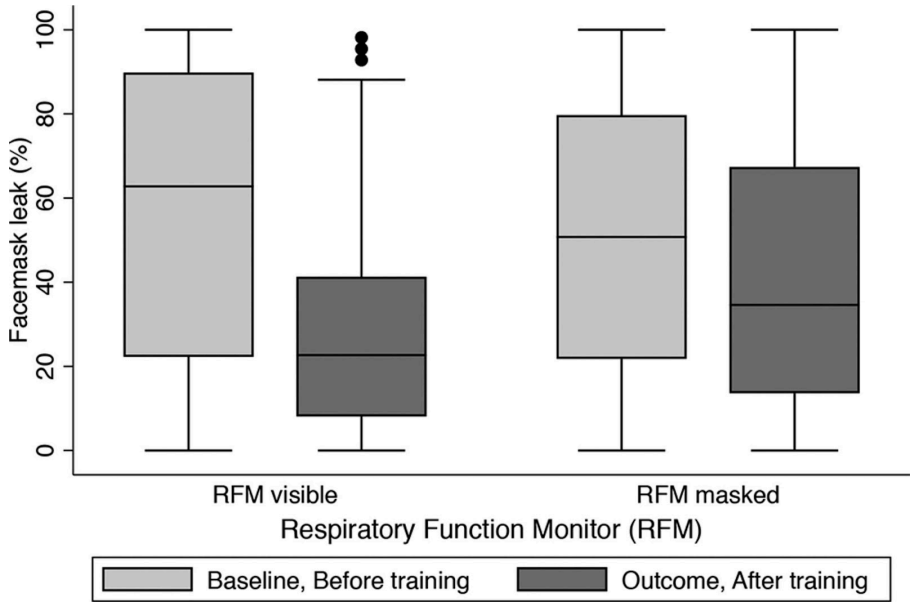


Figure 6: Graph showing the comparison of the leak (%) with respiratory function monitor (RFM) visibility, before and after training from the study. *O'Currain et al.*

There was an additional study on the ideal location that display devices should be placed. The results showed that having a flat screen display directly in front of the user increases comfort as well as posture.[13] An additional study showed medical staff perform best when real time tracking is used so the user can adjust, and when the display system is clear enough so that they can quickly determine results due to time sensitivity.[14]

Past Work

Sponsor Research

PhD student Jacqueline Hannan is currently completing a study in order to understand the applied forces on the face and back of the head of the baby. By quantitatively describing the maximum and

minimum forces that can be applied to the neonates face, the training sessions could be adjusted so that the trainees are provided with active and specific feedback. The experiment was set up so that there are four microforce sensors placed on the nasal bridge, mentum, and the left and right zygomatic arches of the high-fidelity SimNewB™ full-term manikin [15]. These locations were determined as they are the bony features of the face and therefore provide the most contact from the mask to the face. A fifth sensor was then placed on the back of the manikin's head. The proximal air flow was measured through the ventilator and face mask using a digital flow meter. The force sensors and flow meters were connected using an Arduino and air flow and pressure were measured at increments of applied force under the head of the manikin. The force was increased from 1.5N to 6N, and the resulting air flow and pressure were then noted. The results allowed her to successfully determine a minimum pressure of 0.5N for the face sensors. Note that while Jacqueline's setup of sensors accurately measures forces, the forces cannot be read out to the user, and the technical setup interferes with normal PPV process. Her work, while vital to quantifying the minimum pressure, does not provide a setup that is usable for our purpose.

In order to expand on her data, a collection of different physicians were categorized as novices or experts based on whether they were medical residents or neonatal physicians, fellows or professionals. The setup was the same as before, with five microforce sensors at the same locations. Two minute trials of simulated PPV were then conducted for each subject, with multiple different types of masks. Upon analysis of the data, there were discrepancies between the different mask types used and the amount of force applied for the sensor on the back of the manikin's head. However, mask type creates no difference in the force applied to the sensors on the face of the manikin. The subjects who were identified as experts provided a significantly greater force than the novices. The experts were also noted to apply more equal force around each of the masks. It was also noted that based on which type of hold was being used, there was more force applied to one side of the mask, depending on the type of hold used. The results of the study allowed Jacqueline to characterize the levels of applied forces on different areas of the manikin during the PPV process. There were several limitations within Jacqueline's study, the first being that a medical manikin cannot directly translate to an actual neonate. Similarly, the conditions of the study could not directly replicate the environment in an actual hospital that could change the results due to distractions and high stress levels.

There is only one other relevant research paper on this matter that has been published. The study focused on determining if this increase in apnea (and bradycardia) was related to applying too much force to the mask during the resuscitation process of PPV. Apnea can cause breathing to stop, bradycardia slows the heart rate, and both lower the oxygen levels and can cause fatalities in infants. In this study, it was shown that with the current application of the face mask, 54% of preterm infants developed apnea, and 77% of preterm infants who were less than 28 weeks old developed apnea[10] . In order to conduct this study, a custom sensor called a Sens-O was developed that allowed the circumferential force along the mask to be measured. Spontaneous breathing was

measured using waveforms and observations such as visible chest excursions, crying, or abrupt movements. The likelihood of apnea was evaluated based on the heart rate, level of oxygen, age and more. The study completed a binary logistic regression of the amount of force, and the other characteristics in order to see if there is an association between apnea and bradycardia, and higher forces. The results were an odds ratio of 1.607 for increased force and apnea, and an odds ratio of 1.14 for increased force and bradycardia. The odds ratio being higher than one indicates that there is a positive correlation between higher forces and these conditions. This study addresses the issues that come from providing too much force during the PPV process. However, there is still no research or knowledge on what quantitative maximum force should be provided. There is a resulting gap in our research due to limited data on this specific subject.

Previous ME 450 Team

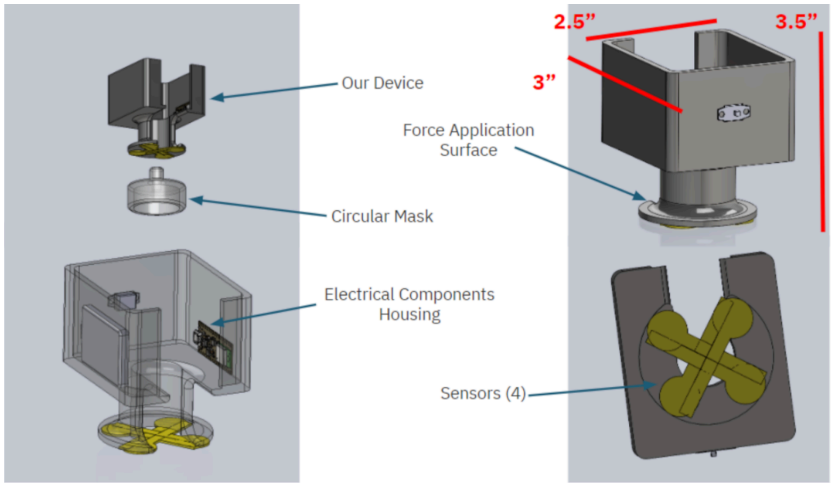


Figure 7: Exploded view of previous ME 450 team’s design.

Last semester, a ME 450 team completed the same project.[16] Figure 2 shows their final design, which consists of a 3D printed object that is placed around a round neonatal mask and T-piece during PPV. There are sensors located at the bottom of the object, which measure the force applied to the top of the mask. The upper portion of their device is housing for the electrical components. In our initial meeting with our sponsor, Jacqueline Hannan, we were told we had the option to either build off the past team’s work or start from the beginning. We were given access to their final design report, where we were able to analyze their successes and shortcomings with their design. The team had success with portability, durability, and cost effectiveness. One challenge they faced was with the material, PLA, due to its rigidity. The PLA material property posed a problem in contact of the sensors with the mask, which impacts consistency and accuracy of the results. Another issue was that their device did not allow for consistency between users and hand placements. Our sponsor specifically emphasized how the weight of their device was a major problem because the electrical components on top of the mask made it too heavy. Finally, the team struggled with the electrical components due to a lack of experience in soldering. In our concept generation stage, we will explore both similar and different designs to this previous one in order to

make the best decision. These successes and shortcomings were all taken into consideration when developing our requirements and specifications.

PROBLEM STATEMENT

Through this research we have identified a gap in knowledge that is detrimental to the PPV process. Currently, 5-10% of neonates require positive pressure ventilation after birth to assist with their breathing. Health professionals must apply an appropriate force to the newborn's face with the mask because too little causes air leakage and too much causes injury to the newborn. There is a need to develop a training device that informs PPV providers on the range of force to apply to the neonate's face. A market solution to this problem does not currently exist, making it our goal to fulfill this need.

Relevant Standards

Because medical devices are critical for the healthcare industry and many come into direct contact with people, there are many recognized standards to ensure safety when developing medical devices. Our group identified the standards that are relevant to our project to be ISO 14971, 10992, 62304, 13485, and IEC 60601.

Risk Management

ISO 14971 outlines a systematic approach to managing risks associated with medical devices throughout their entire life cycle. It provides a framework for identifying, evaluating, and controlling potential hazards, ensuring patient safety and regulatory compliance.[17] It is crucial for ensuring that our medical device undergoes a thorough risk assessment, minimizing potential harm to patients, healthcare professionals, and the broader public.

Biocompatibility

ISO 10993 sets the standard for evaluating the biocompatibility of medical devices, ensuring that materials used do not induce adverse reactions in the human body. It includes various tests assessing cytotoxicity, genotoxicity, and other biological responses.[17] The ISO 10993 standard is important for preventing harmful reactions, allergies, or infections caused by medical device materials, promoting patient safety and device effectiveness and should be considered when our team selects materials for our device.

Medical Device Software

ISO 62304 focuses on the software lifecycle processes specific to medical device development. It provides guidelines for software development, validation, and maintenance, ensuring the reliability and safety of medical device software.[17] The ISO 62304 standard is relevant for the growing integration of software in our medical device, guaranteeing that software functions correctly, is secure, and complies with regulatory requirements.

Quality Management

ISO 13485 outlines the requirements for a quality management system in the design, development, production, installation, and servicing of medical devices. It is tailored to the medical device industry and aligns with regulatory expectations.[17] It is critical for ensuring the consistency and reliability of our medical device, demonstrating compliance with regulatory standards, and enhancing overall product quality.

Product Safety Standards for Medical Devices

IEC 60601-1 ensures the safety of patients using medical electrical equipment. The IEC 60601 standards provide a consistent framework for safety requirements across different types of medical electrical equipment. The uniformity helps our design team to understand and implement the necessary safety measures for our device.[18]

These standards collectively establish a comprehensive framework for the development, testing, and maintenance of our Neonatal Respiratory Training Device. They play a pivotal role in ensuring patient safety, product effectiveness, and regulatory compliance within the healthcare industry. Adhering to these standards is crucial for manufacturers, fostering confidence among healthcare professionals, regulatory bodies, and end-users in the reliability and safety of medical devices.

DESIGN PROCESS

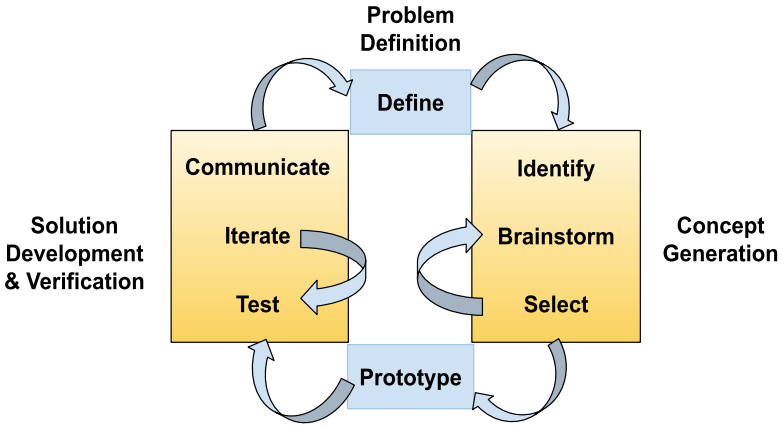


Figure 8: Visual of our stage based design model which includes multiple iterative steps.

Figure 8 shows the design process that our team will be following this semester. In designing this framework, we considered various models provided to us in the learning block, but we were particularly drawn to the ME 450 Capstone Design Process Framework. Therefore, we created a model that mirrors the three major stages of the ME 450 Capstone Design Process Framework, but breaks down the specific steps involved in each stage. We believe a problem oriented and stage based model is best due to the nature of our project. Each phase in our process has its own set of objectives, activities, and deliverables. The arrows emphasize the iterative aspect of this framework as we receive feedback from our stakeholders.

We have dedicated extensive time and effort to defining our problem statement, identifying stakeholders, outlining requirements and specifications, and benchmarking. Throughout our endeavor, we have embraced design thinking principles, with a focus on diverging and converging within the problem definition space.

In terms of our progress, we are currently at the stage of selecting an Alpha design and completing initial engineering analysis. Looking ahead, we intend to conduct parallel testing of select concepts to figure out viable solutions. We will engage in prototyping, testing, and ongoing dialogues with stakeholders, all aimed at identifying the optimal solution.

DESIGN CONTEXT

When contextualizing our design challenge, our team identified key areas and individuals to consider that would be affected by our proof-of-concept design. They are listed and discussed below.

Social Context of Design Challenge

The societal aspect driving this project extends beyond the interests of the sponsor by addressing critical healthcare needs in neonatal resuscitation training. Neonatal resuscitation is a vital skill in healthcare settings, with errors potentially leading to adverse outcomes for newborns.[10] By improving training methods through innovative devices, the project aims to enhance patient safety and healthcare outcomes. While the sponsor likely prioritizes educational advancements, the social impact of the project remains significant, given its direct implications for patient care and safety. The order of these priorities may influence design decisions, as hospitals emphasizing profit could lead to cost-cutting measures that compromise quality or safety.[19] Prioritizing social impact and patient safety may result in more robust and effective solutions, ultimately benefiting society as a whole.

Stakeholder Analysis

In order to conceptualize our design problem and define our requirements and specifications, it is essential for us to observe the impacts our solution could have on various stakeholders. To determine the relative involvement of the different stakeholders, we decided to utilize the 3-tier map as outlined in the ME 450 Social Context Learning Block[20], with each stakeholder classified into the following roles: supporters and beneficiaries of the status quo (SB), complementary organizations and allies (CO), opponents and problem makers (OP), beneficiaries and consumers (BC), affected bystanders (AB), and resource providers (RP). Our stakeholder map is found below in Figure 4.

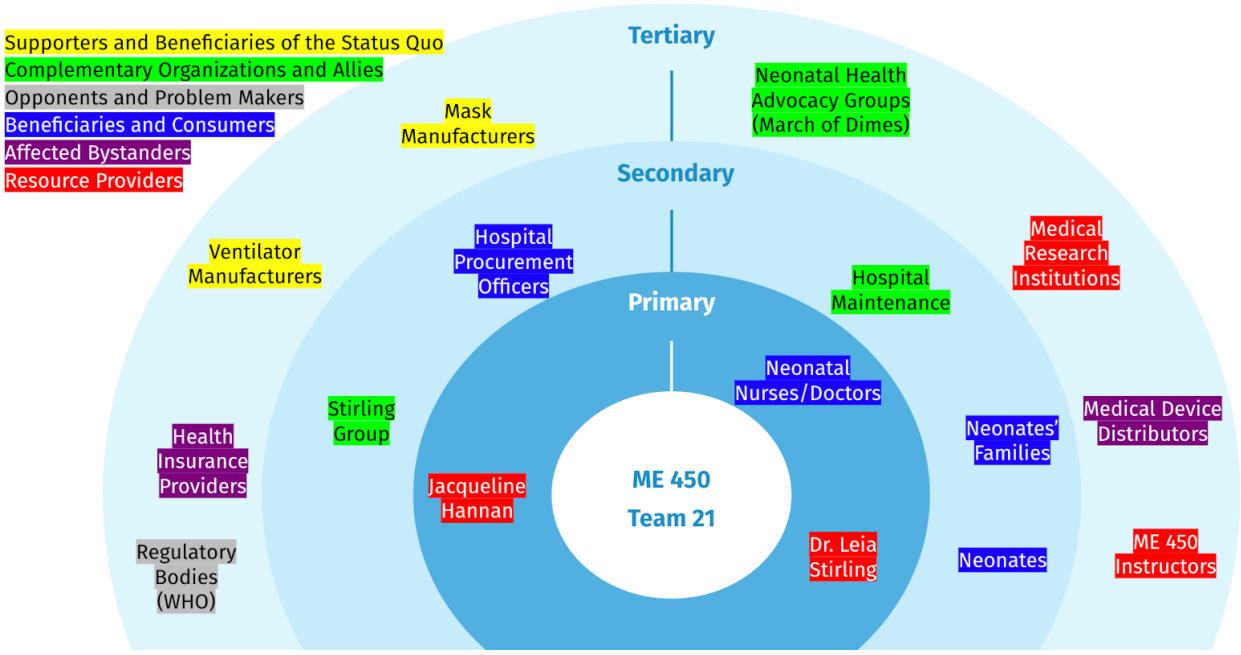


Figure 9: 3-Tier stakeholder map organizing stakeholders according to role and proximity to potential impacts from our solution.

The innermost ring of the stakeholder map in Figure 9 highlights our primary stakeholders, which are those whose lives or work would be directly affected by the development of our solution. These include our project sponsors, PhD student Jacqueline Hannan and Doctor Leia Stirling, as they have brought the design problem to us as part of their research projects. They have provided us with useful research, networking connections, training equipment, and consistent guidance to aid in our design process. As the actual users of our PPV training device, the neonatal clinicians fall into the primary BC category. Our training device could directly impact their work by increasing the effectiveness of the training and potentially boosting their PPV success rate.

The second ring of our map features secondary stakeholders, all of which are relevant in the problem and solution context, but experience the outcomes of our development on an indirect level. For example, hospital maintenance crews are in the second tier because while they may not directly benefit from our training device in terms of their core responsibilities, they could be supportive allies in the project. Their role would involve ensuring that the facilities and infrastructure necessary for training sessions with the device are well-maintained and operational. They would also be involved in the implementation and maintenance of the devices themselves.

The third and outermost ring is home to several tertiary stakeholders in our project who are not directly associated with our design problem or solution, but may be able aid or inhibit our development from an outside perspective. Because the extent of the ME 450 project is a proof-of-concept prototype, several of these stakeholders, especially ventilator and mask manufacturers, as well as medical device distributors, are not impacted in our scope. However, we

envision these stakeholders being involved as our product progresses to a commercial level in the future. Medical Research Institutions would fall into this tier, as they may be able to provide our team with relevant medical insight or studies that could further our knowledge and development of our device.

While we categorized each stakeholder into their most likely or prominent roles on the map, it is important to note that these categories are not mutually exclusive and can change depending on the stakeholders' motives and actions. For instance, hospital procurement officers are currently tagged in the BC category since their role in ensuring that the hospital obtains effective training tools could directly benefit them and their hospital's public rating. However, if the procurement officers decide that they will not buy into our training product or allocate any resources to our cause, they could step into the opponents and problem makers role. Another example would be current medical training equipment providers (masks, ventilators). If our device threatens the market demand for current equipment, the negative impact on them would likely cause them to resist our innovation and support the status quo. On the other hand, if our device is a complementary product and leads to increased demand for neonatal care equipment, current PPV training equipment providers could see additional business opportunities and could fall into the BC category.

Environmental Considerations

We want to design the device with sustainability in mind, which includes being mindful of the manufacturing process, the use and maintenance of the device, and the disposal of the device. These largely depend on the materials we select, so during our design process we will benchmark materials according to their emissions, lifetime, and recyclability. Additionally, we expect the electronic components to be large contributors to the carbon footprint.[21] We hope to minimize the number, complexity, and mass of the electronic components included. Throughout its use, the device will use electricity, so it will be our goal to make the system as efficient as possible. Some of these decisions may lead to increased costs but will be evaluated when the choices are finalized. By being conscious of all of the potential impacts, we aim to make our design sustainable in today's environmentally aware society. Our chosen material TPU is a recyclable material that can be reprocessed, minimizing environmental impacts. [22] This can then be considered an environmentally friendly choice as it has a small carbon footprint and promotes sustainability.

Disability Considerations

In our commitment to inclusivity, we acknowledge the potential challenges faced by nurses with disabilities such as color blindness and deafness. By incorporating disability considerations into our design process, we aim to ensure that our device is accessible and functional for all users. Specifically, for nurses with colorblindness, we will avoid relying solely on color-coded indicators or instructions, opting instead for alternative methods of conveying information that do not rely on color discrimination. Likewise, for nurses who are hard of hearing or deaf, we will ensure that our device's interface and operation do not rely solely on auditory cues.[23] By prioritizing the needs of

individuals with disabilities in our design approach, we strive to create a training device that fosters equal participation and effectiveness for all healthcare professionals, regardless of their abilities or impairments. Moving forward, we will have further discussions and investigations into the human factors that could influence our design. Studying human factors will allow our device to incorporate a successful interface between technology and humans, creating the most optimal performance.

Power Dynamics

Our team members, sponsors, and stakeholders share a power dynamic that is framed by our varying cultural, socioeconomic, and educational backgrounds. Despite our varying backgrounds and experiences, our team and our sponsors are all part of the University of Michigan Engineering community and collectively strive to uphold the highest ethical standards and expectations of honesty and integrity.[24] As undergraduate students with minimal experience in researching neonatal ventilation processes, we benefit heavily from the expertise of Jacqueline and Dr. Stirling. Jacqueline is our main source of contact on this project, as we have weekly meetings where we update her on our progress and she offers advice, gives us additional resources, and helps us with stakeholder engagement. While this project was brought to our attention by our sponsors, they have granted us the flexibility to decide our own requirements, specifications and design concepts without restricting us on any designated path. The open nature of our communication allows us both the freedom to exercise our own ideas while still bouncing ideas of our sponsors in a healthy and developmental manner. This freedom has continued throughout our design generation and selection process, engineering analysis, and prototyping stage. Jacqueline has been very supportive by making accommodations to help us conduct our tests. In light of our collaborative and supportive environment, we have felt continually encouraged in our progress and are enthusiastic about bringing our project to fruition.

Intellectual Property

As a condition of participating in this capstone project, the intellectual property rights were signed over to the University of Michigan, including patent rights, which might come from our invention. Team members would be inventors if novel intellectual property is generated. There have not been any conflicts with external entities thus far due to the lack of similar products being commercially available.

Problem Domain Analysis

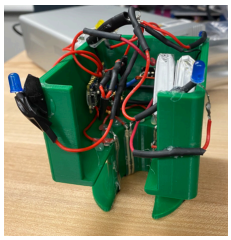
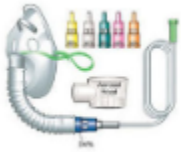
The lack of research surrounding the maximum force that can be safely applied to a neonate's face during positive pressure ventilation is a significant gap in current knowledge. The absence of data on the upper limit poses a challenge in ensuring the safety and effectiveness of neonatal resuscitation practices. Our sponsor, Jacqueline, is currently conducting research on the minimum force, but addressing this unknown requires further investigation. As part of our project, we are continuing our search through current medical research to determine this critical threshold when establishing the range of appropriate forces for our training device. We encourage more research to

be done in this area as it is essential in enhancing neonatal care and ultimately saving newborn lives.

Instrumented Mask Benchmarking

Our team explored a wide range of instrumented masks to use as benchmarks for our design, as shown in Tables 1 and 2.

Table 1: Instrumented Mask Benchmarking

	Previous ME 450 Group[16]	**CPAP Mask[25]**	**Venturi Oxygen Delivery Masks[26]**	**Firefighter Masks (SCBA)[27]**
Picture				
Weight	138 g	118.8 g	120 g	< 15875.7 g
Size	76.2 x 88.9 x 88.9 mm	120.65 x 82.55 x 63.5 mm	1008000 mm^3	393.7 x 304.8 x 165.1 mm
Has ability to monitor force	Yes, pressure sensors measure force applied	No, measures H2O levels	No, only monitors amount of oxygen delivered to the user	No, monitors and regulates pressure
Cost	$61	$202.60	$2.91	>$500
Training required	Device requires no training to set up.	No, videos available for assembly and use	Medical Professional	8-12 training sessions
Lifetime	500 training sessions	3 months	5 year shelf life (masks are single use)	30 minute air supply
Setup Time	< 30 seconds	< 1 minute	< 1 minute	< 10 minutes
Provides Live Feedback	Yes, device uses LED lights	No	No live feedback from mask	Yes

We have determined that the most important specifications in benchmarking against existing products is the weight, ability to measure the force applied, and the ability to provide live feedback. Components such as size and lifetime are considered to be of medium importance and setup time and training required are considered to be of low importance. The previous ME 450 team's device is the only benchmark that contains a force sensing component, which is why it is crucial to consider its specifications in formulating our design. The weight of their device was a major shortcoming as mentioned previously, which is something our team took note of when beginning concept development.

A CPAP (Continuous Positive Airway Pressure) mask is primarily used in treating sleep apnea. The CPAP medical device serves similar purposes to a PPV mask, which is why it was selected for benchmarking. A CPAP mask can measure H2O levels, but does not provide any live feedback to the user. The Venturi Oxygen mask delivers a controlled fraction of inspired oxygen (FiO2) to patients requiring oxygen therapy. Although this mask also serves similar purposes to a PPV mask, it is significantly less expensive than a CPAP mask and measures oxygen levels delivered to the user.

The purpose of firefighter SCBA (Self-Contained Breathing Apparatus) masks is to provide respiratory protection to firefighters during firefighting operations or other hazardous situations where the air may be contaminated with smoke, toxic gas, or other harmful substances. The SCBA mask is the first non-medical instrumented mask we benchmarked in order to gain further insight. Firefighter SCBA masks can monitor and regulate pressure for air supply. This benchmark was useful for evaluating the characteristics of the pressure gauge and live feedback. Table 2 presents additional instrumented masks that our team used as benchmarks.

Table 2: Instrumented Mask Benchmarking (continued)

	Scuba Mask (OTS Full Face Mask)[28]	**Airplane Mask[29]**	**Anesthesia Mask[30]**
Picture			
Weight	1420 g	90.7 g	2721.55 g
Size	300 x 300 x 300 mm	85.09 x 76.2 x 85.09 mm	90 x 80 x 85 mm
Has ability to monitor force	Yes, monitors with the demand regulator.	No, uses adjustable straps	No measures CO2 content
Cost	$912.77	$195	$220-$385
Training required	Yes, diving equipment requires training.	Briefing when sitting on plane	>25 procedures[31]
Lifetime	Two years	3 years	5 years
Setup Time	< 5 minutes	Under 15 seconds	< 5 minutes
Live Feedback	No	No	Side stream measurement of EtCO2

The Scuba mask was the second non-medical mask we analyzed, which contains a demand regulator that maintains internal pressure of the mask slightly above ambient water pressure. The Scuba mask was included as a benchmark because the demand regulator is an aspect we could examine more in depth to potentially incorporate into our future design. The airplane mask is a safety device provided to passengers on commercial airplanes. The standards for airplane masks prioritizes fit, which would be an essential component to our design. The Anesthesia mask is used to administer inhalational anesthetic gas or provide oxygen during anesthesia induction or other medical procedures. The ability to measure CO2 content and provide live feedback in the form of a side stream measurement is something to note in comparison to our goal.

The main takeaway from these benchmarking tables is that there are no commercially available masks that measure force applied to the face for neonates, children, or adults, aside from the previous ME 450 team's prototype. It is important to recognize this fact as we continue into our design development because there is an apparent lack of research being done in this area. Our team is exploring a gap in research that does not have much precedent.

USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

In this section, we explain our user requirements and translate them into precise engineering specifications for our project. User requirements serve as the foundation, capturing the essential functionalities and features expected by stakeholders. The importance of each requirement was established through consultations with stakeholders, prioritizing functionalities that directly impacted the effectiveness and compatibility of the training device. We explore how these requirements have been transformed into measurable engineering targets, forming a set of specifications that will guide the design and development process. The alignment between requirements and specifications ensures that the final solution not only meets the users' needs but also adheres to predefined engineering standards. We first present each requirement and specification in Table 3 followed by a general discussion of their development and an in-depth description of each requirement and specification.

Table 3: Requirements and Specifications

Priority	Category	Requirement	Specifications
Must Have	Functionality	Allows user to perform four hand positions	One-handed CE hold, two-handed hold, spider hold, and stem hold
Must Have		Does not contribute to excessive air leakage	<25% air leakage (Low Leak - minimal) <10 % air leakage (Optimal)
Must Have		Accurately detects forces in the correct range	Force sensing range: 0 -10 N Resolution: < 0.045 N
Must Have		Measures force in four key locations	Nasal bridge, left and right zygomatic arch, and mentum
Must Have		Outputs readings proportional to readings from existing sponsor setup	Vary <5% (considering a factor of proportionality)
Must Have		Supports the most common training masks	60 mm round mask (minimal) 35-60 mm round mask (optimal)
Must Have		Provides real time feedback for the user	≥ 1 sensory feedback signal < 250ms of reaching target force range ≥ 4 locations

Priority	Category	Requirement	Specifications
Must Have	Practicality	Is transferable	No residue Separable from manikin ≤ 2 tools required to transfer
Must Have		Prototype is within the ME 450 budget	< $400
Must Have		Is safe to use	No risk of shock[18] No sharp edges or surfaces[18]
Like to have		Is durable	Withstands >1250 10-minute cycles Withstands 40N applied force
Like to have		Is lightweight	< 600 grams (minimal) < 200% of weight of the respirator (optimal)
Like to have		Can be set up quickly	< 1 minute for complete set up (hardware and software)
Like to have		Is easy to use	Device takes < 25 cycles to learn how to use

Development of Requirements and Specifications

The relative importance of requirements was determined through discussions with stakeholders, considering factors such as user safety, functionality, and budget constraints. All requirements were explicitly stated, covering functionality, durability, usability, and budget considerations. Compliance with relevant standards such as ISO 14971, 10992, 62304, 13485, and IEC 6060 was ensured. Must-have requirements are critical for functionality and safety, while like-to-have requirements serve to enhance practicality and user experience. The most important requirements include functionality, accuracy of force detection, and compatibility with existing setups, while preferences like practicality and ease of use are less critical but desirable. All requirements have been translated into quantifiable engineering specifications, ensuring clarity and measurability. The engineering specifications are reasonable, with each requirement quantified and aligned with project objectives and constraints. Our requirements and specifications list serves as a live document and we expect these requirements and specifications to change as we progress through the design process.

Allows User to Perform Four Hand Positions

The “Allows user to perform four hand positions” requirement comes from an understanding of how neonatal resuscitation is currently performed with neonates. The four recognized hand positions are one-handed CE hold, two-handed hold, spider hold, and stem hold[32]. For our device to accurately simulate neonatal resuscitation correctly, all of these hand holds must be achievable while using our training device. The divergence in hand holding techniques implies that each four

of these hand holding positions must be obtainable with our device being applied, and therefore that our device cannot interfere with the natural holding positions. Without this requirement, our device would not be able to necessarily accurately simulate neonatal resuscitation, and would therefore fail as a training device. These holds are pictured below in Figure 10.

Figure 10: Top left: Stem Hold; Top Right: One-handed CE hold; Bottom Left: Spider Hold; Bottom Right: Two-Handed Hold.[32]

Does not Contribute to Excessive Air Leakage

The "Does not contribute to excessive air leakage" requirement was defined based on the medical definition of *Low Leak* and our sponsor imposing a limit. Air leakage between the face and mask is a crucial aspect of neonatal resuscitation as it is ideally minimized so that ventilation is as effective as possible. A *Low Leak* occurs when less than 33.3% of the air supplied escapes.[11] Noticeable air leakage can be a form of feedback for nurses as they try to avoid it; this can lead them to press harder to form a better seal between the mask-face interface. To be a useful training device, we want to minimize excessive air leakage to properly emulate the real scenario so that nurses do not learn to press harder than necessary.

Accurately Detects Forces in the Correct Range

The requirement "Can accurately detect forces in the correct range" was established in order to ensure that our device utilizes sensors that can measure the appropriate magnitude of forces that are typically applied to the neonate's face during the PPV process. Detecting the correct forces is vital

because without adequate sensors, our device will read out unreliable and insufficient data. According to a study conducted by our sponsors, Jacqueline Hannan and Dr. Leia Stirling, the range of applied force is about 0-10 N.[15] We also specify that the resolution of the sensor readings must be less than 0.045 N. The resolution number is derived from the Weber Weight Discrimination Experiments, which determined that the minimum difference in force a human can detect while pressing on an object correlates to a factor of 0.09 in relation to the force being applied.[33] Since the minimum force applied to the mask is 0.5 N, the minimum detectable force is 0.045 N.[38]

Measures Force in Four Key Locations

The requirement "Measures forces in four key locations" was devised based on the facial bone structure of neonates, which offers distinct hard surfaces for force measurement.[15] These key locations— the nasal bridge, the left and right zygomatic arch, and the mentum—were chosen to accurately assess the forces exerted by resuscitation masks and their interface with the newborn's face[34] By focusing on these specific facial locations, our design aims to provide comprehensive data on pressure points and contact areas during positive pressure ventilation. Figure 6 shows the four key locations on a manikin's face.

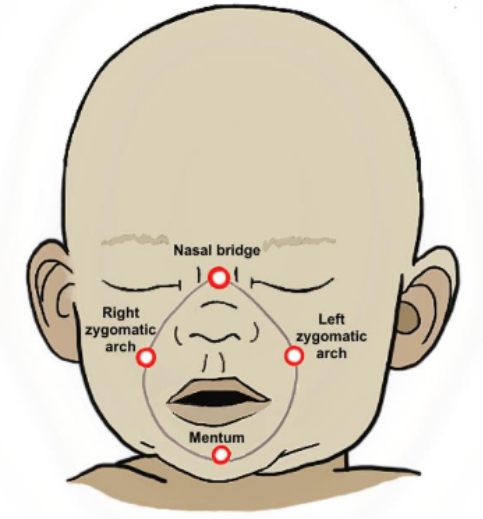


Figure 11: Diagram of the four key locations on a manikin's face. *University of Michigan*

Outputs Readings Proportional to Readings from Existing Sponsor Setup

The requirement "Outputs readings proportional to readings from existing sponsor setup." was created with the intention to make sure our device is able to accurately represent the force reading that will be gathered using a force sensing setup. This setup will consist of four pressure sensors placed on the nasal bridge, the left and right zygomatic arch, and the mentum as outlined in the requirement "Measures force in four key locations". The specification being proportional comes from knowing that our force sensors may not be in the same location, meaning readings may not be in perfect harmony. However, being able to achieve proportional results suggests that our sensors

are able to replicate the force applied to the neonates face through a correction factor that could simulate the pressure readings of the sample force sensors.

Supports the Most Common Training Masks

The determination of engineering targets for the requirement "Supports the most common training masks" involved analyzing existing products and practices within the field of neonatal resuscitation training. Our team wanted our training device to be as accessible as possible, meaning it is critical that our training device is able to function in conjunction with current training devices used for neonatal resuscitation training. We identified the 60 mm circular mask to be the most commonly used[34] along with the Laerdal medical manikins[35] based on research our team was able to find on neonatal resuscitation and communicating expectations with our sponsor. We defined our optimal specification to be that our device can work along with the full range of 35-60 mm neonatal round masks used in industry.

Provides Real Time Feedback for the User

The engineering requirement “Provides real time feedback for the user” was formulated based on the nature of the training our device is trying to deliver. Because we are providing feedback on the force a user is providing to a manikin, it is necessary that this feedback is translated into the user in real time. After speaking with Jacqueline Hannan, our team determined that at least one or more forms of sensory feedback would be sufficient to meet our device standards. The second part of this standard outlines what real time would be quantified as. We set the response time of our device to be 250 ms, this being the response time to sensory input of humans.[36] We then compared this specification to similar medical devices and found it to be comparable to this specification when achieving real time feedback.[37] The final part of this specification includes that our device informs the user of the force measured at each of the four key locations (the nasal bridge, the left and right zygomatic arch, and the mentum). The user then can adjust the force distribution across the four key points to ensure that an equal load is being applied.

Is Transferable

In our conversations with Jacqueline, she stressed the requirement of “Is transferable”. We want our design to be accessible to hospitals and due to the high costs of existing training manikins, it should easily integrate with current manikins. Creating our design to be transferable will allow our device to have the most impact possible. Jacqueline’s current benchtop setup for research is not transferable, which limits how the manikin can be used. Jacqueline's research and setup led us to define that the training device should not be a permanent fixture and be separable from the manikin. In addition, it should not leave a physical trace such as residue on the manikin after its use. Lastly, to easily integrate the device, it should require ≤ 2 tools to transfer. Ensuring the requirement is met is crucial, as we endeavor to scale the device for widespread adoption in hospitals, maximizing its accessibility and impact.

Prototype is Within the ME 450 Budget

The requirement "Within the ME 450 Budget" was determined by the guidelines provided to us by the ME 450 Instructional team. The specification is < $400 because we are not allowed to exceed $400 in costs for production of our prototype device.

Is Durable

The requirement "Is durable" is included to ensure users that our device will be able to last for a long time in order to sustain regular training use. The specifications for the durability of our device include that it must be able to withstand at least 1250 10-minute cycles and can survive an applied force of 40N. The 1250 cycles comes from an estimation based on the following parameters: expected shelf life, number of uses per training, number of trainees per session, number of devices per hospital, and number of training sessions held per year. According to 3M, the expected shelf life of healthcare respirators and masks is five years.[38] We expect the same lifetime for our medical training device. Since typical mask ventilation training requires a median of 25 procedures, we assume our device is used 25 times per trainee in each training session.[31] For estimation purposes, we assume that there would be 2 PPV training sessions with five new trainees per hospital held anually and one device provided per hospital.[39] Taking these parameters into consideration, we estimate that our device needs to sustain 1250 cycles. The 10 minute cycle length is from the maximum time required to complete a PPV procedure.[40] We also specify that the device must survive a 40N applied force to ensure that it can handle the maximum force applied during PPV, which is 10N as highlighted in the "can accurately detect forces in the correct range" requirement explanation, with a safety factor of 4. The safety factor of four comes from the IEC 60601-1 standard, which highlights safety guidelines for medical devices.

Is Lightweight

The requirement "Is lightweight" was created in order to guarantee that our device will not inhibit functionality with using the mask. The minimum specification for this requirement is that it must weigh less than 600 grams. The maximum weight number comes from an ergonomic analysis of how much female workers can hold without experiencing fatigue. The analysis to achieve this number was based off of a study of women picking up and putting down weighted items throughout a work day. The women were in the 50th percentile, which the study considers the average woman.[41] Our specific number comes from a scaled conclusion of the study as the number had to be modified so it matches the weight of our item and the duration. Because this study was over several days and with breaks between work, the number was also modified to include a safety factor of 1.5. The calculation is still an estimation on the safe side as we considered an analysis based on women rather than men, and also using the largest possible range for the length of duration. The optimal weight will be roughly 100 grams, which is 200% of the weight of the respirator and was specified by our sponsor. These two weights as minimal and optimal specifications give our future device a limit of reasonableness for what is applicable to the average worker, as well as addresses what is ideal for our sponsor and for the ideal application of the device.

Can Be Set Up Quickly

The requirement “Can be set up quickly” was created with the intention of not inconveniencing neonatal nurses and doctors in training with a device that is difficult to prepare for use. The specification for this requirement is that the hardware and software associated with the device can be set up in less than a minute. In determining the amount of time for this specification, we referenced the past ME 450 team’s design as well as the setup times for other instrumented masks.

Is Easy to Use

Since our device is not designed to be used by engineers, the requirement “Easy to Use” was specified to make sure the trainees are able to understand and use our device in a reasonable amount of time. Our specification of less than 25 procedures was based on an analysis of similar training devices. These devices took a median of 25 procedures to train participants to achieve a 20% failure rate or better, and we are specifying our devices to be comparable to other training devices.[31]

Is Safe to Use

This device is intended to be used for training purposes only, but because it is still a medical device, and a device that users interact with, there is still a requirement of safety that needs to be upheld. The specifications for this requirement are that there is no risk of shock and no sharp edges or surfaces. The standard associated with this specification is IEC 60601. The IEC 60601 standards provide a consistent framework for safety requirements across different types of medical electrical equipment, which covers both electric shock and sharp edges.[18] This standard must be met for the device to be deemed safe.

Anticipated Challenges with Requirements and Specifications

Assessing the engineering specifications given our previous state of knowledge and available resources presented several challenges. The overarching difficulty lay in ensuring that our design met the criteria of being transferable, accurate, and non-interfering with the four-hand holds used during positive pressure ventilation. We expected it to be challenging to accurately measure the forces applied at the four key points during PPV due to the deformation of the manikin's face. Moreover, designing a physical device that seamlessly integrated with existing training devices and did not obstruct nurses' ability to use it as they would in a real scenario presented another major problem. Additionally, designing the electrical system presented challenges due to our team's lack of experience and potential component interference issues. Given our group's limited background in medical devices, addressing these complexities required thorough research and collaboration with domain experts as well as in-depth engineering analysis. We believed these measures would ensure the efficacy and safety of our solution.

Addressing these challenges necessitated ongoing collaboration with Jacqueline, who provided access to specialized equipment and served as our primary liaison with healthcare professionals. Currently, we lacked experience in using the device for measuring air leakage, a skill we intended

to develop during our upcoming meetings to facilitate the testing of our design. Jacqueline's logistical support in communicating with healthcare professionals was also crucial for gaining insights into the current training procedure and obtaining feedback from nurses. Our group acknowledged the gap in our understanding of the medical field, and we were actively conducting research and seeking opportunities to enhance our knowledge in this area. Leveraging our partnership with Jacqueline, we aimed to tackle these challenges effectively.

CONCEPT GENERATION

Design Exploration & Selection Diagram

Our team followed a systematic approach to generate design concepts and eventually select an "Alpha" design. Our approach is displayed visually in Figure 7 below.

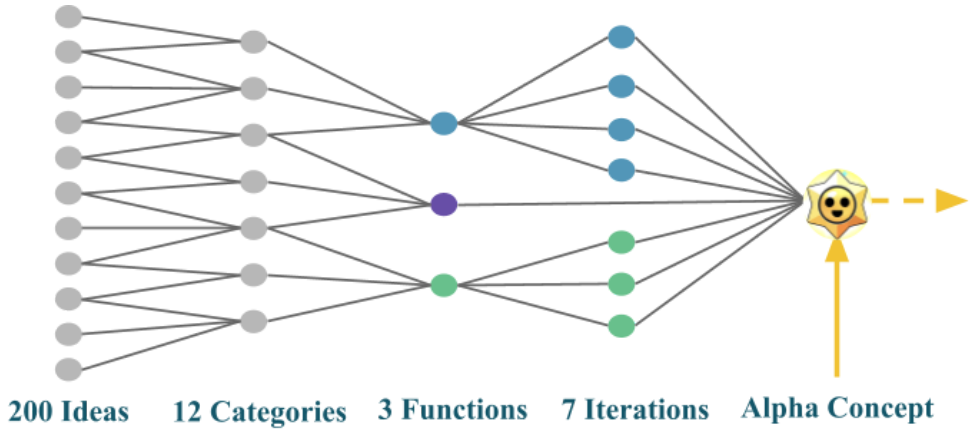


Figure 12: Design Exploration and Selection Diagram. Gray dots represent original brainstorming concepts. Concepts associated with the three functions: sensing, processing, and feedback are shown by blue, purple, and green dots respectively.

During the concept generation phase, each member of our team individually generated 40 design concepts using morphological charts and design heuristics, which resulted in 200 unique designs as a team. We then narrowed these ideas down into 12 specific categories by identifying similarities between the various ideas. We then used a functional decomposition process to identify three primary functions of our device: sensing the applied force, processing the data, and delivering feedback to the user. After dividing the concepts into their respective functions, we identified seven different design iterations to further analyze; three for feedback and four for sensing. For the sensing and feedback functions, we utilized Pugh charts to score each concept based on its ability to achieve key requirements of the device. For the processing component, we prioritized stakeholder compatibility by choosing an Arduino unit, which is the same processing software as the current sponsor setup. After comparing the Pugh chart scores, we were able to comprehensively determine a final "alpha" concept that featured the most effective sensing, processing, and feedback function. In the future, we plan to use engineering principles and iterative methods to analyze this final concept and further refine and adjust the design before finalizing the prototype.

Concept Generation Methods

In the first step of the concept generation phase, each member of our team channeled creative and innovative thinking skills in a distraction-free environment to come up with 20 completely unique solution concepts. Then, in order to foster more variation and facilitate idea generation, our team individually utilized design heuristics and morphological charts to expand the original 20 ideas into 40 different design concepts.

One key tool used in the concept generation process was design heuristics.[42] We chose to use design heuristics in concept generation to provide structured guidelines and prompts that foster creativity, streamline ideation processes, and ensure that potential solutions are systematically explored and evaluated. Design heuristics feature 77 cards, each with a description of the heuristic with images and sketches showing the application of the heuristic. One of the specific cards that was implemented in our concept generation phase was the "Apply existing mechanism in a new way" card (#13). In this concept, the idea of a force-sensing strip on the mask was applied in a new way by including the "capacitive touch" aspect. The "capacitive touch" aspect means that instead of simply measuring the force applied, the conductive strip would be able to detect both the live force and positions applied to the mask. The brainstorm drawing for this heuristic is shown below in Figure 13.

Figure 13: Design Heuristic Example

Another tool that was employed by some members in the brainstorming process was the morphological chart.[43] The morphological chart allowed us to generate ideas by taking individual designs or sub-sections and "morphing" them by changing one parameter at a time. One sample row of a morphological chart used by one team member in their individual brainstorming process is shown below in Figure 14. In this particular case, the idea of a cloth/tape with embedded sensors was perturbed in several ways to generate a total of six variations.

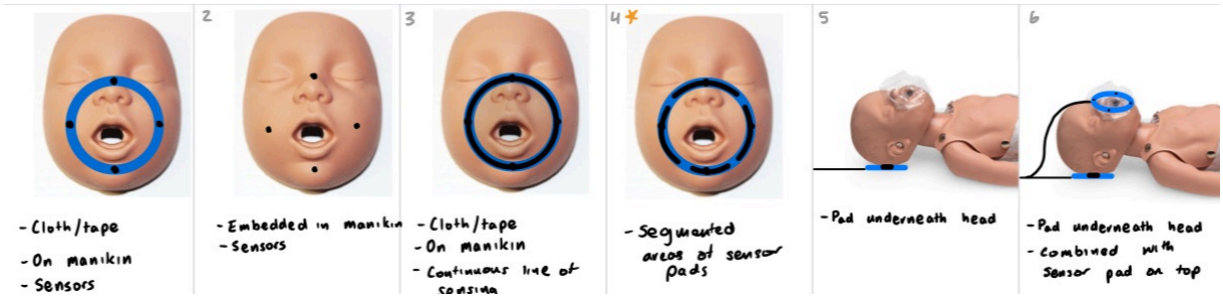


Figure 14: Morphological Chart Example.

The implementation of design heuristics and morphological charts in each of our team member's concept generation process facilitated the creation of a collective 200 unique ideas, spanning from simple, realistic ideas to complex, "bizarre" ideas that allowed for a holistic decomposition and concept selection approach. Images of these 200 ideas are found in Appendix A.

Idea Decomposition & Elimination

After generating 200 unique ideas individually, our team organized the concepts into 12 separate categories based on function. These categories can be seen in Figure 15.

Haptic	**Previous team's design**	**Gloves**
Visual	**Sticky Sensors**	**On top of mask**
Audio	**Embedded in Manikin**	**Underneath head**
Straps	**Circumferential pressure sensors**	**Mold**

Figure 15: Twelve categories for the original 200 ideas

These categories were determined based on the prevalent types of designs that were generated, which can all be seen in Appendix A. There were feedback designs, such as haptic, visual, and audio, as well as sensor placement designs. To provide some context, examples of designs from a few categories are displayed in Figure 16.

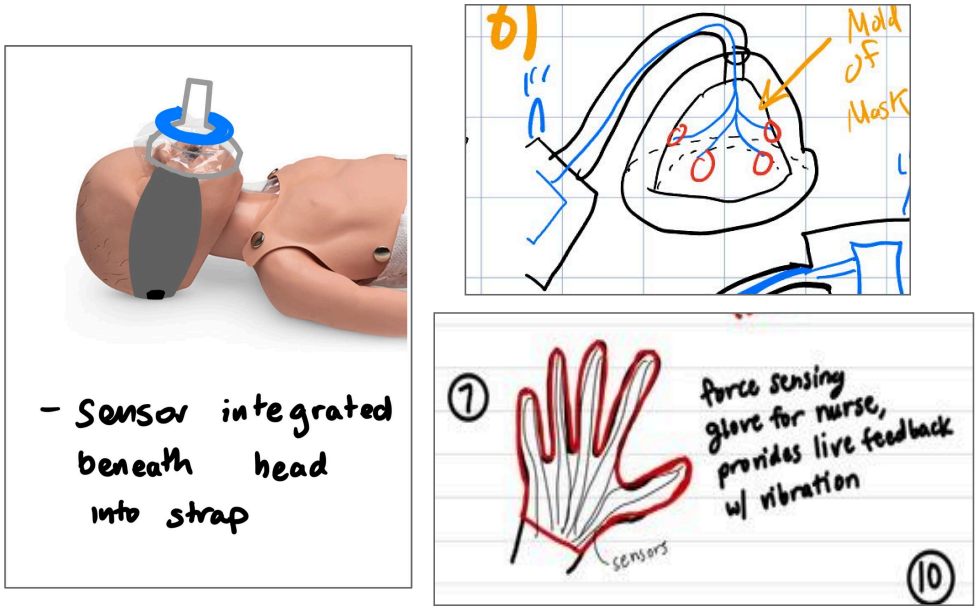


Figure 16: The design on the left is an example of "straps" and "underneath head." The design on the top right is an example of "Mold." The design on the bottom right is an example of "Gloves."

The idea for the design on the left is that there are sensors placed underneath the manikin head within a strap. The sensors would then measure the amount of force being applied to the bottom of the manikin head as the strap would hold them in place. The idea for the top right design is to create a mold of the PPV mask that would go on the outside and integrate sensors to accurately measure the amount of force being applied at that location. The idea for the bottom right design is to create a glove that has embedded sensors and would be worn by the nurses performing PPV. The glove would then measure the amount of force being applied to the manikin's face and provide live haptic feedback. This concept was one of the more "out of the box" ideas.

Through analysis of our requirements and specifications, we were able to eliminate certain categories. The results can be seen in Figure 17.

Requirement	Previous Team's Design	Gloves	Embedded in Manikin	Straps	Underneath Head
Allows user to perform four hand positions	X				
Outputs readings proportional to readings from existing sponsor setup.	X	X		X	X
Measures force in four key locations		X		X	X
Does not contribute to excessive air leakage					
Transferable			X		

Figure 17: Elimination of certain idea categories. The red Xs indicate that the category fails a requirement.

If an idea failed any requirement, it was automatically eliminated. For example, if the sensors were to be embedded into one manikin, the device would not be transferable to multiple manikins, which is why this category was removed. The process of "failing" the designs using our requirements allowed us to narrow down the potential ideas in an effective manner.

Through concept generation, it became apparent that we could divide our overall device into multiple subfunctions. There is a sensing component, a feedback component, and a processing component. Figure 18 demonstrates how we planned to continue with concept selection for each component. We decided to create Pugh charts for sensing and feedback because this method allows us to weigh criteria to efficiently rank each idea and identify the best one. For processing, we decided to proceed with an Arduino due to stakeholder compatibility. Our sponsor, Jacqueline, has already been using an Arduino in her own research and it is the processing tool we are most familiar with due to prior experience.

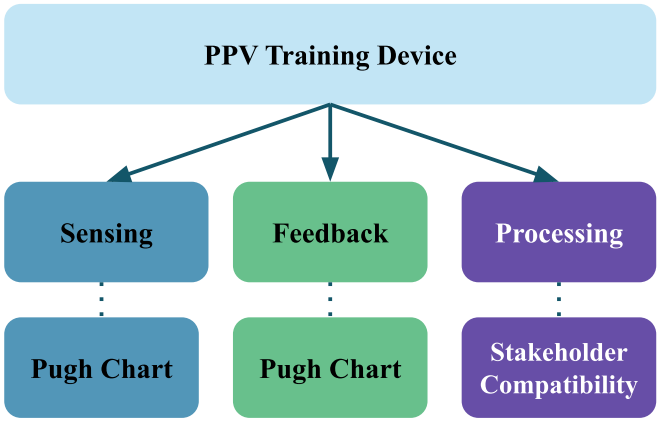


Figure 18: Functional Decomposition of PPV Training Device

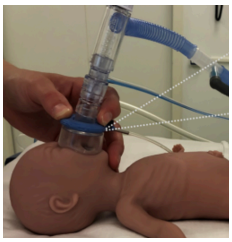
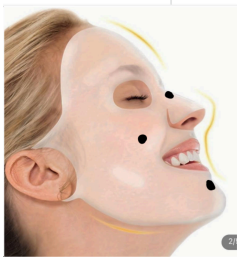
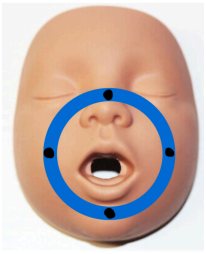
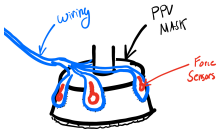
CONCEPT SELECTION

Pugh Charts

Sensing

After choosing our 12 different categories, we narrowed down our selection to four final designs to analyze using a Pugh chart, as seen in Table 4. These four designs were determined through grouping of similar ideas to ensure that we would end up with four unique concepts. This resulted in two designs that had the sensors resting on top of the mask, and two where the sensors were beneath the mask, which accurately reflects the most prevalent concepts we generated.

Table 4: Pugh Chart Analysis of sensor orientation and placement.

Criteria	Weight of Criteria	Concept #1: SensO-like design	Concept #2: Thin TPU face mask	Concept #3: Adapted from Jacqueline's design	Concept #4: Separate Electronics from force sensors
Picture					
Allows user to perform 4 hand positions	**9**	**3**	**10**	**10**	**5**
Does not contribute to excessive air leakage	**9**	**10**	**6**	**4**	**10**
Outputs readings are proportional to readings from existing sponsor setup	**9**	**2**	**7**	**8**	**5**
Measures force in 4 key locations	**9**	**4**	**10**	**8**	**3**
Supports the most common training masks	**9**	**5**	**10**	**5**	**10**
Is durable	**3**	**9**	**9**	**8**	**3**
Is transferable	**9**	**9**	**8**	**7**	**5**
Can be set up quickly	**1**	**6**	**9**	**7**	**3**
Easy to use	**1**	**8**	**9**	**7**	**7**
TOTAL	**59**	**338**	**504**	**416**	**361**

The Pugh chart is focused solely on how we plan on positioning the sensors along the mask and manikin in order to get an accurate reading. The weight of criteria was split using the one, three, nine rankings in order to more clearly see the differences among designs. The different weights are based on whether the requirements are must-haves or nice to have, what our sponsor has identified as most important, and what we deemed more important for the functionality of our design. The first design is based off of a pre-existing force sensor, Sens-O where there is a circumferential pressure sensor lying within a tube that rests on top of the mask itself.[10] Having a circumferential pressure sensor could give a more thorough reading on the forces. However, because the sensors lay on top of the mask, rather than the interaction point between the mask and the manikin, the major issue here is getting proportional readings to where the force is actually being applied. It also could cause interference issues with the user as it lies where the hands are usually positioned.

The next design involves four separate pressure sensors embedded in some kind of TPU material that is either molded or thermoformed to fit the face of the manikin. The design has no interference with the resuscitation process, would have proportional readings, and is transferable and easy to use. Some cons of this design is that it could contribute to more air leakage and the sensor readings could be less accurate due to being embedded in the material.

The third design also has four individual sensors attached to a firm cloth-like material, laying on top of the material so they make contact with the mask. A large issue with this design is that it will almost certainly add to the air leakage within the procedure, and because the sensors are only attached to the top it could interfere with the resuscitation process.

Our final design for comparison also had four sensors that are attached to an adhesive that is then stuck to the mask itself. The ability to move the sensors during setup allows for variance on where the sensors are located and can therefore be adjusted to lay in the correct places. Having to move the sensors to the correct positions also hurts the ease of use criteria for setup. The location of the sensors also will likely have proportionality issues due to lying on top of the mask. In addition, because it is using an adhesive material it will become less sticky over time and is therefore less durable.

Based on the resulting numbers from the Pugh chart, our group decided that there is a large enough difference between the scores in order to move forward with a final design concept. Our concluded final design concept is the second design, where four individual pressure sensors will be embedded into a TPU type material and then either thermoformed or molded to the shape of the manikin's face. For our purposes, we are focused solely on the type of manikin provided by our sponsor, the SimNewB.

Feedback

To determine the delivery of feedback our team wanted to produce, our team identified three

possible modes of delivering feedback to the trainee. These modes include visual, audio, and haptic feedback. To make this decision, we used a Pugh chart with relevant requirements listed. Using our Pugh chart and other analysis we were able to decide that visual feedback would be the most effective form of feedback. The results of this analysis, our Pugh chart, is pictured in Table 5 with a discussion of these results.

Table 5: Pugh Chart Analysis of feedback delivery.

	Weight of Criteria	Concept #1: Visual	Concept #2: Audio	Concept #3: Haptic
Picture				
Informs about four key locations individually	9	10	1	1
TOTAL		**90**	**9**	**9**

We identified the relevant requirement of this Pugh chart to inform the user about the four key locations. We gave this requirement the highest weight of nine because our device would not function without this requirement. We gave visual a 10 for information about four key locations as the user would be able to distinguish lights for each location. We gave audio and haptic both one respectively as these feedback forms could not effectively communicate information about different locations. Users would not be able to separate individual sounds or haptic feedback to distinguish between four groups that would correspond to four different force locations without training, making them impractical. Some factors that were considered that were not included in our Pugh chart include a potential loud training space that could make audio feedback less effective as well as the potential for haptic feedback to interfere with the administration of PPV by the trainee. We also considered the ability of the feedback mechanism to accommodate common disabilities, such as color blindness and hearing impairment. These considerations reinforce the results of the Pugh chart and allow us to select visual as the best means of providing feedback to the user.

Alpha Design

Following a rigorous design exploration and selection process, we have finalized the components for our Alpha Design. Utilizing objective criteria, including Pugh charts, we confidently arrived at our selection, ensuring minimal influence from external factors such as sponsors or instructors. Our chosen concept involves the integration of a TPU mask over the existing manikin, housing our selected pressure sensors and wiring within it. A sample drawing of the design is shown in Figure 19.

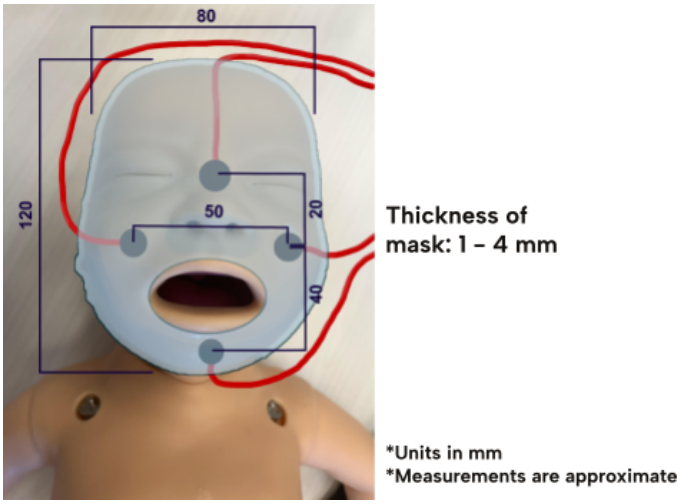


Figure 19: Mockup image of our Alpha design consisting of a flexible mask with embedded sensors and wiring placed over manikin.

Informed by discussions with Don Wirkner, we have devised a plan to construct our prototype.[34] We will acquire multiple TPU sheets, which we intend to thermoform to the shape of the SimNewB manikin. To accommodate the embedded sensors, we will sandwich them between two layers of thermoformed TPU sheets, which will be securely affixed either through adhesive bonding or heat sealing methods. We expect the thickness to be between 1- 4 mm from preliminary research of available TPU sheets. Using a method such as thermoforming allows us to have lower equipment and tooling costs, and decreases the manufacturing time in comparison to methods such as molding.[44]

In terms of processing, we have opted to utilize an Arduino platform for compatibility with stakeholders. Our sponsor, Jacqueline, has extensive experience with Arduino in her own research endeavors, making it a natural choice for seamless integration. Additionally, our team members are well-versed in Arduino programming from previous prototyping projects, further facilitating the implementation process. Specifically, we have selected the Arduino Nano model for its compact size and suitability for our application.

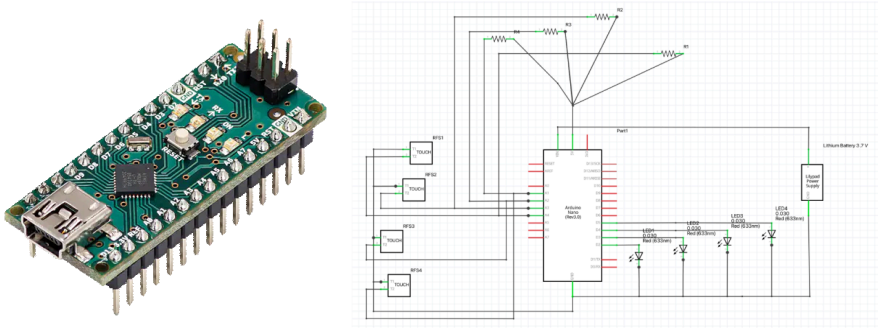


Figure 20: On the left, an image of an Arduino Nano. *Mouser Electronics* On the right, the previous 450 group's wiring diagram which we expect our wiring diagram to resemble closely. *University of Michigan*

Furthermore, we have referenced a wiring diagram from the previous ME 450 group's project, which illustrates the configuration of four sensors interfaced with an Arduino Nano.[16] Our wiring diagram will closely resemble this setup, providing a visual representation of the electrical connections and ensuring consistency with established practices.

In alignment with our Pugh charts evaluation, we have decided to incorporate a visual display component into our design for providing feedback. Ensuring continuous, real-time feedback at the four key locations is paramount for the effectiveness of our device. To achieve this goal, we intend to adapt our sponsor's existing user interface, which has been effective in her previous studies.

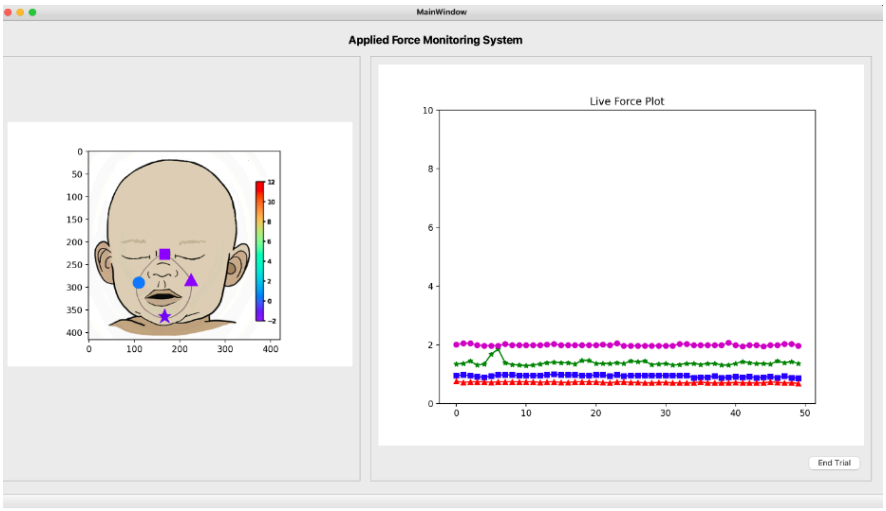


Figure 21: A screenshot of Jacqueline Hannan's user interface used during her studies to display continuous force readings at four key locations. *University of Michigan*

Throughout the development process, we will iteratively refine the design to optimize usability and consider human factors, including accommodations for color blindness. Visual displays are widely employed in the medical field for their effectiveness in conveying critical information, and we aim to harness this familiarity to enhance the usability and accessibility of our device.[45]

Beta Design

Building on our Alpha Design, the Beta Design, as seen in Figure 22, incorporates several refinements and modifications based on initial testing, stakeholder feedback, and our ongoing design evolution.

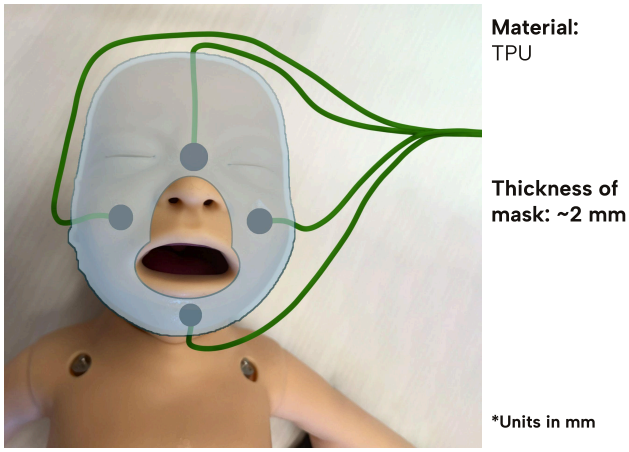


Figure 22: Mockup image of our Beta design with changes made to un-obstruct the nostrils and mouth as well as combine the wiring into a single tail.

Our most significant change in the Beta Design is the selection of Thermoplastic Polyurethane (TPU) as our material, a decision we will elaborate on in a later section. We will be using Plastruct Plastic Weld to bond the layers together. Given that the selected TPU sheets are one millimeter thick, the mask will have an approximate thickness of two millimeters.

After our second design review, our sponsor highlighted the importance of not obstructing the nostrils. To address this, we extended the mouth cutout in the mask design. Furthermore, we have consolidated our wiring into a single tail to ensure a cleaner and more organized appearance. This adjustment aims to prevent interference with the nurses' ability to complete the training procedure.

After designing our Alpha feedback system, we found that high cognitive loads displayed too rapidly can challenge and stress medical teams. [14] Based on these findings we simplified our feedback system to display results as transparently as possible. To enhance the user feedback system, we have focused on a graphical display that showcases the four key locations and their corresponding force readings in color directly on the manikin's face, which is shown in Figure 23.

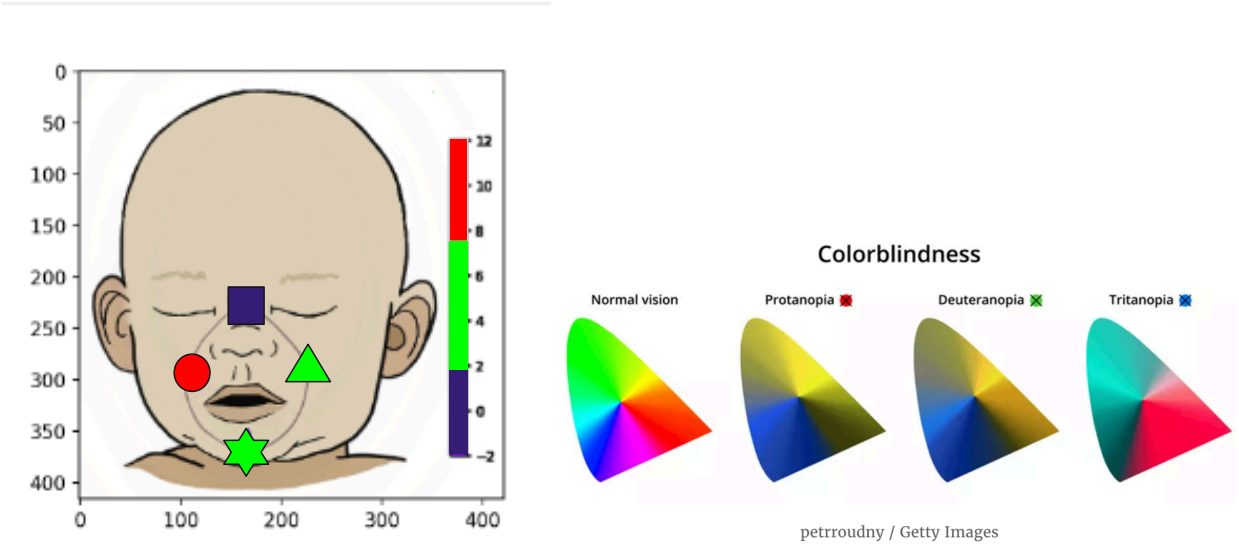


Figure 23: A mockup of our graphical user interface based on our sponsor's interface with changes made to the color scale (Left). An illustration showing how different types of color blindness affect the perception of colors (Right).

To indicate the appropriate force range, we have color-coded the scale into three distinct categories: red for excessive force, green for the correct force, and purple for insufficient force. To accommodate individuals with color vision deficiencies, we will implement system settings that adapt the colors according to the type of color blindness of the user, mirroring the functionality of other computer programs.

Post-training, users will have access to a continuous time-series graph displayed on a summary page, which will provide a detailed visual representation of the force exerted at each of the four key locations over the duration of the training session. This is shown in Figure 24.

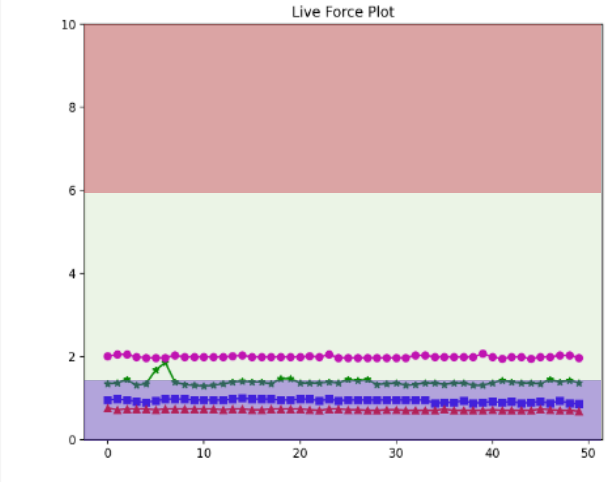


Figure 24: A mockup of our graphical user interface based on our sponsor's interface which will be shown after completing the training session.

For the processing component, we have transitioned from using an Arduino Nano to an Arduino Uno R3 due to its availability, pictured in Figure 25. Consequently, this change will also be reflected in the updated wiring diagram moving forward.

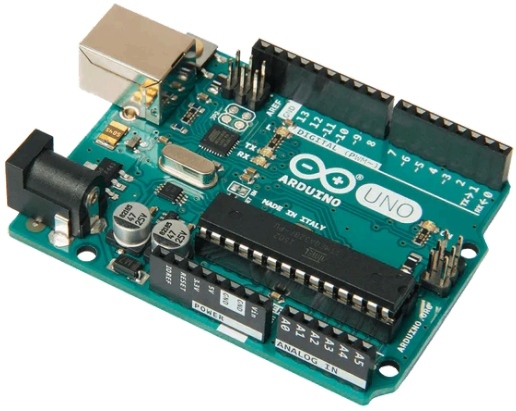


Figure 25: An image of an Arduino Uno R3. *Elektor*

Setup and Usage

In order to fully visualize how each function of our device connects and will be used, we have created a comic book style visual as seen in Figure 26.

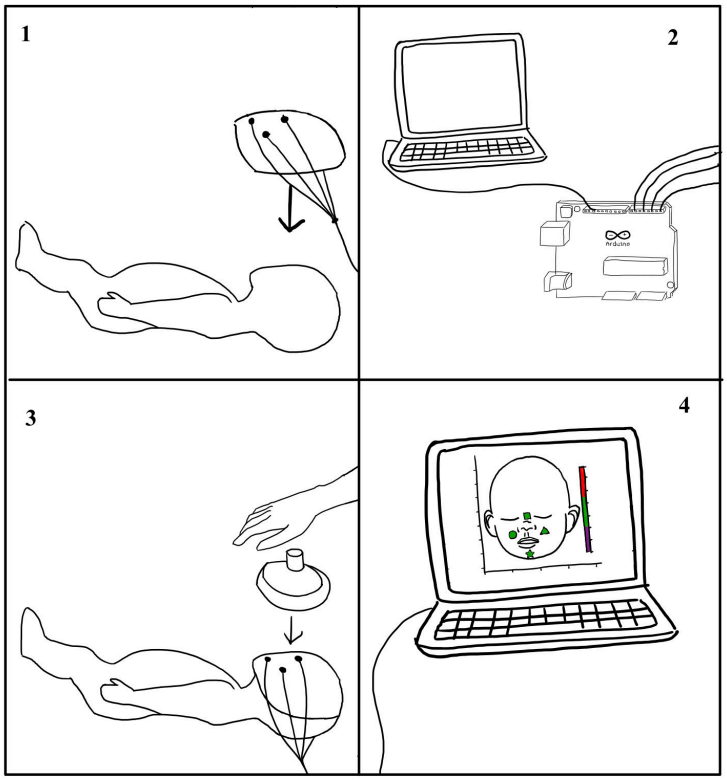


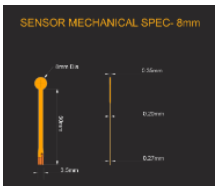
Figure 26: A demonstrated comic book style design of how the full system will be set up and used.

The first step of the procedure is to place the mask on the manikin, with the wires already attached to the sensors within the mask and grouped together in order to not interfere with the training space. Next, with the wires already connected to the Arduino, the Arduino then connects to the display device, in this case being a computer with code through Python. Next, the user begins the resuscitation process as usual. The computer will then display the force results at each of the four individual pressure sensors with the associated color indicating if they are in the right range of force, or too high or too low. The location of the display device will be straight ahead, eye level from the user in order to maximize the efficiency of reading the results. [13] The user can then adjust the force applied accordingly.

Sensor Benchmarking

We created a sensor benchmarking table, as seen in Table 6, in order to evaluate the available options. We focused on researching small and thin sensors with a resolution less than 0.045N that could be incorporated into the alpha design at the four key locations.

Table 6: Sensor Benchmarking Table

	SingleTact Calibrated 8mm Diameter Sensor[46]	**Round Force-Sensitive Resistor[47]**	**FlexiForce Force Sensors[48]**	**Flexible Thin Film Ring Pressure Sensor[49]**
Picture				
Thickness	0.30 mm	0.56 mm	0.203 mm	0.3 mm
Resolution	< 0.2 % of Full Scale (FSR)	Continuous (Analog)	< 0.43 %	< 0.037 %
Cost	$135.95	$3.95	$19.15	$13.00
Range	0-10 N	0.3N - 10N	Low: 0 - 4N Medium: 0- 111N High: 0 - 445N	0.3 - 10N
Response Time	< 1ms	1ms	< 5 us	< 1 ms

The first sensor is the SingleTact Calibrated 8mm Diameter Sensor, which is the sensor used by our sponsor Jacqueline. As this sensor is used in her research about the minimum force applied to a mankin's face during PPV, its specifications align with our requirements. It is the most expensive sensor, however, and purchasing four of them would not fit within the allotted ME 450 budget. The Round-Force Sensitive Resistor was used by the previous ME 450 team and also aligns well with our requirements. The FlexiForce sensor is the thinnest, which is optimal because we want our design to replicate the manikin's face as close as possible. The FlexiForce sensor only has a range of 0-4N, which does not cover the full expected range of force. Finally, the Flexible Thin Film Ring Pressure Sensor aligns with our requirements, but there is unreliable documentation for its specifications.

Through analysis of the pros and cons of each sensor, we determined that the Round Force-Sensitive Resistor is the most viable option. It has the largest thickness, which could pose issues in the prototyping phase of the project. However, the sensor range aligns with the expected range of force applied to the manikin face during PPV, is affordable in terms of the budget, and the response time is favorable.

Material Selection

In our selection of viable material candidates, we decided that the material had to be elastic in order to fit to the shape of the mankin's face as it deforms during typical PPV application. The decision to move forward with an elastic material ruled out any hard plastic polymers, and any other materials not compatible with thermoforming. We researched relevant material properties, including hardness, elasticity, tensile strength, and tear strength and found them to not vary distinctively between thermoformable materials. Therefore, we primarily considered cost, as it would directly impact the manufacturing cost of our device, as well as the quality of the sheets and number of sheets sold, in our material decision making process.

The primary candidate for the device is TPU. TPU is commonly used in thermoforming and molding applications, and is known for its elastic properties and durability. TPU also meets our budget requirement and is sold in packs of 20, allowing for ample prototyping. We also considered the TPU standards sheet and determined that TPU would fit our safety requirement when thermoforming and would not cause harm to the user while training. TPU is considered to be biocompatible for medical devices and is considered a safer alternative to other plastic materials. TPU is therefore an ideal choice for our purpose.[22] While TPU is our current material selection due to its material properties and ample research available, we are also considering TPE and Rubber as viable options due to their similar material properties and price, in case a new problem arises with using TPU. We plan to use both empirical engineering analyses as well as continued research and communication with experts to either verify the decision to move forward with TPU or pivot to a different material in future iterations of the prototype.

Preliminary Bill of Materials

Table 7 outlines our preliminary Bill of Materials for our Alpha design concept. We expect this table to expand as we continue to develop our Alpha concept. The listed costs are our current best estimations for the materials.

Table 7: Estimated Bill of Materials for the selected alpha concept.

Part	Quantity	$/part	Total Cost ($)
Force-Sensitive Resistors [47]	4	3.95	15.80[50]
Arduino Uno R3[50]	1	27.60	27.60
3.7V Lithium Battery[51]	1	8.59	8.59
Resistor 250 Pack[52]	4	7.99	7.99
24 AWG Wire 100’ Roll[53]	1	26.27	26.27
Vaquform Forming Sheets VFlex - 20 Pack[54]	1	58.30	58.30
BABY Born My First Baby Doll Annabell[55]	1	18.01	18.01
TOTAL COST	13		162.56

The preliminary Bill of Materials is well below our given budget and requirement for cost. The cost being less than the $400 budget gives us the flexibility to purchase more materials as needed for engineering analysis and testing.

ENGINEERING ANALYSIS

In our initial engineering analysis, we developed multiple design concerns based on our Alpha design. To begin our engineering analysis we collectively came up with seven different concerns that we had with our selected design concept. Table 8 presents these design concerns ranked with their respective priority levels.

Table 8: Design Concern Table

Priority Level	Design Concern	Progress
High	Will the thermoforming manufacturing process work? - Will the chosen manufacturing process produce a flexible, functioning mask (ie. will the material hold shape)? - Will the manikin be usable for the manufacturing process?	In progress
High	Will the thermoformed layer interfere with the accuracy of the sensor readings?	In progress
High	Will the thermoforming material wrinkle and contribute to air leakage?	In progress
Medium	Will we be able to integrate the electronic components within our material?	Not started
Medium	Will our device slip around on the mankin's face?	Not started
Medium	Will our device be too heavy for practical application?	Not started
Low	Will our device be durable enough for our application?	Not started

Our first concern about the thermoforming process is divided into two separate questions. The first question is related to the effectiveness of the chosen manufacturing process. We are not certain that thermoforming will produce a flexible, functioning mask because there are a variety of problems we could face, such as the prototype not holding shape or being difficult to remove from the mold. We do not have experience with thermoforming, meaning we are limited to our research and conversations with experts to choose the appropriate material and conduct the process efficiently. Our second question revolves around usability of the manikin. The manikin is located at the hospital, meaning it is not readily accessible for our testing. In addition, thermoforming the material could damage the medical manikin. Since the medical manikins are very expensive, we would be unable to move forward with the design plan if it is reliant on a procedure that disfigures the manikin. The other problem is that the manikin head cannot be removed from its body, which would make the thermoforming process difficult because we are focused on only the face of the manikin. Both of these questions make this design a high level priority.

The next concern is that having the sensors embedded in a material could limit the accuracy of the readings that we will get. The accuracy of the sensors is a high-priority concern as it would interfere with one of the main functionalities of our device.

Our final concern that was ranked a high level of priority is that the material could deform and

crumple during the procedure and therefore contribute to air leakage. Not contributing to excessive air leakage is one of our must-have requirements, making this concern a high level of priority.

Another concern is that the electrical components could become difficult to integrate while embedded within the material. While this worry is important to the functionality of our design, after an interview with a manufacturing expert, Don Wirkner, we do not foresee it being a major issue. It was therefore ranked a medium-level concern.

Similarly, because our design currently only rests on the manikin's face, there is a concern that the mask could move around during the procedure and consequently not provide accurate results. However, the mask moving around is not a major anticipated issue and could be easily corrected with simple design additions such as adding a strap to secure the mask, which makes it a medium-level concern.

One of the major stresses from our sponsor and other interviews was that the design does not weigh so much that it interferes with the resuscitation process. The importance of this requirement makes it a medium-level priority, but not a high one because with our current design process if we can maintain a certain level of thickness it should not be a major issue.

Finally, with our chosen material there is a level of concern that the TPU will not hold shape and withstand cracking over a long period of time. However, our final design is not likely intended for commercial use and the majority of concerns with durability with this material will be over a long period of time. So, while this is a worry, it is one of low priority.

Will the manufacturing process produce a flexible, functioning mask?
The empirical test we performed involved purchasing an inexpensive doll with similar features and using a heat gun to thermoform the TPU sheet to the doll's face. This approach provided a quick and straightforward method to assess whether thermoforming could be a successful manufacturing process for our intended application. While this empirical test assumed that the surface of the manikin would be comparable to the replica doll in terms of facial features, which we believe to be a valid assumption, we also recognize it as a limitation of the test. Figure 23 demonstrates the thermoforming process applied to a doll's face.

Figure 27: Thermoforming process of a TPU sheet to the doll's head with a heat gun.

Two trials of the process were conducted, and the results of these trials are presented below in Figure 28. The first trial utilized a rectangular sheet of the TPU material and yielded very promising results. The resulting TPU mask exceeded our expectations in the level of detail captured. However, we observed wrinkling around the edges of the face. To mitigate these wrinkles, we cut a second material sheet to fit the shape of the doll's face and also made slits in the four corners. Despite these adjustments, the second trial also exhibited wrinkles around the edge of the face.

Figure 28: The first row of images shows the thermoforming process and result of our first trial. The second row of images shows our second trial.

The results suggest that while thermoforming can capture intricate details, further refinement is

needed to reduce wrinkles and improve the overall fit and finish of the TPU masks. Functionally, the design appears to be effective in capturing the facial features. We have high confidence in our analysis, considering the promising initial results, but also recognize the identified limitations and the need for further refinement. Had this test failed, we would have needed to adjust our material choice or select a different manufacturing process. To enhance the quality and consistency of the TPU masks, we employed vacuum forming, which we discuss in further detail below.

Will the manikin be usable for the manufacturing process?

Our concern about thermoforming comes from the potential for damage to the $40,000 medical manikins being used with our training device.[56] Despite not damaging the doll, the high cost of the manikin and potential risk created by the high temperature of TPU while vacuum forming makes use of the actual manikin in prototype development near impossible. Furthermore, our team is concerned about accessibility to the manikin as the manikin is stored at the hospital.

To test our concern, our team believes an empirical test would be most appropriate given our concern about damage to the manikin with our specific manufacturing process. We scanned the face of the manikin and used that STL file to 3D print a replica manikin that was used for thermoforming. We believe a high level of detail was most appropriate as the cost to scan and 3D print is zero and performing our thermoforming process was inexpensive and not time-consuming. We began this process by first using the photo scanner in the Duderstadt to scan our manikin. We then used the app Metascan and compared the results. Metascan produced a better model and our team moved forward with that scan. We were then able to 3D print the scan, as shown in Figure 29.

Figure 29: STL model of SimNewB manikin (Left). 3D print of scanned face (Right).

We then used this mold to vacuum form a mask for the SimNewB manikin. We decided to explore this manufacturing process to help remove the wrinkles seen in the mask when using a heat gun

shown in Figure 28. This is because after heating the TPU, the vacuum former uses a pump to create a sucking force that removes air pockets between the TPU and the mold that is forming. After exploring available options, we decided to use the vacuum forming machine in the MBSE Leadership Lab located in the Francis-Xavier Bignoud Building. Pictures of this process are shown in Figure 30.

Figure 30: 3D model of manikin being vacuum formed in the MBSE Leadership Lab (Left). Results immediately after vacuum forming (Right).

After creating our new vacuum formed mask, the next step was to examine the fit between our vacuum formed mask and the SimNewB manikin. These results are pictured in Figure 31.

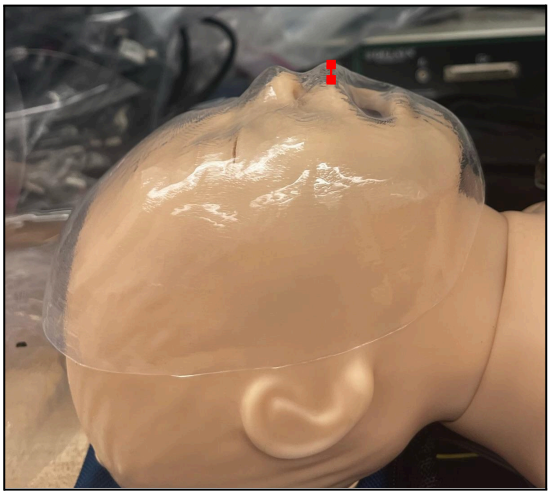


Figure 31: Mask produced from 3D printed scan of SimNewB mask. Shown in red is the gap between the SimNewB manikin and the mask.

After placing our mask on the manikin, we were able to see gaps in between the manikin and mask, as shown in Figure 31. After examining the vacuum form and the 3D scan, we believe the discrepancy is due to the quality of the scan as both the layer thickness and the vacuum form were both able to accurately preserve the details of the previous steps. To remedy this, we plan to rescan the manikin and explore other forms of photo scanning to produce a better model of the manikin.

Will the TPU layer interfere with the accuracy of the sensor readings?

Our concern of whether or not the layer of TPU will interfere with the sensor reading is based on the assumption that when force is applied, some of the force could be distributed within the TPU layer and therefore cause the force sensor to not get a fully accurate reading. In order to address this concern, we devised an empirical test that involved inserting a layer of TPU both on top and underneath an individual force sensor, replicating the sensor embedding. A known load was then applied and compared to the force readings from the sensor. A schematic of this empirical test is shown below in Figure 32.

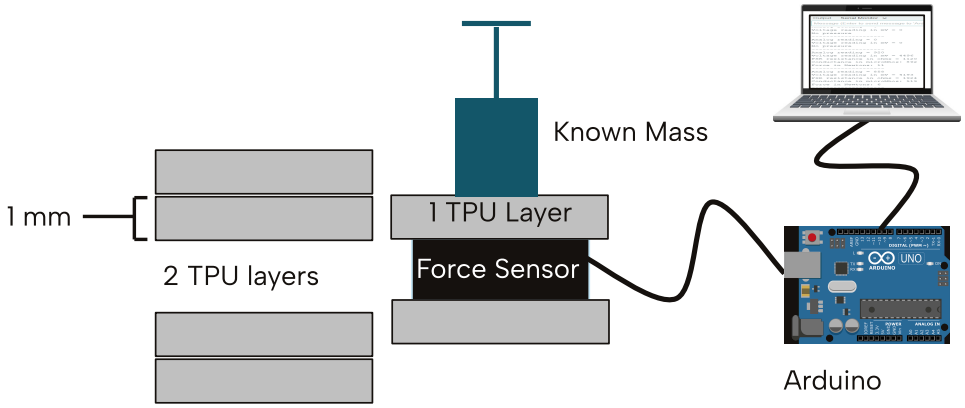


Figure 32: Setup for TPU thickness empirical test.

The motivation for using this type of empirical approach is that it allows us to quickly determine whether or not embedding the sensors in a layer of TPU will distort the force readings, and furthermore depict what the maximum thickness of the TPU can be. Since we only considered the interface between the applied force and the sensor, we did not take into account the complex curvature of the manikin's face in this experiment. This simplification allowed us to complete this experiment with minimal materials in a short period of time to determine the viability of our selected design concept with a medium-level confidence.

In order to complete this experiment, we obtained a set of calibration weights from the University of Michigan ME 495 Lab in the GG Brown Laboratory building, which had masses ranging from 10 grams to 500 grams. Using two sets of these weights, we tested 14 different masses from 40 grams (~0.4 N) to 920 grams (~9 N) to encapsulate the typical range of force applied during PPV (0.5 N - 10 N).

First, to create a baseline curve for the force readings from the sensors corresponding to the calibrated mass applied, we conducted the test with zero layers of TPU in between the force sensor and the mass. Three trials were conducted with each mass to mitigate error and improve the confidence of our results. The Arduino setup is shown below in Figure 33.

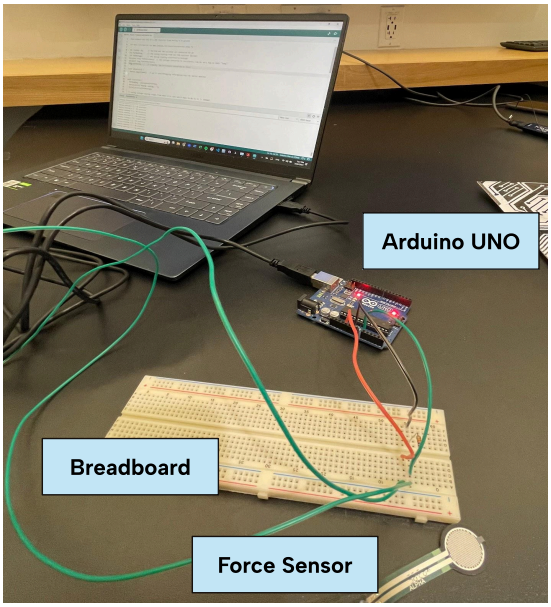
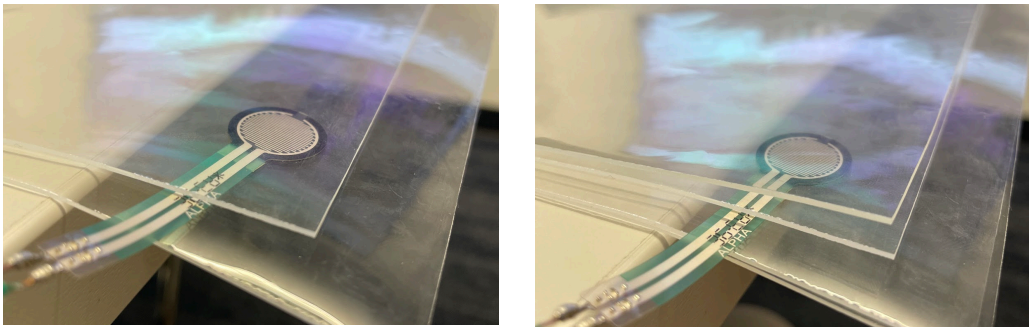


Figure 33: Arduino setup for force testing. Setup includes an Arduino UNO R3, 10K ohms resistor, breadboard, wiring, and force sensor. Arduino code outputs analog readings that represent the force applied (0-1024).

Once we collected data with zero layers of TPU, we then repeated the force measurements for both one layer and two layers of TPU on the top and bottom of the sensor. The physical setup involving the layers of TPU and the force sensor is displayed below in Figure 34.



(a) **(b)**

Figure 34: Physical force testing setup. Left image (a) shows one layer of TPU surrounding the force sensor. Right image (b) shows two layers of TPU. Images were captured with the material overhanging off the table to more clearly show the layering of the TPU. Actual testing took place on a flat surface.

After collecting the data, we plotted the analog readings from the Arduino versus the mass applied (grams) for zero, one, and two layers of TPU. The plot is shown below in Figure 35.

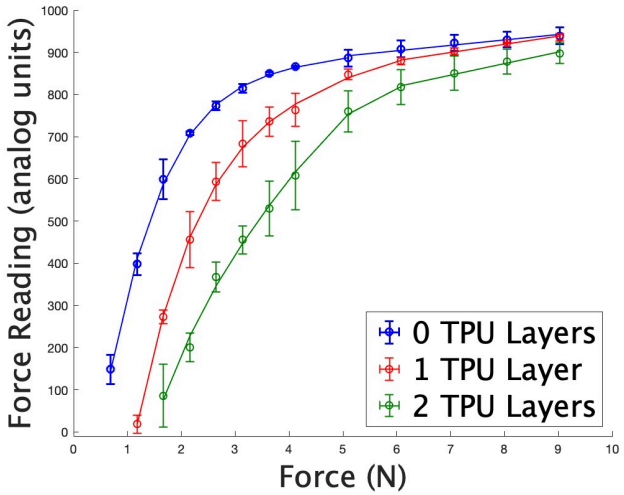


Figure 35: Analog readings from force sensors versus mass. The blue line represents the data with zero TPU layers in between the mass and the sensor. The red and green lines represent 1 and 2 layers, respectively. Error in these readings is derived from the standard deviation of 3 trials. Error in mass is negligible because weights are assumed to be calibrated.

As we can see in the figure above, there is a clear correlation between the thickness of the TPU layer and the force readings from the force sensor. As layers of TPU are added in between the sensor and the mass, the magnitude of the force readings become increasingly damped, especially at low force magnitudes. The low end of the range of measurable force is also truncated when adding TPU layers. As shown in the graph, the smallest detectable measurement for 1 TPU layer is for 120 grams (~1 N), and the smallest detectable measurement for two TPU layers is 170 grams (~1.5 N). With no layers of TPU, the sensors were able to distinguish weights as low as 70 grams (~0.7 N). It is also important to notice that at low force magnitudes, the data appears to fit a curved polynomial trendline, meaning that the resistance of the force sensor at low forces (< 500 g) is very sensitive. Due to this high sensitivity and relatively cheap quality of the sensors, we see large error bars on the low end of the force measurements. At larger weights (> 500 g), the sensor readings follow a linear trend and are much more consistent. The inconsistency at low weights as well as the truncated measurement range could potentially be mitigated by using more expensive, high-quality force sensors, such as the SingleTact sensor, which is used by our sponsor, Jacquline, in her current force-sensing setup.

Based on the results of this empirical analysis, we conclude that the TPU layer does interfere with the force readings using the Round Force-Sensitive Resistor as our force sensor. However, by collecting data for several layers of TPU and comparing it to the baseline test with no TPU layer,

we can mathematically calibrate the device to accommodate the damping effects of the TPU. In the future, we plan to repeat this experiment with the thermoformed material on the manikin to more accurately calibrate the device and raise the confidence level of our empirical engineering analysis method.

Will the thermoforming material wrinkle and contribute to air leakage?
Our assumption for this concern is that the chosen material could develop wrinkles during use, which will create gaps between the material and the PPV mask, therefore contributing to air leakage. This concern stems from the understanding that flexible materials like TPU can wrinkle under pressure, potentially compromising the integrity of the seal between the mask and the manikin's face. To address this concern, we have devised an empirical testing approach aimed at assessing the TPU's behavior under pressure and its impact on air leakage. Given the complexities of flexible and deforming materials like TPU, we believe that empirical testing is the most appropriate form of analysis. Computational models may struggle to accurately replicate the real-world behavior of such materials due to their complexity. As such, our approach emphasizes practical experimentation to iteratively refine our design and address potential air leakage issues effectively.

To measure air leakage, we will be using the Monivent Neo Training Device, as shown in Figure 36, which is located at the University of Michigan Hospital. This tool has been used by our sponsor, Jacqueline, for her research and has proven to be a reliable and accurate method of measuring air leakage during PPV. There is a sensor module that attaches to the ventilation mask and wirelessly transmits continuous data to a display screen. The air leakage percentage is already part of the data display.

Figure 36: Sensor module that attaches to the ventilation mask (left). Display screen with continuous feedback and air leakage percentage shown in top right (right).

The proposed testing procedure is to first use the original setup and collect data on the air leakage through multiple trials. The original setup would be performing PPV on the manikin without the addition of our prototype. The data collected from these trials would be used as a comparison to testing with our prototype.

Next, we will place the vacuum-formed one-layer TPU prototype over the face of the manikin and complete multiple trials following the same procedure. Between each trial, we will visually check for wrinkling of the material to ensure the prototype is in place and that we are producing consistent results. If the results average to < 10% air leakage, which is our optimal specification for our air leakage requirement, we will feel highly confident that our TPU mask prototype does not contribute to air leakage. In the case that the results only average to <25% air leakage, which is our minimal specification, we will feel moderately confident with our prototype and proceed with the design.

We have set up a time to go to the University of Michigan Hospital with our sponsor this week to complete this testing. The limitations associated with this testing approach include that it is dependent on the creation of an accurate prototype. Our current prototype is just a single layer of TPU and we expect our final design prototype to be two layers of TPU with sensors embedded in between. This could impact our results as the current prototype has a smaller thickness and the absence of the sensors could mean surface differences. In terms of potential consequences, we would have to pivot to an alternate material if air leakage exceeds 25%.

Anticipated Challenges with Beta Design

In addition to the concerns addressed in our engineering analysis, we encountered other challenges. One potential obstacle was ensuring a fully functional interface. As described in our alpha design, we planned to adapt our sponsor's existing user interface, which provided live, continuous feedback for each of the four key locations on the manikin's face. We faced issues in ensuring that our interface fully and accurately displayed the information for each of these four locations. Another challenge was electrical integration with the chosen material. We completed engineering analysis to determine whether the TPU layer would interfere with the accuracy of the sensor readings in order to prepare for this potential issue. Our plan to sandwich the electronics between two layers hopefully circumvented this anticipated challenge. Finally, manufacturability was another concern as we were not certain about the thermoforming or molding manufacturing process that we planned to use.

Following the development of our Beta design and completion of engineering analysis tests, we thought through more anticipated challenges. Incorporating the Python code for the user interface was something we had to troubleshoot because we were making changes with our chosen sensors and the way we wanted the feedback to be presented. Wiring in the Arduino was another potential challenge because we were working off of the previous ME 450 team's wiring diagram, which was not entirely accurate to our design. We used an Arduino Uno rather than an Arduino Nano and had

to determine which values of resistors would work for our setup. Access to a vacuum forming machine was another concern of ours, but we discovered a vacuum forming machine in the MBSE Leadership Lab in the Aerospace Engineering Department that was readily available to us.

Beta Design Prototypes

Following our engineering analysis of the manufacturing process, which revealed promising results using vacuum forming, we proceeded to create beta design prototypes for further analysis and testing. Employing the vacuum forming method described, we crafted two molded TPU layers. Additionally, we prepared the Force-Sensitive Resistors by soldering wires to them. In our initial attempt, we placed the sensors in the four key locations using the adhesive backing, and then applied Gorilla Glue to any areas not covered by the sensors on one molded TPU layer. We then placed the second molded layer on top and held the two layers together while the glue cured. However, this method proved messy and resulted in numerous air gaps, leaving us dissatisfied with the outcome.

Subsequently, we attempted to seal the edges between two layers of TPU using a heat gun, but this caused the material to melt and wrinkle, which was also unsatisfactory. Finally, we devised a method to directly mold the second layer onto the first using the vacuum forming process, thereby thermally bonding the two layers together.

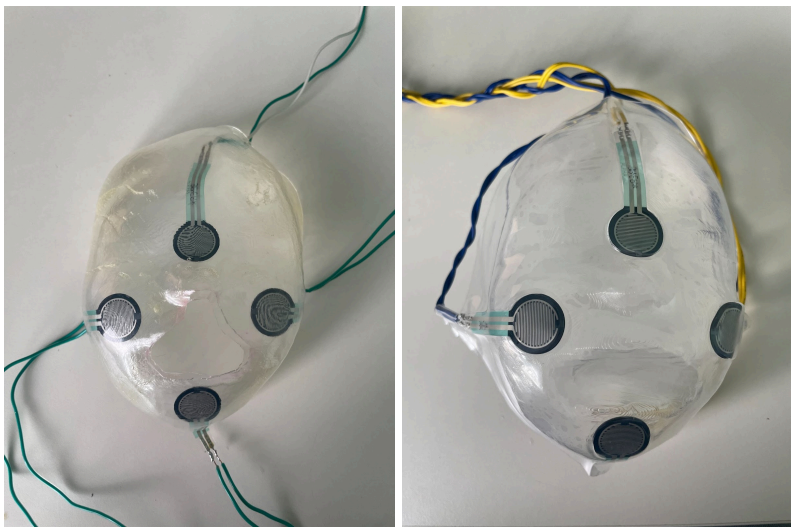


Figure 37: Photos of Beta Design Prototypes. The first version (left) attempted to glue the two layers of TPU together. The second version (right) used vacuum forming to thermally bond the layers together.

Our second prototype, depicted in Figure 37, demonstrated significant improvement and promise. The layers were cleanly bonded without damaging the sensors. However, we encountered issues with wires getting caught and pulled in the vacuum forming machine, leading to unwanted gaps, which we aimed to address in subsequent iterations. Additionally, we noted that the direction of the sensors caused the solder connections to be pulled at a 90-degree angle, which could potentially become a failure point with repeated pulling. Despite these challenges, this second prototype was highly promising and marked a significant step forward in bringing our ideas to fruition.

Gamma Design

For our Gamma design, we've made minor yet crucial adjustments to enhance the reliability of our prototype. Recognizing the potential issue of solder connections being pulled at a 90-degree angle due to sensor orientation, we opted for a simple solution. In the Gamma design, we adjusted the sensor orientation so that their tails point towards the top of the head, where the wires converge into a single tail. This minor change aims to mitigate potential failure points associated with repeated pulling, ensuring the longevity and durability of our design.

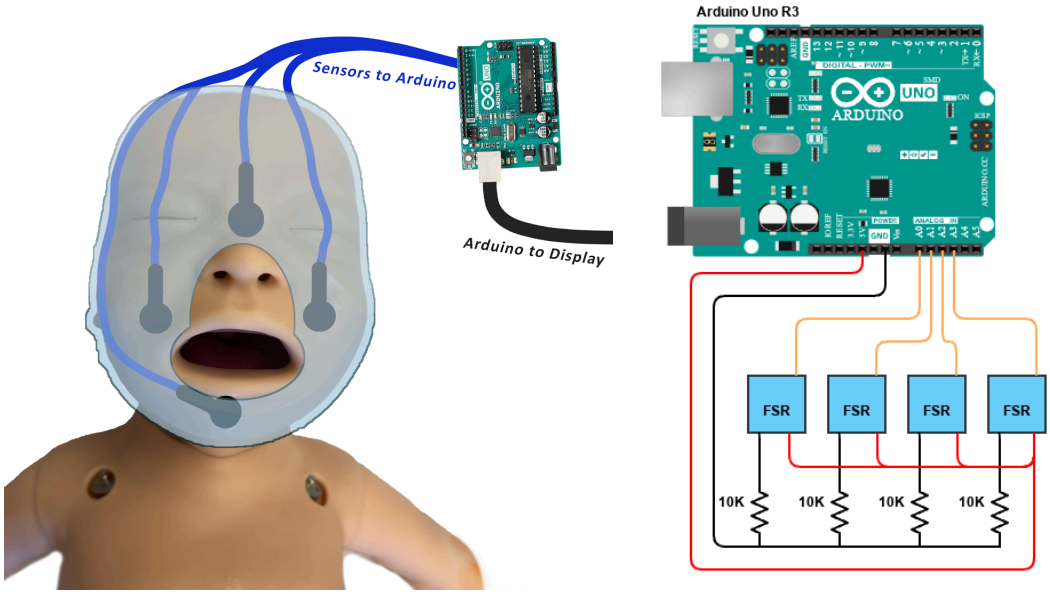


Figure 38: Mockup image of our Gamma design with changes made to change direction of sensor and wire routing (left). Wiring diagram of Arduino, Round Force-Sensitive Resistors, and 10K Ohm resistors (right).

Additionally, we finalized the wiring diagram for our system, providing a clear layout of the electrical components. The diagram includes the Arduino Uno R3, the four Round Force-Sensitive Resistors, and the corresponding 10K Ohm resistors. Each Round Force-Sensitive Resistor is connected to the analog input pins A0-A3 and the 5V output pin on the Arduino. To power the system and enable data transfer, the Arduino is connected to a computer using a USB 2.0 Cable Type A/B.

Gamma Design Prototype - Final Build

This prototype served as our final iteration for ME450 and will be considered as our final build. The Gamma design prototype was constructed using a similar method as before, with the notable change of orienting the wires to minimize potential failure points. During the manufacturing process, when positioning the sensors, we taped the wires down to the edge of the mold to prevent the snagging issue encountered previously, effectively minimizing unwanted gaps. It was used for verification testing to evaluate the functionality and reliability of our design modifications.

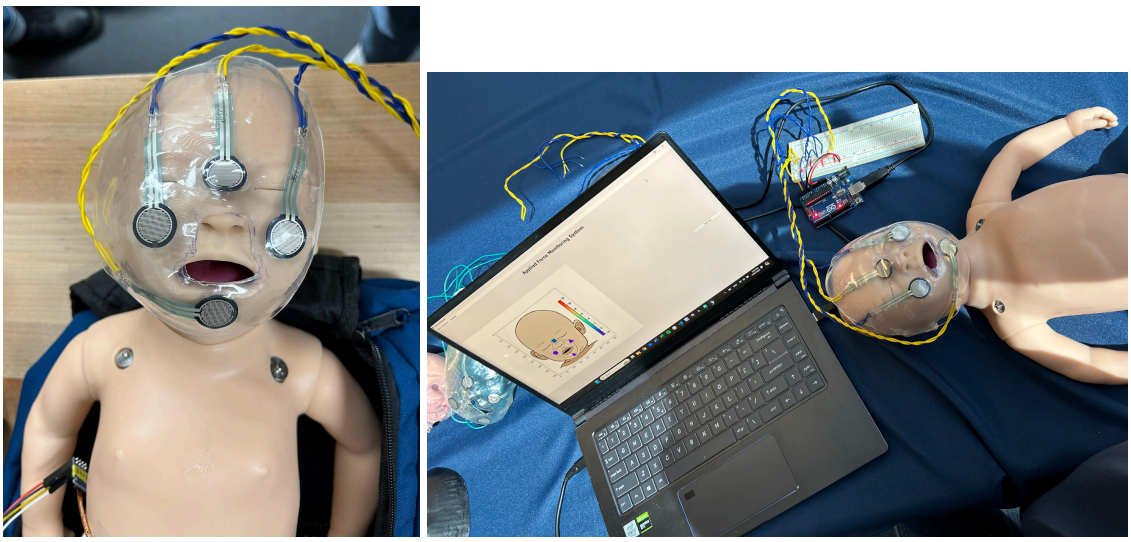


Figure 39: Photo of our Gamma design prototype placed on the manikin's face (left). Photo of entire setup with Arduino and feedback system display shown (right).

Bill of Materials and Manufacturing Plan

Our detailed bill of materials and manufacturing plan for our build can be found in Appendix B. The total cost of the final build came out to be $50.31. The manufacturing plan involves using the Mayku FormBox Desktop Vacuum Former in combination with Vaquform Forming Sheets VFlex - 20 Pack - 1.00mm material.[57] This plan outlines a series of steps aimed at ensuring the accurate fabrication of our TPU masks. The process begins with heating the TPU material and molding it over a 3D-printed mold of the manikin's face using vacuum forming. Force sensors are then carefully positioned and embedded between layers of TPU material in a subsequent vacuum forming cycle. While we didn't specify critical dimensions due to the tight conformity of the vacuum-formed material to the mold, precise placement of sensors remains crucial. Hence, attention to detail during sensor positioning is imperative to maintain accuracy and functionality in our manufacturing process.

Areas for Improvement with Gamma Design

Our project scope is defined as developing a proof-of-concept design that brings our sponsor closer to developing the final design for production. As we work towards refining our design, it is essential to acknowledge the current disparities and areas for improvement. While our Beta design

was initially conceived to be fully functional, our engineering analysis, prototyping, and ongoing discussions have highlighted areas requiring refinement. Table 9 summarizes the main design critiques associated with the Gamma Design.

Table 9: Gamma Design Critiques

Prototype Critique	Future Work
Low-Quality Sensors ● Results from analysis are inconsistent ● Sensors cannot read low forces, especially with TPU layer	● Embed **SingleTact Force Sensors** to **increase accuracy**
TPU Mask is not an exact fit to manikin ● Gaps causing air leakage ● Prevents force sensors from reading correct location	● **Thermoform** onto **actual face of manikin** given optimal equipment and accessibility
Feedback ● Does not currently include full diagnostic review post-use. ● Could be more visually appealing	● Develop a **comprehensive program** to enhance user experience and visual appeal

One of the most significant areas requiring improvement is the fit of our thermoformed TPU mask to the manikin. We are utilizing a 3D-printed mold for our thermoforming process. Although the scan we are using is of good quality, it is not perfect, leading to discrepancies when creating the TPU mask. Due to the high cost and inaccessibility of the manikin, we have been unable to use it for molding. However, we aim to address this disparity by employing better scans. We expect that the final design may utilize the manikin itself to achieve a more accurate fit.

We are currently assessing the need for higher-quality sensors. As mentioned in our engineering analysis, the current sensors we are using lack accuracy within the range of forces we are concerned with. We will continue to evaluate this need and note that the final design may incorporate more expensive sensors, such as the SingleTact force sensors, to improve the reliability and precision of the measurements.

The graphical user interface program used in the current prototype could be further honed to improve usability and efficiency. We aim to continue iterating on this aspect of our prototype as we continue to explore human design factors. Our next focus will be centered on expanding our post-training summary page. Alongside the current graph, additional performance feedback will be provided to offer insights and recommendations for improvement based on the user's performance during the session. We envision that the final design offers effective feedback in a comprehensive

and aesthetic program.

Several other aspects require refinement to enhance the overall functionality and user experience. These include the cleanliness of wiring, which needs to be improved to ensure a more organized and professional appearance. Additionally, we are currently using an Arduino for our prototype, and in the final design, we may opt for a customized electronic board to better suit the specific requirements and functionalities of the device.

While our ME450 prototype serves as a valuable proof-of-concept, these identified areas of improvement will be addressed as we continue to iterate towards the final design. Our commitment is to optimize the prototype to meet the specific needs and requirements of our sponsor, thereby ensuring the successful development of the final product.

DESCRIPTION OF VERIFICATION AND VALIDATION APPROACH

Verification Plans

Table 10 presents a brief description of the initial verification plan associated with each requirement and specification in order to ensure that our requirements are met. The status of the verification testing is represented on the rightmost column, with the green checks designating that the specifications are met, and the yellow clock depicting that verification is still in progress.

Table 10: Verification Plans

Requirement	Specifications	Verification Plan	Verification Status
Allows user to perform four hand positions	One-handed CE hold, two-handed hold, spider hold, and stem hold	In order to verify this requirement we will test all hand positions with neonatal nurses who have experience with PPV. If the conclusion from each trial is that there is no interference we can conclude that the design does not interfere with these hand holding positions.	
Does not contribute to excessive air leakage	<25% air leakage (Low Leak - minimal) <10 % air leakage (Optimal)	Using our sponsor's pre-existing air leakage setup we will find the air leakage that comes from our device being added to the setup. This will give us the percent of air leakage that comes from our device. Comparing this result to our specifications we can determine if we meet our minimal or optimal (or neither) requirements.	

Requirement	Specifications	Verification Plan	Verification Status
Accurately detects forces in the correct range	Force sensing range: 0 -10 N Resolution: < 0.045 N	We will apply known forces in the 0-10 N range increasing on a set increment and record the analog output. Resolution will be verified by the sensor datasheet specifications.	
Measures force in four key locations	Nasal bridge, left and right zygomatic arch, and mentum	As this requirement will be inherent to the design, it will be verified by design intent; either we will have force measurements in the four locations or we will not.	
Outputs readings proportional to readings from existing sponsor setup	Vary <5% (considering a factor of proportionality)	The output of proportional readings will be verified by comparing our force sensor readings to our sponsor's existing setup when the same force is applied. If they vary by less than five percent, given a factor of proportionality if needed, then the requirement is verified.	
Supports the most common training masks	60 mm round mask (minimal) 35-60 mm round mask (optimal)	We will put our device on the 60 mm round mask and if it works with this mask (visual assessment) the minimal specification is verified.	
Provides real time feedback for the user	≥ 1 sensory feedback signal < 250ms of reaching target force range ≥ 4 locations	These specifications will be verified by design intent in terms of the number of sensory signals and the location; either we will have them or we will not. The response time requires a more complex testing procedure to determine the amount of time from when force is being applied, to when the display device shows the results. These results will be compared to our specifications to ensure that the requirement is verified.	
Is transferable	No residue Separable from manikin ≤ 2 tools required to transfer	We will place and remove the device from the manikin multiple times to assess the ease of transfer. The number of tools used and visually assessing any residue or damage done to the environment can be used to verify this requirement.	

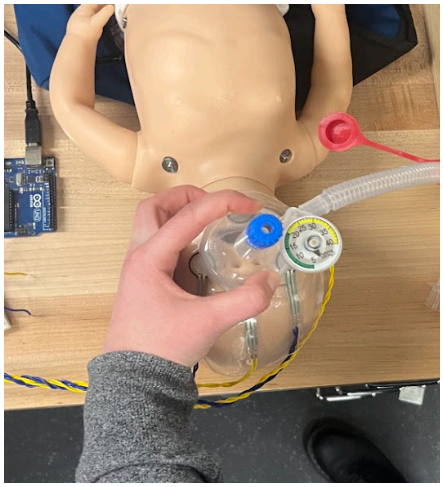
Requirement	Specifications	Verification Plan	Verification Status
Prototype is within the ME 450 budget	< $400	The cost requirement is considered verified if we do not exceed the given budget.	
Is durable	Withstands >1250 10-minute cycles Withstands 40N applied force	Complete PPV testing with our device 1250 times. After these tests, visual analysis of the device can be completed to assess how the material holds up over the different cycles. We will also apply 40 Newtons of force to different areas along the device and ensure the mask withstands the weight.	
Is lightweight	< 600 grams (minimal) < 200% of weight of the respirator (optimal)	We will weigh our final design and compare the results to our specifications based on our designated minimal and optimal weights.	
Can be set up quickly	< 1 minute for complete set up (hardware and software)	We will test how long it takes to set up all functions of the device with our sponsor, Jacqueline. The resulting time can then be compared to our specification.	
Is easy to use	Device takes < 25 cycles to learn how to use	The ease of use will be verified by assessing the performance of a sample of neonatal nurses and participants with no medical background. They will use the device less than 25 times and then complete a survey on the ease of use.	
Is safe to use	No risk of shock No sharp edges or surfaces	Conduct cross-examination of our device with IEC safety standards to verify that our device adheres to each one. We will perform a careful physical examination to verify there are no sharp edges or surfaces. We will also examine wiring components and make sure there are no loose wires and there is proper sealing all around.	

The level of complexity of each of these verification plans is directly related to the level of complexity of the specifications. Some of the specifications have design intent verifications, meaning that either they will exist or not and do not require testing. Other requirements have more complex empirical verifications that involve measurements to compare to our specifications.

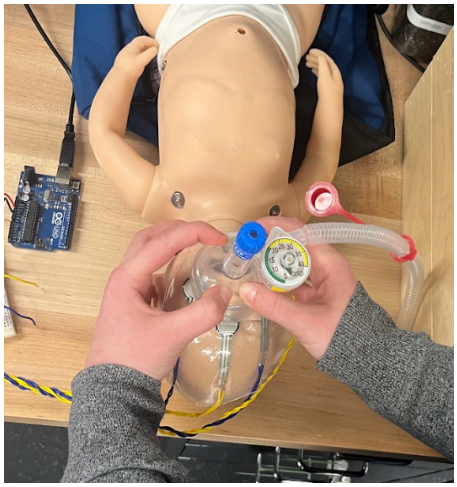
Verification Results

Allows user to perform four hand positions

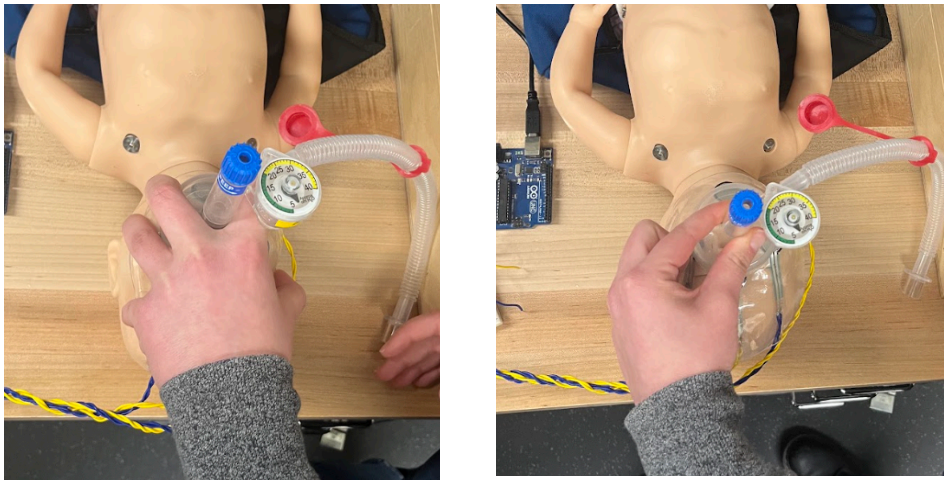
Verifying that our training device allows the user to perform all four hand positions with no interference is essential for the effective operation of PPV with our device. To test this requirement, since we did not have access to neonatal PPV staff, we devised a procedure involving our sponsor, Jacqueline Hannan, who has sufficient knowledge and experience with the PPV process to accurately depict the different hand positions used by neonatal nurses. This procedure involved photographing Jacqueline performing each of the four hand positions (one-handed C hold, two-handed hold, spider hold, and stem hold (two-point top hold) on the 60 millimeter round mask, which is placed on top of our sensor-embedded TPU device. These photographs are displayed below in Figure 40.



One-handed CE hold



Two-handed hold



Spider hold Stem hold (two-point top hold)

Figure 40: Four different hand positions with device applied to manikin.

Since our device is placed below the mask on the manikin, it by principle does not interfere with the holding techniques used by PPV providers. As shown in the images in Figure 40, Jacqueline was able to perform all four hand positions. Therefore, this requirement is effectively verified.

Does not contribute to excessive air leakage

In order to verify the requirement that our design does not contribute to excessive air leakage the air leakage with our design on the manikin has to be less than 25% (minimally). To test this we used an air leakage testing system provided by the University of Michigan Hospital called the Monivent Neo Training Device. The device has a sensor module that is attached to a mask that is then placed over the manikin's mouth and nose. “Breaths” are then simulated by pressing down on the top apparatus. The SimNewB manikin has inflatable lungs so when a breath is simulated air reaches the lungs and comes out of the mouth and nose. The device measures the amount of air going in and then coming out and presents the results as a percentage of air leakage coming from the manikin. The device and the results screen it displays can be seen in Figure 36 and the inflatable lungs in the manikin are shown in Figure 41.

Figure 41: Inflatable lungs within SimNewB manikin

We initially completed this testing with a rough prototype of our design in order to address a design concern. The prototype used consists of two TPU sheets vacuum formed to the face of the manikin, but without any sensors or wiring added between the two layers. An image of the setup and device in use can be seen in Figure 42.

Figure 42: Air leakage testing done on just the manikin itself.

There were several issues we ran into when completing this initial testing. The NewSimB manikin used for our project had pre existing leaks within its lungs. This made its air leakage without our device added at around 80%, when it should have been around 10%. In order to still collect some data we altered our testing plan to instead compare the results of air leakage from the manikin itself to the air leakage with our prototype mask added. Breaths were simulated on the manikin using the Monivent Neo Training Device for two minutes for each setup (training device and no training device). The results are shown in Figure 43.

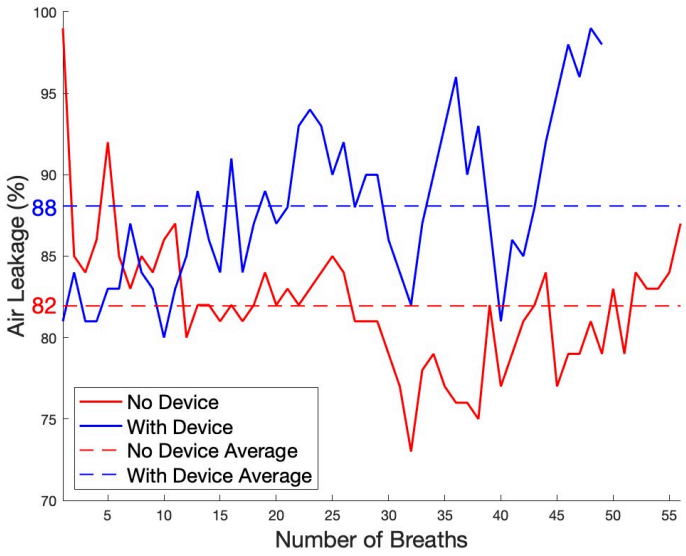


Figure 43: The percent air leakage against the number of breaths for the two different setups, with and without our training device added.

The resting air leakage is not entirely accurate due to leak within the manikin making the overall numerical results futile. However, we were able to tell that on average our training device adds at least 6% of air leakage to the process. If the air leakage results should theoretically be resting around 10%, the added 6% is within the limits of our specification. Due to the limitations of this testing such as the broken equipment and use of a premature prototype, this requirement has not been verified and it is still considered in progress. In the future, the same test would be repeated with some slight modifications. The test would only be conducted with only one setup, the manikin with our training device added. Several trials of the same time duration would be conducted and the overall average air leakage results would then be compared to our specification of needing less than 25% of air leakage.

Accurately detects forces in the correct range

The first specification used to define the requirement “accurately detects forces in the correct range” is that the sensors must be able to detect the applicable PPV force range, which is 0-10N. Since our design involves embedding the sensors in two layers of TPU, it was imperative to empirically test the range of the sensors rather than simply relying on the specification sheet for the

sensors. As described in the results of our engineering analysis, "Will the thermoformed layer interfere with the accuracy of the sensor readings?", the inconsistency and truncated lower end of the force range was attributed to the low-end quality of the Round Force Sensitive Resistors (FSR) sensors in our prototype. However, our final design is intended to embed the higher quality SingleTact sensors, which are currently used by our sponsor, Jacquline. To verify that our final design would meet this requirement, we completed the same test as our engineering analysis, but with one of the SingleTact sensors provided by Jacqueline. The results of this experiment are shown below in Figure 44.

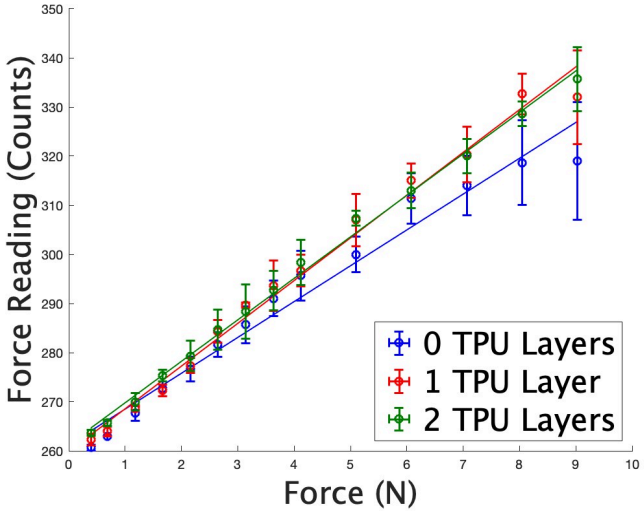


Figure 44: Force reading versus applied force with zero, one, and two layers of TPU sandwiching the sensors. This test was completed using the SingleTact sensors (final design).

From this plot, we can see that the higher-quality SingleTact sensors are able to read forces across the 0-10 force range, even with two layers of TPU sandwiching the sensors. We also notice that there is much less damping from the TPU, and the error bars are much tighter than for the Round FSR sensors. One limitation of this verification test is that the smallest calibration weight tested was 40 grams, which is equivalent to about 0.4N. Thus, the complete 0-10N range was not tested. However, since the minimum force applied during PPV is 0.5N, which is larger than the lowest force detected by the SingleTact sensors, we concluded that this test verifies that our final design can detect forces in the correct range and ensures confidence that the readings will be consistent and reliable.

The second specification in this requirement is that the resolution of the sensors must be less than or equal to 0.045N to make sure that the sensor will be able to detect changes in force at least as small as humans can perceive while pressing down on the mask. To verify this specification, we used the SingleTact datasheet[47], which claims that the force resolution is less than 0.2% of the full scale (FSR). By multiplying this percentage by the FSR of about 10N, we determined that the force resolution is 0.02N. Since this is less than our specification of 0.045N, this specification is verified.

Measures force in four key locations

This requirement is verified through design intent. Our device contains four sensors placed in the four key locations for PPV force measurement. When the sensors in the device are connected to our feedback system, each sensor actively measures the force applied. Therefore, this requirement is verified. Figure 45 shows our device side by side with the feedback display to emphasize the measurement in the four key locations.

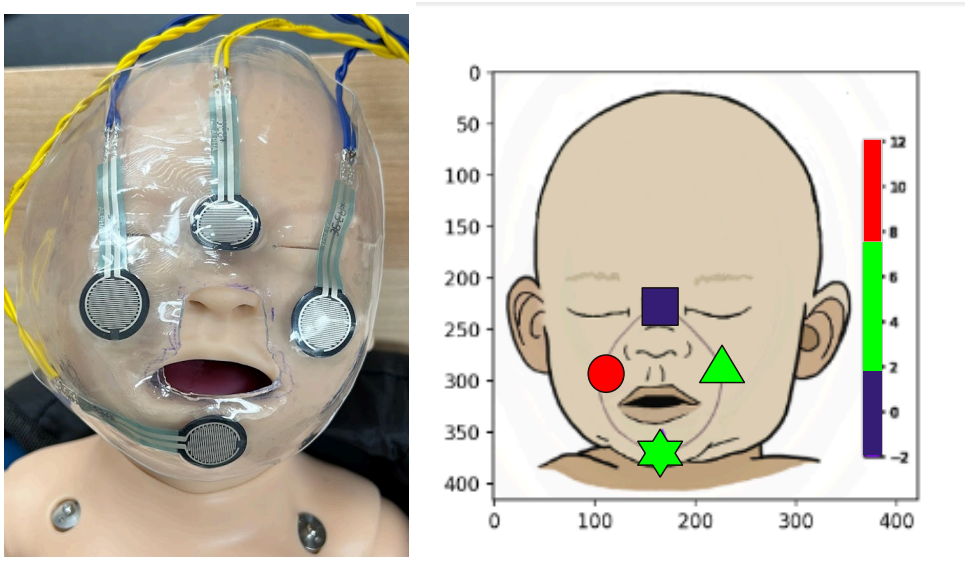


Figure 45: Device containing sensors in the four key locations (left). Feedback display with visual of the four key locations updated in real time with force reading (right).

Outputs readings proportional to readings from existing sponsor setup

This requirement was verified by applying forces to both our prototype mask and our sponsor force setup to compare these force readings based on known time stamps. The setup is pictured below.

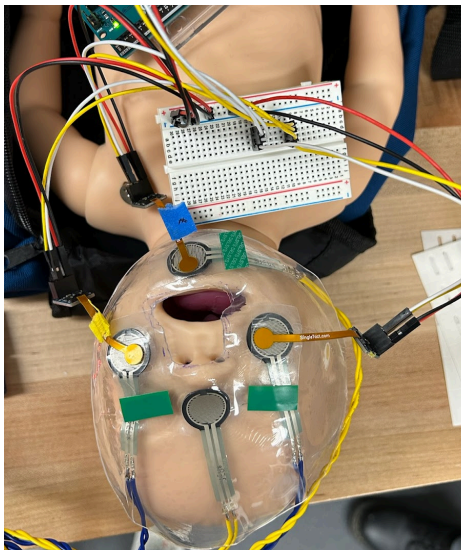


Figure 46: Experimental setup for running verification testing for Outputs readings proportional to readings from existing sponsor setup

During the verification process, the new force sensor's outputs were compared to the existing sponsor's sensor under identical force conditions. These readings, converted into Newtons using our previously shown conversion factor from testing, and normalized against the maximum value for comparability, were expected to have less than a five percent variance after accounting for proportional scaling. However, the data analysis revealed that our sensor's outputs deviated significantly from the sponsor's benchmark, far exceeding the allowable five percent variance, thus failing to meet the established requirement. During testing, we found that the force sensor on the mask's forehead was not responding, so those results were considered a failure and not pictured.

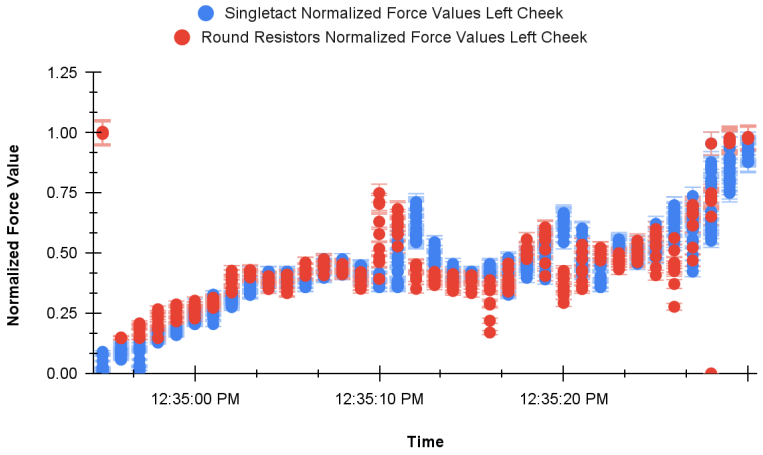


Figure 47: Normalized force values comparison for sponsor setup vs prototype mask Left Cheek. 5% error bars are shown on each data point.

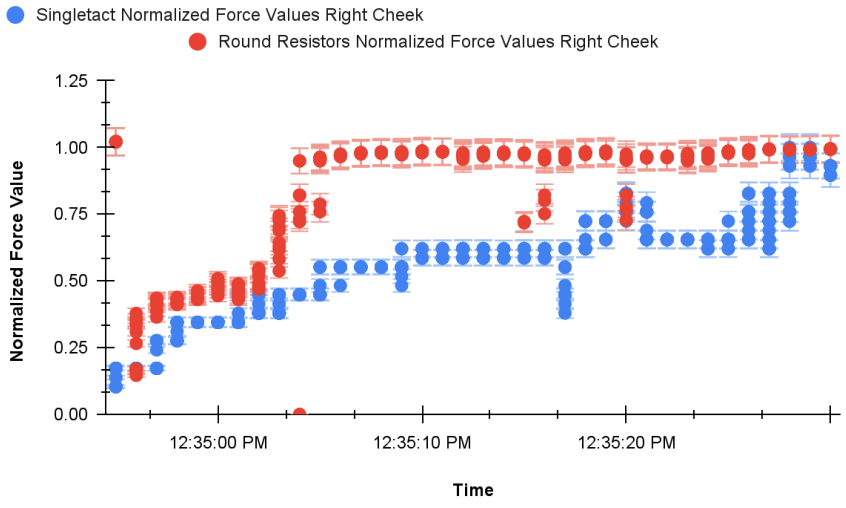


Figure 48: Normalized force values comparison for sponsor setup vs prototype mask Right Cheek. 5% error bars are shown on each data point.

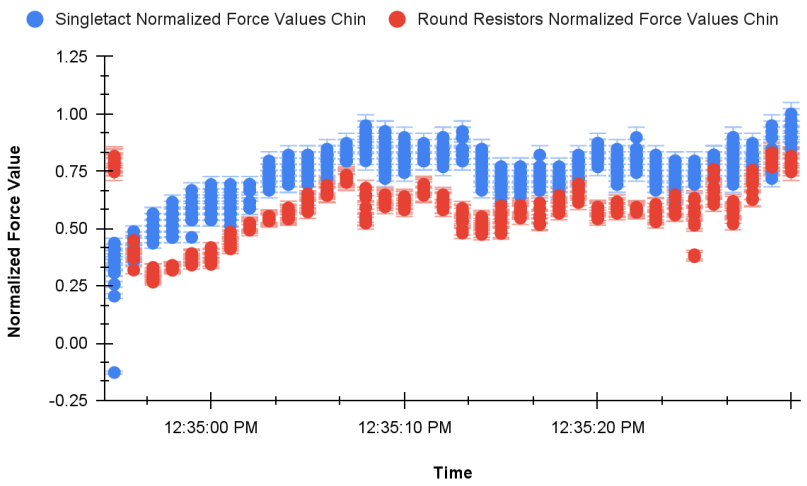


Figure 49: Normalized force values comparison for sponsor setup vs prototype mask Chin. 5% error bars are shown on each data point.

Despite our mask showing periods where it falls within the 5% error bar range shown in our graphs, our mask was not able to consistently demonstrate that it was able to meet this requirement. Despite this, we believe that when using the more accurate singletact force sensors, our mask will be able to meet this requirement in the future and verify this requirement with the more effective force sensors.

Supports the most common training masks

This requirement is verified through design intent. In correspondence with the proposed verification plan, we placed a 60 mm neonatal round mask on top of our device and tested with the feedback system to ensure that all four sensors were aligned with the mask. After multiple uses of the 60 mm round mask on our device, we confirmed that our minimum specification was met through visual analysis of the fit. If brought to market, this device would be produced for different size and shape medical manikins used in resuscitation training. The final design is intended to be adaptable to the most common training masks (35-60 mm round), meaning the optimal specification would be met as well.

Provides real time feedback for the user

This requirement has three specifications and is verified through design intent as well as additional testing.

Visual feedback was selected to address the specification of " ≥ 1 sensory feedback signal." The sponsor's existing visual feedback system was adapted to our device. Based on success with the use of the device transmitting accurate signals to the visual feedback display, this specification is verified.

Verifying the specification "< 250 ms of reaching target force range" is in progress. A test still needs to be conducted to accurately determine the response time of our device. The datasheet of the Round Force-Sensitive Resistors states a response time of 1ms. In our final design, the Single Tact Force Sensors would replace the Round Force-Sensitive Resistors in the final design because they are higher quality and produce more accurate results. The Single Tact Force Sensors have a response time of < 1 ms as provided on the datasheet. However, there are more factors to consider when measuring response time, such as how the computer and program have their own response times in addition to the sensors. Measuring the response time of a sensor to output a signal on a computer feedback display requires specific equipment and tools. We would need the sensors, connected to a computer or device capable of receiving its output signal. Software for data logging and analysis is essential, which would allow us to record timestamps accurately. We would ensure the system is configured to timestamp events precisely, marking both the initiation of the stimulus (sensor activation) and the display of feedback on the computer screen. If network communication is involved, network monitoring tools could help track any latency. Testing under various conditions may necessitate load generation tools to simulate different sensor inputs. Depending on the precision needed, we would consider calibration equipment to ensure accurate measurements. Although this test has not been completed, we are confident that the specification of response time being < 250 ms would be met based on the combined response times of the system.

The sponsor's existing feedback display that was adapted to our device contains an image of the manikin face with the four key locations. These four key locations show the amount of force being applied in real time using a color range to the user. Throughout our iterations of prototypes, these four key locations in the feedback display have all successfully worked in visually showing the user how much force they are applying as they are performing PPV. Therefore, the specification of "≥ 4 locations" is verified.

The feedback display connected to the device is shown in Figure 50 to provide a visual on how this verification was completed.

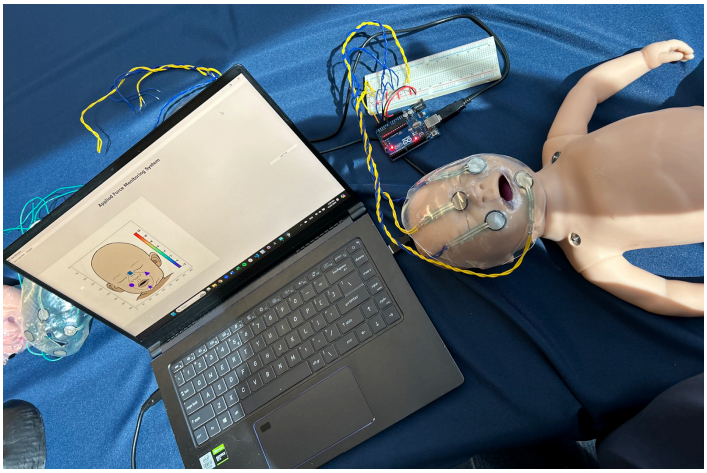


Figure 50: Feedback display and device.

Is transferable
This requirement is verified through design intent. Our design was created with transferability in mind based on the specifications of less than two tools required to transfer and no residue left behind. Our test for this verification simply consisted of applying the device to the manikin and removing it to assess transferability. The device did not leave any residue or marks, only required hands to move, and was easily separable from the manikin. Therefore, the requirement "is transferable" has been verified.

Prototype is within the ME 450 budget
The cost requirement is considered verified because we did not exceed the given budget in ME 450 of $400. Please see the final Bill of Materials in Appendix B for more information.

Is durable
To verify this requirement, we devised a test procedure to directly test the first specification, "withstands >1250 10-minute training cycles". This procedure would involve applying force, either by pressing down manually or by applying appropriate calibrated weight to the mask, for 1250 10-minute cycles and examining the wear on the TPU, sensors, and wiring. Unfortunately however, due to the time constraints of the ME 450 semester, this test was not completed. Thus, we consider this specification still in progress, as future testing is needed to verify it.

The second specification, which states that the device must be able to withstand at at least 40N of force, was verified by simply placing the device on the 3D printed mold to establish stability, and manually applying large amounts of force all over the device. We then examined the components of our device for any sources of damage or displacement, and found that the device was fully intact. This test effectively verified that our device can withstand forces of 40N.

Is lightweight
The specification for our requirement "is lightweight" is that our device has to be at least less than 600 grams, and optimally less than 100 grams (roughly 200% of the weight of the respirator). In order to verify this requirement we simply weighed our device. The resulting weight was 62 grams, putting us well under both our optimal and minimal requirements. Therefore this requirement is considered verified.

Can be set up quickly
This requirement was verified by having our sponsor setup our prototype to confirm our device could be set up in under 1 minute. We selected our sponsor, Jacqueline, for this test because she is well versed in the neonatal resuscitation training procedure and the closest person to a PPV provider we were able to meet with within the ME 450 timeline. Jacqueline was able to set up our mask in 20 seconds so we considered this requirement verified.

Is easy to use

This requirement, based on our verification plan, is in progress. A functioning prototype that can be brought to a hospital and tested with neonatal nurses is required to determine if they could learn how to use it in the specified number of cycles. This requirement therefore needs further testing and can be verified with a more complete prototype in the future.

Is safe to use

The verification process undertook a cross-examination of our device's design and construction against the relevant International Electrotechnical Commission (IEC) safety standards. This involved a physical inspection to ensure the absence of sharp edges or surfaces that could pose a risk to users, which confirmed compliance with the mechanical safety requirements. Additionally, the team assessed the device's electrical wiring integrity. Through this review, it was determined that our device successfully meets each of the prescribed IEC safety standards. The physical and electrical component inspections were performed, ensuring that no aspect of the device poses a safety threat.

Preliminary Validation Plans

There are two proposed validation plans that align with the deployment and usage of our device. One is aimed at seeing if our device is effective for training purposes and improving the amount of applied force during PPV. We refer to this validation plan as efficacy and learning outcomes because the goal is to benefit the user's performance. The second validation plan is centered around usability, which calls for representative users to perform representative tasks as a means to reveal the interactive strengths and opportunities for improvement of a device.[58]

The efficacy and learning outcomes validation plan would begin with a pre-test assessment to establish participants' baseline understanding of Positive Pressure Ventilation (PPV) techniques. Subsequently, participants engage in a structured training session with the developed device, focusing on hands-on practice and live feedback. Following the training, a post-test assessment measures improvements in the appropriate amount of applied force. Participant feedback, combined with rigorous data analysis, would ensure a thorough evaluation of the training device's efficacy in achieving learning outcomes.

The usability validation plan would employ usability testing, questionnaires, and interviews to assess the practicality and user-friendliness of the training device. Participants would undergo tasks involving device setup, calibration, and PPV practice, while providing feedback on ease of use. Expert evaluation complements participant feedback, guiding iterative design improvements to address usability issues. Through this iterative process, the final evaluation would ensure that the training device meets usability standards and is ready for effective implementation in clinical practice. The test session might wrap up with an interview focused on what the participants liked and disliked about the device, the cause and effect of use errors, and opportunities for design improvement.[58]

FINAL DESIGN DESCRIPTION

In envisioning our final design iteration, we aim to build upon the progress made throughout our ME 450 project, addressing key areas for improvement identified during our development process. To address the challenges encountered with sensor accuracy, we plan to integrate higher-quality sensors, such as the SingleTact force sensors, to enhance the reliability and precision of our measurements. Additionally, we will focus on refining the graphical user interface program to improve usability and efficiency, with particular emphasis on expanding our post-training summary page.

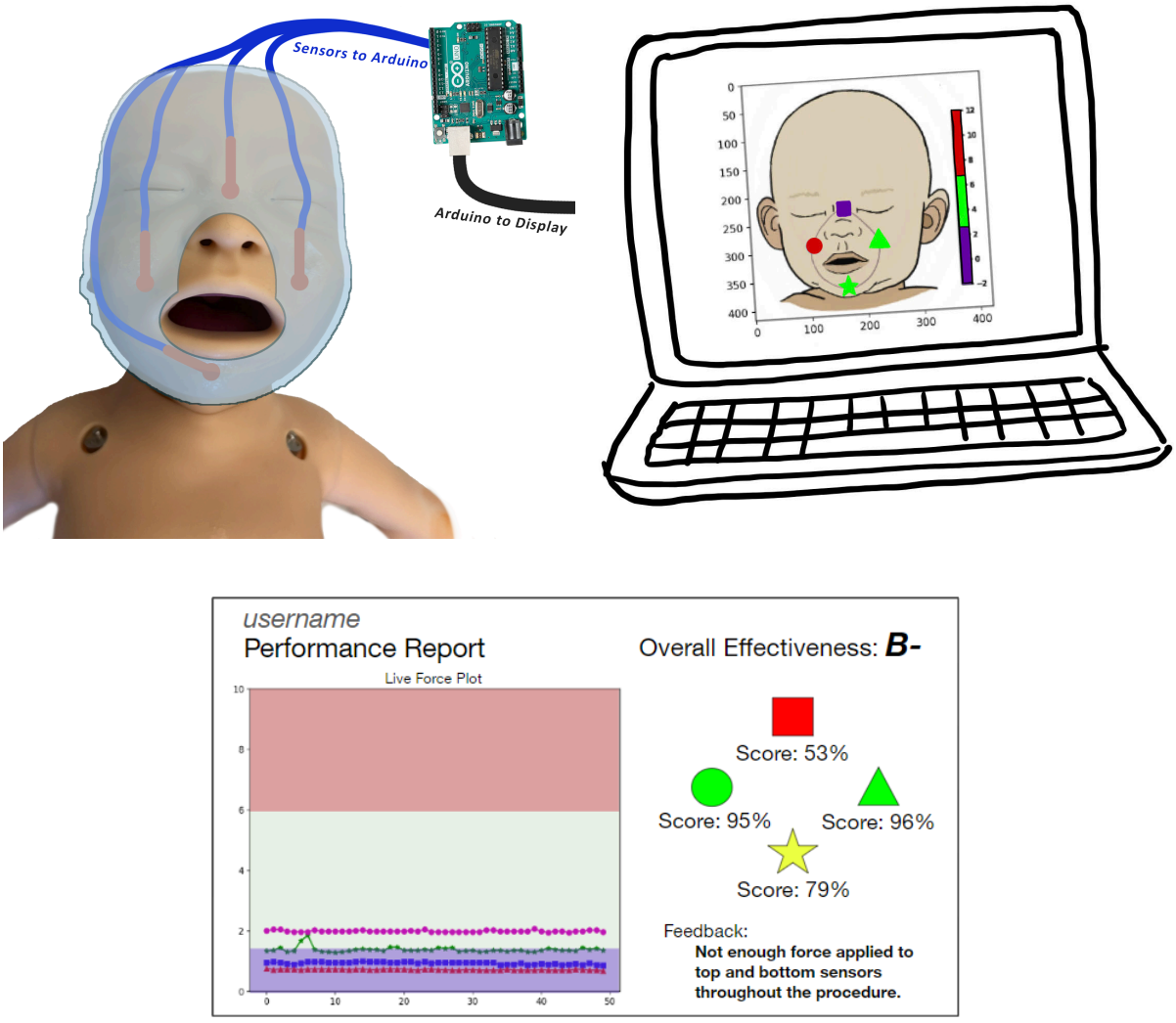


Figure 51: Mockup image of our Gamma design with changes made to reflect use of different sensors (top left), the feedback system shown on display (top right), and the post-summary performance report (bottom).

Our envisioned post-training summary page will feature a comprehensive performance report,

providing users with valuable insights into their training session. This report will include a continuous time graph displaying performance data throughout the session, metrics on the four key locations, and a performance grade to inform users of their training session efficacy. Furthermore, user performance data will be saved and tracked over multiple sessions, allowing users to monitor their progress and track improvements over time.

The operation of our training device is detailed in the Setup and Usage section above. A critical aspect of our design's success lies in its seamless integration into training sessions, providing nurses with an easy-to-use system that minimizes interference with the training space. The mask, pre-attached with sensors and wires, is easily placed on the manikin, while live force feedback is displayed on the computer screen throughout the resuscitation process. The strategic positioning of the display device, directly ahead and at eye level, aligns with current training procedures. This design integrates seamlessly into existing training setups while providing real-time feedback at the four key locations. Additionally, after the training session, nurses can review a post-training summary performance report, offering comprehensive data on their performance and aiding in further skill development and refinement.

We anticipate that the manufacturing process will resemble our previous methods, albeit with the incorporation of more specialized tools. However, we recognize the potential for further enhancements to achieve better and more consistent results. Fine-tuning parameters such as time and temperature in the vacuum forming process, along with the utilization of specialized machinery or fixtures for trimming excess material, are among the considerations for optimization. Additionally, we envision replacing the 3D printed mold used in our prototypes with a more precise mold of the manikin's face, thereby enhancing the fit and accuracy of the TPU layers.

Our final design represents the culmination of an iterative development process, drawing upon feedback and lessons learned from previous iterations. By prioritizing key concerns such as sensor accuracy and feedback system refinement, our aim is to deliver a product that not only meets but exceeds the functionality, usability, and effectiveness standards for users undergoing training sessions. Confidence in our design stems from its simplicity and innovative manufacturing method, which we've meticulously refined through analysis and verification. Promising results have validated the viability of this approach, showcasing its potential to meet the requirements and specifications we set out to address.

DISCUSSION

Due to the limited time and resources allotted during this semester of ME 450, the scope of our project was limited to being just a proof-of-concept for our final design. If we had more time, funding, and accessibility to the hospital and its resources, our scope would have likely been expanded to involve more of our tertiary stakeholders as our design would be intended for commercial purposes. These include, but are not limited to, ventilator and mask manufacturers, as

well as medical device distributors. To properly define our problem, we would conduct interviews and studies with neonatal nurses and hospital leaders, as well as industry material suppliers. This would help us to better curate our design to a commercial product.

Through the development of our prototype and final design concept, we have identified several strengths of our design. Due to the innovative and efficient manufacturing method of thermoforming to the shape of the manikin and embedding the sensors between two layers, our design is scalable to different manikin shapes and sizes. Our verification testing also produced encouraging results, as most requirements were effectively verified, which proved the design viability. The verification results that displayed some issues with our design include our sensor testing, both with accuracy and proportionality. However, as we previously mentioned this can be combated by simply purchasing higher quality sensors. With our strengths, however, also come weaknesses. While our design benefits from the easy scalability, it still means that a new device would need to be created for each different type of manikin. With several different manikin providers, each with different size offerings that update often, the product would need to be remanufactured very often. This limits the ability for it to be effectively mass manufactured in a commercial setting, which drives up unit costs and assembly time. As the manufacturing method is crucial to our design strategy, this weakness is inherent in the design, therefore there are no small modifications that could be made to our design to improve this. While there are no clear design improvements for this weakness, we understand that this could be mitigated by the hospital industry normalizing manikin designs, so less iterations of the design would need to be produced.

In our design process, we encountered several challenges, notably the limited research on tracking the force applied during Positive Pressure Ventilation (PPV) to neonates. The absence of force-sensing PPV devices on the market exacerbated this issue. Furthermore, the appropriate force to apply to a neonate's face is not well-defined, particularly considering the diverse stages of development among newborns, especially preterm babies. Each infant possesses unique bone structures and developmental stages, complicating the establishment of standardized force thresholds. Given these complexities, we initially grappled with a broad array of ideas and struggled to envision a solution meeting our requirements. However, through an extremely iterative design process, where we devised several prototypes to identify strengths and weaknesses, as well as guide our final design process, we were able to successfully meet the majority of our requirements and produce a viable proof-of-concept design.

As our device would be used by neonatal nurses in their PPV training process, it is imperative that it has accurate force readings and can provide nurses with the appropriate feedback on their applied forces. If nurses receive incorrect or inconsistent feedback, they may not fully understand the correct range of force to apply to neonates in real practice, and could end up losing effectiveness or injuring the neonates. These risks were heavily weighed upon as our team defined the problem and prioritized key requirements.

Recommendations

Our first recommendation comes from how the manufacturing process was performed. When developing our prototype, we used a photo scan of the manikin's face that was then 3D printed to act as a mold for thermoforming. Although the manufacturing process worked, discrepancies in our mask and mankin formed due to differences between our scan and the manikin itself. It is our recommendation that when manufacturing a working device you would instead use either the manikin itself as a mold or a model of the face of the manikin taken from the manufacturer.

Our second recommendation comes from our manufacturing process itself. Currently, our prototype mask does leave air bubbles and regions where the two layer masks have not combined. In one of our prototypes the edges round the end of the masks did not join together and also damaged our force sensors. We propose refining the manufacturing process by fine-tuning temperature, time, and methods to mitigate these issues. This includes optimizing parameters such as vacuum forming temperature and duration to prevent air bubbles and ensuring proper bonding between TPU layers.

Our third recommendation comes from the force sensors that would be used inside the mask. Currently we are using Round Force Sensitive Resistors, but based on testing of sensors and comparisons of our device to our sponsors currently setup, it is clear that the Singletact force sensors performed better and should be implemented in any future masks. We also believe that it would be worthwhile to pursue increasing the number of force sensors used in the mask. Currently our setup is based around identifying the four key locations we determined to be important for neonatal resuscitation and having force sensors in these locations but increasing their number might increase the effectiveness of our mask.

REFLECTION

Reflecting on our work for the Force-Sensing Neonatal Ventilation Training device is crucial to understanding the potential impact of this product on the market. This device contributes to public health, safety, and welfare by ensuring that healthcare providers receive proper training in newborn resuscitation, potentially reducing the risk of injury or complications during this critical procedure. In a global marketplace, the design could be beneficial by standardizing and improving training for healthcare providers worldwide, especially in regions with limited access to specialized training resources, ultimately improving neonatal resuscitation outcomes on a global scale.

Social impacts associated with the design could include improved healthcare access and outcomes for newborns, as well as potential job creation or training opportunities for individuals involved in neonatal resuscitation training. The feedback system within the PPV training device can enhance training effectiveness, standardize care globally, and raise awareness about neonatal resuscitation practices. The stakeholder map that we developed early on in the process and iterated over time was used to inform us on design decisions when considering stakeholder impact. Economic impacts may include cost savings for healthcare facilities through less frequent purchase of force sensors due to

this transferable solution. This device also reduces the incidence of injuries during neonatal resuscitation, which could lead to reduced healthcare costs associated with complications.

In addition to its social and economic impacts, our training device also presents significant environmental considerations. While a comprehensive life-cycle analysis is pending, we are conscientious of the manufacturing, disposal, and transportation effects associated with our device. Its lightweight and compact design facilitate ease of transportation, potentially reducing carbon emissions during transit. Moreover, the use of TPU in our device manufacturing process offers environmental benefits, as TPU production typically consumes less energy compared to other plastics. Furthermore, TPU is recyclable and biodegradable[22], minimizing its environmental footprint after full use. However, it's important to acknowledge the potential for electronic waste generated by the device's electronic components, necessitating proper disposal and recycling measures to mitigate environmental impact effectively.

Cultural, privilege, identity, and stylistic differences among team members influenced our approaches by fostering diverse perspectives and problem-solving strategies, enriching our project with a variety of insights and ideas. Varying levels of familiarity with this problem led to creative concept generation and productive discussion in developing our final design. Natural roles were formed due to varying experience with electrical components, manufacturing, and coding. While our group members share a similar racial and socioeconomic background as white individuals from upper middle-class families, we recognize the importance of acknowledging and addressing potential biases in our design process. Cultural, privilege, identity, and stylistic differences with our sponsor influenced our design processes by prompting considerations of the current PPV training procedure and healthcare setting, ensuring that our design was adaptable and relevant to diverse settings.

Our team, sponsors, and stakeholders operated within a power dynamic influenced by diverse cultural, socioeconomic, and educational backgrounds. Despite these differences, we all adhered to the highest ethical standards within the University of Michigan Engineering community. While our undergraduate team lacked expertise in neonatal ventilation, Jacqueline and Dr. Stirling provided invaluable guidance, resources, and support in our weekly meetings. Our sponsors afforded us the autonomy to determine project requirements and design concepts, fostering open communication and a collaborative environment conducive to idea exchange and development. This support bolstered our progress and helped see our project through to completion. Our individual identities and experiences shaped our perspectives by providing insights into potential cultural nuances and preferences among end users, while collaborating with each other allowed for the integration of diverse expertise and perspectives into the project. Approaches for including diverse viewpoints included conducting interviews with key stakeholders, such as Gary Weiner, soliciting feedback, and fostering an inclusive team environment where all voices were valued and heard.

Throughout the duration of our work there were many contrasting opinions on how to move forward with our project, both with the stakeholders and within our group. We focused on an open communication between the team members as well as our sponsor. By communicating clearly with the sponsor about their expectations about the project we were able to ascertain our primary focus throughout our work. Between group members we were able to discuss openly about what we thought the best approach would be, and why. This allowed us to not only compromise between the best options but also take advantage of each other's strengths.

There were different communication styles and design making decisions that were built from varying backgrounds. For example, choosing to prioritize the functionality of the design, rather than aesthetics or cost effectiveness. In addition, with five different people there are varying communication styles that exist, like whether we should be in person to work on our project or simply split up work and do it separately. These same issues showed up with our sponsor as well. Similarly, this influenced how we approached issues, both with the design and with communication styles.

Because the majority of our differences came out in the decision making and communication processes, we had to find a way to ensure that all points were being heard and considered. This was navigated by meeting regularly and ensuring that we had clear expectations, not only for our project, but also for how we would communicate to address any potential issues that could arise. Because we felt our differences were the same between our sponsors, we still focused on clear communication. However, we also respected the power dynamic differences as our sponsor has a higher level of authority and therefore her opinions also held more authority. This allowed us to produce a final product that was truly suited to her needs.

There were several ethical concerns that arose during our design process. The first was related to the intellectual property agreement we signed with our sponsor, a PhD student at the University of Michigan, which raised questions about privacy and ownership. This prompted considerations about how much information to reveal and led us to establish clear boundaries and limitations with our sponsor from the outset to ensure transparent communication. Another ethical consideration stemmed from the intended use of our device within the medical community. While designed for training purposes, its potential role in certification processes meant failure or inaccurate results could lead to poorly trained personnel. Though beyond the immediate scope of our project, we prioritized factors like sensor accuracy and minimal air leakage to enhance the safety and reliability of our design for training scenarios.

In navigating the Medical–Industrial Complex, our device intersects with political and religious views on newborn resuscitation, transcending partisan lines. Political debates around healthcare policies, funding for neonatal care, and government involvement in medical decisions influence perspectives on resuscitation methods. Similarly, religious beliefs inform opinions on the sanctity of

life and the moral implications of medical interventions, with various groups advocating differing levels of medical intervention based on spiritual or ethical considerations

In order to maintain an ethical work environment our group focused on principles such as honesty, integrity, fairness and respect. This helped to maintain a healthy group dynamic and allowed us to navigate any potential conflict. These principles are reflected in other codes of conduct, particularly in the University of Michigan's code of conduct. This conduct focuses on responsibility and compassion for students, qualities that we also try to uphold. In the future employers may have different specific ethical codes they wish to follow. However, in any well respected community these same ethical qualities would be upheld and considered to maintain the best work environment possible.

CONCLUSION

The development of a training device to inform providers of Positive Pressure Ventilation (PPV) on the range of force to apply to neonates' faces addresses a critical gap in neonatal resuscitation training. We have meticulously examined the social context, stakeholders, and environmental considerations surrounding the design challenge of enhancing neonatal resuscitation training. Through a comprehensive stakeholder analysis and benchmarking against similar products, key user requirements and engineering specifications have been established. Following our design exploration and selection process, we developed an Alpha design based on our engineering specifications. We continued to iterate on our solution by conducting engineering analysis to address design concerns. Throughout our engineering analysis and further research on the subject, we made changes to our Alpha design, bringing a Beta concept, and then a final Gamma design to present as our final prototype. With our final prototype, we were able to begin verification testing to see how our design met our specifications. In the future, more validation and verification testing would be concluded not only to see how our device performs, but to continue to make improvements and iterations. We believe this methodology will ensure that our device meets the needs of healthcare providers and contributes positively to neonatal PPV training practices. Through collaborative efforts, we aim to make a meaningful impact in the field of neonatal medicine and patient safety.

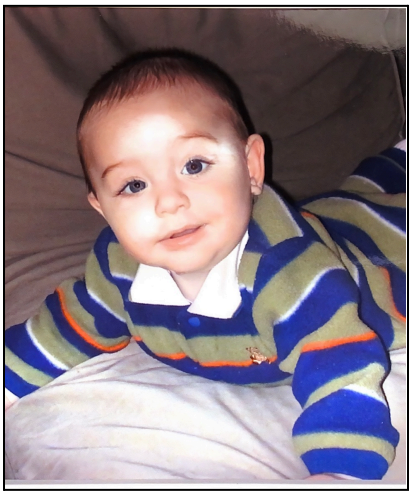
Acknowledgements

We extend our heartfelt gratitude to Dr. Sienko, Jacqueline Hannan, Dr. Stirling, Don Wirkner, Randy Schwemmin, Brian Hoey, and Anupama Kar for their invaluable guidance, support, and assistance throughout this project. Their expertise and mentorship have been instrumental in shaping our design process and achieving our goals. We are deeply appreciative of their dedication and contributions.

Team Bios

Alex Birnbaum is a fourth year Mechanical Engineering Major and Computer Science Minor Undergraduate at the University of Michigan. He is from Elmhurst, IL. His love of Mechanical Engineering stems from his passion for math and science while taking on complex and multifaceted challenges. Alex has spent the past summers working at various companies including United Airlines and Consulting Firms. He plans to return to Chicago after graduation as a CIO Advisory Associate at KPMG, applying his problem solving skills as well as his computer science background and eventually pursuing his MBA. Outside of school Alex is a passionate snowboarder, basketball player, and traveler and hopes to spend this upcoming summer traveling all over the world.

Tori Caracciolo is a fourth year Mechanical Engineering Major and International Minor for Engineers. She is from Long Valley, NJ. Her passion for engineering stems from her love of problem solving. Tori is a member of the Engineering Global Leadership (EGL) Honors program and will be pursuing a Master's Degree in Industrial & Operations Engineering this upcoming fall through SUGS. She will also be interning at Nestle Purina on their digital manufacturing team this summer. In Summer 2023, she was a manufacturing intern at Procter & Gamble. She has previously worked as a Battery Lab Research Assistant in the ME department and studied abroad in Rome, Italy in 2022. Tori is passionate about global volunteering and has completed projects in Ecuador and Iceland through M-HEAL and EGL. In her free time, she enjoys playing pickleball, singing, and traveling.



Owen Dollins is a graduating Mechanical Engineering Major and Business Administration Minor Undergraduate at the University of Michigan. He is from the Village of Clarkston, MI. His passion for Mechanical Engineering stems from his lifelong interest in cars and motorsports. Owen worked as an E-mobility Heat Exchanger Engineering Intern at MAHLE. He is planning to continue working for MAHLE as a product team lead for HVAC modules. He also worked as a Mechanical Engineering intern at Consumers Energy in the summer of 2021. Outside of school and work, Owen enjoys boating, skiing, and making zero mistakes on his IM volleyball team.

Anna Eaglesham is a fourth year Mechanical Engineering undergraduate student at the University of Michigan. She grew up in Lexington, Massachusetts where she developed a love for the environment and sciences. This created a passion for following a degree in engineering. In the past three summers Anna has participated in internships at First Solar, and Commonwealth Fusion Systems, as well as completing materials research on harmonic structures in Lund, Sweden. After graduation she will continue her academic career, pursuing a masters in Materials and Metallurgy at the University of Cambridge. She then hopes to work in renewable energy to continue her passion towards the environment. In her free time she enjoys reading and listening to music.

Filip Zachwieja is a fourth year Mechanical Engineering Major and Computer Science Minor Undergraduate at the University of Michigan. He currently plans on pursuing his Master's through Michigan's SUGS program. His hometown is Elmhurst, IL. Growing up, he was exposed to disassembled cars and many other products. He's always had a passion for design and an innate curiosity for understanding how systems work. At school, he has been a part of the Sa' Nima' Collaborative and is currently part of the Perot Jain Electrification Cohort where he's working with a startup to develop electric ATV's. Filip has previously interned at Flowserve, BASF, and looks forward to working at Daimler as a Product Design Engineering intern. Beyond the classroom, he enjoys playing intramural sports with friends, crafting elite March Madness brackets, and cooking.

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APPENDIX A

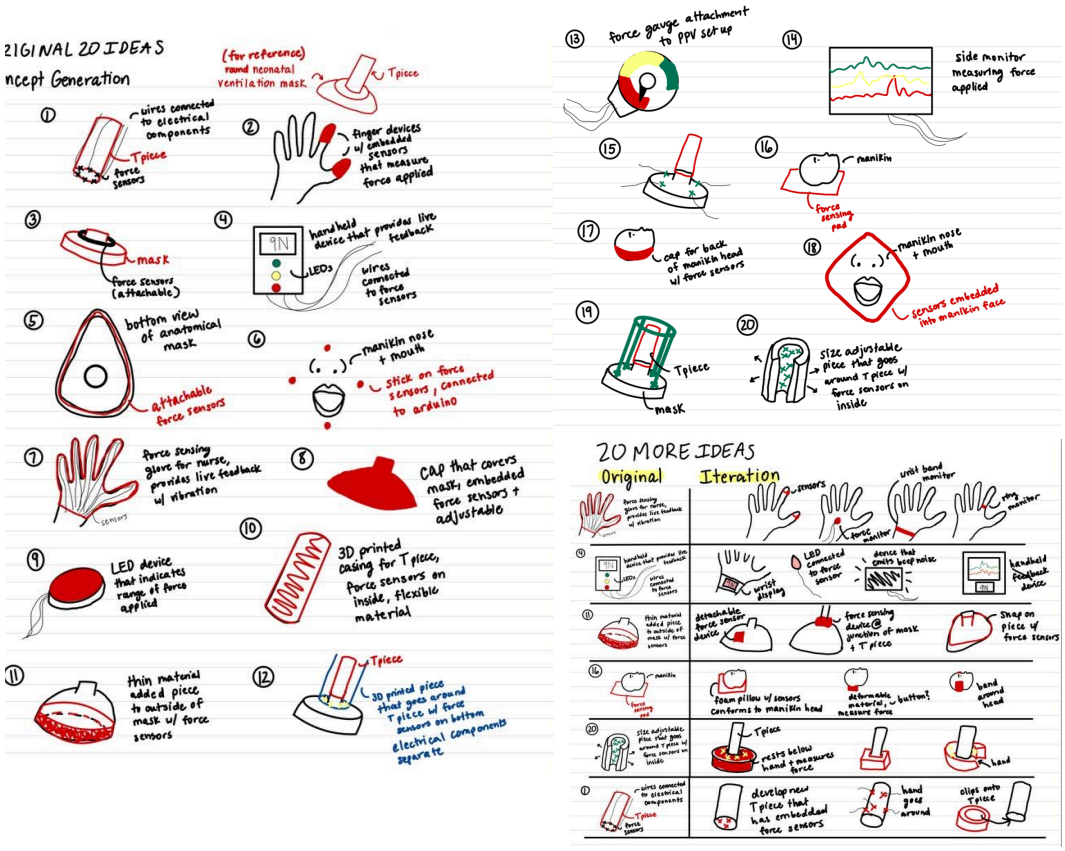


Figure A.1: Tori's 40 design concepts.

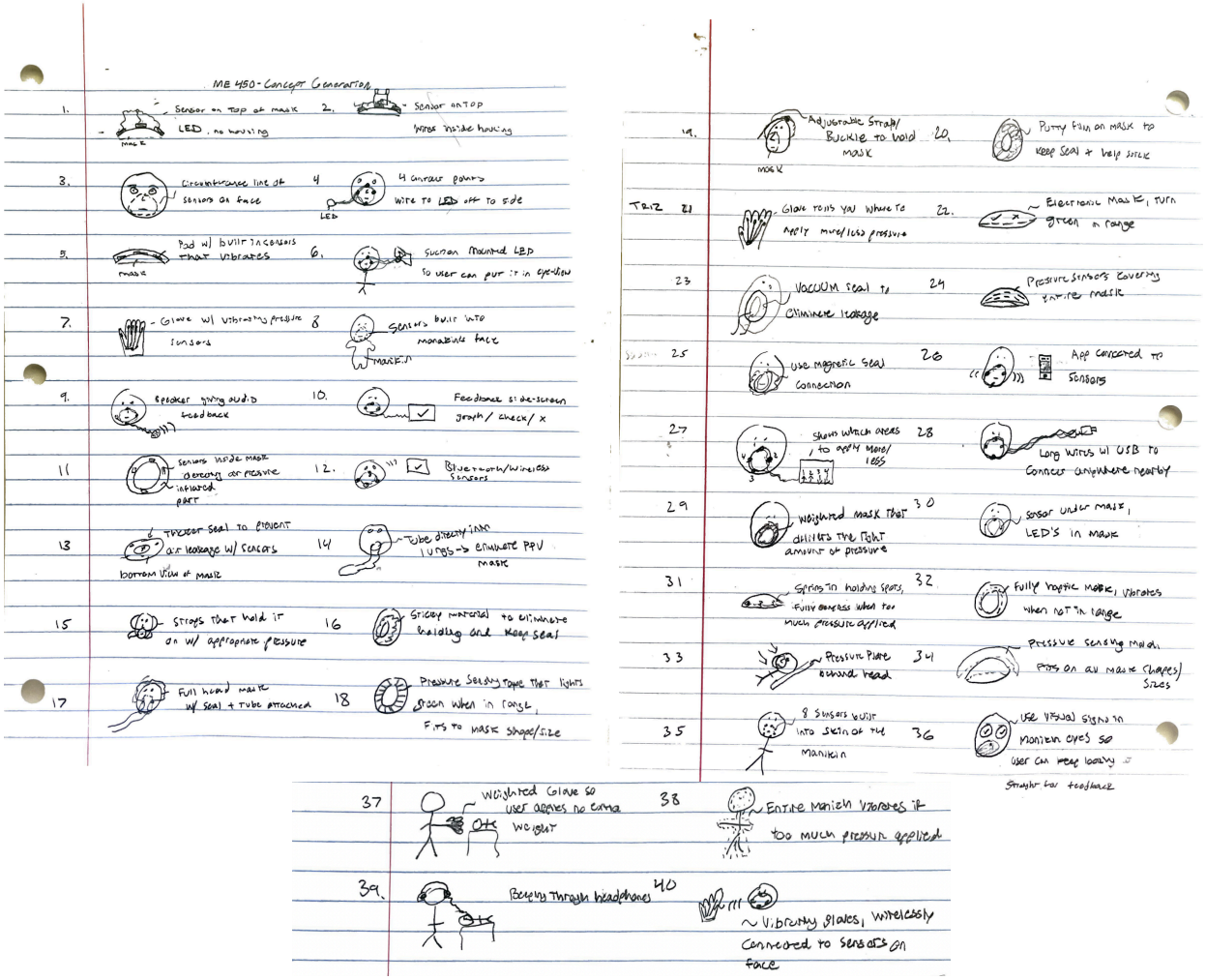


Figure A.2: Owen's 40 design concepts

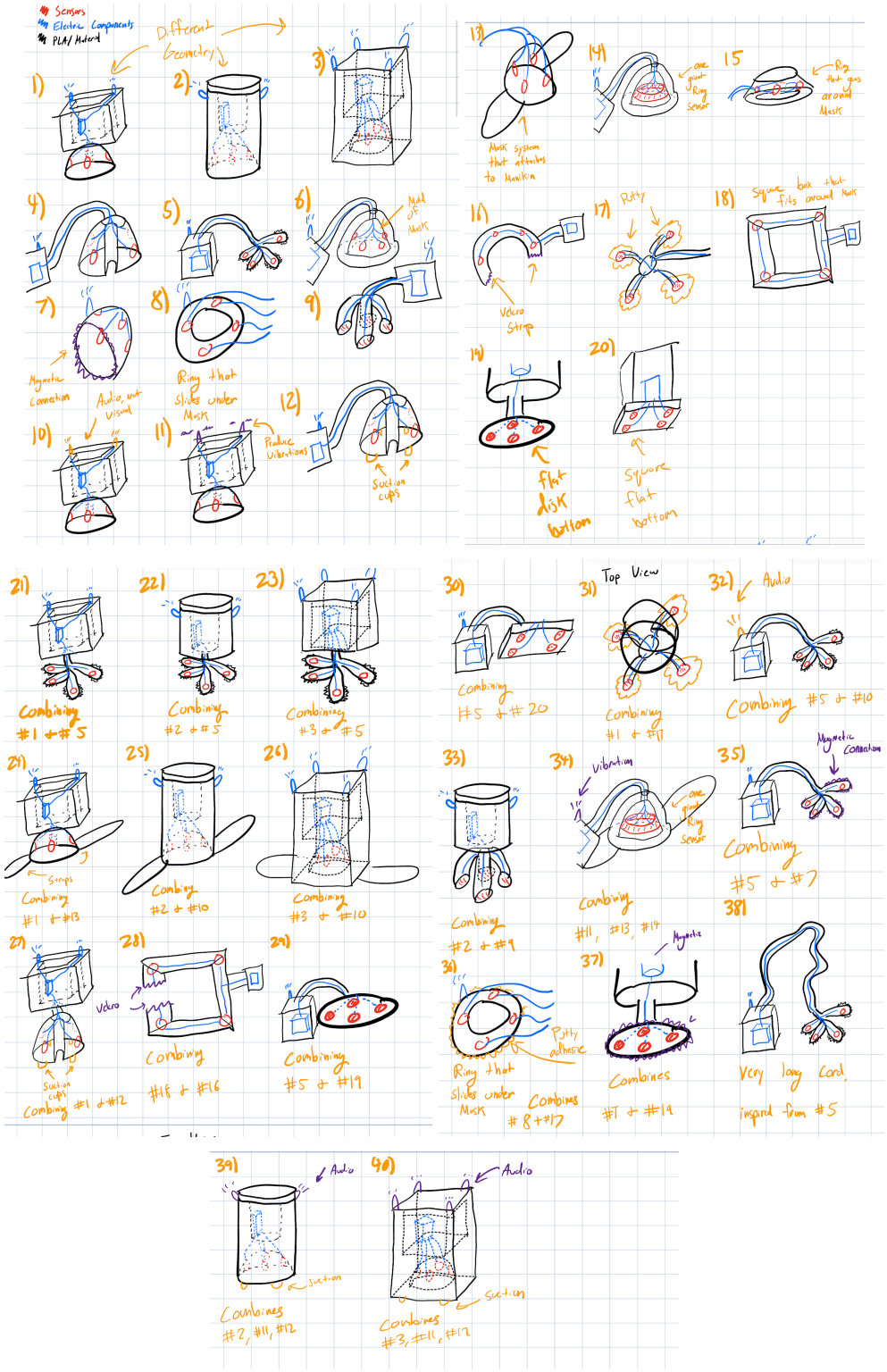


Figure A.3: Alex's 40 design concepts

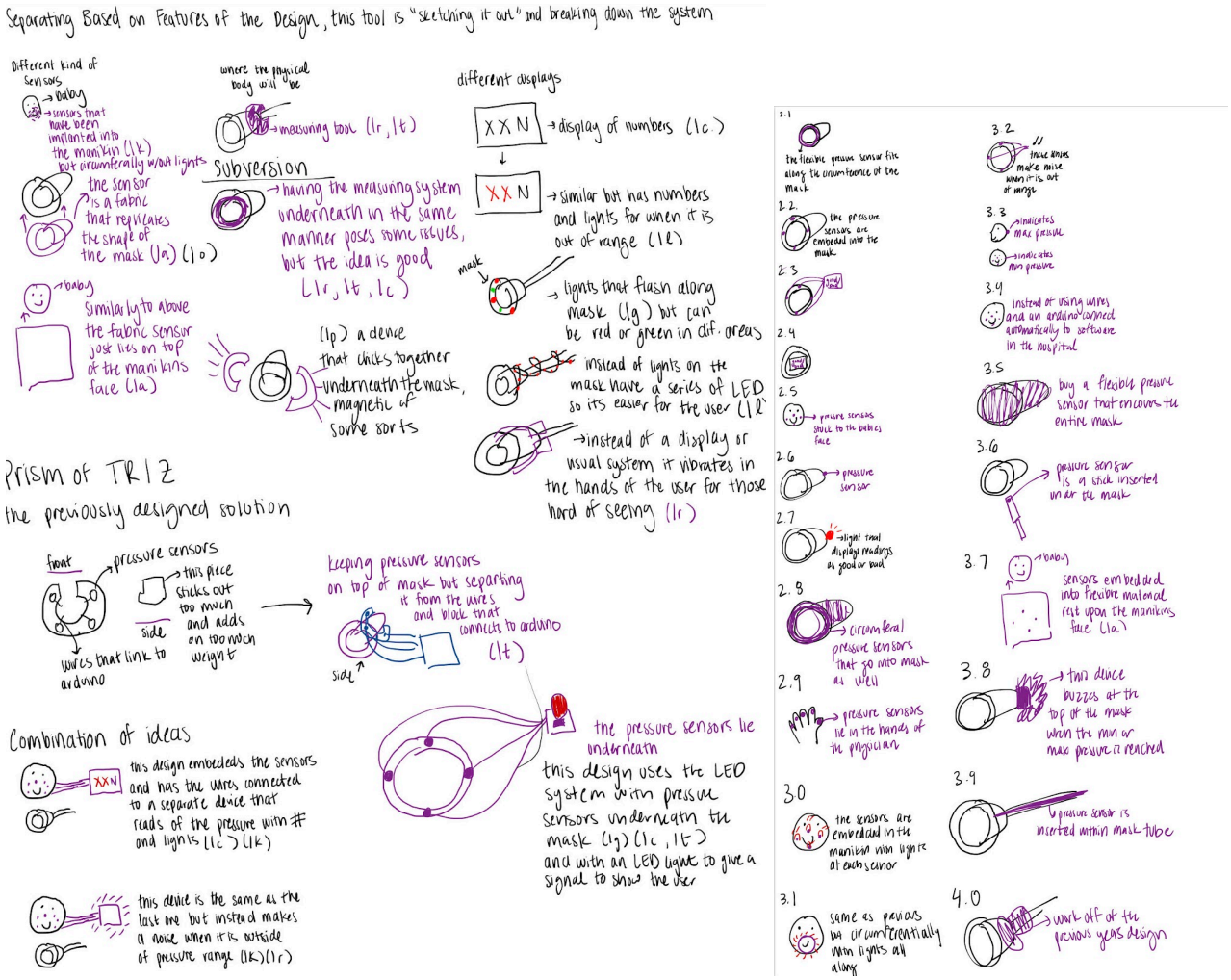


Figure A.4: Anna's 40 design concepts,

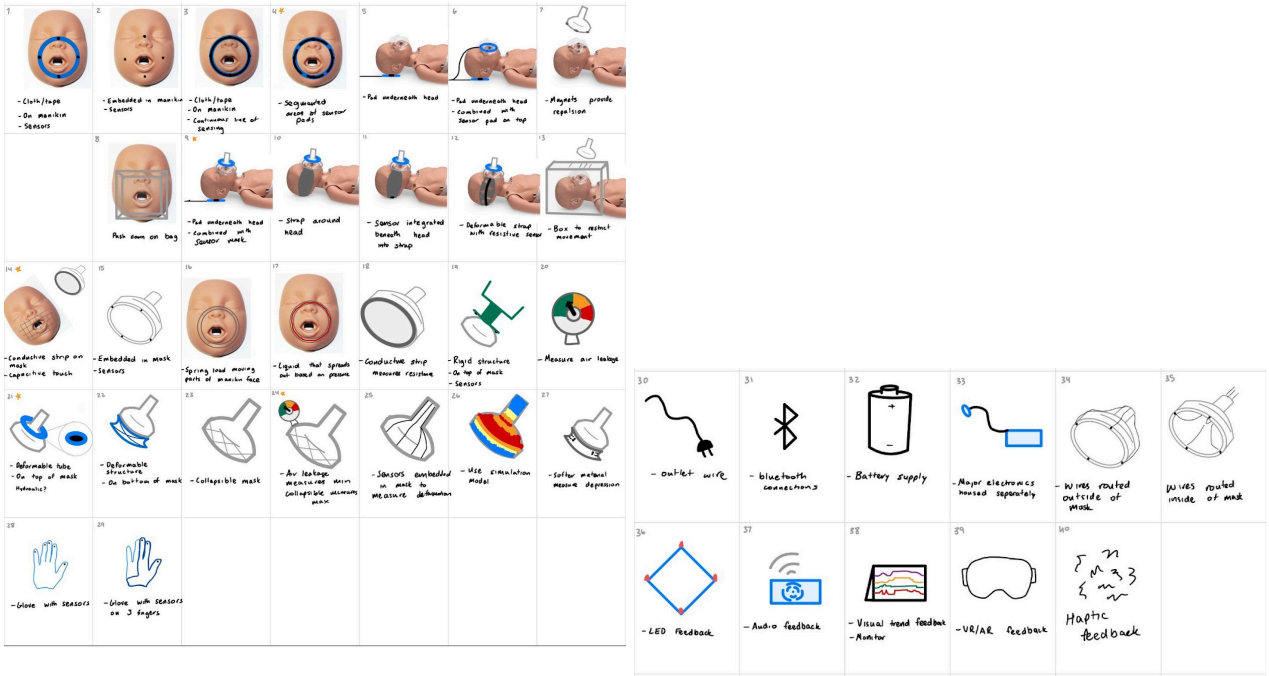


Figure A.5: Filip's 40 design concepts

APPENDIX B

Build Design Bill of Materials

Below is the Build Design Bill of Materials, detailing the prices for components used in the Gamma design prototype. Costs reflect individual component prices from packs, accounting for expenses incurred for a single prototype build.

Table B1: Build Design Bill of Materials

Part	Quantity	$/part	Total Cost ($)
Round Force-Sensitive Resistor [47]	4	3.95	15.80
Arduino Uno R3[50]	1	27.60	27.60
Through-Hole Resistors - 10K ohm 5% 1/4W - Pack of 25[59]	4	0.75	0.12
22AWG Solid Core - 6 x 25 ft[60]	1.5 ft x 6	15.95	0.96
Vaquform Forming Sheets VFlex - 20 Pack[54]	2 sheets	58.30	5.83
TOTAL COST			50.31

Manufacturing Plan

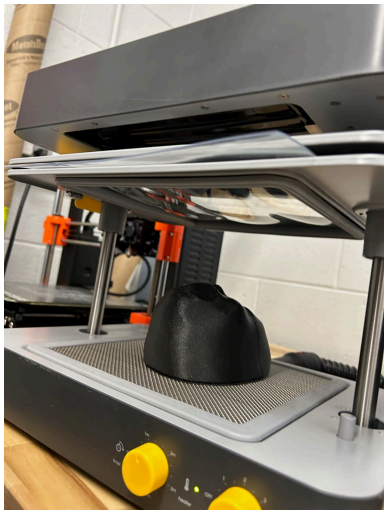
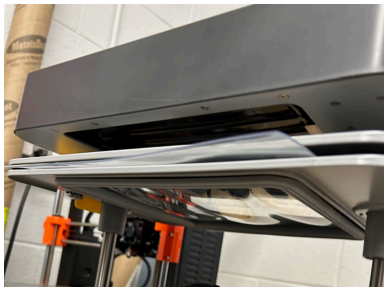
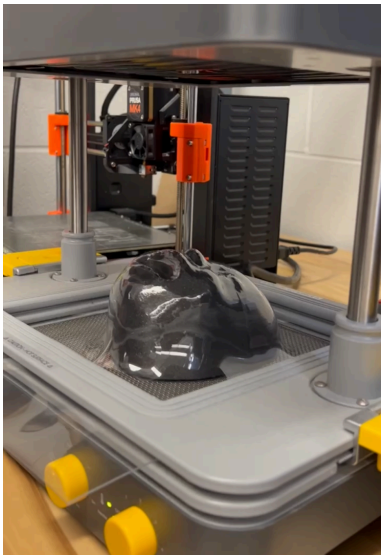
We referenced the "Vacuum Former Instructions and Example" provided by the MBSE Lab as a guide for utilizing the vacuum former in our manufacturing process.[61]

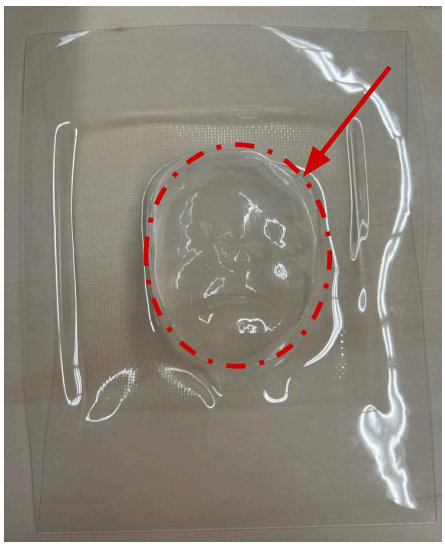
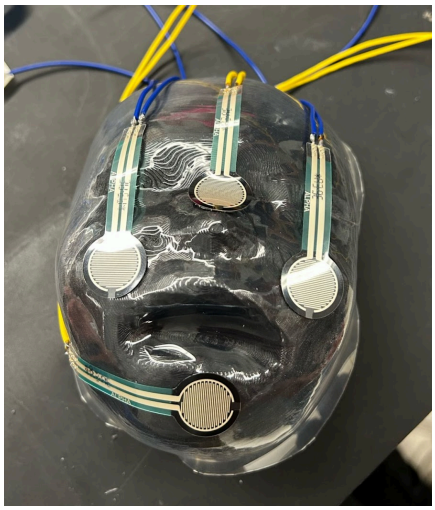
There are potential dangers associated with heating up TPU. Users should exercise caution to avoid inhaling harmful fumes and prevent burns from handling hot TPU or heated surfaces. Adequate ventilation, proper protective equipment, and careful monitoring of the heating process are essential safety measures to mitigate these risks.

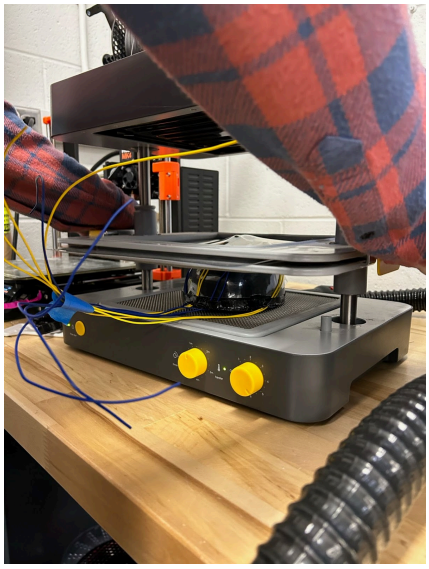
Machine used: Mayku FormBox Desktop Vacuum Former
Material used: Vaquform Forming Sheets VFlex - 20 Pack - 1.00mm material.

Table B2: Manufacturing Plan

Step	Description	Photo
1	Turn on the vacuum forming machine, set to preheated temperature of 5, and wait for 1 minute.	
2	Place the TPU material sheet in the machine under the heating element.	

3	Position the 3D-printed mold of the manikin's face in the vacuum forming machine.	
4	Wait for the TPU material to droop and watch for ripples.	
5	Slide the TPU sheet down and activate the vacuum, suctioning the material to the mold.	
6	Allow the material to cool for approximately a minute with the vacuum on.	

7	Remove the mold and molded material from the machine and trim it down to only cover the mold.	
8	Place the force sensors in their designated locations on the molded TPU material, ensuring proper adhesive attachment. (1.5 feet of 22 AWG wires should be soldered onto sensor tails beforehand)	
9	Route the sensor wires carefully, taping them down to the side of the mold to prevent snagging during the manufacturing process.	
10	Repeat the process of heating up a TPU sheet (steps 2-4).	

11	Place the mold with the previously molded sheet, sensors, and wires into the vacuum forming machine.	
12	Slide the heated TPU material over the mold and activate the vacuum to thermally bond the sheets and embed the sensors between the layers.	
13	Allow the assembly to cool.	
14	Remove the final molded TPU mask from the machine and trim it down to size.	
15	Utilize the wiring diagram to guide the connection of electrical components to the Arduino.	

Wiring Diagram

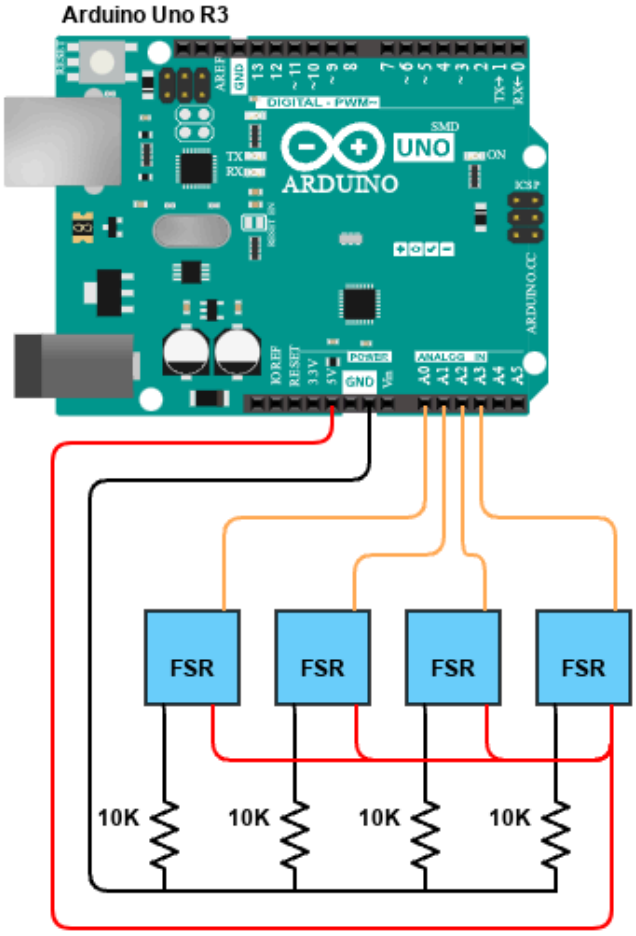


Figure B1: Wiring Diagram