N95 MASK WITH INTEGRATED NASAL CANNULA

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Technical Design Report

Final Report

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Abstract

In the midst of the COVID-19 pandemic, Americans have an increased desire to protect themselves against disease via personal protective equipment such as face masks. People who require a nasal cannula full time are at a much higher risk of extreme illness from everyday pathogens, and cannot use the standard face masks that exist today because the cannula tubing breaks the seal of the mask, rendering it useless. The team's motive is to create an N95 face mask for nasal cannula users that can protect them from airborne pathogens, specifically COVID-19. After brainstorming possible solutions, the team decided to create a reusable N95 mask with a disposable N95 filter that can hold and seal a nasal cannula. In this design, the main subsystems are the face seal, the cannula seal, the straps, the hinging component, and latch. The final product successfully demonstrates a viable solution for combining N95 filtration with nasal cannula integration to adequately protect the user.

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1. Acknowledgements

The team would like to thank Ms. Liz Johnson for bringing this project to the attention of Northeastern University as well as for her time and participation in an informational interview. Furthermore, the team would like to thank Mr. Joe Byrne and Dr. Selim Arcasoy for their time and contributions to the team research on nasal cannulas and user experience.

2. Copyright

3. Introduction

Individuals who require oxygen delivery through nasal cannulas generally have a severe respiratory condition such as COPD, cystic fibrosis, or pneumonia [1]. In normal times, these illnesses can cause people to be at a much higher risk of extreme illness from everyday pathogens, but the COVID-19 pandemic has created a much more dangerous situation. It can be unsafe for individuals to leave their homes if not adequately protected by something like an N95 mask, which has been suggested for use by healthcare workers to protect them from bacteria and viruses [2]. Nasal cannula users cannot use the standard N95 masks that exist today because the cannula tubing against the face breaks the seal of the mask, rendering it useless. Unfortunately, there is no N95 mask on the market created specifically for nasal cannula users.

4. Problem Statement

To protect nasal cannula users from pathogens, the team will create a mask with N95 filtration and an airtight nasal cannula integration.

5. Background

In order to properly understand the problem and related challenges, research was conducted to better define the task. Two of the major areas investigated were key technologies and prior art. A survey was also distributed to numerous nasal cannula users to provide feedback on their wants and needs, and a handful of additional people were interviewed by the team to gain further insight into the problem. Furthermore, any additional research into specific solutions for the current design is included in the corresponding subsections of the current design section later in the report. .

5.1 Key Technologies

The key components of the overall mask are the N95 mask and the nasal cannula. These two parts need to be fully and clearly understood in order to properly combine them while still maintaining their original integrities.

5.1.1 <u>N95 Mask</u>

N95 respirators are regulated by the National Institute for Occupational Safety and Health (NIOSH) [3]. They are rated to filter out at least 95% of particles as small as 0.3 microns in diameter, including bacteria, viruses, and other airborne particles. The typical users for N95 masks are healthcare workers, industrial workers, and those who are at high risk of infection.

One of the key features of the mask is the air-tight seal around the face so that no air escapes or enters through an unfiltered gap in between the face and mask. Some N95 masks also include an exhalation valve which is a critical feature for users who have issues expelling carbon dioxide and cannot rebreathe it [2].

The N95 filter contains four layers: two support layers, an inner liner layer, and a filtration layer. In addition to filtration advantages due to multiple layers, the mask also uses the science of electrostatic attraction within the filtration layer. The layer has electrically charged fibers that physically attract particles of all sizes so they stick to the fibers instead of passing through the mask. The particles eventually build up, which causes the mask to have a relatively short lifespan of only 8 hours or about 5 uses [4]. A N95 Respirator Mask is shown below in Figure 1.

Figure 1: 3M N95 Respirator Mask [5]

5.1.2 Nasal Cannula

Nasal cannulas are generally used for supplemental oxygen delivery for people who are on long term oxygen therapy [1]. One of the key features is that it supplies anywhere from one to six liters of oxygen per minute, depending on the prescribed flow for the specific patient. The oxygen tube is connected directly to an oxygen tank to deliver pure oxygen into the user's lungs by way of prongs inserted into the nose [6]. The tubes are typically made from a soft polymer, but the exact material varies among different manufacturers. This means that the hardness and stiffness of nasal cannulas are not consistent.

It is recommended that the cannula be changed every 2-4 weeks, depending on how often the user wears the cannula [7]. The user might also choose to wear their cannula for more or less time depending on their preference. It is important to understand that the cannula has a much longer usable life than the N95 mask, and this is considered in the final design. A patient wearing a nasal cannula is shown below in Figure 2.

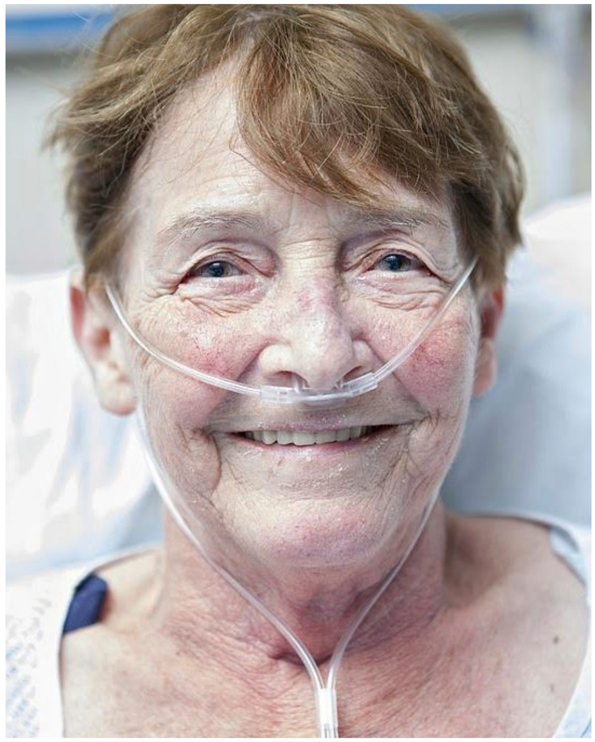

Figure 2: Patient Wearing a Nasal Cannula [8]

6. Literature Search

To inform the brainstorming process, the team searched for patents, studies, and existing products that relate to the problem statement. Each provided inspiration and information, some more than others, that led to the multitude of brainstorms and the final design.

6.1 Patents

Patents helped the team understand the current specifications of products currently on the market and therefore, identify the constraints with the design and design ideas. Patent "Nasal Cannula" [9] outlines a nose bridge design that ensures cannula security, shown in Figure 3. Similarly, Patent "Nasal oxygen cannula with supply tube management" [10] shows a nasal cannula routing path that does not interface with the user's ears, shown in Figure 4. Both of these designs gave the team creative ideas about cannula routing and support when integrating with an N95 mask, but did not provide any air filtration to protect users from possible airborne particulates.

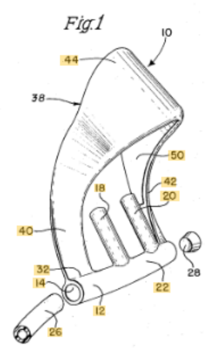

Figure 3: Nasal Cannula Nose Bridge Patent [9]

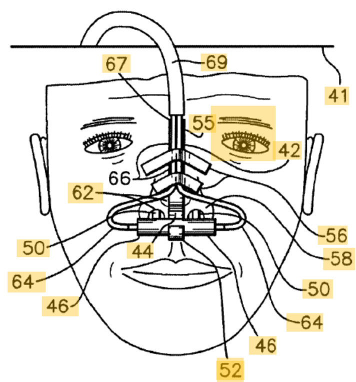

Figure 4: Nasal Cannula Routing Patent [10]

Patent US20050033247A1 [11] helped the team identify the general hardness of a nasal cannula face tube, as many companies keep the material selection of their face loop proprietary. This hardness number will determine the best way to interface with the cannula tubing when designing the mask. The patent indicated a tubing of 40 - 75 Shore A Hardness. Material selection most likely has changed since this patent was filed in 2003, but the hardness is a reference from which to move forward.

6.2 Previously Published Work

The team came across a study published on the National Center for Biotechnology Information website entitled "Modified N95 Mask Delivers High Inspired Oxygen Concentrations While Effectively Filtering Aerosolized Microparticles" [12] This study determined that an N95 mask modified as an oxygen mask, shown in Figure 5, would maintain the filtration and isolation capabilities of an N95 mask, regardless of the flowrate of O_2. Despite how promising this study was, no product that fits the scope of this project has been created based on this study.

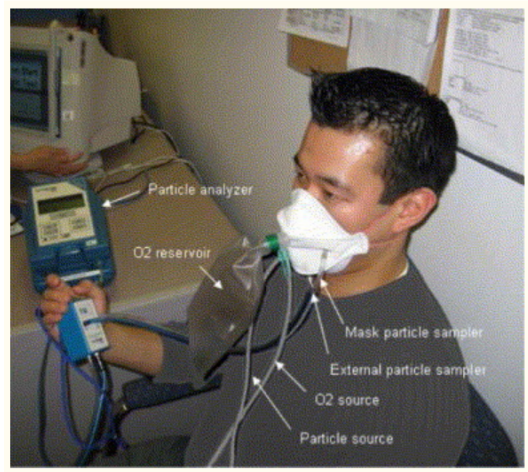

Figure 5: N95 Oxygen Mask [12]

6.3 Existing Products

No current existing product incorporates an N95 filtration system with a nasal cannula. Despite that, there were a few types of masks that the team came across that influenced design decisions. The first is a standard N95 mask. This product provided a lot of information on the N95 material [13] and testing for a proper face seal [14].

Another mask, the Envo® mask [15], provided inspiration towards brainstorming. The Envo® mask has a plastic body, a gel seal to the user's face, and a removable and replaceable N95 filter, shown in Figure 6.

Figure 6: Envo® Mask [15]

Finally, the HEPA respirator mask [16], seen in Figure 7 provides oxygen through a removable tube and an arm mounted HEPA filter. This product is meant to allow users to breathe more easily while performing day to day activities, though is still not meant for long-term oxygen therapy patients such as nasal cannula users.

Figure 7: HEPA Respirator Mask [16]

7. Survey and Interview Contributions

To ensure that the best possible mask is made, a survey was sent out to various nasal cannula users. The purpose of this survey was to collect information on the safety habits of nasal cannula users and to ask them what qualities they would like to see in the mask. After the survey was sent out, the team had various virtual interviews that helped gather more information. The full survey is attached in Appendix A.

The highlights from this feedback are as follows:

- **71%** of respondents wear their oxygen for **over 12 hours** of the day, showing the need for a mask to protect them
- **86%** of respondents only wear a **cloth mask** when leaving their house
- **78%** of respondents who have worn N-95 masks previously have had **difficulty breathing** through them
- Comfort is slightly more important to the user than cost
    - Comfort was rated at 4.36/5
    - Cost was rated at 4.29/5

7.1 Needs

7.1.1 Breathability

With users who already have difficulty breathing without an N-95 mask, ensuring that the mask has high breathability is crucial to making a good product. As the results showed, 78% of users had difficulty breathing through an N-95 mask. Numerous design steps must be taken to increase the breathability of the mask.

7.1.2 Ease of Use

The mask will likely have some form of interchangeable cannula and filter. With multiple changing parts and the mechanisms involved with them, there are a lot of opportunities for the integrity of the mask to fail. The seal of the mask is critically important, and any fault of that seal will cause the mask to fail and endanger the user. The mask and the part-changing mechanism needs to be designed to eliminate the risk of any human error causing the mask to fail.

7.1.3 Replaceable Cannula

There are various types of cannulas available to users. This includes different tube materials, tube softness, and nose prong shapes. To ensure that users want to use this product and are comfortable using this product, it is necessary that users can incorporate their own cannula and can replace it independently from every other part of the mask.

7.2 Wants

As with any product, low cost is important. Users responded to the poll indicating that, for a reusable mask, they would be willing to pay approximately $15-30. Cost can be kept low by using low-cost materials that still fully meet the needs of the mask.

7.3 Interviews

Virtual interviews were held with three different users and experts to gain insight into the survey responses and the project overall.

7.3.1 Joe Byrne, Nasal Cannula User

The first person interviewed was Mr. Byrne, who has been using a nasal cannula since 2016. Mr. Byrne helped the team brainstorm ideas with insight from an actual user. He continually reinforced that **comfort is a huge factor**. Nasal cannulas alone are already uncomfortable, and this product should strive to not add to that discomfort.

7.3.2 Liz Johnson, User and Project Inspiration

Miss Johnson helped create the idea for this capstone project. She was incredibly insightful during the interview, providing background for why this product is helpful and necessary. The key takeaway from this interview is that a **reusable mask is greatly preferred** over a single use mask. She emphasized that a reusable mask needs to be easily cleanable, but that a cleaning and filter replacement routine would be familiar to a nasal cannula user.

7.3.3 Dr. Selim Arcasoy, Lung Transplant Doctor

Dr. Arcasoy provided clarity on the various types of cannula. He confirmed that there is only **one size of tube** that is common, with the other size being used for full oxygen masks. Dr. Arcasoy continues to be available for questions when necessary.

7.4 Effect on Current Design

While the replicability of the cannula was originally thought to be a “want,” it was quickly evolved into the key feature of the design. After further discussion among nasal cannula users, it was determined that the mask must be able to use the user’s own cannula. The breathability aspect has directly led to the integration of the exhale valve and subsequent exhale valve cover. Lastly, cost has played less of a factor that originally intended, as the challenges of providing an effective seal have taken priority.

8. Preliminary Design

8.1 Mask Requirements

The team compiled information gathered from the interviews, questionnaire, prior art and research to determine the functional requirements of the N95 with Integrated Nasal Cannula. Each requirement fell under one of three categories: performance, comfort, and modularity.

The performance of the nasal cannula integrated N95 mask is critical to ensure user protection and ease of use. First, the mask must have N95 standard sealing between any of the mating surfaces, such as between the face and the mask or between the cannula and the mask. Second, the mask must remain secured to the face of the user during normal use such as talking and regular activity. Finally, the cannula performance must be maintained while integrated with the mask assembly to ensure that no damage comes to the cannula and users can receive their prescribed amount of oxygen.

Comfort wise, the mask must be relatively comfortable to wear, as comfortable as a typical N95 mask. In addition, the mask must be comfortable for the user to inhale and exhale. Masks are notoriously difficult to breathe in and out of, so to not make this matter any worse, this mask will be as easy to inhale and exhale out of as a typical N95 mask with an exhale valve.

Finally, modularity plays a large role in the design requirements. As per the information gathered from cannula users, there are individual preferences when it comes to what cannula to use. In addition, the life cycle count of N95 material and nasal cannulas is different, 5 days and 14 days respectively. To ensure that users can use their own cannula, along with allowing for interchanging filters and cannulas on differing time tables, the mask must be modular. All of the above requirements can be seen outlined in Table 1.

Table 1: Mask Requirements

Performance	Comfort	Modularity
N95 Standard Sealing	User Physical Comfort	Replaceable Filter
Security	User Breathing Comfort	Insert/Remove Cannula
Cannula Performance		

8.2 Design Overview

The preliminary conceptual design, shown in Figure 8 & 9, takes inspiration from the Envo® mask, with the main differences being a main hinging mechanism with an internal lock to allow for insertion and removal of a nasal cannula, while keeping the mask closed during usage.

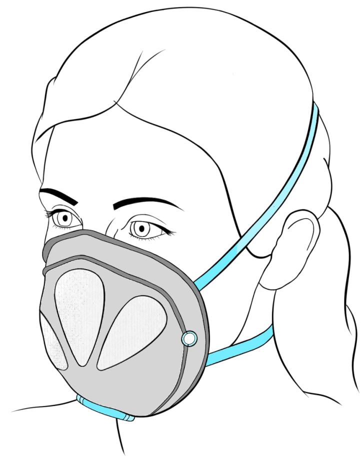

Figure 8: Preliminary Conceptual Design on User

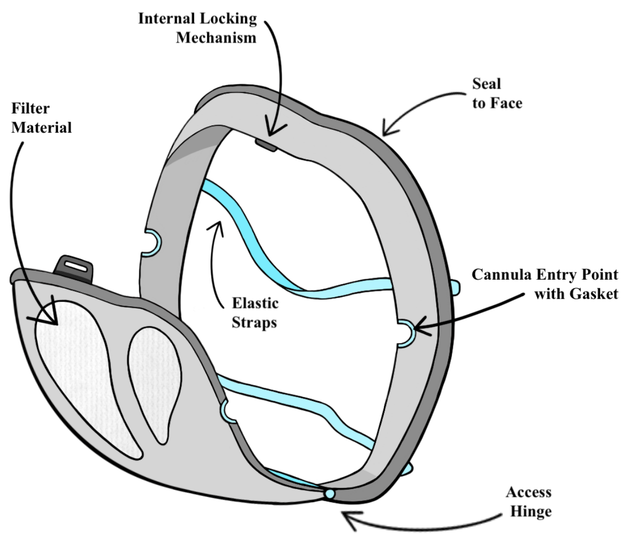

Figure 9: Component Breakdown of Preliminary Conceptual Design

The initial design called for a mask made from sturdy plastics that can support two pressure seals, one on either side of the mask, serving as the point of entry for the nasal cannula tubing. The main hinge can be open and closed before or after placing the mask on the user's face for easy adjustment of the cannula tubing and nose piece. Additionally, this design allows for regular replacement of a filter material, elongating the life of the mask. In order to properly address the requirements set forth by the team, the mask is divided into six main subsystems. Each subsystem is outlined in the following subsections and further discusses the key requirements.

8.2.1 Filter and Plastic Body

The cornerstone of the filter subsystem is the hinging component. The team will need to create an effective seal around a moving hinge, whether from a mechanical or material perspective. It is important that the hinge does not introduce leakage into the design and upholds the N-95 standard along with the rest of the mask. The insertable N-95 filter material will be an off-the-shelf part, which will drive the front-facing geometry of the plastic body. This shape will alter the curvature of the preliminary conceptual design.

8.2.2 Exhale Valve

The team began by considering that the mask may not require a nasal cannula to effectively deliver oxygen to the user. Looking at existing solutions, such as the respirator mask represented in Figure 10, the team determined that such an idea would be excessively bulky and uncomfortable, as well as inefficient. Nasal cannula users tend to have difficulty breathing, so a direct oxygen supply is necessary. Additionally, the team determined that the use of an exhale valve would facilitate further ease of breathing.

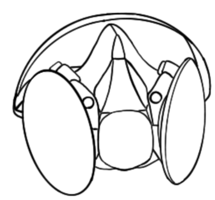

Figure 10: Solution Excluding a Nasal Cannula

8.2.3 Face Seal

The seal between the face and mask is not only important for the protection of the user and effectiveness of the product, but also for the ergonomics and comfort of the design. The highest priority is providing a functional seal in order to comply with N95 standards, which requires an investigation into deformable materials like elastomers, rubbers, and synthetic polymers. The design must account for the varying size, contours, and overall geometry of user faces, as well as typical movements such as smiling and speaking, while maintaining an effective seal. The material selection is also a key factor in the ergonomics and comfort of the design. The team will perform both computational and experimental analysis in order to determine what material will be optimal for the user.

8.2.4 Cannula Seal

The connection between the cannula tubing and the mask is critical to the integrity of the design. The team will need to ensure a proper seal in order to maintain the N95 standard. Furthermore, this subsystem directly influences the placement of the cannula and overall comfort for the user as the tubing is adjusted to fit specific needs.

Looking at chemical and pressure seals, the team primarily focused on an O-ring solution or some type of compliant mechanism to contract around the nasal cannula and hold it in place. While these ideas, represented in Figure 11, would create an effective seal, they ultimately limit the modularity of the product as the user would not be able to insert or remove the nasal cannula for replacement. The team concluded that a similar effect would take place if an epoxy glue was used, and the user would not be able to utilize their own preferred cannula. Instead, the team plans to utilize the hinging subsystem in the preliminary conceptual design in order to facilitate cannula insertion, as well as introduce a flexible gasket to create an effective seal. It is important that the team be mindful of materials selection as well as the amount of force applied to the cannula by the gasket and enclosure. Analysis of the clamping force will be performed to ensure that the cannula is held in the desired position, but will not compress the material or diminish the efficiency of airflow.

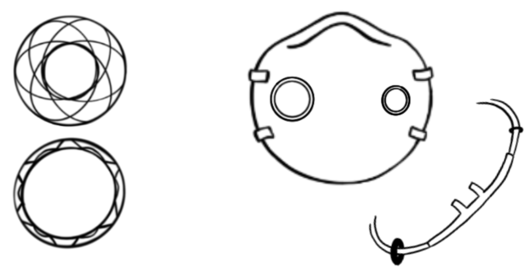

Figure 11: Preliminary Point-of-Entry Seals

8.2.5 Internal Mask Seal

The internal locking mechanism will need to be easy to use, while maintaining a proper seal in order to comply with the N-95 standard. The user must be able to quickly and effortlessly open and close the mask in order to adjust the position of the tubing, insert or remove the nasal cannula, and replace the filter material when needed. The materials selection will likely be similar to that of the face seal, relying on a deformable material like elastomers, rubbers, or synthetic polymers. This material will be relating two rigid plastic bodies, and will need to be strong enough to maintain the closure, while interfacing with the gasket material at the cannula point of entry. Computational analysis to determine the appropriate sealing force as well as experimental analysis will be necessary to ensure both ease of use and integrity of design.

8.2.6 Supporting Hardware

There are several additional components within the preliminary conceptual design that will need to be investigated at further lengths in order to construct a final prototype. These supporting hardware components include the strap connection points and the sealing latch.

Many existing N-95 masks place two straps around the head rather than over the ears in order to remove stress and allow for a tighter seal. This is more efficient when working with a nasal cannula, as supporting straps and a cannula behind the ear would be uncomfortable for the user. The straps will need to maintain a high enough force to form a seal with the user face without causing N95 standard sealing issues.

The entire mask will be held together by a latching component at the top of the preliminary conceptual design. This component will need to be sufficiently strong in order to hold the rigid body components in place, while still being easy to open and close.

8.3 Formal Design Review

Following the solidification of the initial design, the team conducted a formal design review with Professor Marilyn Minus. After a brief presentation, the discussion largely focused on materials selection for the plastic body as well as the face and cannula seal. For the body itself, 3-D printing was discussed at length. The group determined that it will be crucial to investigate the sealing properties of certain materials such as polyurethane, common in SLA printing, as well as the airflow through connecting parts. The interaction between parts will also greatly impact the cannula seal. The team discussed several materials options for the cannula seal including EPDM, Teflon (PTFE), EBTM, and Vitol. It will be important to test the desired material to ensure flexibility does not impede airflow. Flexibility is also a big factor in the materials selection for the face seal, as the team still aims to design a comfortable product. A few materials options such as foam or silicone-based gels were discussed, however, the defining factor will likely be the geometry itself. The team has taken all notes from this formal review under consideration as design iteration continues.

9. Current Design

9.1 Design Overview

The current design further iterates upon the preliminary mask design, while more closely considering human factors. The conceptual geometry is modified to better fit the contours of a user's face as shown in Figure 12, and an exhale valve is introduced to not only improve user experience, but to protect those around them as well. Figure 13 points out the specific details of the current mask.

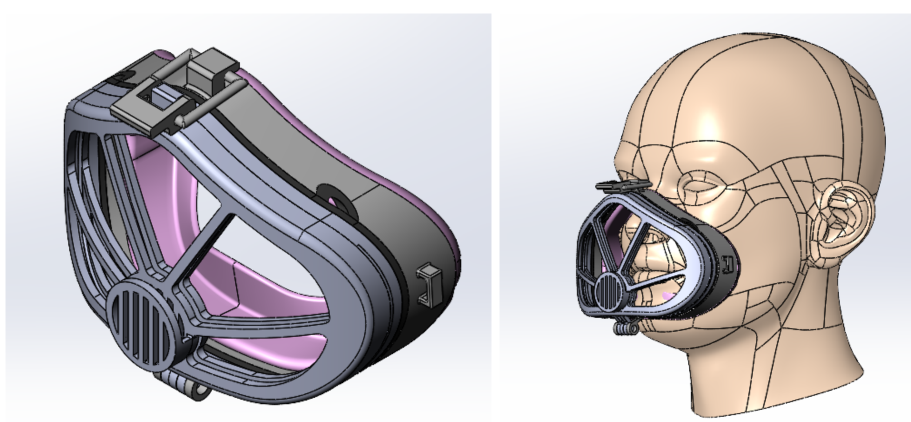

Figure 12: Current Design on User

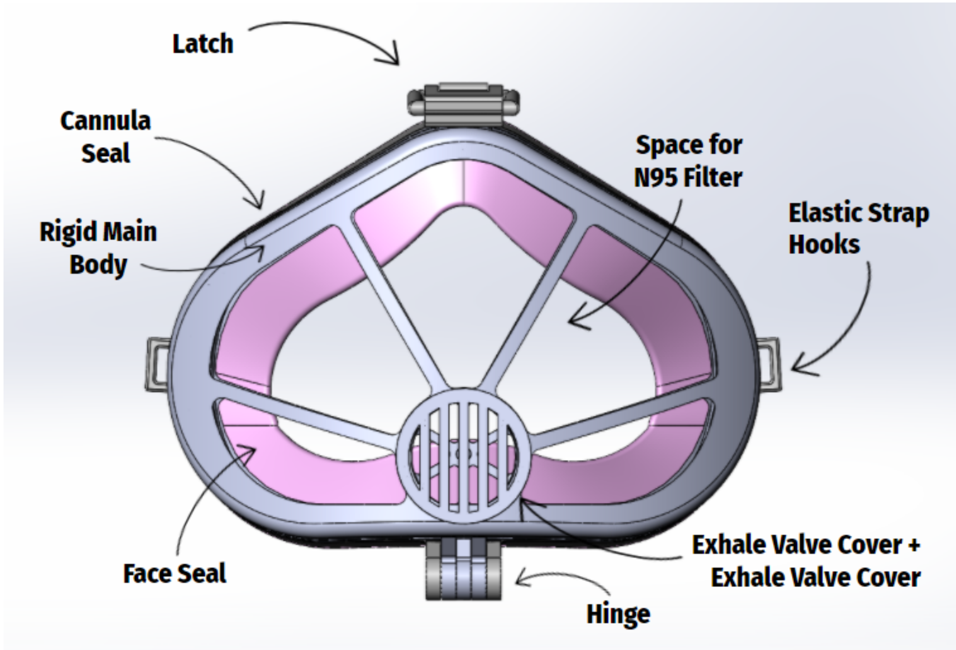

Figure 13: Component Breakdown of Current Design

The final design also greatly considers materials selection and manufacturing processes. The team determined that the mask would require a flexible and deformable face seal material in order to create an effective seal since not every face is the same size and shape. However, the body of the mask itself would need to be relatively stiff in order to facilitate the seal. Through research and the formal design review with Professor Marilyn Minus, the team determined that a feasible option for manufacturing a prototype of the rigid body would be 3D printing. While the team originally investigated FDM printing, it was concluded that the process could introduce pores and compromise the N95 standard. Instead, the group used SLA printing for the rigid body prototype, keeping in mind that future upscaling may require alternative methods for cost and efficiency. The group contacted Noah Joseph from the Sherman Center who assisted with the SLA 3D prints. The materials selection, design interactions, and intended manufacturing process of each of the subsystems are discussed in the following sections.

9.2 Filter

The final design incorporates geometry to accommodate the Envo filter, shown in Figure 14. This filter can be purchased online for $2.50 per unit and is consistent in size. The alternative was to modify full N95 masks, but the inconsistencies of cutting as masks would introduce difficult to control variables in the N95 Validation test. This selection of the Envo filter became a design constraint that influenced the design of the main body of the mask. The Envo filter placed constraints on the curvature and surface area of the mask, along with the placement and size of the selected exhale valve. In addition, this mask design required that the main body of the mask have a grate to compress the filter and hold it into place during use. This grate is 1mm wide, and has additional cylindrical posts of 0.5 mm to secure the filter. This use of the Envo N95 material will also hopefully discourage users from cutting into an N95 mask to make a replacement filter.

Figure 14: Envo Mask Filter [17]

9.3 Exhale Valve

To increase the comfort and breathability of the mask, a one-way exhale valve was integrated into the mask. Without this valve, all the air that the user breathes out would go back out through the filter. Not only does this make it difficult to breathe, but it reduces the life of the filter. With this valve, users will be able to comfortably exhale while wearing the mask.

As the current global pandemic rages on, exhale valves have rightfully been criticised as putting those around the wearer in danger. As opposed to a normal cloth mask, the exhale valve does not stop or limit the spread of particles and droplets from a breath from entering the air. To combat this, there is a replaceable, cloth covering that slides over the exhale valve to prevent particles from that breath from being suspended in the air. It is functionally a scaled-down version wearing a cloth mask over a mouth, where the exhale valve cover is a modified surgical mask, and the exhale valve is the mouth. The exhale valve recycles the inner flap (green part), as seen in Figure 15, from an off the shelf device.

Figure 15: Exhale Valve [18]

The team added geometry to the mask, shown in Figure 16 below, to integrate the flap and create a custom exhale valve. The exhale valve cover sits within a pocket on the outside of the mask, for easy removability and replaceability. Testing functionality of the exhalve valve was done experimentally by applying the Bitrix test, outlined below, to the subassembly. Just like any other cloth mask, this exhale valve cover will have to be cleaned between uses.

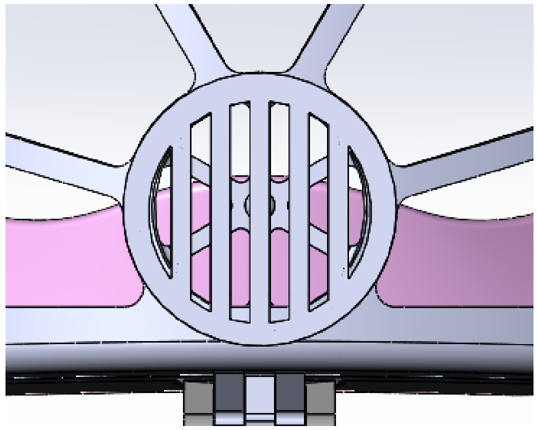

Figure 16: Mask Exhale Valve Geometry

9.4 Face Seal

The face seal was made of a silicone based compound, Smooth-On Dragon Skin Shore 30A, since silicone is standard for biocompatible devices due to its structural compliance and hypoallergenic properties. This allows for a wide variety of users from different face shapes to different reactions to certain materials. Inspiration for this material selection comes from the face seal on a large respirator mask, as seen in Figure 17, which also uses silicone.

Figure 17: 3M Respirator Mask [19]

The face seal geometry has changed since the last update, incorporating a varied cross sectional area on the different contact locations of the face. The previous L cross section can be seen below in Figure 18, and the new cross section can be seen in Figure 19. The new cross section was designed with a varying angle, from 50° to 90°, between the mounting surface and face surface to create more compliance around the users' faces.

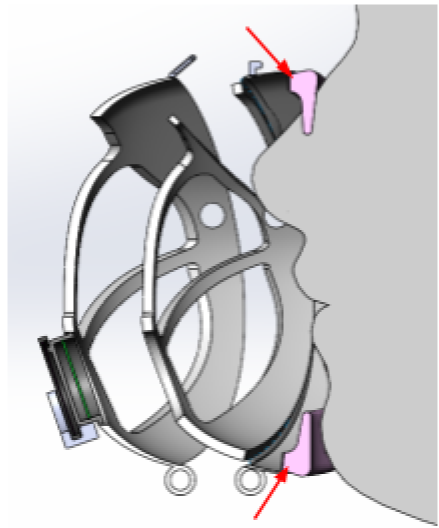

Figure 18: Previous Cross Section of Mask Seal

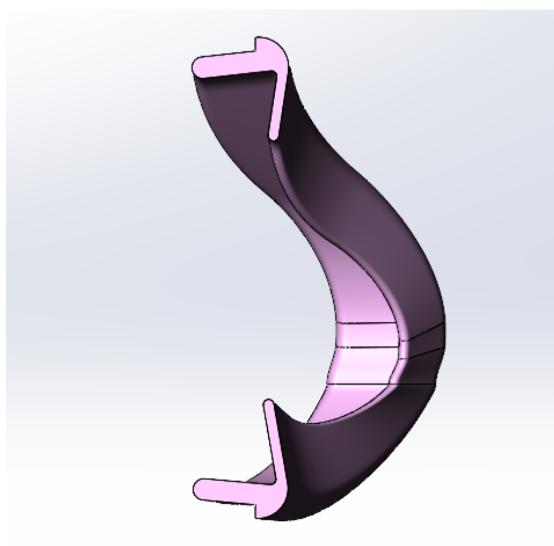

Figure 19: Updated Cross Section of Mask Seal

This model was created with advanced SolidWorks surfacing. The decision was made to empirically test the face seal by creating a physical prototype to truly identify the production and design pain points for future iterations.

The mold negative core and cavity were created in SolidWorks by creating a parting line and removing the face seal body from the two halves of the mold. Holes were then placed in the halves for silicone injecting and air venting. The resulting mold halves can be seen in Figure 20 and Figure 21.

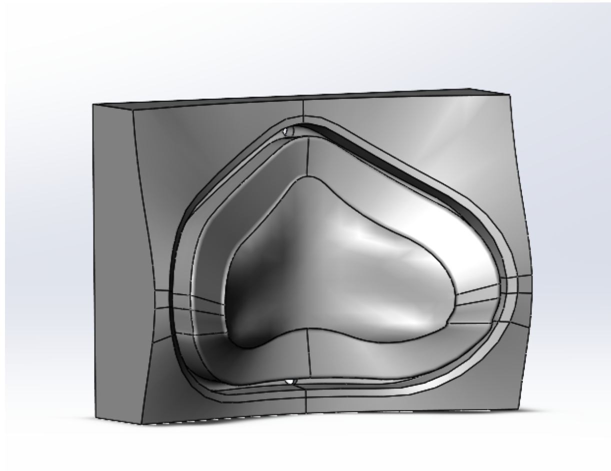

Figure 20: Silicone Injection Mold Core

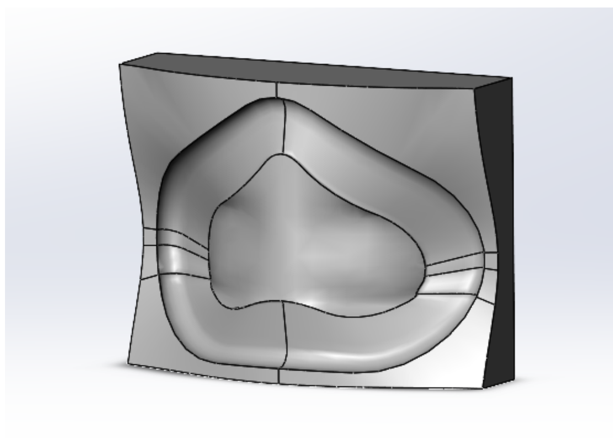

Figure 21: Silicone Injection Mold Cavity

The mold was then sent to the Onyx printer in the capstone lab to create the two halves of the mold. This printer was selected for its high resolution and material strength to ensure no cracking occurred during injection molding. The printed mold can be seen in Figure 22. Mold release was applied to the mold prior to injecting silicone to ensure that the cured mold could be removed.

Figure 22: 3D Printed Silicone Injection Mold

The silicone injection molding was performed with Dragon Skin Shore 30A. Part A & B were mixed, then degassed in the vacuum chamber as recommended in the instructions, shown below in Figure 23. The Dragon Skin was then poured into a syringe and injected into the mold while clamps were applied to the mold.

Figure 23: Dragon Skin Degassing in Vacuum Chamber

Figure 24: Curing Injection Mold

The final product of the injection mold was very promising, seen in Figure 25. This iteration was very close to sealing, but did not quite pass the Birtix test, outlined below in 10.3. The CAD for the face seal has been updated with human factors taken into heavier consideration, and would likely seal in the next iteration. The face seal was bonded into the mask using Sil-Poxy, a product of Smooth-On. It proved to bond well to the resin material of this SLA printed mask, with a cure time of 12 minutes.

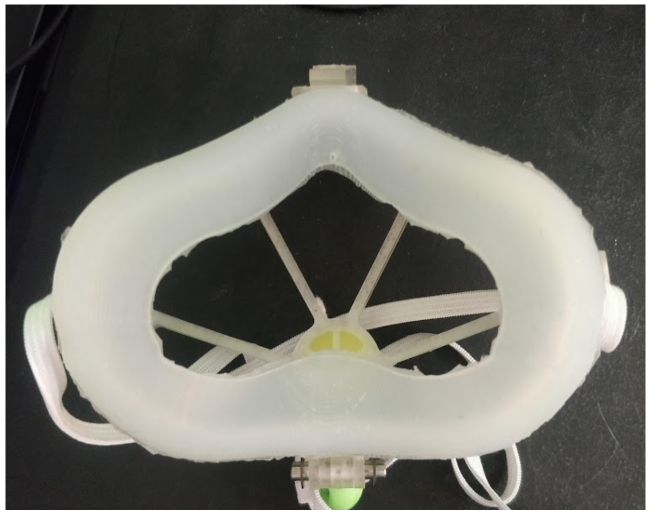

Figure 25: Face Seal Installed

9.5 Cannula Seal

The cannula seal is the most novel part of the mask, as well as being the most challenging mechanical problem that the team came across. The cannula needed to be placed in a comfortable position that follows a normal tube routing along the face. The cannula also couldn't be modified because the team didn't want to alter an existing biomedical device. Not being able to alter the cannula drove the design to need a separate operable compartment in the mask that would have a sealing component that sealed to the N95 standard, didn't crush the tube, and allowed for different sized cannulas.

The team used an EDPM hybrid closed cell foam for this seal. Using a neoprene rubber was also discussed, but the low Poisson ratio and high deformability of the foam made it more desirable, as any deformation will stay in the desired axis. This foam is also being used for the internal gasket subsystem discussed in section 9.6, so using this material will allow for a continuity between the two subsystems, and will ultimately drive material costs down.

The two geometries below in Figure 26 show some earlier stage concepts for the cannula seal. Both of them involve using two "C" shaped structures to create one seal.

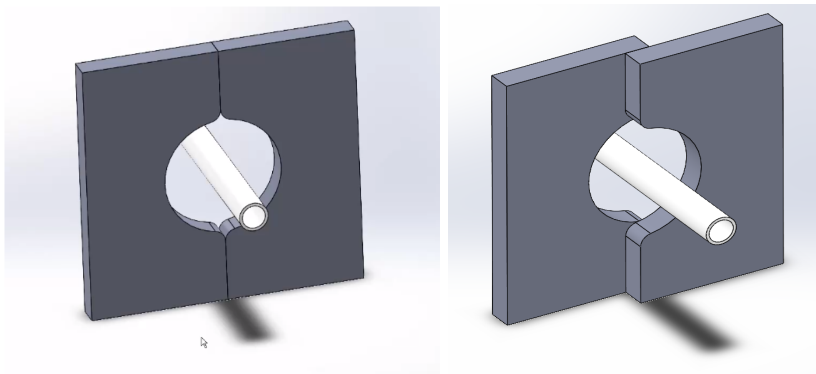

Figure 26: Both Cannula Seal Geometries

In the structure on the left of Figure 26, the two parts of the mask meet and touch. The sealing material (not shown in the images above) wraps along the inner edges and touches end to end. In this design, it would be challenging to create a cohesive seal through the top and bottom of the connection. The sealing success depends upon the deformability of the chosen material, but is likely to result in flaws, which led the team to consider the other geometry (shown on the right in Figure 26) more desirable.

In the alternative design on the right of Figure 26, the material wraps along the inner edges (not shown in the image), but ultimately touches on the sides to create a seal. This design has the two parts of the mask interfacing side by side instead of end to end. In order for this design to work, the material of the gasket must protrude past the end of the plastic mask. While this design provides greater surface area for sealing, there is the issue of the seal deteriorating as the rubber is continually moved side to side. The team anticipated that the material would begin to break down, or inhibit the closure of the mask. The team considers this to be a greater design risk, so the original geometry represented by the picture on the left has been chosen moving forward. A simple FEA analysis, shown below in Figure 27, of this design was done to determine how the seal would deform.

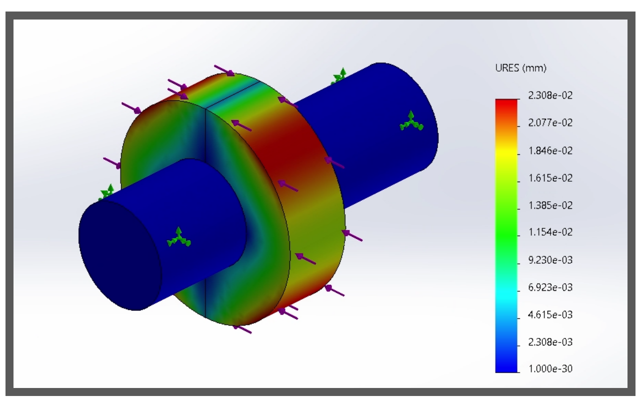

Figure 27: The FEA analysis of the foam seal

The edge to edge orientation shown on the left of Figure 26 was chosen for further testing, however instead of two C's of the same size, the team has considered using different sizes. In this approach, one C is about two thirds of a circle while the other is the remaining third of the circle.

The thickness of the EDPM hybrid closed cell foam for the seal was determined through testing. The test fixture, shown in Figure 28 below, also tested the perimeter seal, and will be discussed in further detail in the section 9.6.

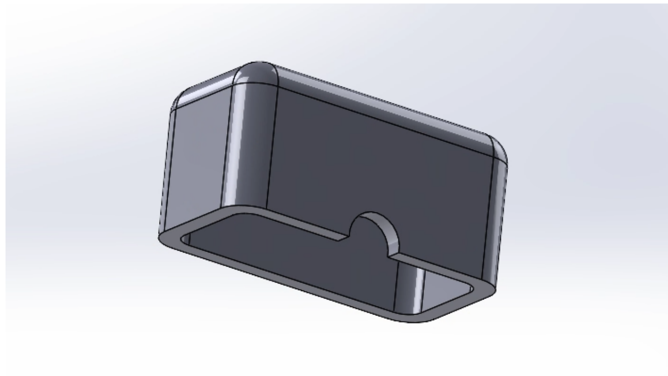

Figure 28: Cannula Seal Test Fixture CAD

In order to determine the appropriate thickness of the foam for the cannula seal, multiple fixtures were created to test four foam widths of varying sizes including 1/16”, 1/8”, 3/16”, and 1/4”. Once the tubing and foam were in place, the two pieces of the fixture fit together and created a seal. The tester then blows air into the cannula while the fixture is held together underwater, and observes if there are any air leaks through the seal around the cannula. An image of this test being performed can be seen in Figure 29 below.

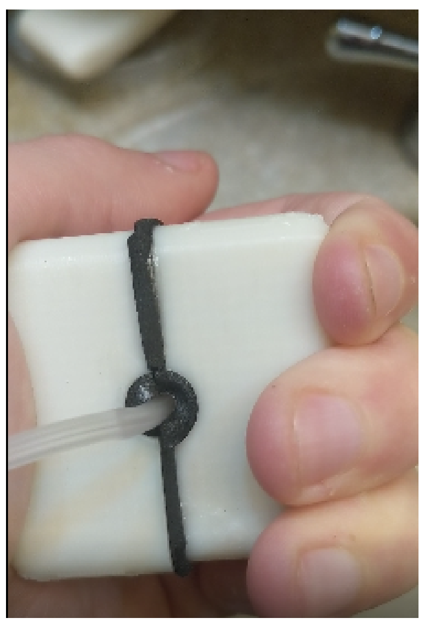

Figure 29: Cannula Seal Test Being Performed

In the test, the seal passed when a low pressure was being applied, but under a higher pressure the seal failed at the corner closest to the cannula. This was not seen as an issue because the team assumed that the exhale valve would alleviate any high pressure difference between the inside and outside of the mask. This test proved the concept and provided optimism for the design, and material choice.

Due to constraints within the CAD model of the mask, the side of the seal with the smaller circle ended up being flat. This was not assumed to be a problem because the Poisson ratio of the EPDM foam is approximately zero, so there was no fear of the foam expanding into the off-axis direction instead of filling the geometry needed to seal. After some calculations (seen below in Equation 1) it was concluded that it only takes about a pound of force to adequately compress the foam. This eased the team's concerns of the foam being too stiff and compressing the tube instead of sealing.

When the cannula seal was isolated and tested during the Bitrix testing, it did not perform as expected and failed the test. This was attributed to the complex geometry of the cannula seal when created in CAD, and the differences of how the cannula seal actually applied pressure to the seal (unevenly), versus how it was expected to apply pressure (evenly). In the isolated fixture test, the cannula was not pulling on the seal in any out of axis direction and the geometry was much simpler. When the seal deformed in the Bitrix testing, it deformed all together in an out of axis direction creating gaps in the seal. To fix this the team used a plastic putty to wrap around the cannula and plug the rest of the hole as shown in Figure 30 below. What was garnered from this was that for a complex geometry and unpredictable loading situation like the cannula seal, a sealing material that deforms plastically was more desirable. A very soft silicone rubber would have been a better design choice for this seal.

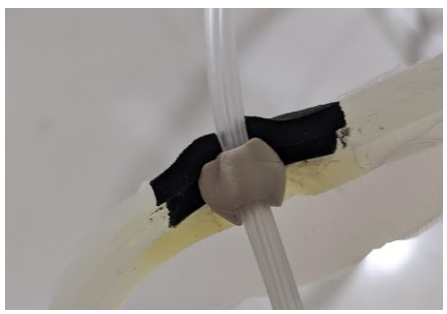

Figure 30: An image of the Cannula seal during Bitrix testing

9.6 Internal Gaskets

9.6.1 Perimeter Seal

The perimeter gasket seals the middle component of the mask to the back of the mask (front to back being from the outside to the patient), seen in Figure 31. As mentioned above in section 9.5, the material for this subassembly is the EPDM hybrid closed cell foam. This material was epoxied to the bottom of the middle lip and compressed against the back piece when hinged shut.

Figure 31: Perimeter Mask Seal

This gasket is how the back and middle of the mask are sealed, aside from the cannula seal. This foam seals when compressed 25%, which occurs when 4 PSI is applied to it. Using the current geometry of the mask, the calculations below were done to find the force needed to seal the mask.

$$P_{Foam} = F_{Latch}/A_S \quad \text{(Eq. 1)}$$

In the above calculations P_{foam} is the pressure needed to compress the foam to the point that it will seal, 4 psi, A_S is the surface area of the gasket, 1.33 in^2, and F_{Latch} is the force needed to reach that desired pressure. Plugging into Equation 1 yields that the force needed from the latch to seal the gasket is around three pounds. This value was set as a design constraint for the latch.

This gasket was tested using the same test setup discussed in section 9.5, and passed as mentioned. This seal also passed the Bitrix test when isolated from the other seals.

9.6.2 Filter Seal

Originally, the front and middle stages of the mask were to be sealed by compressing the filter between two grates, seen in Figure 32. This grate was spaced 1 mm apart which is 1.5x less than the thickness of the Envo filter to properly secure the filter in place.

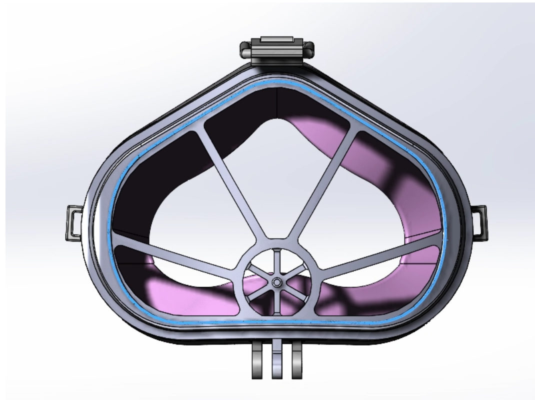

Figure 32: Filter Seal Wall

Although the 1 mm spacing effectively held the Envo filter in place, the Bitrix testing proved that the filter was not properly sealing the mask. To eliminate this problem, the team created a filter seal using the same 1/16" EPDM foam used in previous subassemblies. Once installed, the subassembly was isolated and tested with Bitrix again, which yielded a pass. An image of this filter gasket in the mask can be seen below in Figure 33.

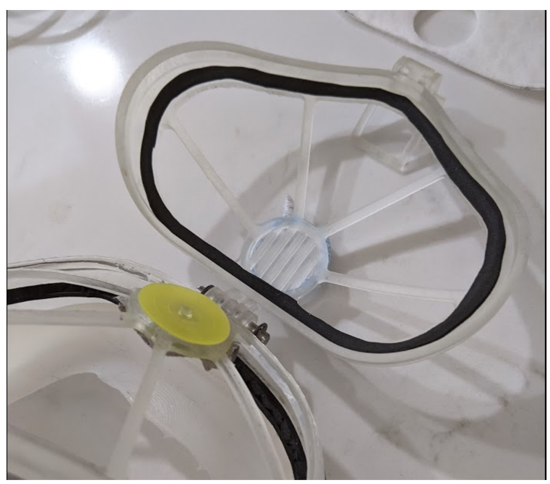

Figure 33: Filter Seal Gasket

9.7 Supporting Hardware

9.7.1 Straps

There is one long strap looped through plastic extrusions on either side of the plastic body that creates two loops around the user's head. The ends of the straps are connected by a round toggle stop to allow for adjustability. The strap being implemented is shown below in Figure 34.

Figure 34: Mask Strap Demonstration

The mask is supported by wrapping tightly around the users head, and specifically not the ears. This ensures that enough force can be applied to the mask to allow for proper face sealing, and is overall more comfortable. The team validated the strength of the strap hooks through empirical testing with the physical prototype.

9.7.2 Latch

The latch is located on the outside of the mask over the nose bridge as shown in Figure 35 below. The geometry and shape of the current latch is shown in Figure 36 below.

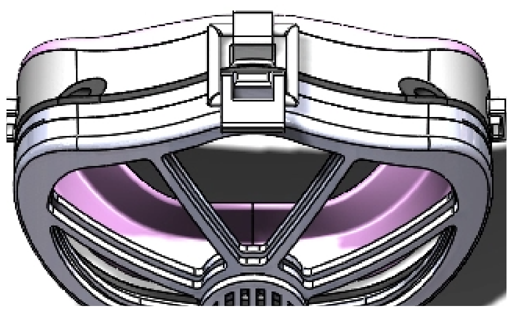

Figure 35: Latch Location

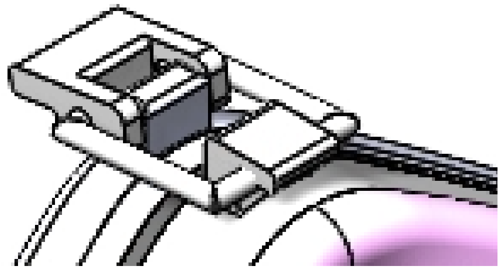

Figure 36: Latch Geometry, tab on left, hook on right

The latch is responsible for securing the all three parts of the mask together while in use. This means that it must hold up against unpredictable or abrupt movements of the face and head. The latch must also be easy enough for the average person to secure, but secure enough to not come apart unless the user is deliberately trying to open it.

The latch operates by the user flipping a tab upwards. This loosens the “hook” part and allows for the mask to open. Once the user has inserted the filter and cannula, the hook is put back into place, and it is tightened by flipping the tab back downward.

10. First Prototype

The first prototype, shown in Figure 37 below, was an FDM ABS 3D printed main body with Vytaflex 10 face seal. Elastic straps and a toggle stop were installed to simulate real use, but the prototype could not be worn since the Vytaflex is not a skin safe material.

Figure 37: First Prototype

Missing in this prototype is the nasal cannula sealing material, as the testing was not yet completed for the sealing material, and the exhale valve subassembly. Although this first prototype didn’t have every subassembly installed, the creation of it gave us key insights into design and process changes that determined how the team moved forward.

Firstly, the extrusions on the side of the base of the mask were too deep. In the CAD model, they ensured the face seal met with the model's face, but these were too long and extended far into the user's face. Additionally, the latch broke immediately when used, and the filter grate did not perfectly fit the Envo N95 filter. The team had planned on attaching a pre-existing exhalve-valve to the mask, but realized that it wasn't possible once seeing this prototype. Design changes on the plan for the exhale valve were also made once seeing this prototype and the mounting location of the top of the face seal geometry will be changed. As these changes are made, many subassemblies and their build processes are becoming finalized which will free up resources for other, more intensive, design and validation work.

11. Final Product

The final product was printed with SLA, and has all aforementioned components included. The steps of mask operation are shown in Figures 38-43 below.

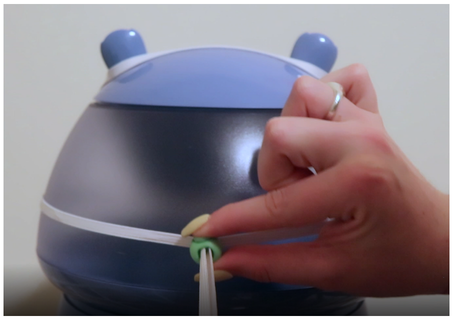

Figure 38: Adjusting Toggle Stop on Straps

Figure 39: Unlatching Mask

Figure 40: Mask with all Stages Open

Figure 41: Replacing Filter

Figure 42: Inserting Cannula

Figure 43: Inserting Filter Cover

12. Analysis and Testing

To analyze the effectiveness of the team's mask design through the iterative prototyping process, qualitative N95 mask checks [14] will be performed to better evaluate filtering and sealing properties of the N95 mask with integrated nasal cannula. True N95 validation is obtained with a sodium chloride aerosol, but this test must be performed by a 3rd party. Similar tests can be performed with a saccharin solution aerosol and denatonium benzoate with different types of smells to ensure seals are complete. These solutions are made of compounds about the size of N95 mask filtration specifications, to determine if the mask is up to standard.

For the safety of all testing participants, one mask must only be used by one person. No participants will be permitted to have facial hair when testing the sealing qualities of the mask.

12.1 Preliminary Fit Test

The preliminary fit test aims to identify any discomfort, pains, or pressure pains in the initial wearing and operation of the prototype. It also aims to test if the mask fit is tight enough to prevent slipping. This test takes approximately 3 minutes, not including time for cleaning and sanitation.

This test does not require the N95 filter or the nasal cannula to be installed in the prototype. At any point in the test, if the participant experiences discomfort or pain, they should note it to the facilitator. This test does not have a standard feedback form. Instead, results will be focused on specific pressure points and specific discomforts. If there is pain or discomfort noticed during the test, the location should be noted, along with a 1-10 gauge of discomfort.

1. Remove cloth mask
2. Following all steps outlined in the instructions, put the prototype on the face
3. Ensure that the fit is tight to the face and the straps are in the correct position
4. Turn head all the way to the left, hold 2 seconds
5. Turn head all the way to the right, hold 2 seconds
6. Look as far as possible upwards, hold 2 seconds
7. Look as far as possible downwards, hold 2 seconds
8. Repeat the last 4 movements
9. Move head in a circle for 10 seconds, reversing directions halfway through
10. Open mouth wide, hold for 2 seconds
11. Repeat last movement
12. Talk for approximately 30 seconds
13. Bend down, as if to pick something off of the ground
14. Repeat last movement
15. Remove prototype

12.2 Long Term Comfort Test

The long term comfort test aims to detect any discomfort from a person wearing the mask for a standard use time. Standard use time is estimated at one hour. This simulates wearing the mask to a store.

This test requires a fully assembled mask. At any point in the test, if the participant experiences discomfort or pain, they should note it. Participants should pay specific attention to breathability. Follow the same reporting instructions as 10.1.

1. Remove cloth mask
2. Following all steps outlined in the instructions, put the prototype on the face
3. Place cloth mask over prototype (if incomplete)
4. Wear the prototype for one hour, continuing daily life as one normally would
5. Remove the prototype and cloth mask
6. Put on cloth mask

12.3 N95 Validation

True N95 validation cannot be achieved without sending the prototype to an external testing organization, so in place of this, the team used Bitrix testing. Bitrix is an aerosol that produces a bitter taste in a person when inhaled. This test first takes a "control" by using the sensitivity spray on an unmasked person. Then, that person puts on the mask and the self contained head fume hood seen in Figure 44. The Bitrix fit test spray is sprayed, and if the bitter taste is not detected, the mask passed the test. The specific testing procedure is outlined in the test kit. There are no inherent risks in this testing method. It is widely used across thousands of companies to determine respirator fit, and the team obtained approval to use the test before using it on any team members. To isolate testing of subsystems, duct tape was used to cover and seal off any subsystem that was not being tested. This allowed the test to "pass" or "fail" a single subsystem.

Figure 44: Fume Hood [21]

13. Project Management

To ensure that the design was completed on time, the team utilized a Gantt chart and updated it frequently to map out the timeline of the design, testing, and fabrication. A visual of the chart is provided below in Figure 45, and the chart can be read for specifics on the timeline, but three key aspects are noted.

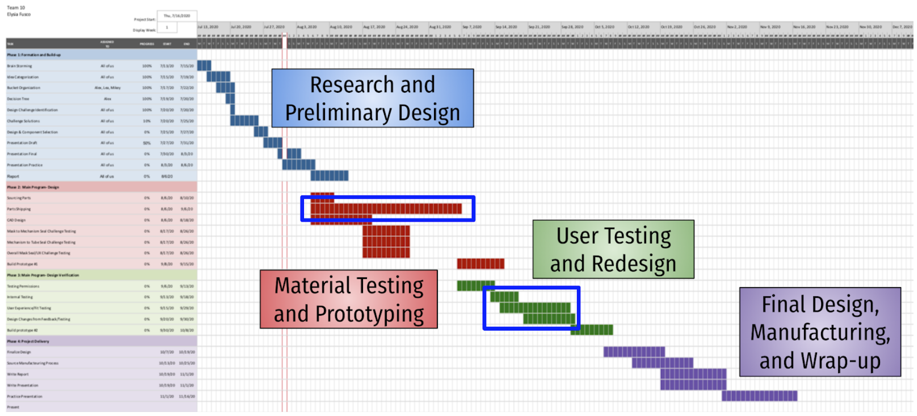

Figure 45: Gantt Chart

13.1 Material Acquisition

Over the course of the project, the world endured a global pandemic, and there were shortages of essential materials, and that included everything related to N-95 filtration. The team left extra time for these materials to ship, keeping in mind any potential delays. The team was successful in obtaining all necessary materials to complete all testing and the final prototype.

13.2 Design Iterations

The team built enough time into the schedule for a first physical prototype, comprehensive testing, and then a complete redesign and build based on testing results. Although the timeline was shifted around due to various delays, the team was successful in completing all of these steps on time. There were a few aspects of the mask that did not work perfectly and as planned, and the team would need more time to work on them if they decided to move forward with the project after Capstone.

13.3 Testing

Testing was a crucial aspect of the timeline. Beyond filtration quality, testing was critical in determining the comfort and breathability of the mask. The testing ultimately led to a number of design changes that would have been overlooked if the team did not leave enough time for it.

14. Conclusion

Throughout the Capstone 1 course, the team dove head first into the project. When first learning of the project assignment, the team immediately divided into research groups and began looking into N95 masks, nasal cannulas, and any relevant information that could help put the two together. The most useful things found during the initial research were the Envo® mask and an experiment testing the seal of an N95 mask, modified to deliver oxygen to the patient. In tandem with research efforts, the team also began interviewing cannula users to gather insight into preferred design aspects.

After better understanding the background and scope of the project, the team began brainstorming solutions. These ideas ranged from disposable masks to space-helmet-inspired designs, covering almost everything in between. As further research was conducted and the team had more conversations with patients, it became evident that patients would like a reusable mask, as well as the option to use their own cannula. This led the team to the current design of a reusable mask with disposable filters and a latching mechanism to facilitate insertion and removal of the cannula. At the end of Capstone 1 the design was broken into four subsystems including the straps, the face seal, the filter, and the cannula seal, each of which poses their own unique design challenges.

Throughout Capstone 2, the team made substantial progress in improving the design of the product. The final design is broken into numerous subsystems including the plastic body, face seal, internal seal, cannula seal, filter, exhale valve, and supplementary hardware. The plastic body was 3D printed, the silicon face seal was molded and attached, and the foam gaskets were installed. The first prototype was tested for functionality and comfort, following the N95 Bitrix Validation test plan outlined in Section 12.3. In order to comply with the standards set forth by the group, the plastic body design was updated after testing to better consider human factors and manufacturability, the face seal was modified to accommodate the contours of a human face, and the geometry of the cannula seal mechanism was slightly altered to ensure proper sealing. With these modifications, the team successfully proved the applied mechanical concepts and is confident in the functionality of the final design.

15. Intellectual Property

15.1 Description of Problem

In the midst of a global pandemic, the team is aware that those with pre-existing lung conditions are at higher risk of death after contracting COVID-19. While a normal person can wear an N-95 mask out to protect themselves, those who wear nasal cannulas cannot, as the tube of the cannula breaks the seal of the mask. Therefore, a mask must be developed that integrates a nasal cannula into an N-95 mask to keep those most at-risk people safe.

15.2 Proof of Concept

The design for this mask involves a hinged mask that opens and allows for a replaceable N-95 filter and a replaceable nasal cannula. The rest of the mask is made from a form fitting material that does not let air through and seals to the face of the user. The mask allows the cannula to be adjustable to fit the comfort of the user. The mask has an exhale valve to allow for easier breathability, and a cloth covering over that to protect others around the user.

15.3 Progress to Date

The group has a prototype that has validated the sealing of the cannula tube and filter cage. This prototype does not pass leak testing for the exhale valve or the face seal, but these parts have been fixed in CAD. All of the minor components, including the hinge, latch, and straps, are fully functional.

15.4 Individual Contributions

Alexander Arcasoy: previous technology research, criteria development for the design, sealing mechanism design, face seal material selection, manufacturing research, plastic body CAD, face seal CAD, silicone molding, and physical mask prototyping and testing

Conor Byrne: background user research, user questionnaire, testing procedure, exhale valve research, silicone molding

Elysia Fusco: material research, problem definition, identifying crucial aspects of the design, project management, supporting hardware CAD, physical mask prototyping and testing

Mikey Melito: challenge/problem solving (sealing difficulties, cannula insertion, etc.), internal gasket design, cannula seal geometry and material selection

Molly Sharpe: design sketches, sealing mechanism design, plastic body CAD, supporting hardware CAD modifications, human factors & supporting hardware research, videography

15.5 Future Work

Another prototype needs to be printed with the corrected geometry for the exhale valve and the face seal. This will allow the mask to be fully functional. The cannula seal, while validated with the putty fixture, should be optimized. Additionally, future manufacturing methods need to be researched. Once the CAD for the mask is finalized, manufacturing of the mask can transition from SLA printing to plastic injection molding, which is much cheaper and more efficient. Bulk suppliers must be found for all materials of the mask, to ensure a steady and cheaper supply of parts.

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Appendix A: Relevant Survey Responses

How many hrs/day do you wear your cannula?	During the pandemic, how often have you had to leave your residence for essential reasons?	Have you worn an N95 mask before?	If yes to the question above, do you have difficulties breathing through an N95?
18>	1-2x a month		
0-6	1-2x a week	No	
0-6	Daily/almost daily	Yes	No
6-12	1-2x a week	No	No
6-12	1-2x a week	No	Yes
18>	1-2x a month	Yes	Yes
12-18	None	Yes	Yes
18>	1-2x a month	No	I have not worn an N95 mask
18>	1-2x a month	No	I have not worn an N95 mask
18>	1-2x a week	Yes	Yes
12-18	1-2x a month	Yes	Yes
18>	1-2x a week	No	I have not worn an N95 mask
12-18	1-2x a month	Yes	Yes
18>	1-2x a month	Yes	Yes
18>	1-2x a week	No	I have not worn an N95 mask
18>	1-2x a month	No	I have not worn an N95 mask
18>	1-2x a month	No	I have not worn an N95 mask
18>	1-2x throughout the pandemic	No	I have not worn an N95 mask

How important is comfort? (1-5)	How important is cost? (1-5)	If this mask was one-time use (approx. 8 hours of use), how much would you be willing to pay?	If this mask was reusable with cheap replaceable filters, how much would you be willing to pay?
3	3	3-4$	5-10$
4	5	2	10
4	5	No more than 5$	No more than 20$
5	5	$3.00	More
5	5	None	Yes
4	5	don't know	more
3	3	One pound	20+ pounds
5	5	Needs to be affordable for ones on medicaid or no insurance. Insurance will not cover it soo, $2/3 .	$5 with the filters being maybe 15 per 50.
5	5	I would not buy a one time use mask.	10
4	2	Insurance or cash	See above
5	3	$5.00	50
5	4	not sure	Not sure
4	5	5.99	10.99
5	5	?	$22
5	5	not sure	not sure
4	4	$2.00	$5.00
4	3	$5	$40
5	1	$3	$20