Pressure-Sensing Neonatal Ventilation Mask

Design Review #3 Report
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Executive Summary

Team 25 has been tasked with designing a training device for the Stirling Research Group at the University of Michigan that can consistently quantify the pressure asserted by a clinician onto a neonate manikin during the positive pressure ventilation (PPV) procedure in hopes of improving the process of PPV training. PPV is a crucial procedure in neonatal resuscitation performed on newborns experiencing breathing difficulties within a few minutes after birth wherein a clinician delivers a controlled oxygen-rich flow into a newborn's lungs through a ventilation mask. The clinician performing PPV must be careful when holding the mask against a newborn's face as too little pressure could result in an improper seal leading to air leakages from the sides of the mask and too much pressure could result in injuries or obstruction of the newborn's airways.

Throughout the semester, we have developed design requirements and specifications that we deemed are of utmost importance given our design context, and we have subsequently undergone the concept generation and exploration process to decide upon a solution that has the capabilities to best satisfy our requirements utilizing methods taught within the course such as a Pugh chart. With the final design route specified, the team moved forward in developing a final CAD model all the while keeping in mind our requirements and specifications by utilizing FEA software and theoretical engineering analysis prior to manufacturing to ensure a strong and durable prototype. With the final CAD model, the team moved forward with manufacturing the device housing on a 3D printer utilizing PLA. Subsequently, the electronic components were attached to the housing and testing plans were created in preparation for further empirical testing to verify against our engineering requirements and specifications.

During empirical testing, testing was conducted focusing on our "Consistent Readings Amongst Hand Placements" and "Proportional Sensor Readings" requirements and their respective specifications. Resultant on our testing, we realized several areas for improvement within our device – namely, several wiring malfunctions as well as consistency and proportionality issues with regards to our sensors. Reflecting on all results from both theoretical and empirical testing, the team implemented changes to address possible sources of error into a second prototype. As the amount of time left in the semester dwindled, we were only able to conduct partial verification tests on our second prototype. The results of these tests revealed to us that many of our errors may be attributed to our choice in material utilized within our housing unit. The rigidity of the PLA housing led to a loss of contact between our sensors and the malleable mask once pressure was applied.

We recommend that future iterations of our design incorporate a more malleable housing material such as silicone, moving some if not all electronic components to be external, and improving upon the connections within the electrical subsystem. Given more time for iterations throughout our design process to implement these changes, we believe that a more optimized solution can be reached.

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Introduction

The Stirling Research Group, led by Professor Leia Stirling, at the University of Michigan focuses on utilizing sensors to measure human performance and human-machine interactions in various fields such as space, medicine, industry, and the military in an attempt to improve human performance through reducing injury risks and providing valuable feedback to experts in various domains [1]. The Stirling Research Group, our sponsors, have asked us to develop a device that can consistently quantify the pressure asserted by a clinician onto a neonate manikin during the positive pressure ventilation (PPV) procedure in hopes of improving the process of PPV training.

PPV is a crucial procedure in neonatal resuscitation that is performed on newborns experiencing breathing difficulties within a few minutes after birth wherein a clinician delivers a controlled oxygen-rich flow via positive pressure into a newborn's lungs through a ventilation mask. PPV can be delivered in two ways: non-invasive PPV is delivered through a face mask and invasive PPV is delivered through an endotracheal tube or tracheostomy – the team has been asked to focus on the non-invasive PPV procedure [2]. The clinician performing PPV must be careful when holding the mask against a newborn's face as too little pressure could result in an improper seal leading to air leakages from the sides of the mask, and too much pressure could result in injuries or obstruction of the newborn's airways. Thus, the team focused on developing a training device to help clinicians quantify safe amounts of pressure to assert during PPV as it helps lower the aforementioned risks posed by improper pressure applied during PPV. A successful project outcome would be one in which the team is able to design and make significant progress towards a user friendly training device that is able to consistently give quantitative feedback on the pressure being applied onto a neonate manikin keeping in mind the safety of the users.

Project Background

Currently, there exists no standardized tool to measure the interaction forces between the force applied onto a ventilation mask and a neonate's head. However, prior to us taking on this project, Jacqueline Hannan – a PhD student in the Stirling Research Group and one of our sponsors, has attempted to quantify the pressure experienced by a neonate manikin undergoing the PPV procedure by utilizing 4 pressure sensing microsensors which were adhered to the manikin's skin. With the sensors adhered, data on the pressure exerted onto the neonate's face and back of head during the PPV procedure was collected [3]. Her work can be better visualized in Figures 1a and 1b below.
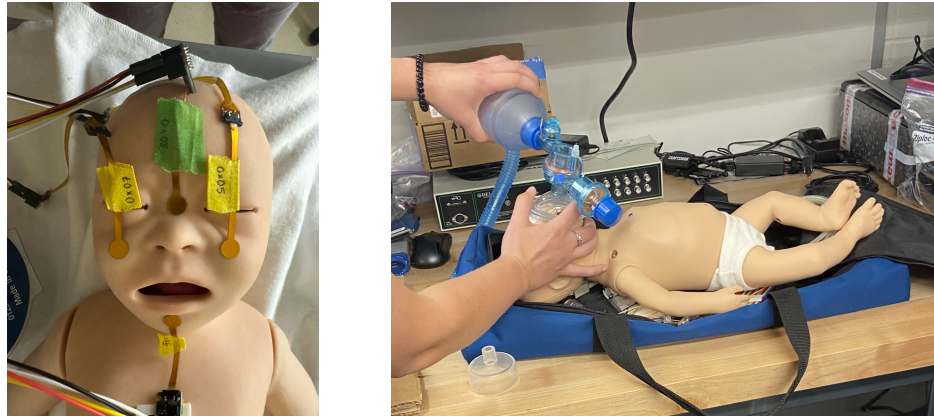
Figure 1a (left) and 1b (right). Photos depicting the locations at which the 4 pressure sensing microsensors were adhered to the manikin's skin (on the left) and the PPV procedure being performed subsequently (on the right). [4]

In terms of pre-existing PPV training, there currently exists a Neonatal Resuscitation Program (NRP) which utilizes a Resuscitation Quality Improvement (RQI) training station. The NRP is a comprehensive training program that aims to equip healthcare providers with the knowledge and skills needed to effectively perform neonatal resuscitation procedures such as PPV [5]. Within the NRP, the RQI training station, shown below in Figure 2, is used to offer healthcare providers a more personalized approach to training for resuscitation by incorporating realistic simulations using manikins and sensors to provide immediate and individualized feedback on the quality of the chest compressions, ventilation, and other aspects of CPR during a specific training session [6].

Figure 2. An image of the Resuscitation Quality Improvement training station utilized by the Neonatal Resuscitation Program. [6]

Although the pre-existing efforts have many advantages, they also have their subsequent drawbacks. Jacqueline's work is hard to replicate – she explained that the process of adhering the pressure sensing microsensors to the manikin was surprisingly hard and took her a long time to

do. Additionally, the sensors that she elected to use each had 4 short wires, making it difficult for her to centralize a location for them all to connect to an Arduino and hard to replicate in a training setting, and having 16 wires at a close proximity to a training manikin can pose a safety concern towards users [4]. The RQI has its own drawbacks as well as it can be extremely costly for healthcare facilities to invest in, would require allocating a lot of resources to – such as staffing and regular maintenance, cannot fully replicate the complexity of real-life resuscitation, and does not quantify the pressure exerted on the manikin's faces during training [6].

It is important to note that given our time constraint and the wide variety of face masks that can be used within a medical facility for the PPV procedure, under the guidance of our sponsors, we focused on developing a solution intended to be used in pairing with a circular mask. A visualization of a circular mask can be shown below in Figure 3.


Figure 3. Photo of a circular mask for which the team is designing a solution around.

Since the team utilized microsensors, there existed a need for our device to meet the standards for Medical Electrical Equipment (IEC 60601-1-2). In particular, our team focused on Parts 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests. This standard helps define electromagnetic compatibility (EMC) considerations for the medical electrical equipment that we are aiming to design [7]. Additionally, because our aim was to design a medical device that can be used in a medical facility, we considered the requirements set forth in ISO 13485: Medical Devices - Quality Management Systems. This standard helps define the design, development, production, installation, and servicing requirements necessary for our device to meet regulatory and quality standards [8]. Lastly, the team utilized the safety procedures established throughout the engineering community and taught through the University of Michigan College of Engineering such as grounding all wires and making sure these wires are well insulated.

Design Context

In determining the involvement of different stakeholders within our project, we elected to utilize a 3-ring ecosystem and stakeholder map as taught in the ME 450 Social Context Learning Block [9]. Within our stakeholder map, we identified the extent to which these potential stakeholders are impacted and involved in the context of our design project through placing them on our map

as primary, secondary, or tertiary stakeholders within economic, social, or public health ecosystems. Each stakeholder has been categorized within 6 color coded stakeholder categories and 3 ecosystem slices, indicating the role that they might play in relation to our design. Our 3-tier ecosystem and stakeholder map can be seen below in Figure 4.
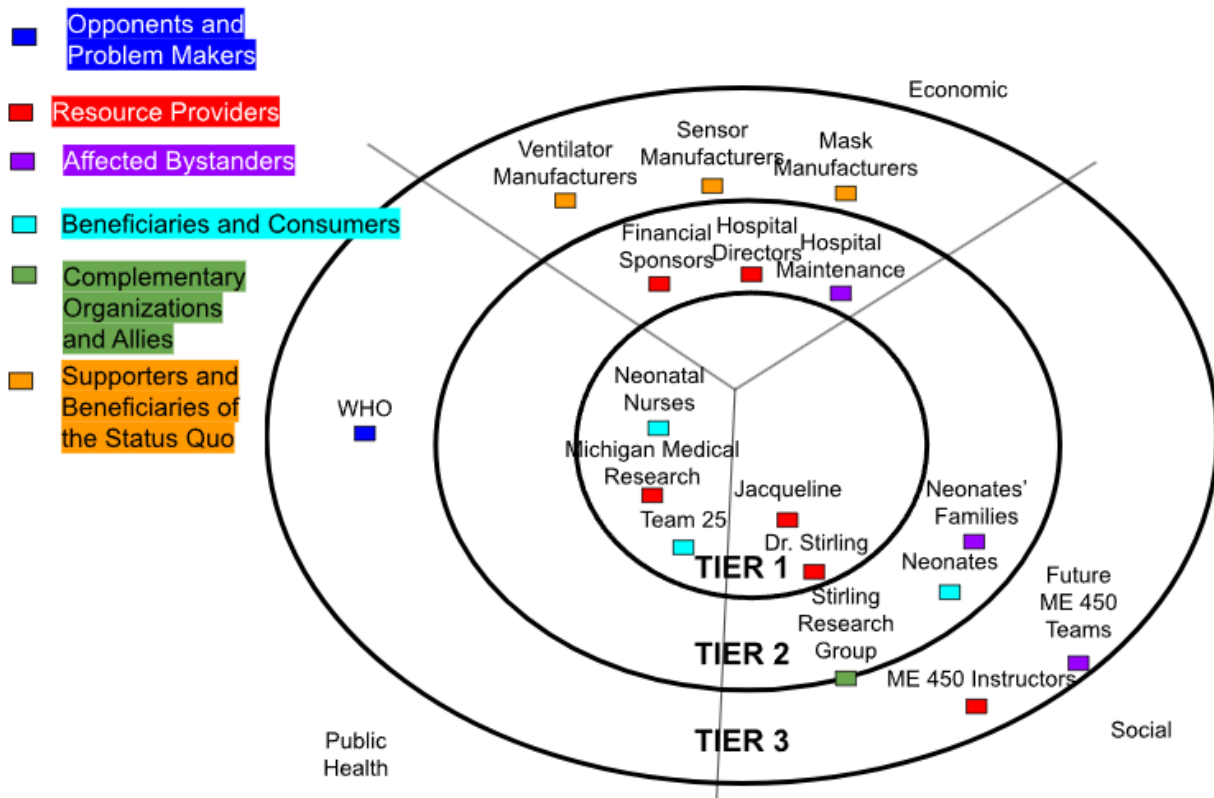
Figure 4. Team 25's 3-tier ecosystem and stakeholder map organizing stakeholders into their respective roles and proximity to the design project.

Some primary stakeholders within our project are Jacqueline Hannan and Professor Leia Stirling, our sponsors, as they have research projects that could directly benefit, in terms of data collection, from the development of our training device. Additionally, their primary role has been identified as Resource Providers in the Social context – as they provided us with financial, knowledge/expertise, connections, and technological resources and present their findings at research conventions. An example of one of our secondary stakeholders is the Neonates as they can potentially benefit from safer PPV performed by clinicians trained with our device. As these neonates' lives can potentially stand to benefit from our device, they have been tagged as Beneficiaries and Consumers within the Social context within our ecosystem. A tertiary stakeholder identified within our project is Future ME 450 Teams as they stand to potentially benefit from our efforts towards a solution in the future and stand to further improve upon both

the research and the solution. Thus, they have been tagged as Affected Bystanders within the Social context within our ecosystem. Medical facilities and practitioners stand to benefit within the Public Health context as the success of our design can potentially increase the probability of successful PPV, thereby increasing the welfare of all neonates.

Some stakeholders that stand to be positively impacted by a successful implementation of our design project would be Michigan Medical Research, Jacqueline and Professor Stirling along with the Stirling Research Group, Neonatal Clinicians, Neonates and their Families, Future ME 450 Teams, and Hospital Directors. Michigan Medical Research, Jacqueline, Professor Stirling, and the Stirling Research Group all stand to benefit from a successful design as it will greatly aid in their research attempts to quantify safe pressures being applied during the PPV process. Similarly, Future ME 450 Teams stand to benefit from our project experiences in the event that they pick up where we leave off in developing such a solution. Neonatal Clinicians and Hospital Directors stand to benefit as the implementation of such a training device would improve the PPV success rates within their facilities. Neonates and their Families stand to benefit from such a solution because, in the event that a neonate will require PPV, a clinician trained utilizing our device will have a better understanding of safe pressures to apply to the neonate during PPV, allowing for a higher success rate. As society stands to benefit from increased success rates within procreation, we expect that a successful design will have positive societal impacts.

Examples of stakeholders that could be negatively impacted by a successful implementation of our design project would be Hospital Maintenance, Hospital Directors, Financial Sponsors, Mask Makers, and Ventilator Manufacturers. Mask Makers and Ventilator Manufacturers could be negatively impacted by a successful design as they might need to develop new devices to accompany our design. Hospital Maintenance could be negatively impacted as an increase in implementations of our device within medical facilities could lead to an increased amount of regular maintenance that they must perform. Hospital Directors and Financial Sponsors can be negatively impacted by an increased expenditure – Hospital Directors will need to incur the costs of purchasing such training devices for their facilities, and Financial Sponsors will need to incur the costs of sponsoring our training device. Additionally, as the manufacturing of the sensors and other materials used within our device all have environmental footprints throughout their entire lifetimes – from obtaining these materials to end of life processing, if we are not cautious about our design choices, our device could have negative environmental impacts.

Within the context of our project, our sponsors – Jacqueline Hannan and Professor Leia Stirling – are prioritizing the potential positive social and educational impacts that a successful design could result in. These priorities will play an important role in our design choices in that we might be more inclined to choose materials with larger environmental footprints for the purpose of creating a successful solution for their intended purposes: mainly research progression. This could lead to a potentially negative environmental impact through higher footprints which can, in

turn, lead to negative social impacts such as increased pollution and carbon emissions. Keeping the potential environmental and social impacts of their priorities, we aimed to utilize materials that can be manufactured and disposed of with minimal finite resources and emissions. Additionally, we prioritized the durability of our design as a requirement, leading to a longer product lifetime and decreasing the potential number of such training devices that need to be manufactured. Being careful in our material selection process as well as designing for durability could increase the total cost of our design, but the team was willing to pay this premium to minimize the potential negative environmental and social impacts of our design.

Within our design context, our dynamics as a team, with our sponsors, and with our stakeholders was relatively inclusive – all parties involved come from different social backgrounds in terms of upbringing and socioeconomic status. Additionally, there is a good representation of different education levels with the team being enrolled as undergraduates at the University of Michigan, our sponsors being a Professor and a PhD student, and several stakeholders being medical professionals who have undergone intensive medical schooling. Everyone involved held relatively similar personal and professional ethics to the ones upheld by the University of Michigan. Keeping communication as a top priority between all parties, the team experienced little to no power dynamics felt within our design process.

Intellectual Property

As a result of there being a lack of pre-existing devices attempting to quantify the applied pressure experienced by a neonate during the PPV procedure, the team's design route was not limited by intellectual property (IP) restrictions. However, in the event that our efforts make significant headway towards a solution proposed in future ME 450 teams, our resulting IP will be owned by the University of Michigan.

Information Sources

The team determined that it would be best to meet with our sponsors to get the best understanding of their needs prior to starting the design process. Following our initial meetings with our sponsors, we met with a Nurse Practitioner who has performed the PPV procedure before to gain an understanding of the preferences of those who will be using a training device such as the one we are aiming to design. With these stakeholders' wants and needs in mind, we met with the librarian to get assistance on retrieving key pieces of literature to guide us throughout our design process. Overall, our best methods for gaining information where we had knowledge gaps was to meet with our sponsors, Professor Kira Barton, and Professor Alanson Sample as they consistently provided us with information and advice to not only answer specific questions but to guide us through our design process.

User Requirements and Engineering Specifications

Utilizing our project background, design context, and information gathered through stakeholder meetings, we chose several requirements that our design must meet to reflect our best understanding of the problem and its desired solution. Subsequently, we conducted followup interviews with sponsors and stakeholders as well as conducted thorough research on each requirement to determine a fitting engineering specification as a way of quantifying our design's ability to meet each requirement. These sets of requirements and specifications were pinnacle to our design process because as we prepared to enter our concept generation phase, these requirements and specifications helped us narrow down our design ideas to ones that were feasible and likely to meet all of our requirements and specifications within the budget and time constraints of the ME 450 course. The aforementioned list of requirements and specifications is listed below in Table 1 along with their respective references and justification.

Table 1. Tabulation of requirements, specifications, references, and justifications for the design project based on background and purpose. Within the table, requirements and specifications are sorted in order of importance with highest importance being up top.

Requirements	Specifications	Reference	Justification
Maintain the integrity of the data	Addition of the sensors and wires must not increase air leakage by an additional 10%	Sponsor interview [4]	Increased air leakage will compromise the legitimacy of the data.
Consistent readings amongst hand placements	Sensor readings should vary by less than 5% amongst various hand positions	Sponsor interview [4]	Different users will place their hands in different positions and apply pressure in different areas. This must not affect the reading of the sensors so that a full seal can be consistently created when our product says there is a full seal.
Lightweight	Under 25% of additional weight to the current mask and pump setup	Sponsor interview [4]	Device should be lightweight in order not produce much excess force on the baby's face, giving the nurse a more accurate feel for how hard to press in a real setting where this product is not used.
Proportional sensor readings	The sensor readings on the four key pressure point locations on the mask-face interface must give readings within 2% of the sensors on our product (with a factor of proportionality	Sponsor interview [10]	With the chosen alpha design, it is important that the sensors in their new locations can read proportionally the same values as the sensors placed directly on the neonate's face so we know that the location of where the user presses on the mask correlates to where on the baby's face the pressure is felt.

	included)		
Real time feedback	The turning on of the LED and the completion of the seal must be within 5ms	Sponsor interview [4]	Any nurse must be able to understand that they have created a full seal when the seal happens in real time.
Strength	Able to withstand 60N of force	Sponsor interview [4]	Device should be able to withstand the maximum force administered during PPV with a safety factor.
Resolution reliability	Have the force sensor resolution < 0.038N	A Dictionary of Psychology [12]	The minimum resolution of our sensors must be able to pick the minimum difference that a human can detect when pressing on an object.
Easy set up	Under 30 seconds for complete setup	Sponsor interview and stakeholder interview [4, 11]	Nurses are very busy and don't have time to spend learning how to assemble our product.
Appropriate force measurability range	Sensor must be able to read forces spanning from 0 to 10N	Sponsor's article [3]	This is the range of forces observed within our sponsor's study.
Durability	Must last 500 training sessions	Comparison to similar product [13]	This device must be able to withstand copious testing before losing its functionality.
Cost effective	Under $400	Sponsor interview [4]	This product should be under the practical budget allowed for this application.
Portable	Complete setup fits in a 10x5x4 in. bag (or around 200 in.^{3}) and is under 8 lbs.	Comparison to similar product [14]	The device should be portable for the sponsor to bring to whatever research site desired.

Our specifications were determined utilizing various sources and sorted in order from highest importance to lowest importance, determined through sponsor and stakeholder interview, within Table 1. Thus, it is necessary for us to highlight the following specifications and their references: From conversations with our sponsor, it was revealed to us that she would prefer a portable final design. Thus, we set our engineering specification for the portability of our device to be similar to the weight and size of an emergency defibrillator – a common portable medical device. Similarly, as we spoke to stakeholders, it was revealed that medical facilities would prefer a

reusable training device over constantly needing to purchase replacements. Thus, we chose to make it a requirement for our design to be durable. We set our engineering specifications for the durability of our device to be similar to the lifetime of a CPR dummy – a commonly used medical training device that undergoes rigorous forces during its use. Additionally, through discussion with our sponsors on how much force is typically applied during the PPV procedure, we deemed it necessary to include a strength requirement with its engineering specification being that it must be able to withstand 60 N of force – representing a 20% safety margin on the upper limit of 50 N provided to us by our sponsor's research. The final specification that we want to highlight is the resolution reliability specification. In discussion with our stakeholders, it was determined that the sensors used within our device need to correctly detect the smallest noticeable change that a human can detect – 0.038 N, thereby allowing users to receive immediate confirmation of variations in pressures that they apply. The value, 0.038 N, was determined by using Weber's Fraction for weight. Weber's Fraction for weight states that a human can notice a change in weight that is 1/53 different from its original value. Multiplying Weber's Fraction by the lower bound of force being applied during the PPV procedure found within our sponsor's research, 2 N, allowed us to determine the specification's value of 0.038 N [3, 12].

Through meetings with our sponsors, stakeholders, and through extensive research, we have concluded that some of our requirements and engineering specifications take priority over others – namely: Maintain the Integrity of the Data, Consistent Readings Amongst Hand Placements, Lightweight, Proportional Sensor Readings, and Real Time Feedback. These requirements hold a common theme: the addition of our design should not compromise the overall integrity and consistency of the data or the PPV procedure. Within the context of our final design, we kept in mind that the implementation of a heavy product adds weight to the mask and can lead to higher pressure readings than are unrealistic within a PPV procedure. Additionally, if our design is unable to provide reliable data and feedback to the user, it cannot improve upon the current training benchmarks as it would be hard to convey what a safe pressure feels like towards trainees to build muscle memory. This ties into the sensors needing to be capable of capturing the entire range of relevant forces, thereby allowing the user to receive accurate and helpful feedback during their training. It will also be important for us to keep in mind that because the sensors within our design will be placed on top of the mask rather than in between the mask and the manikin's face, we will need to verify that an increase in pressure on the top of the mask leads to a proportional increase in pressure between the mask and the manikin's face – the importance of this relationship is to be discussed later within the Problem Analysis and Iteration section.

Although we highlighted the aforementioned requirements and their subsequent specifications as a priority, the other requirements and specifications shown in Table 1 are still relevant to the success of our design. Requirements such as portability and set up time are important wants that

our sponsors and stakeholders would prefer to have, but overall, they are not essential to the functionality of the product. For example: it would be nice for our end users to not have to struggle in figuring out how to set up the device, but having a device setup time of less than half a minute is simply a "nice to have" wish as training situations are not life-and-death situations and do not require that sense of urgency.

It is important to note that we have chosen to leave out the standards mentioned in the Project Background section (ISO-60601-1-2 and ISO 13485) as there are a myriad of specifications within those standards that need to be met by our project [7, 8]. However, it should be noted that we kept those standards in mind throughout the design process.

Design Process
In deciding on a Design Process route, the team considered multiple design processes including the ME Capstone Design Process Framework and the Dym and Little five-stage design process model – a more linear model that provides no feedback loop [15]. Taking into consideration the time constraint posed by the ME 450 class, our team elected to follow a modified design process based on the ME Capstone Design Process Framework as taught by Professor Heather E. Cooper. We elected to forgo the Realization phase as we will most likely run out of time before then. Additionally, seeing that our sponsors have provided us with a well defined task, there was no need for us to include the Need Identification phase [16]. This modified design process entails a Problem Definition phase followed by a Concept Exploration phase which is subsequently followed by a Solution Development & Verification phase. We iterated through each phase as we noticed areas for improvement within our design and prototype. Additionally, as we iterated through our design process, the requirements and specifications within the Problem Definition phase changed along with stakeholder and sponsor expectations once we realized our design route during the Concept Exploration phase. The aforementioned modified design process is shown below in Figure 5.
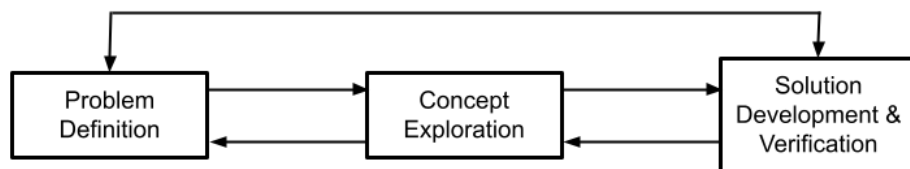
Figure 5. Team 25's elected design process showing the Problem Definition, Concept Exploration, and Solution Development & Verification Phases. As indicated by the arrows pointing both ways between each phase, the elected design process is rather fluid, allowing the team to return to phases after completing them when deemed necessary.

During our Concept Exploration phase, we generated a multitude of design concepts and subsequently down selected these concepts until we arrived at a final concept – our "Alpha Design". We then conducted engineering analysis on our selected alpha design to determine whether or not it was likely to achieve many of our requirements and specifications prior to prototyping. It is important to note that the iterative aspect of our chosen design process proved to be useful during our Concept Exploration phase: As we gained more information from our sponsors through their feedback on our design concepts, the feedback was used to update our problem definition with new requirements and specifications for our design to meet sponsor expectations.
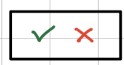
As we wrapped up Concept Exploration, we moved into the Solution Development & Verification phase. During this phase, we utilized theoretical analysis during the development of our design in preparation for manufacturing to ensure that our manufactured prototype was optimized to meet our requirements and specifications. Subsequently, we manufactured our solution prototype and developed verification testing plans. Through our testing, many areas of improvement were revealed, leading us to reiterate through our Concept Exploration through narrowing down the sources of error within our design. Upon further iteration, we implemented various changes within our design onto a second prototype, hoping to leave our sponsors and the next ME 450 team off with a prototype that more closely met our requirements and specifications.

Concept Generation
During the concept generation phase, the team utilized a comprehensive brainstorming session wherein we aimed to harness creativity and innovation by synthesizing ideas in a distraction free and non-judgemental environment. Each team member conducted individual preparation prior to the brainstorming session utilizing methods including but not limited to design heuristics and morphological charts to create 40 individual design concepts – totalling in approximately 200 individual design concepts as a team. When presenting our individual design concepts to one another, we ensured that we utilized structured communication, avoided fixation on certain concepts, and welcomed "crazier" concepts such as a glove that pumps air into a neonate's mouth upon insertion – a solution that would eliminate the need for quantifying pressure altogether. These multiple design concepts generated are displayed in Appendix A.

Coming together with our individual ideas, we noticed that there were many overlaps and similarities among the generated ideas. These design overlaps and similarities were then sorted into subsystems as each design contained: a Sensor Holding Apparatus to allow the user to interact with the sensors; a Feedback System allowing the device to communicate to the user whether the pressure being sensed is within the safe range, a Method of Seal as a method to eliminate air leakage between the mask and manikin interface, and a Wire Configuration to connect the sensors to the user interface. We then decided to consolidate these overlaps and

similarities utilizing a Morphological Matrix – a structured method for generating and exploring design ideas and solutions with each row representing a specific sub-system and each column representing a different design option within that sub-system [17]. The aforementioned Morphological Matrix can be seen below in Figure 6.

Figure 6. A Morphological Matrix used to consolidate and explore possible design concepts featuring the Sensor Holding Apparatus, Feedback System, Method of Seal, and Wire Configuration as sub-systems.

As shown in the Morphological Matrix in Figure 6, after meeting as a group, our design concepts were quite distinct from one another – some designs involved manipulating sensors onto the mask (whether it be on top of or below the mask), while others involved manipulating the sensors within the Manikin or onto the gloves used by the clinicians. Additionally, our concepts varied in their methods of feedback – whether it be visual, audio, or haptic – and the method of which our sensors would communicate with the user interface – whether it be via a cable, bluetooth, or direct sensor feedback. A more in depth exploration of the multitude of design concept possibilities within our Morphological Matrix is provided within Appendix A.

Concept Selection Process
Utilizing the consolidation of our initial 200 individual design concepts in the form of a morphological matrix, the team entered a concept-down selection process, narrowing down our possible design routes even further. As our requirements and specifications serve as a pinnacle measure of the success of our design, we made sure to reference and incorporate them as much as possible during this process.
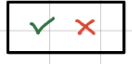
The first requirement taken into account was the ability for our design to "Maintain the Integrity of Data" – in other words, our design should not impact the airflow within the mask by a magnitude of over 10% in comparison to Jacqueline's original study [3]. With this requirement and its subsequence specification in mind, the team decided against a design where the sensors will be placed between the mask and manikin's face as doing so would most likely lead to increased leakage at the interface. We also decided against designs utilizing haptics as a feedback subsystem as any additional vibrations would likely increase the probability of improper seals, introduce extra noise into pressure readings, and create an unrealistic training setting. Additionally, upon further discussions with our stakeholders, we were deterred from designs utilizing a "sealing" sub-system as it would provide an unrealistic training setting in comparison to a real PPV scenario in which the clinician would need to manually ensure a proper seal between the mask and the neonate's face [18]. Taking this requirement and specification into account, we were able to further trim down our possible design concepts as displayed below in Figure 7.

Figure 7. An updated Morphological Matrix showing the team's elimination of design routes when taking into consideration the feasibility of certain design aspects to "Maintain the Integrity of the Data" – a high priority requirement.

Secondly, the team took into consideration the "Cost Effective" requirement – specifying that the design should not exceed the prescribed budget of $400 – and the "Resolution Reliability" – specifying that the force sensor resolution should be less than 0.038 N. Taking these requirements into account, we decided to eliminate both bluetooth sensors and sensors with built in feedback systems as both types of sensors would neither be cost effective – with bluetooth

microforce sensors averaging $129 per sensor and microforce sensors with incorporated feedback systems not having a probably product relative to our size– neither satisfy the resolution requirements – with bluetooth microforce sensors averaging 5 psi and microforce sensors with incorporated feedback systems being 20 psi in their respective resolutions [19][20]. Taking this requirement and specification into account, we were able to trim down our possible design concepts, leaving us with 3 different sensor holding apparatuses, 2 feedback systems, and 1 wire configuration. These remaining sub-system design concepts are displayed below in Figure 8.

Figure 8. An updated Morphological Matrix showing the team's elimination of design routes when taking into consideration the feasibility of certain design aspects to both be "Cost Effective" and maintain "Resolution Reliability" – both high priority requirements.

After trimming down our morphological matrix to reflect our most practical sub-system designs when taking into account our high priority requirements and specifications, we moved forward with 3 possible design configurations to take into further consideration: a rigid sensor ring on top of the mask, sensors within a manikin's face, and sensors placed on a clinician's fingers. These 3 main design concepts will be described in more depth in the following subsections.

Rigid Sensor Ring on Top of the Mask
The Rigid Sensor Ring on Top of the Mask design concept consists of an over the mask sensor holding apparatus, possibility for either an audio or visual feedback system, and a wire configuration consisting of cables. The idea is for there to be multiple sensors – the exact number of which can be further determined through empirical testing – arranged in a circular fashion on

a thin ring. This thin ring will then be placed on top of the circular mask – with the mask connection point going through the middle of the ring – during PPV training for the clinician to press on and for pressure data to be collected. A conceptual rigid sensor ring design concept can be seen below in Figure 9.
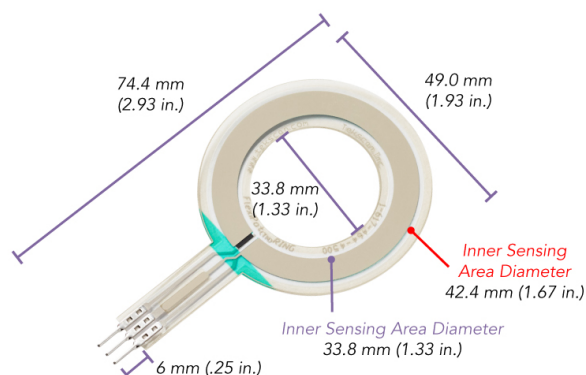
Figure 9. Conceptual rigid sensor ring design concept configuration [21]

It is important to note that in the conceptual configuration shown above in Figure 7, the wires for the sensors are shown exiting the side of the sensor ring. If the team were to elect to follow this design concept, further investigation on safety and practicality of wire orientation will need to be conducted to decide upon final wire configuration – whether it be that the wires come out of the side of the sensor ring or up through the center of the sensor ring.

Sensors Within a Manikin's Face
The Sensors Within a Manikin's Face design concept consists of a manikin sensor holding apparatus, a visual feedback system, and a wire configuration consisting of cables. The idea is for the microforce sensors to be embedded within the manikin's face at the 4 key locations shown above in Figure 1a. The wires corresponding to the microforce sensors will be routed through the body of the manikin to a feedback display. With this design concept implemented, during a PPV training session, a clinician would perform the PPV procedure as normal onto the modified manikin and data would be collected by the embedded sensors within the manikin's face. A visualization of a design concept involving sensors embedded within a manikin is shown below in Figure 10.

Figure 10. Conceptual design showcasing a manikin with embedded sensors [22]

It is important to note that in Figure 8, the manikin is shown with sensors embedded within its torso. If the team were to elect to follow this design concept, we would be embedding the sensors within the manikin's face, making sure to capture the key points on the face at which pressure is experienced.

Sensors Placed on a Clinician's Fingers
The Sensors Placed on a Clinician's Fingers design concept consists of a glove/finger attachment sensor holding apparatus, a visual feedback system, and a wire configuration consisting of cables. The idea is that these sensor attachments will be adjustable to each clinician's fingers. These sensors should be placed on a clinician's hand where contact is made with the mask during the PPV procedure. From there, the sensors will collect data and relay that data to a feedback display wherein visual feedback will be given to the clinician. A visualization of such an adjustable sensor is shown below in Figure 11.

Figure 11. Conceptual design showcasing a sensor that can be worn on one's hand [23]

With the 3 aforementioned possible design concepts, we further conducted down-selection by comparing each design's advantages and disadvantages in relation to our requirements and specifications. To easily compare the 3 different designs, we utilized a Pugh Chart – a method for translating the qualitative pros and cons of each design into quantitative data [24]. Within our Pugh Chart, each row represents a criteria on which each design was judged – these criteria were chosen based upon our requirements and specifications and are weighted on a scale from 1 to 10 (with 10 indicating the highest importance). Each of the 3 design concepts are represented in their own columns where they are rated on a weighted scale from 1 to 10 based on how well they meet the criteria (with 10 indicating the highest ability to meet the criteria). Additionally, within each row, justification as to why the criteria was chosen, why each criteria received the weighting that it did, and why each design concept received its respective score is provided. Our Pugh Chart is shown below in Table 2.

Table 2. Pugh Chart of Team 25's final 3 design concepts. Each row represents a different criteria upon which the designs were judged against. The weight column indicates the importance of each criteria on a scale from 1 to 10 (10 being the most important), and each design's column indicates the ability of the design to meet said requirement on a scale from 1 to 10 (10 representing the highest ability). Justifications for each criteria, weight, and design score is provided within the light gray box in each cell.

Criteria	Weight	Rigid Sensor Ring on Top of Mask	Sensors Within a Manikin's Face	Sensors Placed on a Clinician's Fingers
Maintain Integrity of Data	9	9	6	10
Increased air leakage due to added sensors/wire placement should not compromise the legitimacy of the data	Wire placement will be crucial to be out of the way of the seal but still existent to obtain real time data	The wiring will happen above the mask, so the integrity of the seal should not be affected	If the sensors are on the inside of the skin, there will be "bumps" coming out of the skin, compromising the seal	The sensors and wiring would not occur where the seal is (they would occur closer to the clinician's hands), so this would not affect the seal at all
Real Time Feedback	9	7	5	4
Any clinician should be able to understand if they are applying a safe amount of pressure in real time. For this to happen, the force readings must be reproducible across multiple training sessions.	It is crucial that force readings are reliable and reproducible so that the design can be used by multiple users during multiple sessions and still be reliable under such variation.	The sensors will stay in the same place with respect to the ring each time, but the alignment of the ring with respect to the mask could pose an issue.	The sensors embedded inside of the manikin never move, but the clinician may place the mask at slightly different locations each time.	Positioning of clinicians' hands is the most variable since attaching sensors at variable locations would create inconsistencies as well as introduce different force vectors, requiring post processing.

Durability	8	9	10	4
This device must be able to withstand copious training sessions before losing its functionality.	The product should be able to withstand built up stress over time sufficiently so facilities will not incur the cost of replacing them frequently	The ring will be composed of a rigid material to be able to experience loads throughout time, but this design runs the risk of breaking as it is a one-off piece.	The sensors will be embedded within the manikin and will require no additional load bearing objects, so this design is a great option for durability.	The sensor attachment apparatus will be made out of the flimsiest material of the 3 design concepts, so durability over time is a real concern.
Lightweight	8	9	10	7
Device should be lightweight to not produce much excess force on the manikin's face, giving the nurse a more accurate feel for how much pressure to apply in a real setting where the training device is not used.	This is important in ensuring a realistic training setting wherein the clinician is taught an accurate safe pressure to apply that isn't altered by the addition of our device.	Additional weight is added, but this amount should not be significant as the material will most likely be PLA.	No additional weight is added to the mask as the sensors are implemented within the manikin.	There will be added weight on the clinician's fingers and hands, affecting how they perceive their hand motions.
Easy Set Up	7	6	8	7
Clinicians have a lot on their plate and figuring out how to set up our training device needs to be a simple process catered towards someone without an engineering background.	Due to the fact that this will be utilized in a training setting, set up time is important because we do not want to waste clinicians' time but it is not crucial to the life of a neonate.	The rigid ring with the wiring will need to be placed over the mask which may lead to increased setup time when trying to connect the mask with the rest of the PPV equipment.	This will take create a long setup procedure for those implementing the sensors into the manikin, but once setup, the manikin will require zero setup time for the clinicians	The clinicians will need to put on specialized gloves/make sure they are placing the sensors on the correct locations. This, along with the additional wires from each sensor, will probably lead to an increased setup time.
Strength	7	10	8	4
The device should be able to withstand the maximum force administered during the PPV procedure with a safety factor.	A product that undergoes mechanical failure is no good because it will limit contracts with hospitals after they see that our devices are not strong enough. This is important but not the most deciding	Only the force of the hand will be felt, not the weight of the mask	The load of all of the mask, hands, and manikin's skin will be felt – this will be more force than in other cases.	Direct contact between the sensor and the mask will be felt, and there would be a high impulse since there would be nothing to "cushion" the force being applied directly from the clinician's hand.

	factor and different from durability in the sense that it can withstand the maximum allowed force at least once.			
Cost This design should be produced within the practical budget allowed for this project.	6 Because this will be used multiple times, this becomes less important since hospitals will be more willing to spend more money on a reusable device.	8 This should be a simple to manufacture part that should not cost much beyond sensors.	2 Extensive amounts of cost and research will be needed to adequately integrate sensors within the manikin's skin.	7 Devices such as this already exist, but in bluetooth. A challenge would be integrating wired microforce sensors into these devices to meet the resolution requirements.
Portable The device should be portable in the sense that it is easy to move it between different clinicians during training.	5 This would be more of a "nice to have" than a "need" based on our stakeholder preferences [4].	10 Relatively small parts that can easily come off one mask and onto another or into storage.	8 Storage of manikin in between sessions could require special enclosures to ensure embedded sensors stay intact.	9 Gloves/attachable sensors can come off one clinician's hand and onto another's or into storage.
TOTAL SCORE		498	423	378

One of our highest weighted criteria was the ability of the device to "Maintain Integrity of Data". It is important to maintain the integrity of the air leakage data through ensuring that the addition of the design does not impact the ability of the mask to seal to the manikin's face. A disadvantage of the "Sensors Within a Manikin's Face" design concept was that bumps from the implementation of sensors within the skin could create barriers to creating a complete seal between the mask and the face. An advantage of the "Sensors Placed on a Clinician's Fingers" design was that the sensors would be implemented between the clinician's fingers and the mask – thus, any sensors and wiring will be completely out of the way of the interface between the mask and the manikin's skin.

Another of our highest weighted criteria was the ability of the device to produce "Real Time Feedback" as reproducible pressure readings between different clinicians throughout different training sessions is crucial towards clinicians' ability to gain muscle memory on what applying a safe pressure feels like during PPV. An advantage of the "Rigid Sensor Ring on top of Mask" design concept is that, given a good design indicating the alignment between the sensor ring and the circular mask, it is easy to reproduce consistent data between multiple training sessions. A disadvantage of the "Sensors Placed on a Clinician's Fingers" design is that the positioning of

the sensors in relation to the clinician's fingers are likely to vary between training sessions, making it difficult to reproduce pressure readings throughout different training sessions.

Based on the results of the Pugh Chart within the Concept Selection phase, the highest scoring design concept was the "Rigid Sensor Ring on top of Mask" design, followed by the "Sensors Within a Manikin's Face" design and subsequently the "Sensors Placed on a Clinician's Fingers" design. Thus, we decided to move forward with the "Ring Over the Mask" design as our "Alpha Design".

Our initial concept upon project assignment consisted of designs wherein the sensors were implemented between the mask and the manikin's face – similar to Jacqueline's setup. In comparison to our selected design concept, our initial concept is quite similar – with the biggest difference being where the sensors are to be located. In our selected design, we plan on implementing the sensors on top of the mask whereas in our initial concept, we envisioned implementing the sensors below the mask where it meets the manikin's face. Although we tried our best to generate concepts uninfluenced by our initial concept, there may be some indication of fixation on our initial concept as one could argue not much has changed. However, we did take into account other vastly different design concepts, but when comparing the concepts to one another and our requirements and specifications, the "Rigid Sensor Ring on top of Mask" design did prevail. This may be due to the fact that, given the circumstances of the PPV procedure and the wide variety of possible users, it would be hard to implement other designs – especially those that do not pertain to the mask – that would allow for consistency and reliability in data collection given our time and budget constraints.

Selected Concept Description – The "Alpha Design"
Utilizing a Pugh Chart, the team decided to pursue the "Ring Over the Mask" design concept as our "Alpha Design". Although our sponsors have raised concerns of possible pain points for designing a device intended to be used on top of the mask as opposed to under the mask, we have decided to go forward with this design as it minimizes the amount of air leakage that could occur as a result of the addition of our device, thereby maintaining the integrity of the data. Additionally, through considering this design concept with other design concepts against our requirements and specifications with as much of an unbiased mindset through our Pugh Chart, this particular design seems to best meet the requirements and is the most feasible design given our budget and time constraints. We believe that a completely objective selection process given the same budget and time constraints would lead us towards this design concept as well – if we were given more time and a larger budget however, a different design concept might be better suited.

Our Alpha Design consists of a couple key subsystems that, when put together, function to quantify the pressure being applied during a PPV training procedure and communicate the safety

of that pressure back to the trainee. To better understand these subsystems and how they work together, Figures 12a and 12b are provided below.
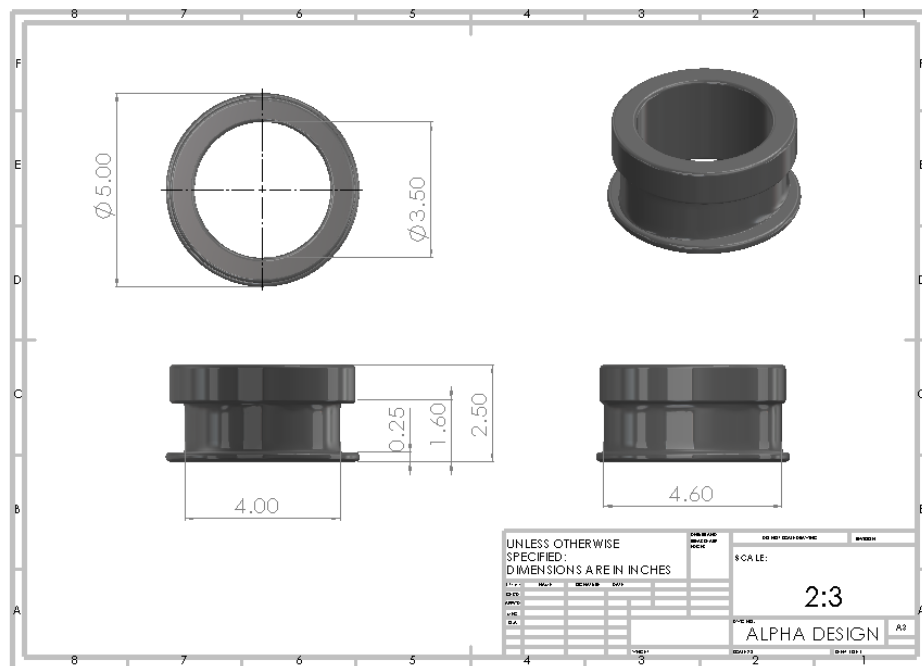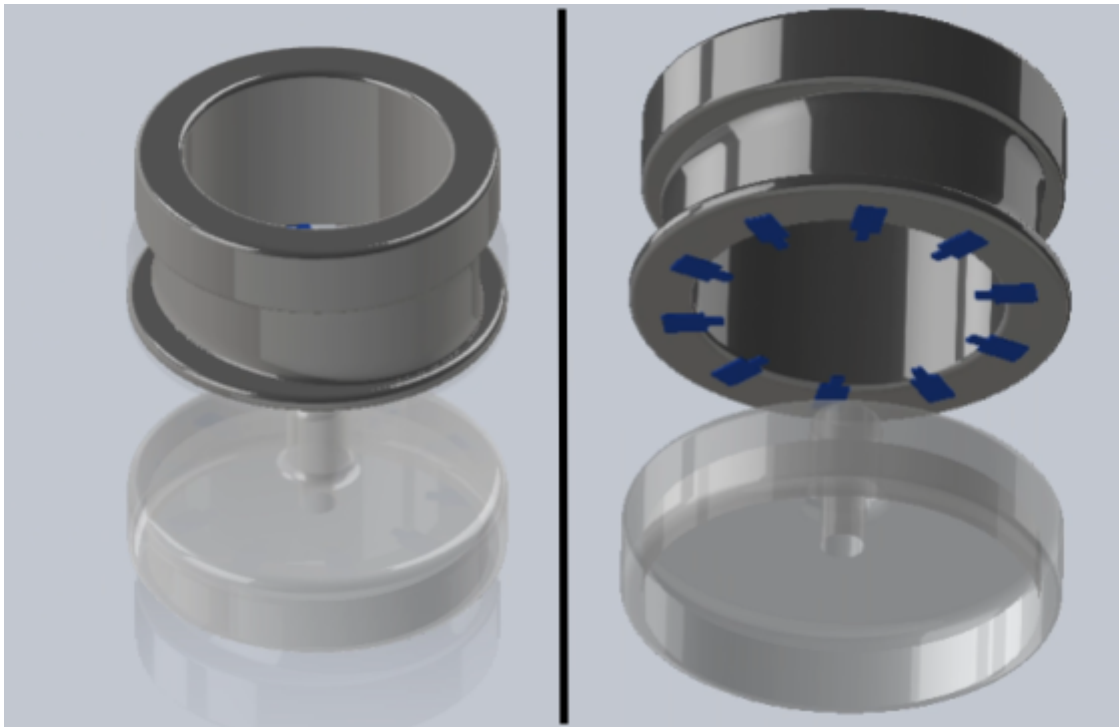
Figures 12a (top) and 12b (bottom). Figure 10a displays a 3-D CAD model showcasing the bottom surface of the ring where the sensors are to be attached. Figure 10b displays

an engineering drawing of the entire ring (not just the bottom surface); it is important to note the elliptical aspect of the ring, allowing for the orientation to be determined.

After doing research on lightweight and sturdy materials, the team settled on polylactic acid (PLA) – a thermoplastic made from renewable resources that is known for being lightweight and having a relatively high strength-to-weight ratio – to be used in manufacturing the rigid ring (displayed in Figure 10b) [25]. The team decided on PLA not only for its ability to be relatively strong while also being lightweight – thereby having the capabilities to fulfill our durability, strength, and light weight requirements, but also based on the fact that it is one of the most popular materials used within 3-D printing [26] – allowing for a relatively cheap and accessible manufacturing process for the team. To verify the durability and strength of this rigid ring, we plan on conducting load testing on a 3-D printed prototype and seeing whether or not it can withstand our upper-bound load of 60 N. It is important to note that the rigid ring is elliptical on its extruded top portion. This was a purposeful design choice so as to indicate the alignment of the ring in relation to the circular mask to be used during training – our plan is to indicate to our users that the front of the mask (where the manikin's nose will be) should be lined up with a circular portion of the ellipse (as opposed to a flatter portion).

Within our design, we plan on implementing sensors onto the bottom-most surface of the rigid ring. Currently, we are in the process of utilizing engineering concepts, such as circuit diagrams, and seeking out advice from electrical engineers and our sponsors to help determine the exact number of sensors to be implemented onto this bottom-most surface. In regards to the wiring of the sensors, our current plan is to thread the wires up through the middle of the ring and up around the PPV equipment tubing towards a user-interface. Keeping user safety in mind, we will try our best to minimize the amount of cables coming through our device through analyzing electrical circuit diagrams and assessing whether or not we can combine cables together. Once our wiring configuration is determined, we plan on developing a user interface – currently, we hope to create a user interface that can be run on any computer, allowing for a plug-and-play easy and intuitive training setup.

As we kept in mind our design constraints – including our budget and time constraints – during our concept down-selection phase, we believe that our design concept is achievable within the timeframe of the ME 450 course. However, we have kept in mind that this initial alpha design may not be perfect. In the event that we run into any issues or notice any areas of improvement, we plan on iterating through our design process and assessing the issue at hand to come up with a solution that can be implemented within the timeframe of the ME 450 course.

Engineering Analysis
In the analysis of our design, we focused on the mechanical engineering fields of solid mechanics as well as electromechanics as the success of our design is largely dependent on the

ability of our electrical components to function properly within a static, PLA housing. During our engineering analysis phase, we focus on static mechanics analysis utilizing FEA in Solidworks to determine the mechanical properties of our design and its capabilities of meeting our requirements and specifications for strength and durability. We also utilized wiring diagrams and the help of Professor Alanson Sample to determine the ability of our electrical components to work well within our housing. With the theoretical analysis completed, we proceeded into our manufacturing process of our first prototype. Utilizing our first prototype, we conducted empirical testing to determine the capabilities of our design to meet several other requirements and specifications utilizing the engineering analysis outlined below in Table 3.

Table 3. A tabulation of our engineering requirements and specifications, their relative priorities, and their plans for engineering analysis.

Requirement	Priority	Specification	Engineering Analysis
Real Time Feedback	High	The turning on of the LED and the completion of the seal must be within 5ms	Attach our wired sensors to a computer to validate that force sensor readings are updating within 5 ms when different amounts of pressure are being applied.
Strength	High	Able to withstand 60N of force	Conduct finite element analysis on the prototype housing CAD model to determine the strength.
Resolution Reliability	High	Have the force sensor resolution be < 0.038N	Mark the sensor readings when 0 and 10N are being applied, then divide 10 by that sensor reading range to derive the resolution.
Durability	Medium	Must last 500 training sessions	Conduct theoretical analysis utilizing Paris' Law for crack propagation during cyclical loading on a simplified shape representative of our prototype housing and verify that 500 training sessions is achievable. [30] Verify with Professor Alanson Sample that our method of wiring electrical components minimizes

			risks of overloading.
Appropriate Force Measurability Range	Medium	Sensor must be able to read forces spanning from 0 to 10N	With sensors wired in conjunction to the rest of the electrical components, conduct standalone tests on each sensor, verifying that each sensor is able to pick up various forces within the range of 0-10 N.
Portable	Low	Complete setup fits in a 10 x 5 x 4 inch bag (or around 200 in^3) and is under 8 lbs.	Measure our prototype and verify that it meets all the dimensions specified.

Analysis Justification

By conducting initial theoretical and empirical analysis on certain subsystems within our prototype – namely the housing and the electrical components, we tried to catch as many possible sources of errors within our prototype as possible and address them before we implement each subsystem into the final product. To start, we ensured that our housing design in CAD resulted in the dimensions stated within the "Portable" requirement of 10x5x4 inches. We also conducted FEA utilizing Solidworks to ensure that our housing design is able to withstand the upper bound of force of 60 N as stated in the specification for the "Strength" requirement while keeping in mind that although FEA is a powerful tool, it still has room for errors as it makes many assumptions such as linear material properties and idealized conditions – all of which is unrealistic. Static mechanics and electromechanical theoretical analysis were then utilized to determine whether or not our housing and electrical components are likely to last 500 training sessions, thereby addressing our specification for the "Durability" requirement. In our analysis of the durability of our housing, Paris' Law for crack propagation during cyclical loading was chosen as it is a common method of determining the number of cycles a material can undergo before failure. To conduct this analysis many simplifications, primarily on the shape of the housing being simplified down to a simple disk shape, were made to allow for calculations to be conducted. Keeping our simplifications in mind, we recognize that the resulting calculation from this analysis will yield an overestimate of the durability of our device. Finally, we ran our electrical diagram depicting the manner in which each electrical component will be wired up across Professor Alanson Sample, an Associate Professor in the Electrical Engineering and Computer Science department of the University of Michigan who focuses his research on embedded systems, verifying that the way in which each device is wired minimizes the load each component bares, thereby increasing the probability of a long life-time for our electrical components.

During initial empirical analysis, by analyzing the capabilities of our sensors alone, we are able to verify the ability of each sensor's reading to update at a reasonable speed in response to changes in force, each sensors ability to have a resolution of less than 0.038 N, and the ability of each sensor to pick up varying force readings within the 0 to 10 N range, thereby assessing the ability of our device to meet the "Real Time Feedback", "Resolution Reliability", and "Appropriate Force Measurability Range" requirements.

Analysis Results

To further explore the results of our analysis, the subsections below intend to break down the results of each analysis conducted and their implications on our design.

Real Time Feedback

In determining the capabilities of our electronic subsystem to provide "Real Time Feedback", the Arduino within the electronic subsystem was connected to a laptop with Arduino software. During our analysis, it was confirmed that all four microforce sensors produced real time force readings within the serial monitor of the Arduino software with a delay time of 1,000 milliseconds. To increase the speed of feedback, we decided to delay the feedback to be within the range of 0 - 100 milliseconds, thereby ensuring immediate feedback from each sensor. In decreasing the delay time, we made sure to check for any signs of issues posed by this decrease, and as no negative effects were observed, we decided to move forward with a 0 - 100 millisecond delay. Then, to ensure that the feedback from the sensors resulted in an immediate visual feedback for the user in the form of activated LEDs, we implemented a "threshold" – minimum force reading value to indicate activation of a respective LED – for each of the four sensors. Utilizing this threshold value, we applied varying forces on each sensor, ensuring that the respective LED was activated each time the threshold value was recorded. Thus, through our analysis, we concluded that our sensors do have the capability of providing real time feedback, thereby enabling us to move forward with our implementation of the selected sensors into the first prototype.

Strength

We used FEA analysis to determine that our strength requirement met our specification of withstanding 60 N of force. Using the solidworks model of our design, we were able to simulate a 60 N force applied evenly along the top surface of the contact ring (The surface below the housing). Dividing 60 N by the area of the ring gave us a pressure of 15 KPa. By fixing the bottom surface and applying the force, we were given the results in Figure 13:
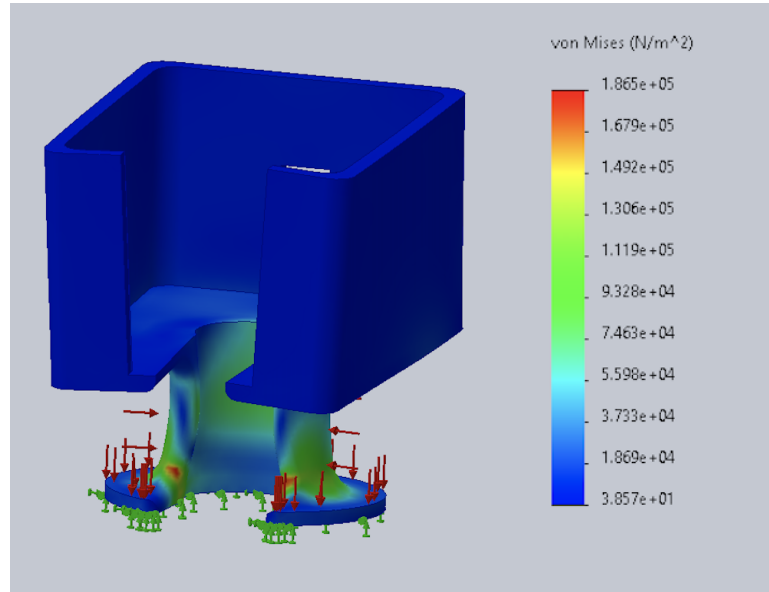
Figure 13. FEA results from our strength test.

From these results, we determined that our design is able to withhold the 60 N force, because the maximum Von Mises stress is not greater than the fracture toughness of PLA [33].

Resolution Reliability
When deciding upon the best force resistance sensor (FSR) to implement within our device, we took into consideration our cost and size restrictions as we needed to take into account our $400 budget and the relatively small housing unit that these sensors will be implemented within. Taking all the aforementioned into account, we also needed to ensure that our sensors had the capability of having a resolution less than 0.038 N, as specified within our specification. With these factors in mind, we chose a sensor that fit well within our budget (thereby allowing us the possibility of purchasing more sensors for future iterations), takes up minimal space to fit within our housing (boasting a diameter of 0.5"), and is documented to accurately read forces within the range of 0.3 – 10 N.

To implement our FSRs within our electrical subsystem, we referred to the FSR documentation which indicated that the FSRs need to be connected in parallel with a 2200Ω resistor to our Arduino. [31] With our FSRs connected to the Arduino, the FSR produced force readings in an arbitrary value referred to as "bits" here on out. By placing a scale under the FSR, an applied pressure can be associated with a corresponding bit value. We tested the FSR reading in bits versus newtons of applied force using this setup ten times. Throughout these tests, we determined that 0N of applied pressure correlated to a FSR reading of 0 bits and an applied pressure of 10N correlated to a FSR reading of 950±4 bits. From this, we were able to determine that one FSR bit corresponds to a .0105±.0004 change in Newtons – a value less than 0.038,

thereby ensuring that the resolution of the sensor is capable of reflecting changes noticeable by the human resolution. Thus, from our analysis, we confirmed that the chosen sensors to be implemented within our prototype is likely to meet our Resolution Reliability requirement.

Durability

To determine the "Durability" of our chosen design and its probability of lasting over 500 training sessions, we turned to theoretical analysis utilizing Paris' law to model cyclical loading on the base plate of our housing where pressure is to be applied. Paris's law is a mathematical justification that simulates crack propagation in a given geometric shape based on an initial crack length.

In order for us to calculate the durability of our housing, several simplifying assumptions needed to be made about the shape of our housing. To determine which assumptions would yield the most realistic calculation, we utilized finite element analysis on our CAD model as shown below in Figure 14.
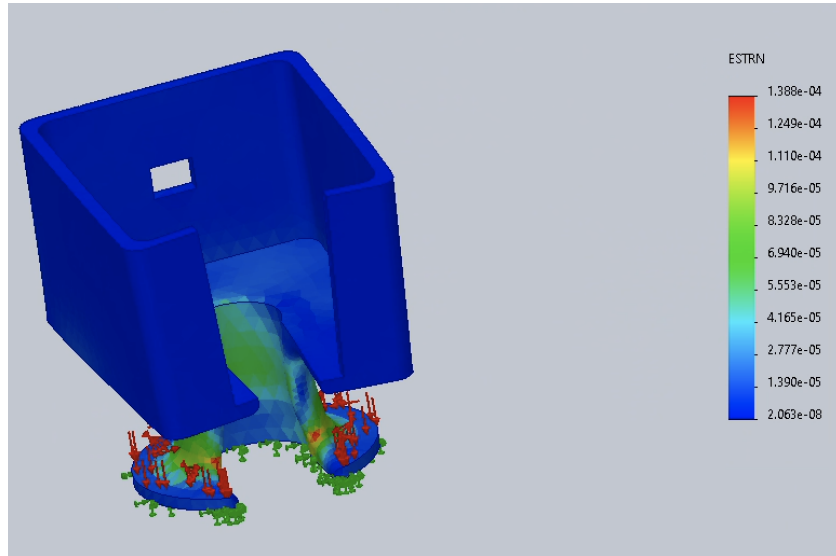
Figure 14. Finite element analysis results showing the inner radius experiencing more stress than the outer radius

As shown above in Figure 14, it is most likely that our device will fail at the inner radius of the surface upon which pressure will be applied during the PPV procedure. Thus, we decided to make a simplifying assumption of the shape of our housing down to a "disk" shape. With this assumption in place, we proceeded to utilize Paris' law for a disk with a crack propagating at the inner radius utilizing Equation 1:

$$\frac{da}{dN} = A\sigma^{50}\pi^{25}a^{25} \hspace{3cm} (1)[30]$$

wherein *a* represents the crack length, σ represents the applied stress, and *N* represents the number of trials. Our initial crack length of 0.1mm was based on the resolution of the *Ultimaker*

3 3D printer, and a failure crack length of 5 mm was based on the fracture toughness of PLA. [32] [33] Resulting from Equation 1, it was determined that our design would last $9.73 * 10^{16}$ trials, which is significantly more than our requirement of 500 trials. However, in making inferences off of this calculation, it is important to take into account that our simplifications may lead to an overestimate of the durability of our design. With that in mind, we believe the immense number of trials that this calculation yields is enough to assume our design will likely last over 500 trials.

Portability

Due to the scale of our design application as well as the preference displayed by our stakeholders for a portable device, we aimed to design a device well within our specified dimensions of 10 x 5 x 4 inches (approximately 200 in^3) and 8 lbs. In comparison, our final design is roughly 3 x 3.5 x 3.5 inches whilst weighing approximately 138 g (approximately 0.3 lbs). As all of our dimensions are well within the specification, we deemed our design is likely to be deemed portable.

Final Design and Build Description

After conducting our engineering analysis, we were ready to proceed towards prototyping. Our final design is shown below in Figure 15.
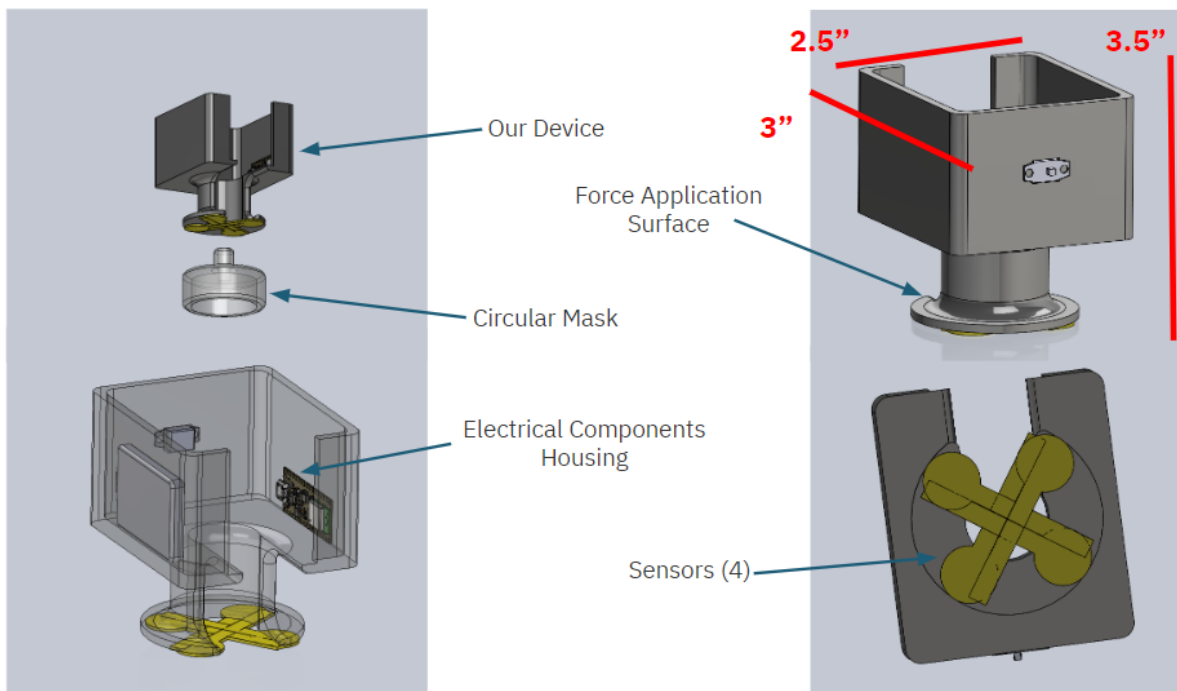
Figure 15. CAD representation of the final design that the team will manufacture for our prototype.

One major manufacturing choice we needed to make was on the shape of the housing of our device as well as the method in which we were going to manufacture it. As a result of our FEA analysis as well as our cyclical loading analysis, we determined that the initial shape of our housing would be adequate in meeting our strength and durability requirements. Additionally, through our first round of empirical testing, we iterated through our design process to implement a cutout within the housing, making it easier to implement within the setup as the manometer needs to fit in that gap. In considering which manufacturing process to utilize, we considered our time constraint as well as our budget constraint – we needed to pick a method to manufacture a durable and lightweight housing that had a quick turnaround time, was accessible to students, and was relatively cheap. Thus, we turned to 3D printing with a PLA material. During the process of narrowing down to 3D printing, we also acknowledged that 3D printing does not yield the best tolerances, but because our housing unit does not depend on tight tolerances and nor does our overall design, we decided that utilizing 3D printing would be adequate for our initial prototype. A closer look at our housing is shown below in Figure 16.
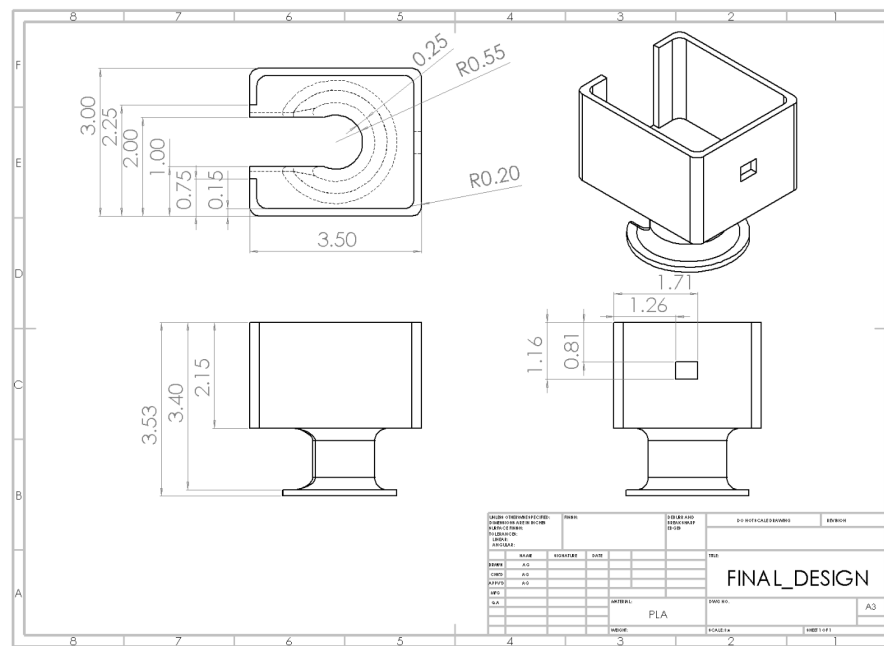
Figure 16. Detailed engineering of PLA housing to be manufactured via 3D printer.

Prior to manufacturing our design prototype, the team met with Professor Alanson Sample to run our idea past him and gain further insight and feedback for us to consider during our manufacturing process. Additionally, we ran our electrical wiring diagram, shown below in Figure 17, across him to ensure that the matter in which our device is wired will result in a working electrical subsystem.
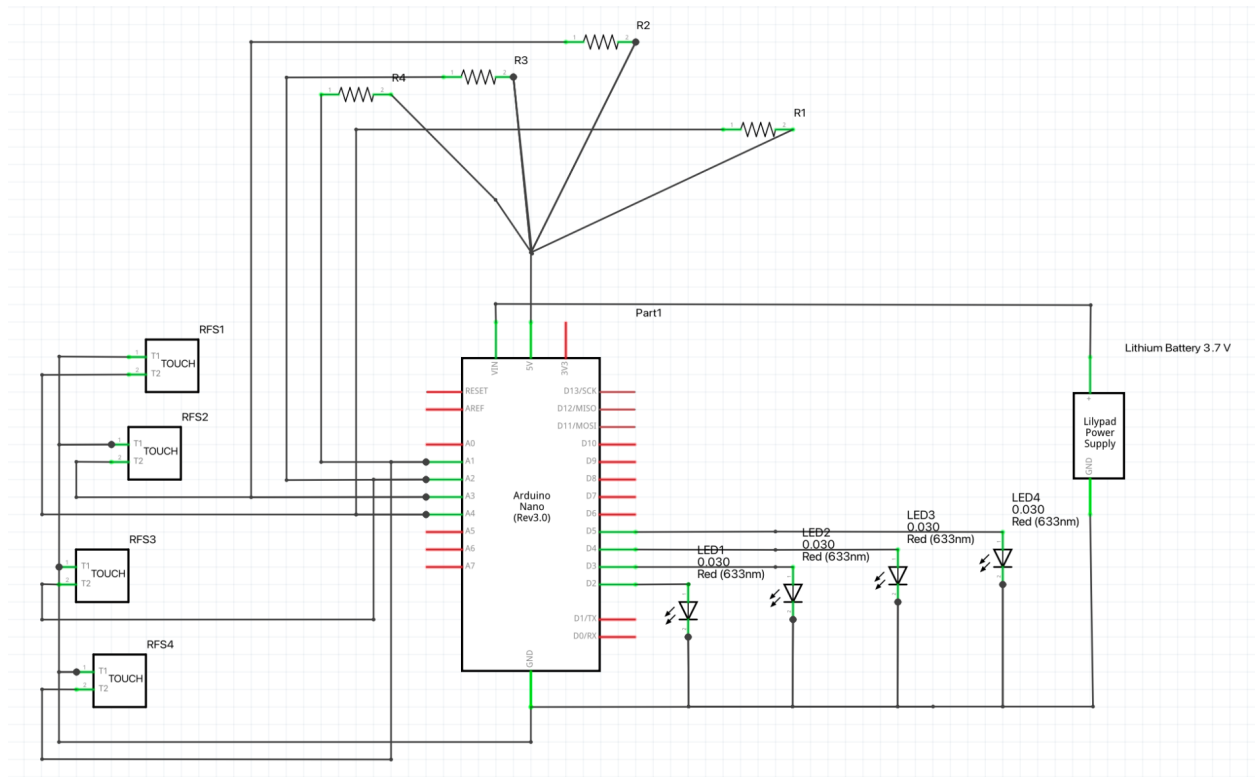
Figure 17. Electrical Wiring diagram to be referenced throughout the manufacturing process of the electrical subsystem.

During this meeting, Professor Sample also provided us with several electrical components to use within our prototype, as reflected below in our Bill of Materials, thereby greatly reducing the cost of manufacturing that we had to incur and ensuring that we were able to stay within our budget. Taking into consideration all of the materials that Professor Sample provided us, we went through our bill of materials and ordered the rest of the materials necessary for us to manufacture our prototype. This bill of materials is presented below in Table 4.

Table 4. Bill of Materials for the team's first prototype, reflecting the manufacturer, part number, per unit cost, total cost, and quantity of each material utilized. Materials provided by Professor Alanson Sample are denoted as "Provided" in the Manufacturer column.

#	Part Description	Manufacturer	Part Number	Quantity	Per Unit Cost [$]	Total Cost [$]
1	Housing	3D Printed	1	1	0	0
2	3.7V Lithium Battery	MONERATOR	953450	2	8.59	17.18
3	Arduino Nano 33 BLE	Arduino	ABX00030	1	27.99	27.99
4	0.5" Diameter 0.3~10N Force Sensitive Resistor Sensors	Adafruit	MF01A-N-221-A01	4	3.95	15.80
5	LEDs	Provided	2	4	0	0
6	Switch	Provided	3	1	0	0
7	2.2 kΩ Resistor	Provided	4	4	0	0
8	Wires	Provided	5	2	0	0
Total Cost [$]						60.91

Manufacturing Plan

Our manufacturing plan relied on the manufacturing of two key subsystems – the plastic housing of the device and the electrical subsystem to be implemented within the plastic housing. As discussed above, with the results gathered from our engineering analysis, the team felt comfortable moving forward with 3D printing out the plastic housing. As the 3D printing process proved to be lengthy and we had physical possession of all of our electrical components, we decided to go forward with soldering all electrical components in accordance with the electrical diagram, shown above in Figure A, approved by Professor Sample.

Once all electronic components were assembled, the Arduino was plugged into a computer with the Arduino software to start programming and verifying that all the electrical components worked as intended. Once programming and troubleshooting were completed upon the electrical subsystem, the electrical subsystem was secured within the PLA housing with the sensors placed on the bottom plate utilizing the preexisting adhesive on the bottom-side of each sensor. The LEDs were secured to the outside of the housing utilizing electrical tape provided within the ME X50 assembly room. Finally, the switch, Arduino, and battery pack were all secured to the inside of the housing with a sticky tack also provided within the ME X50 assembly room. Keeping in mind that our prototype has room for improvement, alternative solutions for mounting the LEDs,

switch, Arduino, and battery pack that are more durable are being looked into for the further prototype iterations.

It is important to note that the team was able to iterate through the design process and produce two prototypes by the end of the semester – the first of which underwent the bulk of the testing discussed within the verification subsections below. With the results from our verification testing on the first prototype, the team made improvements in an attempt to address several possible sources of error such as repairing loose soldering connections and reprinting the housing in order to attain more flat bottom surface. These improvements were then implemented into our second prototype, which underwent further testing limited by the time constraints of the semester. Both our first and second prototypes can be seen below in Figures 18a and 18b.
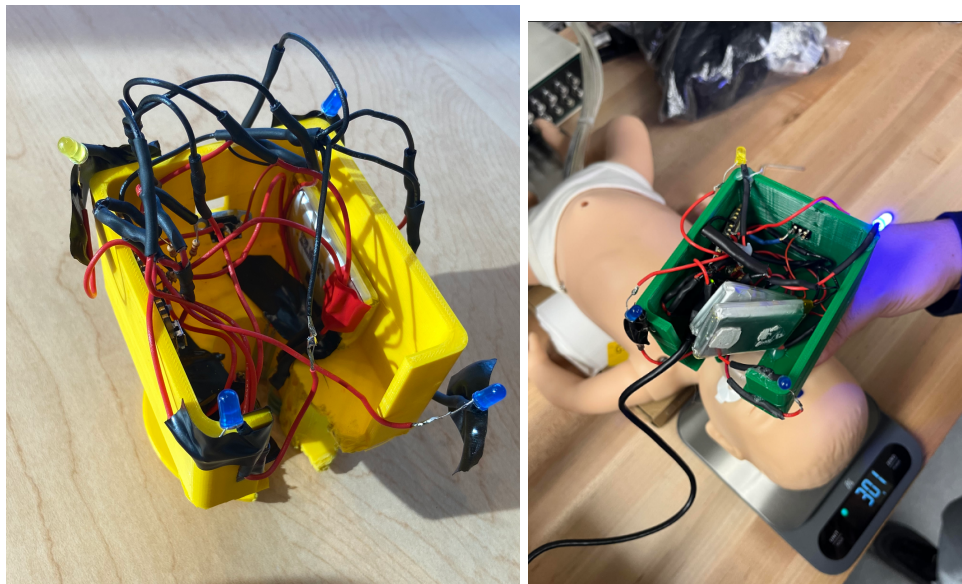
Figures 18a (left) and 18b (right). Figure 18a depicts our first prototype and Figure 18b depicts our second prototype.

Verification and Validation Plans

With our manufactured first prototype, we moved forward into our Verification and Validation phase. An overview of our methods of Verification for each requirement and specification is shown below in Table 5. As a result of the time constraints of the project posed by the timing of the semester, we were unable to address all of the resulting errored verifications. However, we implemented changes to address several errors into a second prototype and performed subsequent testing limited by the constraints of the semester. We also gained valuable insights on areas for improvement and recommendations for future iterations that will be discussed subsequently.

Table 5. A tabulation of verification plans for each requirement and its subsequent specification as well as the priority of each requirement.

Requirement	Priority	Specification	Verification
Consistent Readings Amongst Hand Placements	High	Sensor readings should vary by less than 5% amongst various hand positions	When set up on manekin's face with a flow meter, press on our prototype using different hand placements and observe the force needed to create a full seal.
Maintain the Integrity of the Data	High	Addition of the sensors and wires must not increase air leakage by an additional 10%	Attach our first prototype in conjunction to our sponsor's testing setup and verify that the addition of our prototype does not increase air leakage by an additional 10% in comparison to the setup without our prototype.
Lightweight	High	Under 25% of additional weight to the current mask and pump setup	Weigh our prototype and compare the measured weight to the weight of the mask and pump setup and verify that our device does not weigh more than 25% of the weight of the mask and pump setup.
Proportional Sensor Readings	High	The sensor readings on the 4 key pressure point locations on the mask-face interface must give readings within 2% of the sensors on our product (with a factor of proportionality included)	Attach our first prototype in conjunction to our sponsor's testing setup and collect data utilizing our sensors during empirical testing. Utilizing the data collected during testing and our Sponsor's data when she did the same exact test with her sensors on the mannequin's face, generate force-time graphs as realized by both systems and compare the results, attempting to determine a factor of proportionality.
Real Time Feedback	High	The turning on of the	With a working prototype,

|		LED and the completion of the seal must be within 5ms	apply the prototype in conjunction to our sponsor's testing setup and see if the LEDs light up when a complete seal is created (as indicated by the manometer).
Strength	High	Able to withstand 60N of force	Apply 60 N of pressure on our prototype multiple times and verify that it does not fail.
Resolution Reliability	High	Have the force sensor resolution be < 0.038N	With sensors wired in conjunction to the rest of the electrical components, conduct standalone tests on each sensor to mark the range in bits it gives between 0 and 10 Newtons.
Easy Set Up	Medium	Under 30 seconds for complete setup	Conduct field research with sponsors and stakeholders and verify that setup takes no more than 30 seconds with our prototype.
Appropriate Force Measurability Range	Medium	Sensor must be able to read forces spanning from 0 to 10N	With sensors wired in conjunction to the rest of the electrical components, conduct standalone tests on each sensor, verifying that each sensor is able to pick up various forces within the range of 0-10 N.
Durability	Medium	Must last 500 training sessions	Conduct theoretical analysis utilizing Paris' Law for crack propagation during cyclical loading on a simplified shape representative of our prototype housing and verify that 500 training sessions is achievable. [30] Verify with Professor Alanson Sample that our

			method of wiring electrical components minimizes risks of overloading.
Cost Effective	Low	Under $400	Utilize our Bill of Materials to verify that costs in manufacturing do not exceed the prescribed $400 limit.
Portable	Low	Complete setup fits in a 10 x 5 x 4 inch bag (or around 200 in^3) and is under 8 lbs.	Measure our prototype and verify that it meets all the dimensions specified.

Detailed Verification Plans

In each subsequent subsection, we will cover the verification plan as well as the results and implications for each engineering requirement and specification.

Consistent Readings Amongst Hand Placements
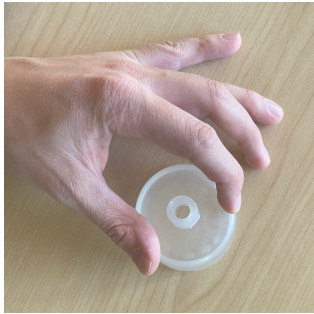
To determine what force is needed to create a full seal with our product, we first need to explore if a variance in users and hand position on our device cause a difference in the force required to make a complete seal. Within our sponsor's research, four sensors are placed on the following bone protrusions on the high fidelity neonatal manikin's face displayed below in Figure 19.
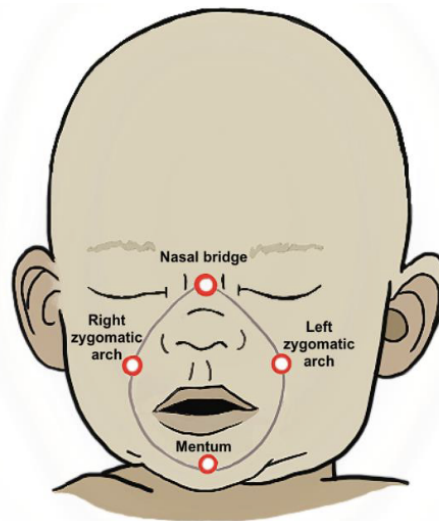
Figure 19. The locations of the four force sensors sit above the bone protrusions on the neonate's face in these locations.

Table 6. Verification Plan for determining the variability in force needed to create a full seal.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A mask and pump - Manometer - Neonate manekin - Serial monitor displaying FSR readings
Procedure	1) Set up our device on the manekin with pump delivering air to the neonate and the bar being red by the manometer 2) Align hands following one of the four positions shown below in Figure 19 3) Apply pressure and close pump until the manometer reads 25 mbar, indicating a complete seal has been created 4) Record the pressure value of each FSR 5) Five people tests each position three times – totalling in 15 data points per position

Left Hand - Out: Left elbow is bowed out and then the hand grips the mask with a CE hold.	Left Hand - In: Left elbow is tucked in and then the hand grips the mask with a CE hold.
Right Hand - Out: Right elbow is bowed out and then the hand grips the mask with a CE hold.	Right Hand - In: Right elbow is tucked in and then the hand grips the mask with a CE hold.

Figure 20. Four different ways to position the CE grip when administering PPV.

This verification plan was carried out utilizing our first prototype. After the data was accumulated, two plots were made. First, the force applied compared to different holds across all four force sensors was plotted. This data was taken from the average amongst the five users. Second, the force applied compared to users holds across all four force sensors was plotted. This data was taken from the average amongst the four holds.
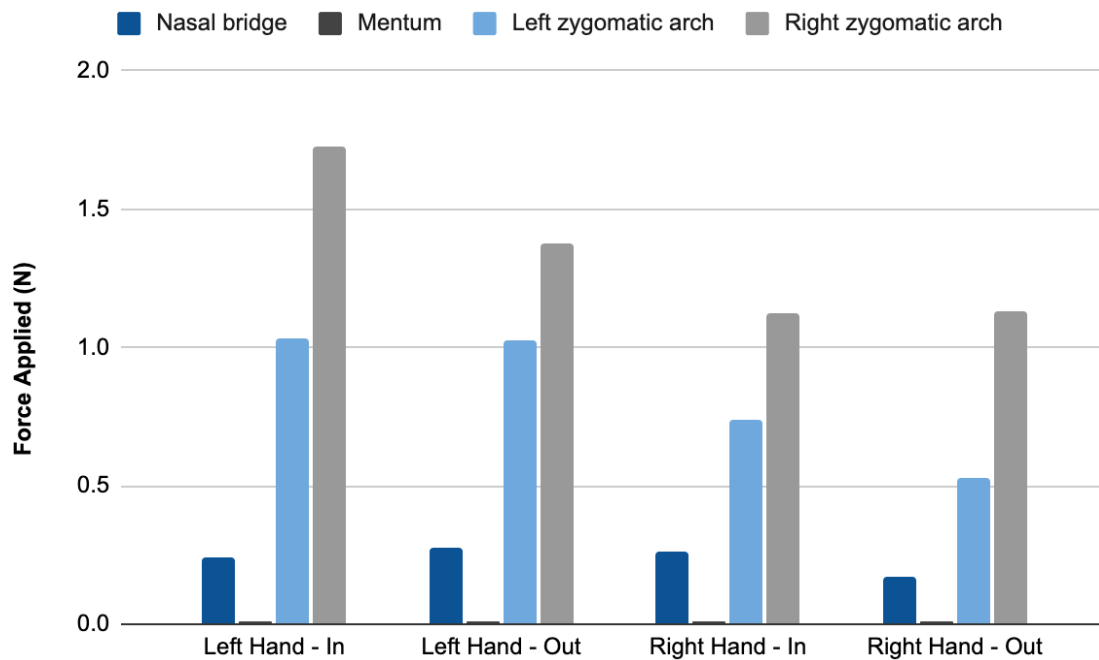
Figure 21. Force applied (measured in Newtons) compared to different holds across all four force sensors.

The purpose of this test was to determine if the different holds produce a different force required to create a full seal. From the data above, the only holds and locations that produced force readings within 5% of each other were the nasal bridge readings across all holds, the left zygomatic arch between the two left handed holds, and the right zygomatic arch between the two right handed holds. The FSR that was over the mentum had soldering disconnection during setup, which is why it did not record any data.
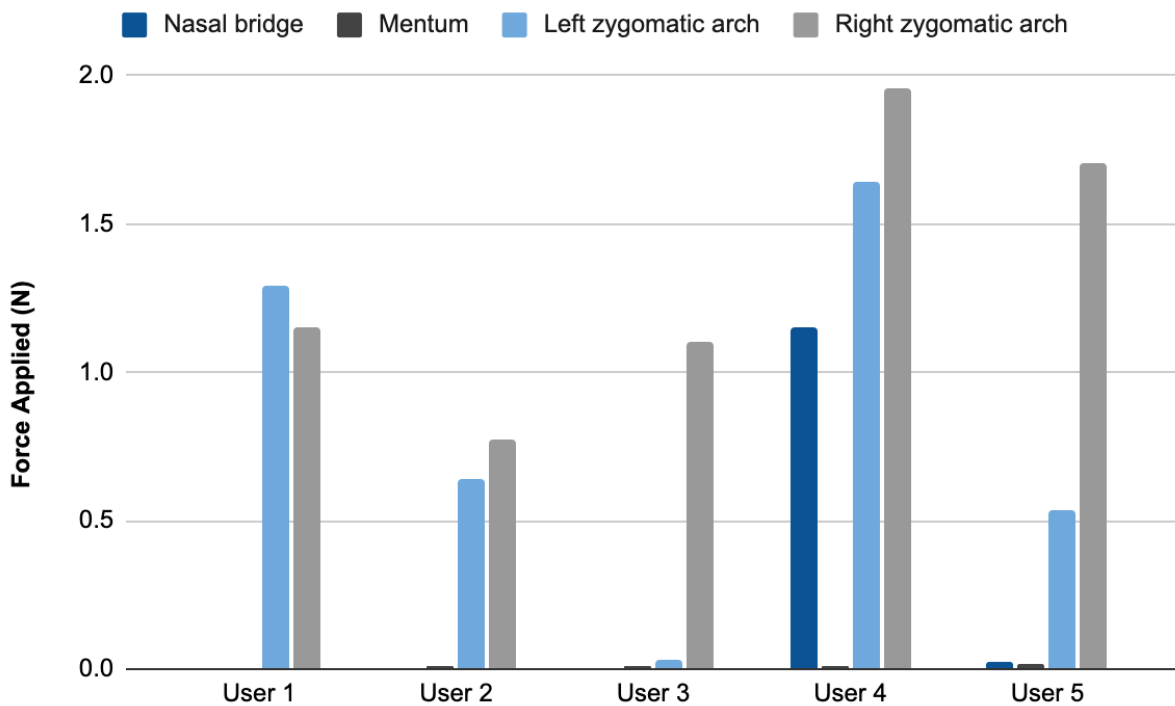
Figure 22. Force applied (measured in Newtons) compared to users holds across all four force sensors.

This graph shows our product's inability to produce consistent data. The force readings required to create full seals varies greatly from user to user. The nasal bridge was thought to give consistent readings when looking at Figure 21, but after graphing this chart, it is apparent that this false consistency comes from averaging all four users, when in reality only User 4 picked up readings for the nasal bridge. User 4 in general needed to apply greater forces across all sensors in order to create a full seal.

Several factors are being investigated as to why our product caused such inconsistent data. First, we suspect there was warping of the bottom surface of our product where the sensors sit due to an error in manufacturing: a dremel was needed to cut a wider hole for the pump to slide in. This warping might have caused uneven pressure to be placed on the different sensors. The next iteration of our prototype will be printed with this wider hole. Another source of error was the rigidity of our housing. The mask used in this test was quite flexible. If the housing could be printed with a more flexible material, it could cave in with the mask, allowing more even pressure to be put on the sensors. Other than these physical changes, it is important to instruct the user to try to align our device with the mask as concentrically as possible to promote consistency amongst users. Another technique to promote consistency amongst users would be to mark specific hand locations where the user should apply the CE grip.

After further consideration utilizing the lessons learned from testing via our first prototype, we implemented changes onto a second prototype to try and address some of the errors discovered during the first round of testing. There were two factors from the first test that negatively impacted the validity of the data: the uneven bottom surface of the housing (caused by the dremel) and the solder disconnections. With the second prototype, better soldering connections were re-made and a new housing was printed. However, due to the time constraint of the semester, we were unable to fully carry out any verification tests as we were no longer able to access the testing setup within Motts Children's Hospital. Thus, we conducted a simplified version of the "Hand Placement" test shown above in Table 6. This simplified version of our verification plan is shown below in Table 7. The main purpose of this test was simply to observe if all of our FSRs were able to more consistently read applied forces. There is verification that is being checked by this, rather this test aims to show proof that our current design is able to repeatedly measure forces.

Table 7. Simplified Verification Plan carried out on the second prototype, testing the consistency of our device.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A mask - Neonate manekin - Serial monitor displaying FSR readings - A scale
Procedure	1) Set up our device on the manekin with scale underneath the manikin's head 2) Zero the scale 3) Apply pressure and close pump until the scale reads 2500g (within the range of under the head forces typically seen in this application [3]) 4) Record the pressure value of each FSR 5) Repeat test using the same hold and user 10 times

This data was recorded, and the average and standard deviation of the forces in Newtons experienced by all four force sensors was recorded. This data is shown below in Table 8.

Table 8. The average forces and standard deviations from the force sensors across 10 tests.

	Average (N)	Standard Deviation (N)
Nasal bridge	0.257	0.217
Mentum	0.444	0.622
Left zygomatic arch	1.214	0.344

Right zygomatic arch	0.107	0.063

As can be seen above, our product still fails to produce reliable force readings. No specification is needed to know that the mentum standard deviation should not be higher than its average. Having this large of a standard deviation compared to the average is not appropriate in any manufacturing setting. It is also worth noticing that similarly to the first Hand Placement Test, the zygomatic arches received a majority of the applied force. This test reveals that the uneven bottom surface of the first prototype is not the sole reason why our part failed the hand placement test specification. Finally, this test also exposes that consistent readings were not only not achieved between holds and users, but even between tests with the same user and hold.

Overall, consistency between holds, users, and tests were not achieved. After our soldering and housing was reprinted, we hypothesize that the rigid housing was to blame for inconsistent readings. With a flexible housing, the user can mold the bottom surface of the housing around any type of mask with their hand. With a rigid housing, any slight tilt that the user applies translates to a large difference in read forces with the FSRs. Furthermore, the cheek arches always received the majority of the force. First of all, this is normal for this test because the cheek bones protrude slightly higher than the nasal bridge and mentum [3]. However, our design exaggerated these differences because our flexible mask deforms with the contour of the neonate's face while the bottom of our housing does not. This means that our mentum and nasal bridge FSRs often lose contact with the top of the mask.

Maintain the Integrity of the Data
To determine the capability of our device to "Maintain the Integrity of the Data", we check that the implementation of our device into a mask and pump setup will not increase the air leakage within the system by more than 10%. Within this verification plan, we assume that the mask and pump setup utilized within our sponsor's high fidelity setup has no air leakages of its own as many researchers and medical professionals have been involved in the testing setup which has subsequently yielded in multiple publications.

Table 9. Verification Plan for determining the ability of the device to Maintain the Integrity of the Data.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - Our sponsor's testing setup with a high fidelity manikin, flowmeter, and mask and pump setup
Procedure	1) Connect the flowmeter to the mask and pump 2) Verify that a full seal can be created on our sponsor's testing setup (indicated by a 25 mBarr reading on the manometer) 3) Connect our prototype to the setup 4) Verify that air leakage isn't increased by more than 10%

Following the aforementioned procedure in Table 9, our prototype passed the verification – the addition of our prototype had no impact on the air leakage of the mask and pump. This is largely due to the fact that when choosing a final design route, we opted to go for one which sits above the mask, thereby minimizing the risk of increased leakage during the implementation of our design.

Lightweight

To determine the capability of our device to be "Lightweight" so as to not create an even more unrealistic training setting, we check to see if our device weighs more than 25% of the mask and pump setup. This verification plan is pretty straightforward and is more so a check to see if our final design meets one of the guidelines specified by our sponsors.

Table 10. Verification Plan for determining the ability of the device to be Lightweight.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A mask and pump
Procedure	1) Weigh our prototype 2) Weigh the mask and pump 3) Check if the following inequality is met $$\frac{Weight\ of\ Our\ Prototype}{Weight\ of\ Mask\ and\ Pump} \leq 1.25 \qquad (1)$$

Following the procedure shown above in Table 10, our prototype did not pass the verification. Our prototype weighed in at 138 grams whereas the mask and pump weighed in at 100 grams. Thus, our ratio was 1.38, which as shown within Equation 1, did not meet our specification.

As a result of our prototype not passing this specification, the team looked further into how the weight of the prototype can be minimized. During this investigation, the team recognized that the Lithium battery was the source of the majority of the weight. Thus, looking forward to future iterations, some considerations should be made as to whether it would be better to design an external power supply to bypass this additional weight.

Proportional Sensor Readings

To determine the capability of our device to produce "Proportional Sensor Readings" we conducted an experiment using our sponsor's set up in the NICU offices of C.S. Mott Children's Hospital.

Table 11. Verification Plan for determining the ability of the device to produce Proportional Sensor Readings.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) connected to our computer with Arduino software

	- Our sponsor's setup with a high fidelity manikin and mask
Procedure	4) Place our prototype on top of the mask and apply the prototype/mask subsystem on top of the manikin's face. 5) Have one person apply the same hand placement on the mask across all five trials 6) Apply an increasing force on the baby's face for twenty seconds with a linear increase in force (subjective) 7) Record force data over time

Following the procedure shown above in Table 11, our prototype did not pass the specification.

The data was recorded from all five trials. For the purpose of this report, one of the trial's data analysis will be walked through. To start, simply display the force readings over time for our prototype and Jacqueline's as seen below in Figures 23a and 23b.

<div align="center">
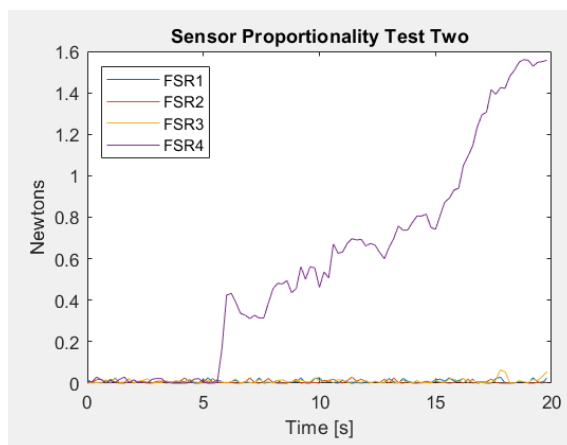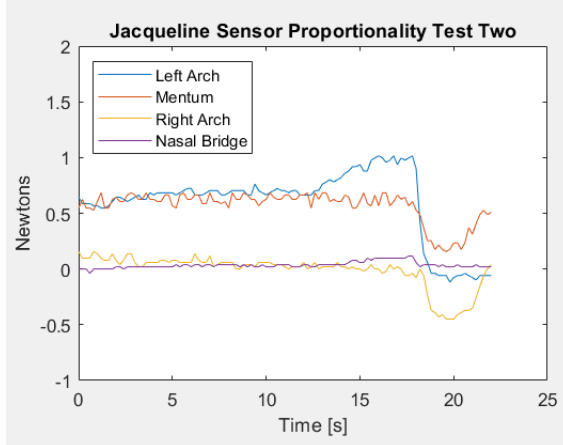
Figure 23a   **Figure 23b**

</div>

Figures 23a and 23b display force over time for the second trial. The only sensor with useful results included FSR4 which was placed on the left arch of the manikin.

To compare maximum force trends in the data, the time at maximum force must first be aligned between the two data batches as seen below in Figures 24a and 24b.
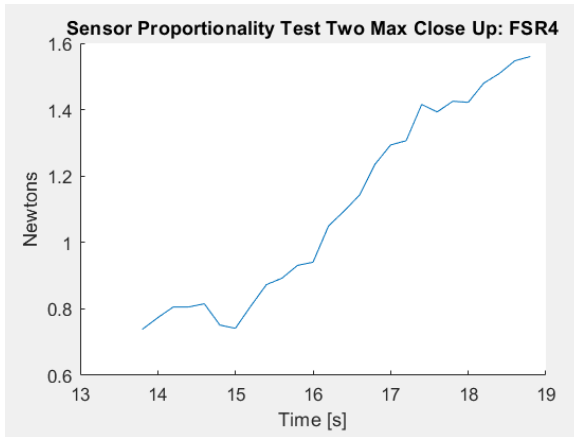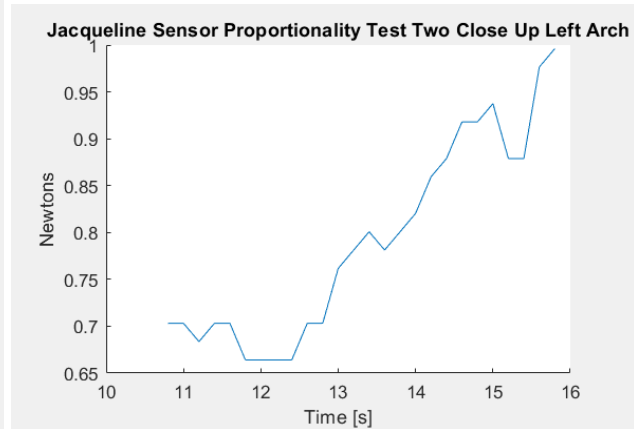
Figure 24a   **Figure 24b**

Figures 24a and 24b. show the maximum force value as the rightmost point on the graphs for the second trial. The five seconds before maximum force was reached was also graphed to see the trend before the maximum force was seen. Five seconds was deemed enough because that still encompasses 25% of the total data.

Using the maximum force trends as seen above in Figures 24a and 24b, the sensor pressure ratio can be obtained by dividing our sensor data by Jacqueline's to obtain a pressure ratio over time graph as seen below in Figure 25.
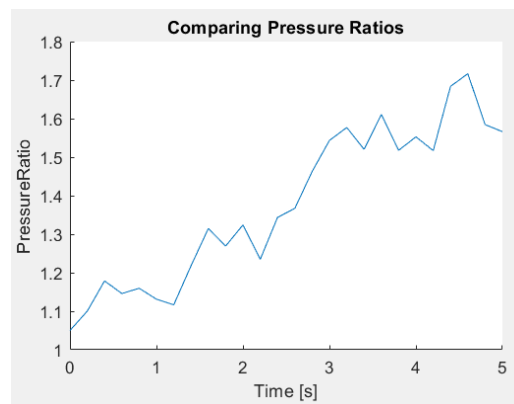
Figure 25

Figure 25 shows the pressure ratio between our sensor configuration and Jacqueline's for the second trial. A ratio was deemed more desirable than the difference between the two configurations because a pressure ratio could help inform to what degree of proportionality there is between placing the sensors on top of the mask versus below the mask.

The results of all five trials can be found below in Figures 26a to 26e.
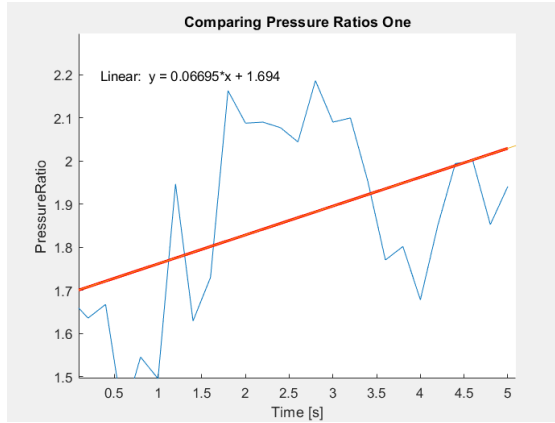
Figure 26a
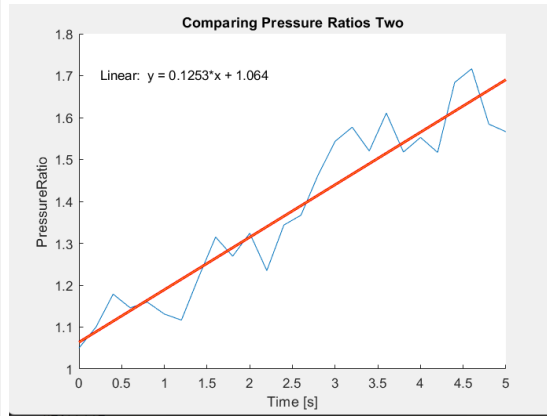
Figure 26b
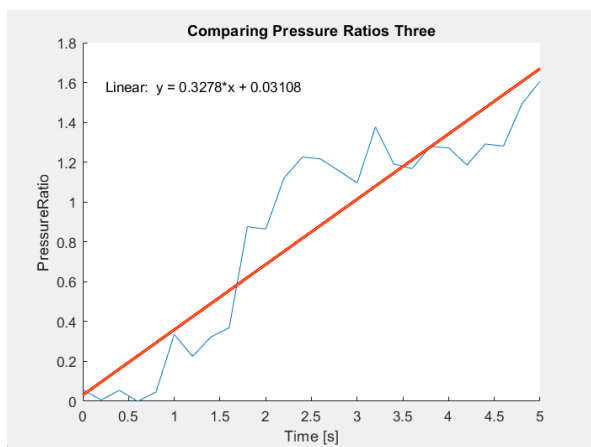
Figure 26c
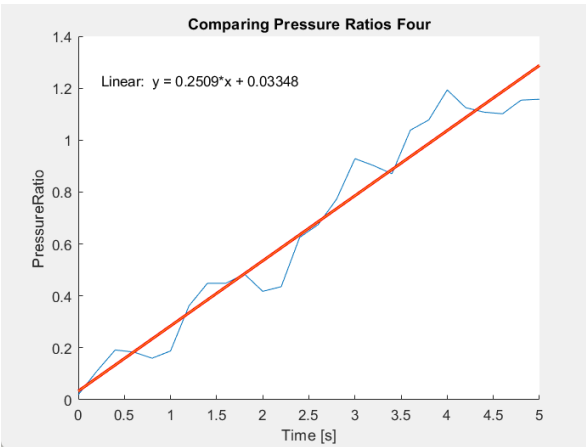
Figure 26d
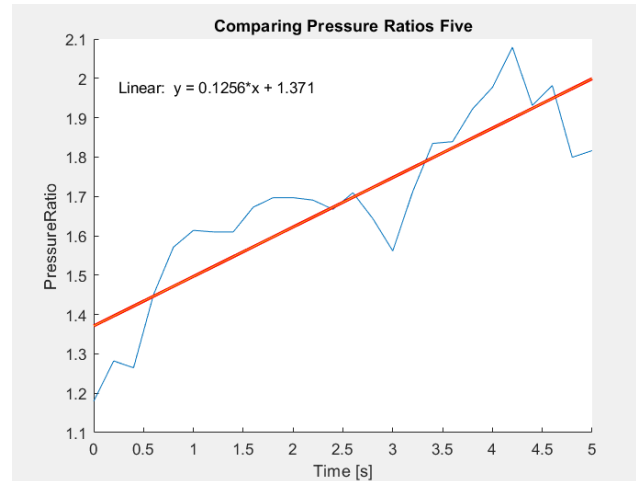
Figure 26e

Figures 26a to 26e. display the pressure ratio results over five seconds and the data crunching methodology followed suit across all five trials as walked through with trial two previously.. The average slope across all five trials was 0.1793 ± 0.1068 and the average pressure ratio was 1.2873 ± 0.5190.

The average slope is too high as we would like to see that number closer to zero and the average pressure ratio was also found to be too high. Including the error, the average pressure ratio had a subrange inside of the 0.98 to 1.02 domain, but we would like the true average pressure ratio to be within the two percent range of a pressure ratio of one.

One drawback that could help explain these results would be the fact that we only had one sensor that gave useful data. We had a sensor lose its soldering connections during setup in the laboratory and two sensors that did not appear to be making contact with the mask due to the warping of the 3D print in our initial prototype. In future testing, we would like to ensure that no soldering connections become lost and that the 3D print produces a uniform and flat surface for the sensors.

Another potential drawback could be that our mask used in testing is flimsy so a lot of the force could be absorbed into the mask. Jacqueline did not necessarily need to worry about this because her sensors were below the mask. This is why proportionality does not necessarily need to be 1 to 1 since we may need to account for the forces lost in the absorption of the mask.

We saw a positive slope for the ratio between ours and Jacqueline's force readings for the right zygomatic arch FSR. This means that at higher forces, our sensors read increasingly greater forces compared to Jacquelins. We hypothesize this is because at higher forces, the mask deflects more and more in the direction of the contour of the baby's face, meaning that contact is lost at the mentum and nasal bridge areas. In consequence, more of the force that is applied is beared on the cheek bones, which is why we saw the positive slope. The next logical step to take would be to print a housing where the bottom is flexible. If our device can deform with the mask and hold firm contact with all four functioning sensors, it could be possible to see constant proportionality among the entire range of forces.

Real Time Feedback
To determine the capability of our device to produce "real time feedback", we need to determine whether or not our device is able to communicate almost instantaneously whether or not a complete seal has been created through the activation of respective LEDs once sensors reach a specified threshold value, as discussed above within the Engineering Analysis subsection.

Table 12. Verification Plan for determining the ability of the device to produce Real Time Feedback.

Set Up	- The Arduino with the FSRs and LEDs attached (as shown in the Manufacturing Plan subsection) - A computer with Arduino serial monitor running the FSR readings
Procedure	1) Set a value for the FSRs to turn on the LEDs (we chose 200 bits). 2) Record if all four LEDs turn on within 5ms of the FSRs reading a

	value of 200 bits.

To record the speed at which LEDs were activated to convey a reached threshold pressure reading, a video of multiple testings was utilized to timestamp the speed at which LEDs activate once its respective FSR read a reading of over 200 bits – an arbitrary value chosen for the sake of conducting this verification test. Within these recordings, we were able to determine that the LEDs are able to activate within 5 ms of its respective FSR recording 200 bits. Thus, we conclude that our prototype is able to meet the Real Time Feedback requirement.

Strength

This verification plan is designed to determine the "Strength" of our device to withstand a maximum of 60 N of force. In addition to the Finite Element Analysis conducted, as explained earlier in the Engineering Analysis section, we conducted empirical testing to ensure that our device could indeed withstand 60 N of force.

Table 13. Verification Plan for determining the Strength of our prototype.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A scale
Procedure	1) Place our prototype on a scale 2) Zero out the scale 3) Apply 6,118.3 grams (a little more than 60 N) of force to the prototype 4) Check for signs of failure

Following the procedure shown above in Table 13, the team determined that our device is indeed strong enough to withstand 60 N of force, thereby verifying our FEA findings as well as verifying that our prototype does pass the verification for the "Strength" requirement.

Resolution Reliability

This verification plan is designed to determine the ability of our device to produce data reflective upon different pressing forces that can be detected by a human, thereby verifying for our "Resolution Reliability" requirement. As discussed within the engineering analysis section above, this is simply a matter of seeing if the sensors implemented within our device have resolutions below 0.038 N.

Table 14. Verification Plan for determining the Resolution Reliability of our prototype.

Set Up	- 4 sensors (the ones to be implemented in our prototype) - A computer with Arduino serial monitor - A scale

Procedure	1) Place each wired sensor (attached to the computer) on a scale 2) Zero out the scale and see that the FSR reading is 0 bits 3) Apply 10N of force and record the FSR reading in bits

Following the procedure outlined above in Table 14, we were able to confirm that all of our sensors gave a reading of 950±4 bits when 10N of force was applied. From this, we were able to determine that one FSR bit corresponds to a .0105±.0004 change in Newtons, a value well under the human resolution of 0.038 N. With the aforementioned information, we were able to deduce that a resolution smaller than what a human can detect can be recorded by our sensors, meaning that differences recognizable by humans will be adequately accounted for by our design. Thus, the selected sensors will work for our application and it has been verified that our device will meet the "Resolution Reliability" requirement.

Easy to Set Up

To determine the capability of our device to be "Easy to Set Up", we need to have a finalized, working device. As there are still many issues with the sensors in our prototype, we are unable to move forward with seeing whether or not our device is easy and intuitive to users. However, we have gone forward with creating a verification plan for when testing is made possible.

Table 15. Verification Plan for determining whether or not our device is Easy to Use.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A training manikin - A mask and pump setup - Our sponsors and stakeholders
Procedure	4) Place a training manikin and mask and pump setup on a table as you would in a normal training setting 5) Present each sponsor and stakeholder with our device 6) Have them go through the process of implementing the device 7) Observe whether or not it takes them longer than 30 seconds to implement our device 8) Receive feedback from each participant as well as observe users to learn areas for improvement

Although we are unable to conduct this procedure at the time due to our sensors not working as intended, we are decently confident that our device will be easy for users to set up. The hope is that our design, with all working electronic devices tucked into the housing, will require nothing more than sliding the device into place and then flipping a switch.

Appropriate Force Measurability Range

To determine the capability of our device to sense an "Appropriate Force Measurability Range", we need to ensure that our sensors are able to pick up on varying forces within the 0 to 10 N range.

Table 16. Verification Plan for determining the capability of our device to sense an Appropriate Force Measurability Range.

Set Up	- 4 sensors (the ones to be implemented in our prototype) - A computer with Arduino serial monitor - A scale
Procedure	1) Place each wired sensor (attached to the computer) on a scale 2) Zero out the scale 3) Start to gradually apply force on the sensor until approximately 1020 grams (a little more than 10 N) 4) See if the sensor readings consistently picked up the changes in force on the Arduino Serial Monitor

Following the procedure outlined above in Table 16, we were able to confirm that all of our sensors were able to pick up differences in forces throughout the range of 0 to 10 N. Thus, the selected sensors will work for our application and it has been verified that our device will meet the "Appropriate Force Measurability Range" requirement.

Durability

In determining the "Durability" of our design, we utilized theoretical analysis as discussed above in the Engineering Analysis section above. However, as there were many simplifications made within the Paris' law calculations, further testing needs to be conducted on our prototype to verify that our device can withstand at least 500 training sessions. Although this sort of testing cannot be conducted within the scope of this course as it requires a possibly lengthy testing procedure of over 500 trials, we have come up with a verification plan for a time permitting situation.

Table 17. Verification Plan for determining the capability of our device to sense an Appropriate Force Measurability Range.

Set Up	- Our prototype (as shown in the Manufacturing Plan subsection) - A training manikin - A mask and pump setup - Our sponsors and stakeholders
Procedure	1) Place a training manikin and mask and pump setup on a table as you would in a normal training setting 2) Present each sponsor and stakeholder with our device

	3) Have them go through the process of implementing the device totaling in over 500 training sessions (or until failure – whichever occurs first)

Although this verification test has yet to be carried out, we are highly confident that our device will last over 500 training sessions. We are able to make this assumption confidently after viewing the results of the Paris' law cyclical loading calculations performed above in the Engineering Analysis subsection.

Cost Effective

To determine whether or not our design is "Cost Effective", we needed to check that our total costs do not exceed the prescribed $400 limit from our sponsors. To do so, we kept a running tally of expenses throughout the semester in the form of a Bill of Materials as aforementioned in Table 4 of the Final Design and Build Description section. In total, our device cost us $60.91 to manufacture – a value much lower than the $400 prescribed limit, thereby verifying that our design is cost effective.

Portable

To determine whether or not our design is "Portable", we needed to measure our finished prototype to ensure that it was both within the specified dimensions of 10 x 5 x 4 inches as well as under 8 pounds (3,628.74 grams). As determined above in the Lightweight subsection, our device weighed in at approximately 138 grams – a weight much less than 3,628.74 grams. Additionally, the final dimensions of our device are 3 x 3.5 x 3.5 inches. Thus, as our prototype passed both parameters, it can be verified that our device is Portable.

Detailed Validation Plans

To validate our final design, we will need to present our final prototype to our sponsors as well as our stakeholders to present user testing. Additionally, it is important to note that, as our device is intended to help build muscle memory towards safer PPV practice, the validation of the impact of our device on this improvement will be a lengthy process. A guideline for this user testing is shown below in Table 18.

Table 18. Validation Plans of our Final Device

Set Up	- Our Final Device - A training manikin - A mask and pump setup
Procedure	1) Implement our device within a training setting with stakeholders 2) Gauge the performance of stakeholders during a PPV training session (how quick they are able to adjust to the correct pressure range and how far off their initial pressure application is from a

	safe pressure)
	3) Repeat these performance gauges over multiple training sessions
	4) Validate that the implementation of our device improves performance gauges overtime (thus building muscle memory)

As it stands, our prototypes have yet to meet all of our requirements and specifications in verification. Additionally, there may be concerns for the ability of the rigid base of our housing to accurately represent the malleable surface of a mask, thereby creating an even more unrealistic training setting than the preexisting setups. However, we believe that, given more time to iterate through our design process, there is potential for optimizing our design to implement reliable and consistent sensor readings as well as creating a more realistic training device, thereby increasing the chances for our device to improve the muscle memory of clinicians within a training setting.

Discussion

Within the contents of the following subsections, we explore the scope of our problem definition, strengths and weaknesses of our design, and an assessment of the risks associated both with our design process and our final design.

Problem Definition

As a result of the complexity of our design project – specifically in implementing feedback sensors into a training device without compromising the integrity of the PPV procedure – we found that we were unable to complete many verification and validation plans successfully. Reflecting back on our time during the r, semester, had we been given more time, we would have focused more on developing what our end goal was: Towards the beginning of the semester, our sponsors had no expectations of what type of product we would design – it could range from anything to be used in an actual PPV setting all the way to just a training device. Additionally, we went into the semester with high expectations of what we could reasonably achieve by the end of the semester. It was not until a couple weeks in that we grounded ourselves down to just a training device.

Once we had locked in on designing a training device, we utilized the concept exploration methods as taught through the ME 450 learning blocks. With our selected "Alpha Design", we moved forward in our design process. One big design choice that, looking back, we should have given more thought to is the rigidity of the base ring of our design. The rigid base made it hard for the force sensors on the bottom to interact with the malleable circular mask used during the procedure, leading to suboptimal force readings. Additionally, the rigid base made for an unrealistic feeling in comparison to the malleable mask. Not only would we question this design choice in particular more, but we would have consulted our sponsors, instructors, and literature resources more with the goal of figuring out a way of manufacturing a potentially silicon base to better mimic the texture of the mask.

As it pertains to our lack of knowledge and experience working with electronic components, we think that we did as good of a job as we could have given our limited knowledge and time. Under the guidance of Professor Kira Barton, we were able to reach out to Professor Alanson Sample to fill in all the missing knowledge and expertise that we had on the electrical sub-system that would ultimately be implemented into our design. However, creating good solders consistently proved to be an issue for our team later down the road and led to weak connections and shorts within our circuits. If given another opportunity, we would dedicate more time to perfecting our soldering skills, allowing us the opportunity to create solid connections within our electrical subsystem.

Design Critique
Some strengths within our design were the strength and durability of the PLA housing, the ease of implementation of our device, the cost effectiveness, and portability of our prototyped design. The PLA housing was extremely durable and strong for the intended purpose of our design – it would have taken a huge amount of force to actually break out housing. The success of our design in durability and strength can be attributed to the engineering analysis – both FEA and utilization of Paris' Law – conducted prior to manufacturing. We also designed our device to be simple to implement within the pre-existing PPV setup – a clinician would just need to slide our device onto the mask and pump setup via the indented cutout, line up the yellow LED to point towards the forehead of the manikin, and flip the switch to activate our device. Additionally, our device was relatively cheap to prototype, costing approximately $61, and was easily portable through our commutes across North Campus and to Motts Children's Hospital.

Some weaknesses within our design were the material chosen for the base ring of our housing, the soldering within our electrical subsystem, and the weight of our device. When deciding upon our options for manufacturing the plastic housing, we opted for 3D printing in PLA as it is a lightweight material that provides great strength and durability. Additionally, as students at the University of Michigan, we had free access to a 3D printer. It was not until after we had conducted our second round of testing on our second prototype that we realized that although our data was consistent with the data produced from Jacqueline's study showing that the forces are greater in magnitude on the high protrusions of the cheekbones of the manikin, our data was still heavily inconsistent between users and hand placements – as explored in the "Consistent Readings Amongst Hand Placements" and "Proportional Sensor Readings" verification sub-section above. From this, we concluded that the chosen material was not the best option for our application as the rigidity of the PLA base caused our sensors to lose contact with the malleable PPV mask under the application of pressure. However, given the time constraints of the course, the timing of our Thanksgiving break, and the long turnaround time of 3D printing via the University, we were unable to create a prototype utilizing a silicone 3D printer. If given the opportunity to improve upon our design, we would highly recommend researching different

materials and manufacturing processes for the housing more to better replicate the feeling of a mask.

In addition to rethinking the material selection behind our housing subsystem, we saw errors within the strength of our soldering in our electrical subsystem as well as the weight of the electrical subsystem posing to be an issue. As we went into the semester with limited soldering experience, even with our best efforts, we were unable to produce an electrical circuit with the durability and strength that would have been best suited for our design. This could be addressed in the future either through seeking assistance from someone highly experienced in soldering to aid us in assembling the electrical subsystem or from us having more hands-on experience in soldering. Once the electrical subsystem had been implemented into our housing, the resulting prototype was heavier than the weight specified within our requirements and specifications. Upon further investigation, we recognized that the majority of the weight was from the battery. Given the opportunity to improve upon our design, we would implement either an external power supply or an external electrical sub-system.

Risks
During our design process, our lack of initial knowledge posed a huge challenge. To overcome this challenge, we made sure to keep in communication with our sponsors, stakeholders, and our instructor and take their advice and guidance to heart. This proved to be extremely helpful for understanding the task ahead of us as well as for us to design as best as we could in the moment for a design route to meet our requirements and specifications.

During the concept selection process, we tried to mitigate the risks of increased air leakage posed by implementing sensors between the mask and the manikin's face by taking another risk in implementing the sensors above the mask. In taking this risk, we hoped to find a proportionality factor between the forces experienced above and below the mask. However, as we opted for a rigid PLA housing, the likelihood of us finding this factor of proportionality was slim as the rigidity of the housing restricted our sensors from meshing with the malleable mask under pressure.

While manufacturing, there were several risks associated with the soldering process: handling the solder is potentially dangerous for the team and exposed wires are potentially dangerous for users. To mitigate the risks that accompany the soldering process, the team made sure to utilize the safety guidelines taught throughout the University of Michigan – namely wearing safety glasses and ensuring a clean and safe working environment. To mitigate the risks posed by exposed wires, we made sure to shrink-wrap all exposed wires within our electrical sub-system.

Looking forward, if our device is implemented within a real-world setting, there are environmental risks associated with the sourcing of materials used within our device. For

example, the lithium battery used within our device contains many limited resources that create negative impacts on the environment both during the manufacturing process as well as the end of life process. Additionally, there could be a risk that users of our device develop a dependence on the device indicating a complete seal, leading to a negative impact on the ability of clinicians to perform PPV in the absence of a training device.

Reflection

The goal of this design project was to design a training device in conjunction with our sponsor's research data to be utilized in helping clinicians quantify safe pressures to apply during a positive pressure ventilation procedure. Seeing that the goal of our device is to help these clinicians build muscle memory, thereby increasing the success rates of the procedure, we believe that our design has the potential to help individuals all around the world from a public health, safety, and welfare standpoint. A successful implementation of a refined device would likely decrease the mortality rates associated with procreation, thereby increasing public health and safety directly. From a welfare standpoint, the manufacturing process associated with our current device is relatively cheap and makes for a durable device, making it possible to be accessible on a global scale with minimal need for replacement.

In considering the potential societal impacts associated with the manufacturing, use, and disposal of our design, we considered potential stakeholders within our 3-tier stakeholder map. Many of our stakeholders stand to benefit from a successful implementation of such a device (namely the clinicians, neonates, our sponsors, and the WHO), but we also need to consider the possible negative impacts of our device. Most importantly, we need to consider the environmental impacts associated with our design choices in utilizing plastics and lithium batteries. Although PLA produces significantly less greenhouse gas emissions when compared to conventional plastics and can be recycled, many PLA plastics still end up within landfills and oceans. Lithium batteries are manufactured using metals such as cobalt, nickel, and manganese. These metals are toxic and if disposed of improperly, can lead to water and soil contamination and fire hazards, thereby negatively impacting the ecosystems in which they are disposed of.

It is important to consider the cultural, privilege, identity, and stylistic differences, and power dynamics between each team member as well as our sponsors when reflecting back on our design process and our choices made. Although we all come from different cultural, privilege, identity backgrounds and all have different stylistic differences, it is important to note that all of our affiliations with the University of Michigan need to be taken into consideration. Being from the University, we held common engineering ethics. Throughout our design process, there were little to no disagreements in terms of ethical dilemmas. We believe that, as a team, we were honest through our design process as well as our data collection and conveyed all errors to both sponsors and instructors in a timely manner. Although we believe that we upheld the ethics as taught by the University and as we would expect from our future employers, there is still an

argument to be made that others may hold different ethical values than ours as we all share a common affiliation with the University.

Within the design process, several decisions were weighed against one another. Although each team member was able to voice their opinions on certain issues – such as preferences for design routes – we ultimately allowed our sponsors' inputs on our final 3 design concepts to guide us in our decision making. We decided that this was the best approach as they both had significantly more experience and expertise on the subject matter than anyone on the team. Throughout much of our design process asides from concept selection, we found that the team had little differences in our approaches towards the project. We attribute this to us all having gone through the X50 and X95 sequences at the University of Michigan – wherein we have all been taught to follow a similar design process. As it pertains to our sponsors, from our very first meeting, they relayed that they wanted us to follow whatever design process we felt comfortable doing so. Thus, we decided that our opinions on the design process would be of utmost importance.

If a refined version of our design were to enter the marketplace, some ethical issues might arise in where we decide to manufacture our devices and how accessible our devices really are for less wealthy areas. As it pertains to manufacturing, we need to make sure that we decide to source our components from companies in which labor laws are implemented to ensure a safe working space where workers are not taken advantage of for capital gains. Additionally, we need to take into consideration that less wealthy parts of the world likely stand to benefit the most from our device as they suffer from higher birth mortality rates. Thus, an effort should be made to boost the distribution of these devices to the less wealthy populus.

Recommendations
For future renditions of this design project within the ME 450 course, we suggest that our sponsors share with future teams our successes, failures, and lessons learned. In the event that future teams decide to improve upon our design, we recommend the following:

We recommend that the material chosen for the housing of the device should be one that holds similar properties to that of the mask utilized within PPV. One such material is silicone – it can also be 3D printed! The usage of a rigid PLA material for the housing within our prototypes proved to be a major pain point as the rigidity of the base on which our sensors were attached did not mesh with the malleable mask once pressure was applied – as the mask deformed to better mesh with the shape of the manikin's face, the rigid flat base of our device did not, causing the sensors to lose contact with the mask and give inaccurate readings.

Another recommendation is for teams to aim for either an external power supply or an external electrical subsystem. The inclusion of our electrical subsystem within the housing of the device created a device that was quite heavy – making for an unrealistic training setting. Although it

would make the device less portable, we believe that the ability of the device to more accurately simulate the PPV procedure is of utmost importance. Additionally, prior to assembling the electronic subsystem, we recommend practicing soldering techniques or asking for assistance from an experienced solderer. Throughout our two prototypes, one issue we ran into was the consistency of our solders – some connections were weaker than others, leading to shorts and breakages during testing as well as a messier appearance. By perfecting the soldering method utilized within future prototypes, teams can lessen the room for electrical errors as well as produce more visually appealing prototypes.

Conclusion

The team's objective is to design a training device to be used with a circular PPV mask that can quantify and give immediate feedback on the pressures applied to a neonate's head during the positive pressure ventilation process, thereby aiming to improve the PPV training process for clinicians. To start out, the team obtained pre-existing background information from interviews with our sponsors and stakeholders as well as doing extensive research on the subject. From these sponsor and stakeholder interviews, we learned about pre-existing work done towards improving the PPV process – such as Jacqueline's research and the RQI training station, the technological approaches used in those instances, and the preferences within a medical facility. Additionally, with the knowledge that we learned from the ME 450 learning blocks, the team adjusted our design process to better fit the time constraints of the course and created an in-depth analysis of our stakeholders to allow for a more inclusive design and minimize our potential of negative social and environmental impacts. Next, we utilized the information gathered throughout the entire process as well as the continuous feedback provided by our sponsors and stakeholders to produce a thorough list of user requirements and specifications to be used to guide us through our design phase. Through these actions, we were able to develop an in-depth problem definition.

Utilizing these user requirements and specifications, we generated a multitude of design concepts. Then, using both a Morphological Matrix as well as a Pugh Chart, we trimmed down our 200 designs to 1 "Alpha Design". This Alpha Design consists of a rigid ring with sensors implemented on the bottom surface of the ring. This ring is intended to be placed on top of a circular mask during PPV training for the clinician to press down on, thereby allowing the sensors to collect pressure measurements to quantify whether or not the applied pressure is deemed "safe". We then conducted empirical testing as well as theoretical analysis during the engineering analysis and verification phases to determine the capabilities of our design in meeting our requirements and specifications. With empirical testing, we tested many aspects as they pertain to our requirements and specifications, such as but not limited to: the strength of our design, the proportionality of sensor readings on top of the mask in relation to sensor readings on the bottom of the mask, and the ability of our device to not create more air leakage within the system. With theoretical analysis, we determined the strength and durability of our device in both

mechanical and electrical viewpoints. Main results in our engineering analysis and verification testing revealed that we need to troubleshoot many issues within our sensor implementation method as well as figure out a way to make our device lighter in weight. Through troubleshooting and analyzing the results of testing via our first prototype, we implemented changes onto a second prototype. As we were limited in the amount of time left in the semester, we were only able to redo a partial verification testing on our second prototype. The results of these tests revealed to us that many of our errors may be attributed to our choice in material utilized within our housing unit. The rigidity of the PLA housing led to a loss of contact between our sensors and the malleable mask once pressure was applied.
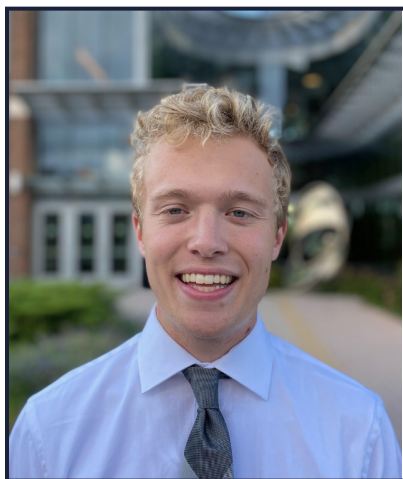
Although our final prototype of the semester was unable to pass verification for all of our requirements and specifications, we believe that we have made significant progress towards a solution. As mentioned within our Recommendations subsection, we recommend that future iterations of our design incorporate a more malleable housing material such as silicone, moving some if not all electronic components to be external, and improving upon the connections within the electrical subsystem. Given more time for iterations throughout our design process to implement these changes, we believe that a more optimized solution can be reached.

Team Biographies

Jack Decker

Jack Decker is a Mechanical Engineering student at the University of Michigan College of Engineering from Troy, MI. His primary study of interest is mechanical design and he hopes to return to the University of Michigan for a one year master's program in Mechanical Engineering starting in the fall of 2024. He hopes to work in the medical device or semiconductor industries in Michigan upon graduation. He worked at KLA Corporation this past summer and loved his experience as a mechanical design intern. One of Jack's many passions is his love for running and he is currently training for a half marathon in Ann Arbor set to take place on October 1. Jack's favorite food is tacos and has celebrated his birthday every year in college at Condado's Tacos in downtown Ann Arbor. He also has strong aspirations in entrepreneurship. Please ask him about entrepreneurship as he loves it and wants to start his own company one day.

Aaron Gronsman

Aaron Gronsman is in his 4th year of a Mechanical Engineering Undergraduate at Michigan. He is from Grand Rapids, MI and has aspirations to become a manufacturing controls engineer either in consulting or machine integration. He is on the Michigan Ski Team and races every weekend in January/February at Crystal Mountain in Northern Michigan. He has had internships at both Ardent Automation and Gentex Corporation, and is hoping to stay based in west michigan for the long term, primarily in Holland (Unless there's a job out west near mountains). He enjoys anything outdoors, with his favorite activities being skiing, running, hiking, disc golf, or any form of water sport.

Noah Hilbig

Noah Hilbig is a fourth-year Mechanical Engineering major at the University of Michigan hailing from Nogales, Arizona. His passion for mechanical engineering is deeply rooted in his love for mathematics and science, as well as an insatiable curiosity about how things function and the desire to innovate. Noah's career aspirations lie in the sports and fitness industry, with a particular focus on athletic apparel and devices, notably sneakers. Enthusiastic about entrepreneurship, Noah has actively pursued his dreams by taking several entrepreneurship courses at UM. Beyond his academic pursuits, Noah is an avid lover of the great outdoors, often immersing himself in nature through activities such as camping, hiking, and biking. During the academic year, Noah contributes to the university community by working as a Building Supervisor for Recreational Sports. In his free-time, he enjoys working out and indulging his passion for basketball.

Kimberly Kerr

Kimberly Kerr is a senior Mechanical Engineering Major with a concentration in Manufacturing Systems and a Minor in Economics at the University of Michigan who originates from Memphis, Tennessee – home of the Bass Pro Pyramid! At home in Memphis, she is a proud owner of 3 dogs, 3 cats, 40 chickens, and 3 goats. Her interest in mechanical engineering started with fixing her car with her dad. Since then, she has gone on to learn more about mechanical engineering concepts at Michigan and hopes to soon apply those concepts in real world situations in an attempt to better the world. Kimberly hopes to work in the automotive industry after college. In the far future, she is considering going back to school for either an MBA or a Law Degree to pursue a career as a Patent Attorney. In her free time, Kimberly enjoys watching sports, building legos, and hanging out with her friends. Her favorite sports teams are anything Michigan and the Memphis Grizzlies. Her love for the automotive industry is apparent in the fact that she owns every Ford lego set and several sets from other automotive companies.

Joseph Kobrossi

Joseph Kobrossi is a Mechanical Engineering Major from the University of Michigan College of Engineering, Ann Arbor. He always felt his educational talents geared him towards mechanical engineering growing up. His primary study of interest is manufacturing and he hopes to work in the Metro-Detroit automotive industry when he graduates college. He worked at Ford Motor Company this past summer and highly enjoyed his experience there as a manufacturing engineer intern. He plans to come back for graduate school, but not right after graduation. He is also almost complete with his Ross School of Business Minor, which he has been pursuing for the past few semesters. He is originally from Livonia, Michigan, a very mundane city 30 minutes outside of Ann Arbor, a place where he wishes to move out of as soon as fiscally reasonable. During the school year, he lives within the city of Ann Arbor. He loves to explore the city and find niche things to do. His favorite restaurant in the city is Jamaican Jerk Pit. For fun, Joe plays golf, disc golf, and any racquet sport. He is not particularly good at any of them but will get very competitive if you play with him. Please ask him about disc golf, he really enjoys it and has no one to talk to about it with.

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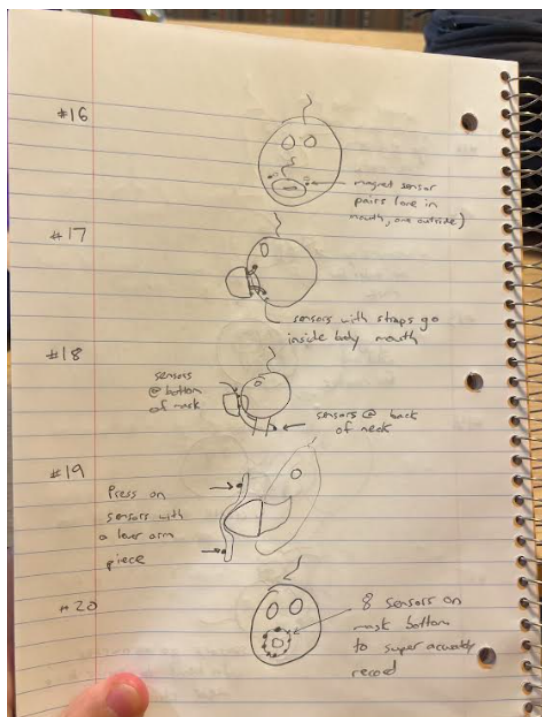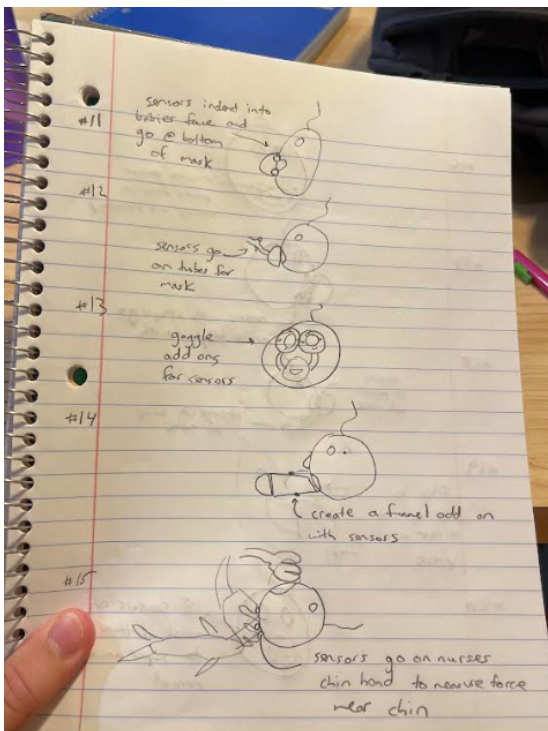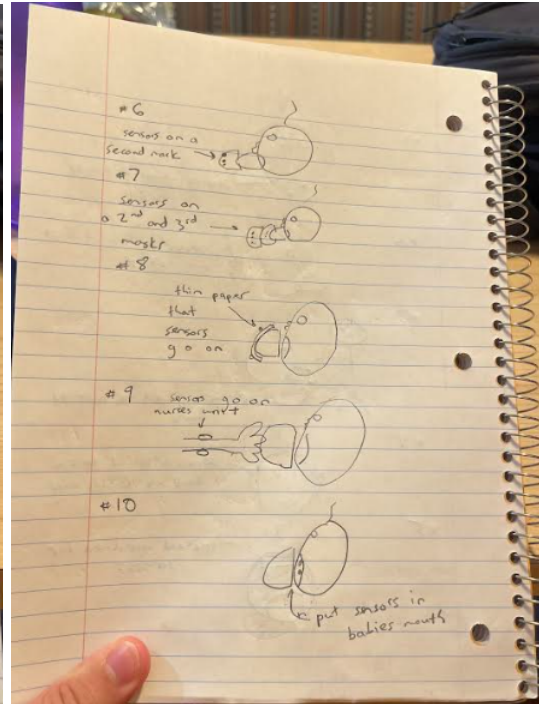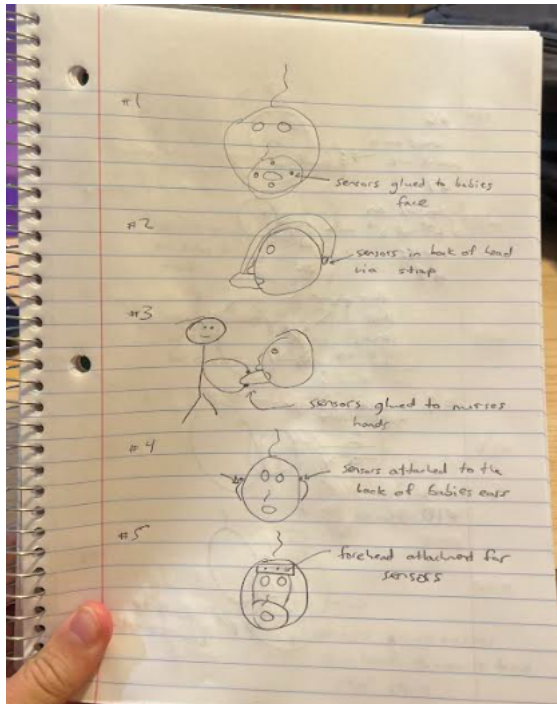
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Appendix A

Below is each team member's individual 40 design concepts generated prior to our team meeting in which the combined morphological matrix was generated.

Jack Decker

Morph Chart

	Solutions			
Sensor Location	Below mask	Nurses Arm/Hand	Inside Mask	Back of Baby
Add on to mask	Funnel	Hand Grip Sleeve	Magnets	Stops
			Top of mask	
			Another mask	

Sub functions

Ideas 21-30:

#21

sensors are magnetic with baby face

#22

glued

sensors are glued to nurse hand + mask

#23

Funnel device with sensors @ nurse wrists

#24 Straps around nurses hands to back of neck

sensor @ back of neck

#25 put another mask with sensors @ the back of the baby

#26 Straps inside baby mouth but sensors @ top of mask

#27 Funnel add on to mask w/ sensors on top of mask

#28 Straps inside mouth + around head w/ sensors in the back

#29 sensors magnetic to nurses wrists

#30 Put another mask inside the baby's mouth w/ sensors in it

Function Decomposition inspiring ideas #31-40

Sense Force Being Applied By Nurse

a.) Wire length should be short
b.) Integrity of seal maintained
c.) Easy to set up

#31 Wires run along nurses arm + sensor on top of mask

#32 Wires along nurses arm but sensors @ bottom of mask

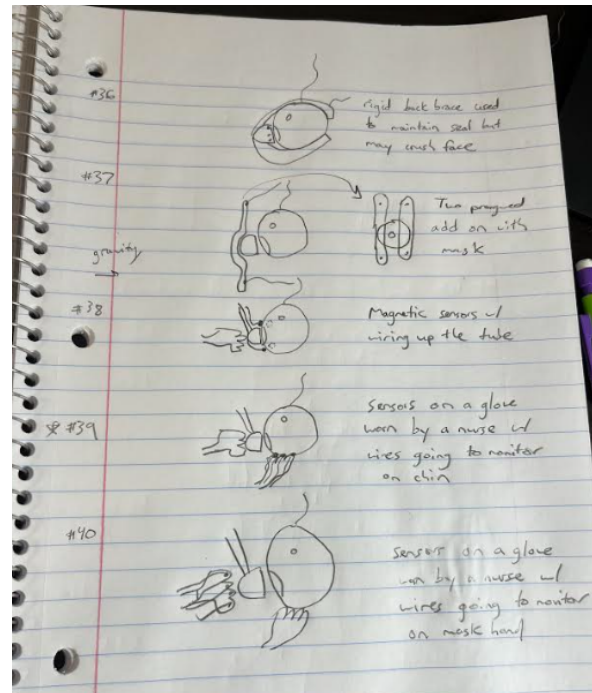#33 Wires go along tube of mask to some outlet + sensors on bottom of mask

#34 sensors on the back of the strap w/ wires coming from back

#35 Add on lever arm w/ wires going to the ground for the sensors
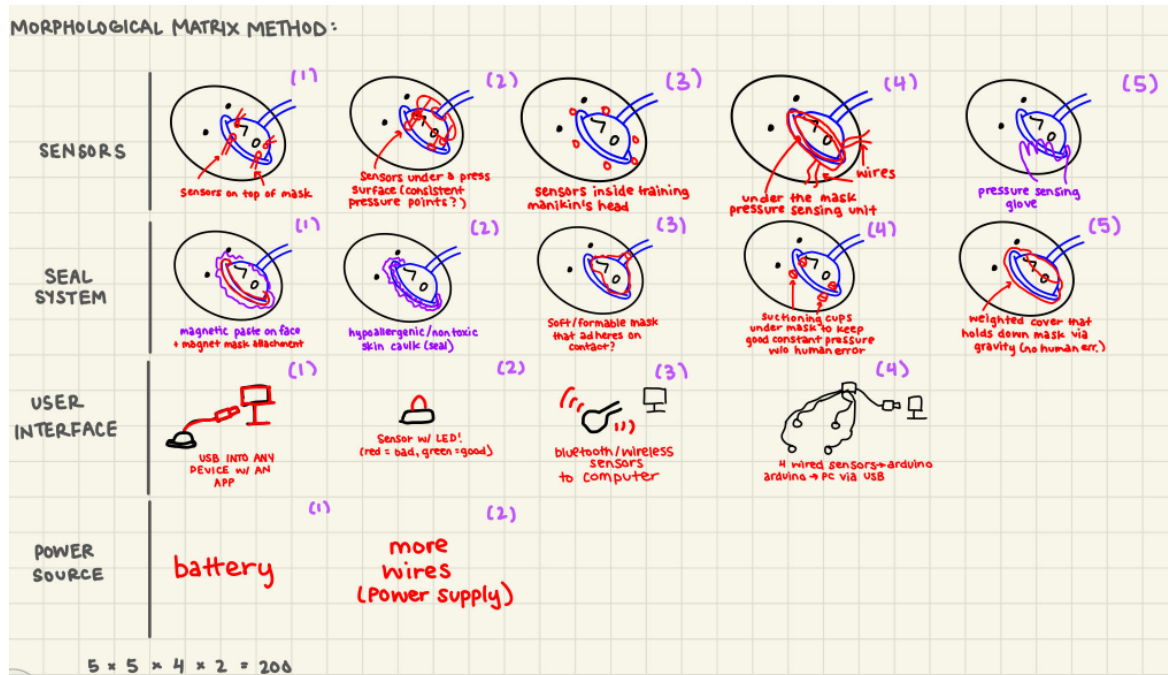
gravity

During Jack's individual concept generation, he utilized methods such as keeping an open mind and welcoming "crazier" concepts to generate as many solutions varying their design concepts as possible. One example of a design concept that was generated during his brainstorming session was a rigid strap for the nurse to create two lever arms on top of the mask as seen in design #37.

Noah Hilbig
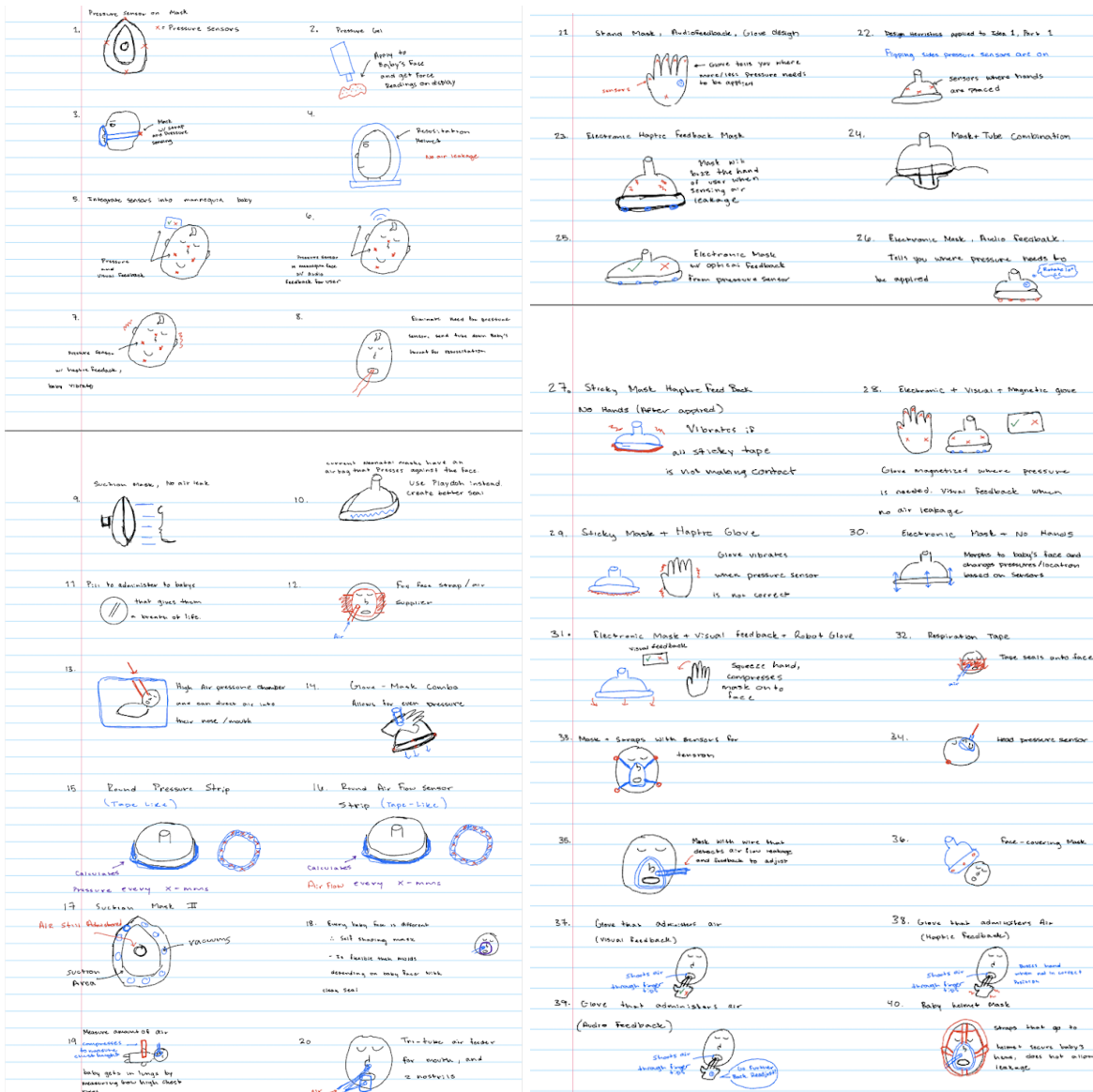
During Noah's individual concept generation, he utilized methods such as switching up his work environment and welcoming "crazier" concepts to generate as many solutions varying their design concepts as possible. One example of a design concept that was generated during his brainstorming session was a way to vacuum seal the mask onto the baby's face so there was no air leakage.

Kimberly Kerr
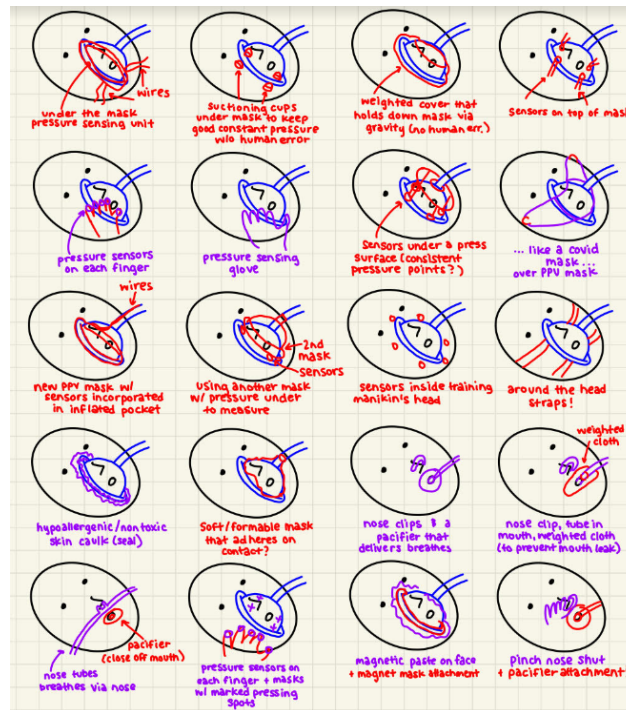
During Kimberly's individual concept generation, she utilized methods such as valuing quantity over quality and utilizing a morphological matrix to generate as many solutions varying their design concepts as possible. One example of a design concept that was generated during his brainstorming session was a pacifier with tubing allowing for breath delivery and utilizing a neonate's lips as a method of sealing.

Joseph Kobrossi
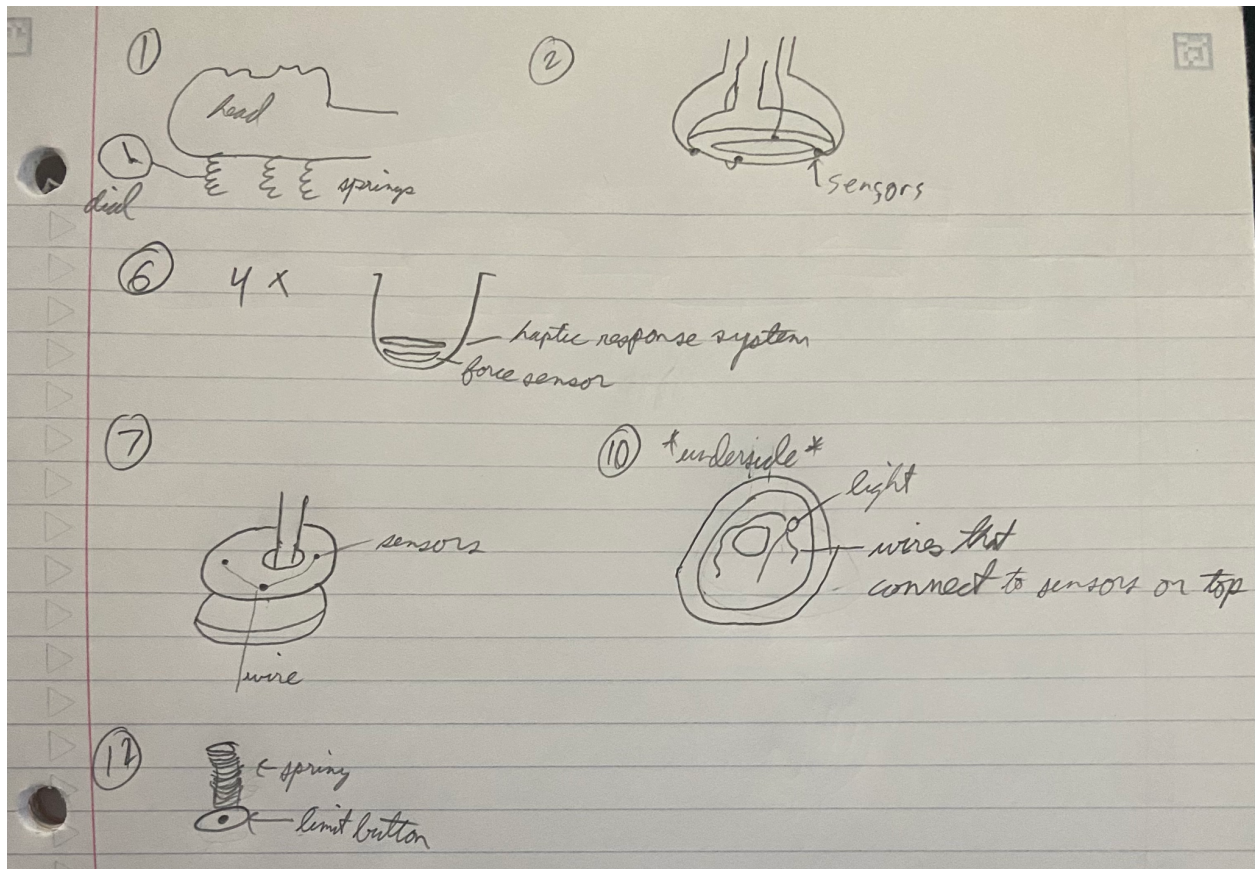
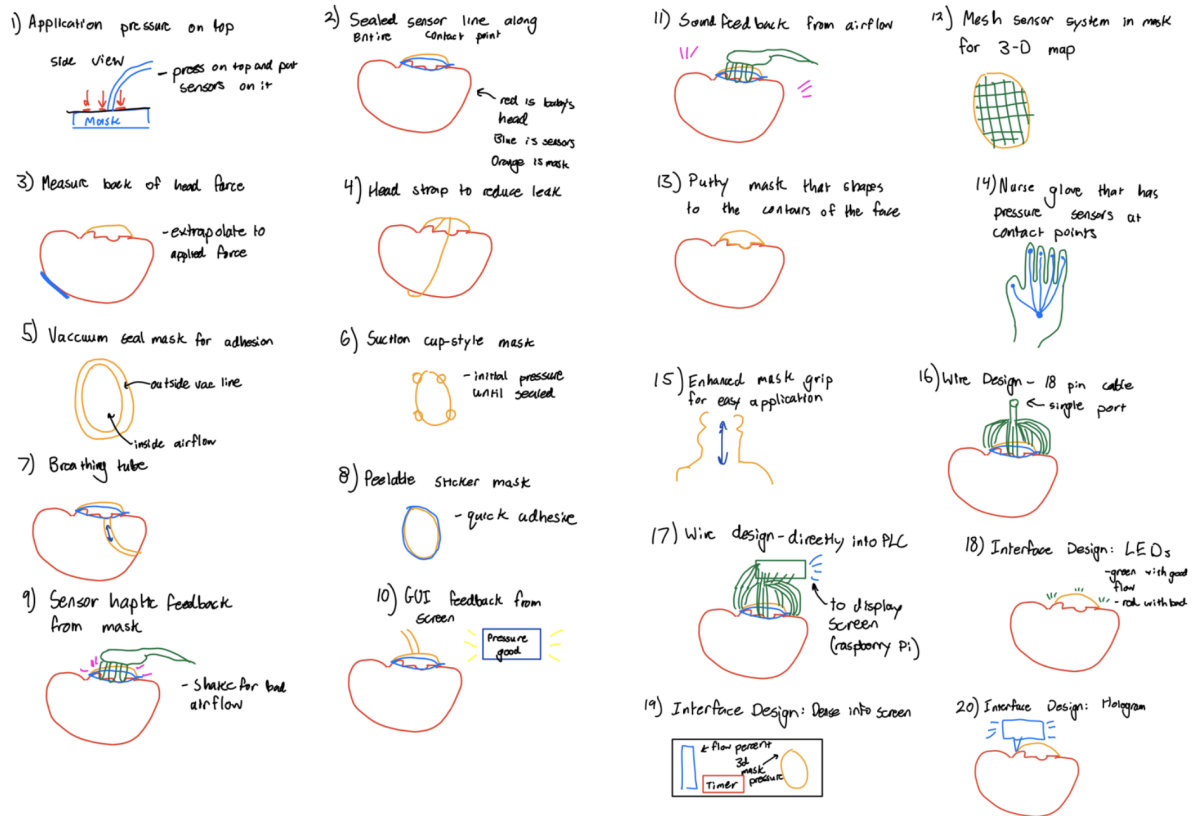During Joe's individual concept generation, he utilized methods such as keeping an open mind and taking breaks in between brainstorming sessions to generate as many solutions varying their design concepts as possible. One example of a design concept that was generated during his brainstorming session was a spring that once fully compressed would press a button at the base of the spring. The custom made compression spring would have the same Newton reading that would be needed to complete a full seal when fully compressed Therefore, when the button is pressed, the user knows the seal is created. This stemmed from his thinking of trying to create a fully mechanical design.

Aaron Gronsman

1) Application pressure on top

side view — press on top and put sensors on it

Mask

2) Sealed sensor line along entire contact point

red is baby's head
Blue is sensors
Orange is mask

11) Sound feedback from airflow

12) Mesh sensor system in mask for 3-D map

3) Measure back of head force

— extrapolate to applied force

4) Head strap to reduce leak

13) Putty mask that shapes to the contours of the face

14) Nurse glove that has pressure sensors at contact points

5) Vacuum seal mask for adhesion

— outside vac line
— inside airflow

6) Suction cup-style mask

— initial pressure until sealed

7) Breathing tube

8) Peelable sticker mask

— quick adhesive

15) Enhanced mask grip for easy application

16) Wire Design — 18 pin cable ← single port

9) Sensor haptic feedback from mask

— shake for bad airflow

10) GUI feedback from screen

Pressure good

17) Wire design — directly into PLC

to display screen (raspberry pi)

18) Interface Design: LEDs

— green with good flow
— red with bad

19) Interface Design: Dense info screen

← flow percent
3d mask pressure
Timer

20) Interface Design: Hologram

During Aaron's concept generation process, design options were collected into a morphological matrix with sub categories of seal type, sensor location, feedback and electronic design. These subcategories were collected into the designs shown above. Most iterations of the design were related to changes in feedback style and sensor location.