COSMIC MEDICAL
Collective Open Source Medical Innovations for COVID-19

# Project Bubble Helmet

# 1.0 Introduction

## 1.1 Background

Many methods for providing respiratory support to patients are currently in use, however more commonly available techniques such as Continuous Positive Airway Pressure (CPAP) are not appropriate for ventilation of patients with airborne infectious diseases due to the risk of aerosolization endangering other patients and hospital staff. A hermetically sealed device to provide NIPPV to patients allows for the provision of respiratory therapy with widely available methods such as CPAP, while minimizing or eliminating the risk of infection for other patients and staff.

The majority of patients who die from COVID-19 experience Acute Respiratory Distress syndrome (ARDS). In ARDS patients, it has been demonstrated that NIPPV with a ventilation helmet rather than a face mask can significantly improve clinical endpoints, reducing intubation rates by 43.3% and death rates by 22.3%[1]. Given that COVID-19 results in ARDS, and it is known that ventilation helmets improve ARDS outcomes, a novel, widely accessible ventilation helmet will clearly be a useful invention.

Respiratory support may require patients to receive treatment for an extended period of time. It is therefore necessary to provide methods of treatment that prioritize the safety and comfort of the user. Any such method of treatment should sit comfortably on the user without impeding vision or communication, and must be fast and easy for the user or care providers to put on or remove. Furthermore, such a device must retain its effectiveness when used in a reclining position.

## 1.2 Our mission

Our team's mission is to support and facilitate the adoption of helmet based non-invasive positive pressure ventilation (NIPPV) in Canadian hospitals in an effort to combat COVID-19.

## 1.3 Design Requirements

Prior to the production of the CBH, a list of requirements was created based on the functionality, safety and manufacturing of this device. The primary focus of these requirements includes functionality, patient and healthcare worker (HCW) safety, as well as ease of device production.

[1] Patel BK, Wolfe KS, Pohlman AS, Hall JB, Kress JP. Effect of Noninvasive Ventilation Delivered by Helmet vs Face Mask on the Rate of Endotracheal Intubation in Patients With Acute Respiratory Distress Syndrome: A Randomized Clinical Trial. JAMA. 2016;315(22):2435–2441

| Type | Requirements |
|---|---|
| **Technical Requirements (TR)** | |
| **TR1** | Materials used for the device must be suitable for direct skin contact, compatible with high oxygen concentration, and have minimal outgassing i.e. should be biocompatible for the application in question. |
| **TR2** | All components of the device must be able to withstand an airflow of up to 120 L/min and positive end-expiratory pressure (PEEP) of up to 30 cm of $H_2O$ |
| **TR3** | Air leakage must be below 5% of the volume entering the device when the helmet is at operating pressure. |
| **Usability Requirements (UR)** | |
| **UR1** | Device preparation and donning must not exceed 10 minutes. |
| **UR2** | The provider must be able to see the patient clearly through the device |
| **UR3** | Patient must be able to communicate visually |
| **UR4** | The noise inside the helmet must not exceed 87dB for 8 hours as per Canadian Federal Noise Regulation |
| **UR5** | Patients must not feel significant discomfort in a prone position, side position and in an upright position while wearing the device. |
| **UR6** | Patients must not feel significant discomfort due to the upward force the device exerts on the neck while in operation. |
| **Safety Requirements (SR)** | |
| **SR1** | Helmet must be easily removable within less than 30 seconds in the case of an emergency |
| **SR2** | $CO_2$ accumulation inside the device must not exceed by 20% as per ISO 17510 |
| **SR3** | Helmet must not collapse and occlude patients' airways in the event of pressure loss. |

| Market Requirements (MR) | |
|---|---|
| **MR1** | The cost of the device must not exceed $100 CAD |
| **MR2** | The materials needed for the device should be easily available and the initial investment manufacturing cost should be low enough so the cost of the device is  below 100 CDN. |

## 1.4 Our Design

The bubble helmet is a helmet that delivers non-invasive positive-pressure ventilation (NIPPV) to patients requiring respiratory support by interfacing with high-flow hospital oxygen, CPAP machines, or mechanical ventilators. The helmet is a single-part device that consists of an optically transparent and flexible hood, within which the patient's head is contained, with a flexible neck gasket that provides a hermetic seal around the patient's neck. Standard medical ports are attached to the hood allowing for the administration of gasses, while straps on the hood secure the helmet to the wearer's body.

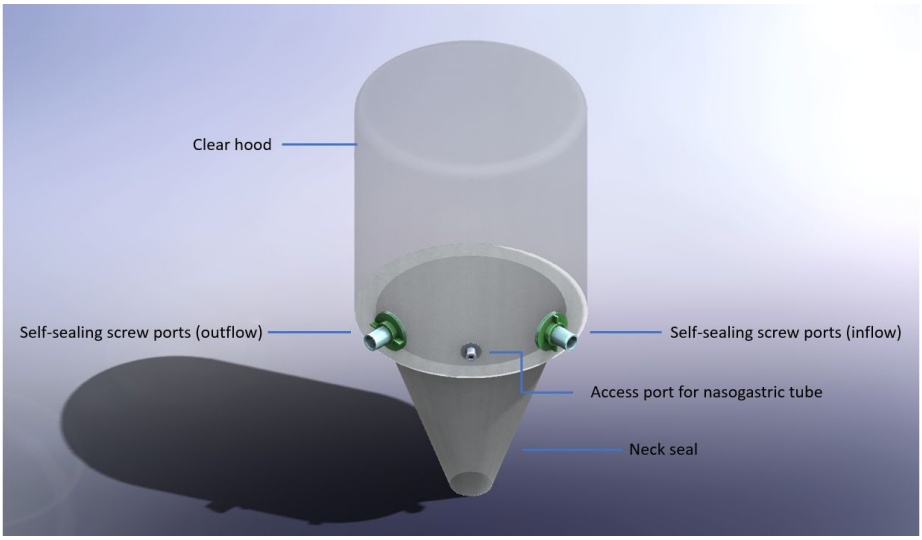



*Figure 1.1: Render of the Bubble Helmet with all components labeled*

# 2.0 The device

## 2.1 Device Overview

The BH consists of two major components: a flexible, transparent hood, and a neck seal. The material, a biocompatible thermoplastic polyurethane (TPU), is attached using heat sealing or other related

modalities to provide an airtight seal and minimize the release of aerosolized particles. The hood transparency and neck seal allows for a clear, unobstructed view for patients and HCW, minimizing claustrophobia and allowing patients and HCW to observe and communicate efficiently. This increases patient tolerability and comfort, while decreasing complications and intubation rates. Unlike most helmets on the market which have a rigid ring connecting the helmet and neck-seal together, the flexibility of our design provides greater freedom of mobility as patients can comfortably sit upright, lie supine or lie prone. The design also incorporates two standard medical ports in the body of the hood, which allows the device to be used with hospital wall gases, CPAP, BiPAP, and ventilators. Shoulder straps with quick-release buckles are used to ensure the device is properly secured when in-use.

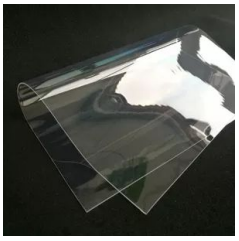
*Figure 2.1: Full assembly of the Bubble Helmet as used in a hospital*

To perform NIV treatment, the hood encloses the patient's head. Both 22mm standard medical ports on the BH hood are connected to the inspiratory and expiratory ports. The neck seal is adjustable and can be cut-to-fit by HCW. The inspiratory gas supply assembly consists of the input oxygen connector, which supplies pure oxygen, and the input air connector from either the CPAP or BiPAP machines or wall-mounted regulators, which supplies medical-grade air to patients. The expiratory port of the BH connects the gas exhaust assembly, which consists of a manometer, a high-efficiency particulate air (HEPA) filter, and a positive end-expiratory pressure (PEEP) valve. The PEEP valve is used for manual pressure control within the BH and the manometer will monitor and read the pressure levels. The pressure within the BH is maintained to ensure the patient's airway pressure is above atmospheric level, ranging

from 5 to 30 cm H20. The HEPA filter is used to contain the virulent aerosolized particles released by the patient, ensuring clean output airflow from the BH system to protect HCW.

## 2.2 Materials

Constructing the Bubble Helmet is quick and simple. For one unit of the BH the materials you will need are specified in the table below:

| Bill of Materials: Prototype 4.1 | | | |
|---|---|---|---|
| **Item** | **Specifications** | **Count** | **Photo** |
| **Clear hood** | 15 mil Aliphatic TPU or other similar thickness clear TPU | 1 |  |
| **Neck seal** | 3-4mil polyether TPU or other similar thickness clear TPU | 1 |  |
| **Option 1: Self-sealing screw ports** [https://www.thingiverse.com/thing:4311901](https://www.thingiverse.com/thing:4311901) By Shawn Lim -Bot Camp | 22mm OD, 15mm ID | 2 |  |

| | | | |
|---|---|---|---|
| **Option 2:**<br>**Mechanical seal** | T-piece 22OD (ideally with corrugate) with 22 ID connectors | 2 sets |  |
| **Velcro** | N/A | 4 x 2 inches strips |  |
| **Straps/ buckles** | N/A | 2 pcs |  |
| **Optional access Ports** | For straws or nasogastric tubes. It has two size openings to accommodate different size tubes and minimize air leak. | 1 |  |
| **Hospital supply - depend on local availability - price only an estimate** | | | |
| **PEEP valve** | 30 mm ID,<br><br>0 – 20 cmH2O | 1 |  |

| | | | |
|---|---|---|---|
| **T-piece one -way valve with ports for manometer connection** | Can function as a small anti-asphyxiation valve with one way valve and connect to manometer | 1 |  |
| **Manometer** | Measure pressure inside helmet | 1 |  |
| **Viral HEPA filter** | Filters particles < 0.1 um | 1 |  |
| **Oxygen supply adaptor for CPAP/BiPAP** | Allows multiple oxygen/air source to be connected at the same time | 1-3 |  |
| **Various Connectors** | 22mm ID – 22mm ID<br><br>22mm ID – 30mm ID | 3 |  |
| **Oxygen line lines** | To connect to gas oxygen supply | 3 |  |

## 2.3 Detailed Design

### 2.3.1 Hood

The hood consists of a top **1** and body **2** joined as shown in Appendix B Fig. 1 and Fig. 2, creating an air-tight seal between the overlap of the hood top **1** and body **2**. The hood components are made of transparent and flexible TPU providing the user with an unobstructed field of vision. The hood's transparency enables HCW to clearly observe the user.

The hood body **2** is connected to the neck seal **5** as shown in the figures, providing an air-tight seal between the inside of the hood and the outside of the neck seal. The neck seal **5** is a flexible transparent plastic material of generally frustoconical shape. As shown in the figures, the neck seal encircles the user's neck in operation resulting in an air-tight seal between the neck seal and the neck. The neck seal can be cut by care providers in order to fit the neck of the user.

The stability straps **6**, comprises a quick release buckle and a nylon material, providing improved stability and comfort for the user. As the helmet inflates and the walls of the helmet experience the pressure, there is a tendency of the helmet to move upward exerting pressure on the patient's neck. This pressure is relieved by the use of straps. Under operating conditions, the strap is connected onto the hood body and wraps under the arm of the user, holding the helmet assembly in place and thus reducing the upward pressure on the patient's neck. As shown in Fig. 1 and Fig. 2 , the straps attach to the hood body **2**. The straps include a quick release buckle providing easy donning and doffing.

### 2.3.2 Ports

The hood body **2** has two holes of equal diameter in the front for the ports. These ports allow for the administration and exhaust of gas from a flow source such as medical wall oxygen, a CPAP machine, or a mechanical ventilator.The ports are rigid that can be locally sourced or 3D printed. Material must only be non-toxic and compatible with TPU.

### 2.3.3 Neck Seal

The neck seal **5**, made from a single piece of 3 or 4 mil TPU, provides improved comfort for the user over conventional designs, and allows for improved comfort when used in a reclining position when compared to traditional designs employing a rigid ring. The transparency of the neck seal piece acts to supplement the transparency of the hood, providing a fully unobstructed field of view for the patient and HCW.

## 2.4 Assembly

The simple design of the bubble helmet allows it to be easily manufactured by making 2D cuts from sheet TPU and welding these pieces together to create the assembly. Some common methods of welding

include heat sealing, RF welding and impulse sealing. This is to ensure an airtight seal between the parts of the assembly.

The hood portion of the helmet is constructed with the hood body and hood roof 2D shapes cut from 15-20 mil TPU. The hood body is a simple rectangle with sides welded together creating a cylindrical shape as shown in **Appendix B Figure 4.** The hood top as shown in **Appendix B Figure 3** is welded to the hood body as shown in **Appendix B figure 1**. The neck seal is also made of a simple 2D shape made from 3 or 4 mil TPU with edges welded together creating a conical shape as shown in **Appendix B Figure 5**. Use the chosen welding method to connect the conical neck seal to the bottom of the hood as shown in **Appendix B Figure 1**.

Connect ports to the hood at the holes in the hood body as shown in **Appendix B Figure 1**. There are two options for the ports: the 3D printed self sealing screw ports as shown in **Figure 2.2** or the combination of two sets of 22mm OD T-piece connector and 22mm ID connector as seen in **Figure 2.2.**

*Figure 2.2: (left) T-piece connector and 22mm ID port (right) 3D printed port*

The straps can be attached to the hood assembly in multiple ways such as velcro, described below, adhesive or welding. To set up the velcro strap connection to the bubble helmet, follow the steps below.

1. Attach two pieces of velcro to each side of the port at a distance of 2” from the outer rim of the port.
2. Attach the short piece of the strap containing the female buckle to the anterior velcro
3. Attach the long piece of the strap containing the male buckle to the posterior velcro
4. Repeat steps 1-3 for both sides of the helmet.

*Figure 2.3: Placement of the straps on the body of the Bubble Helmet*

At the inspiratory port, connect the desired flow provider - wall oxygen, CPAP, BiPAP, or ventilator shown below in **Figure 2.4**. If connected to wall oxygen, connect a manometer, HEPA filter, and PEEP valve in series at the expiratory port. If connected to CPAP/BiPAP, connect a manometer and HEPA filter to the expiratory port. If connected to a ventilator, plug the expiratory port.

*Figure 2.4: (left) Connection of the manometer, HEPA filter, and PEEP valve in series at the expiratory port for wall oxygen interface (right) plugged expiratory port for ventilator interface.*

## 2.5 Usage

For complete usage instructions please refer to section 4.1.

**DISCLAIMER**:

**THIS DEVICE IS FOR USE WITH QUALIFIED HEALTHCARE PROFESSIONALS ONLY. THERE IS A HIGH RISK OF ASPHYXIATION IF NOT PROPERLY OPERATED AND MONITORED.**
**APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT MUST BE WORN AT ALL TIME WHEN USING THIS DEVICE.**

***Insufficient Flow :***

**DO NOT operate the helmet below minimum airflow of 30L/min** to prevent $CO_2$ build up inside the helmet leading to $CO_2$ rebreathing and narcosis. Therapeutic flow level will typically be higher and will be determined by responsible physicians based on the patient's respiratory condition.
**BEWARE of potential circuit disconnection which disrupts air flow.**

**Ensure patients understand and are able to demonstrate how to remove the helmet themselves in case of emergency or feeling of suffocation.**

***Pressure Build-up:***

**Inadvertent blockage of the outflow port will lead to pressure buildup within the helmet. Educate patients about this risk.** If at any point the patient experiences discomfort from too high pressure, the patient can insert a finger into the helmet and expand the neck seal to allow air to escape and lower the pressure. **Prolonged excessive pressure >30cmH2O may lead to barotrauma of the lung.**

# 3.0 Testing

## 3.1 Verification tests to conduct to check for proper assembly

Currently, the team is in the process of applying for the clinical trials. However, the verification tests are conducted on COSMIC Bubble Helmet. The results indicate the following.

***Leakage Test***
Leakage test was conducted at the PEEP pressures of 5mm, 10mm and 15mm of $H_2O$. The results indicated consistently fewer occurrences of leakage that the commercially available StarMed Helmet.

***$CO_2$ Accumulation Tests***
Static $CO_2$ accumulation tests indicate that the helmet does not allow for dangerous increases in $CO_2$ levels at flow rates above 40L/min which is generally employed in the bubble helmet based ventilation. The test was also conducted with BiPAP and the results indicated $CO_2$ levels within the safe limits.

***PEEP Pressure Test***

The tests were conducted in the pressure range of 5 to 30 mm of $H_2O$. The results indicated no observable failure of any component of the device.

In order to verify the proper assembly of the helmet, two vital tests must be performed: leakage and pressure containment. Please see the protocols in the testing documentation attached (Section 4). The results should be similar to those obtained in the testing documentation.

## 3.2 Usability tests previously conducted

The following usability tests were conducted on all prototypes constructed by the COSMIC group.

***Hood Visibility***

This test was used to assess the transparency of the helmet, for the benefit of both the user and HCW. The test subject performed tasks such as reading a book and observing others, while another made observations on the helmet user. The COSMIC bubble helmet provides transparency of the hood as well as the neck seal. These designs allow the patient to perform tasks such as reading a book, working on computers and also provide an unobstructed view of the patient for the HCW.

***Donning/Doffing***

This test determined the ease of putting on and removing the helmet, which must be performed rapidly and easily in case of an emergency situation. The COSMIC bubble helmet allows for quick donning by a single HCW with assistance from a cooperative patient or with two HCW. Donning can be done in less than 30 seconds and doffing by HCW or patients takes less than 15 secs. The soft construction of the helmet allows for emergency removal using a pair of scissors.

***Setup and assembly***

This test was used to assess the difficulty and time required for HCW to set up the helmet. The time required for a test subject, provided with a manual, to assemble the helmet, was observed.

***Operating noise***

To ensure that the helmet was comfortable enough to be worn for the extended periods of time that may be required for NIV treatment, this test evaluated the comfort of wearing the helmet for up to 3 hours.

## 3.3 Further tests

To ensure the reliability of the Bubble Helmet, prolonged durability testing must be conducted in a simulated setting. As the Bubble Helmet is designed to be worn for up to a week by a single patient, the

neck seal integrity under different pressure levels must be tested for that duration. This testing was beyond the capacity of our group but is vital to ensure the functionality of the device.

# 4.0 Attachments

## 4.1 Donning/doffing guide pdf

Please see the donning/doffing guide on GitHub: https://github.com/COSMIC-medical/bubble-helmet

## 4.2 Testing documentation

Please see the full testing documentation on GitHub that verifies the functionality of the Bubble Helmet: https://github.com/COSMIC-medical/bubble-helmet

## 4.3 Appendix B

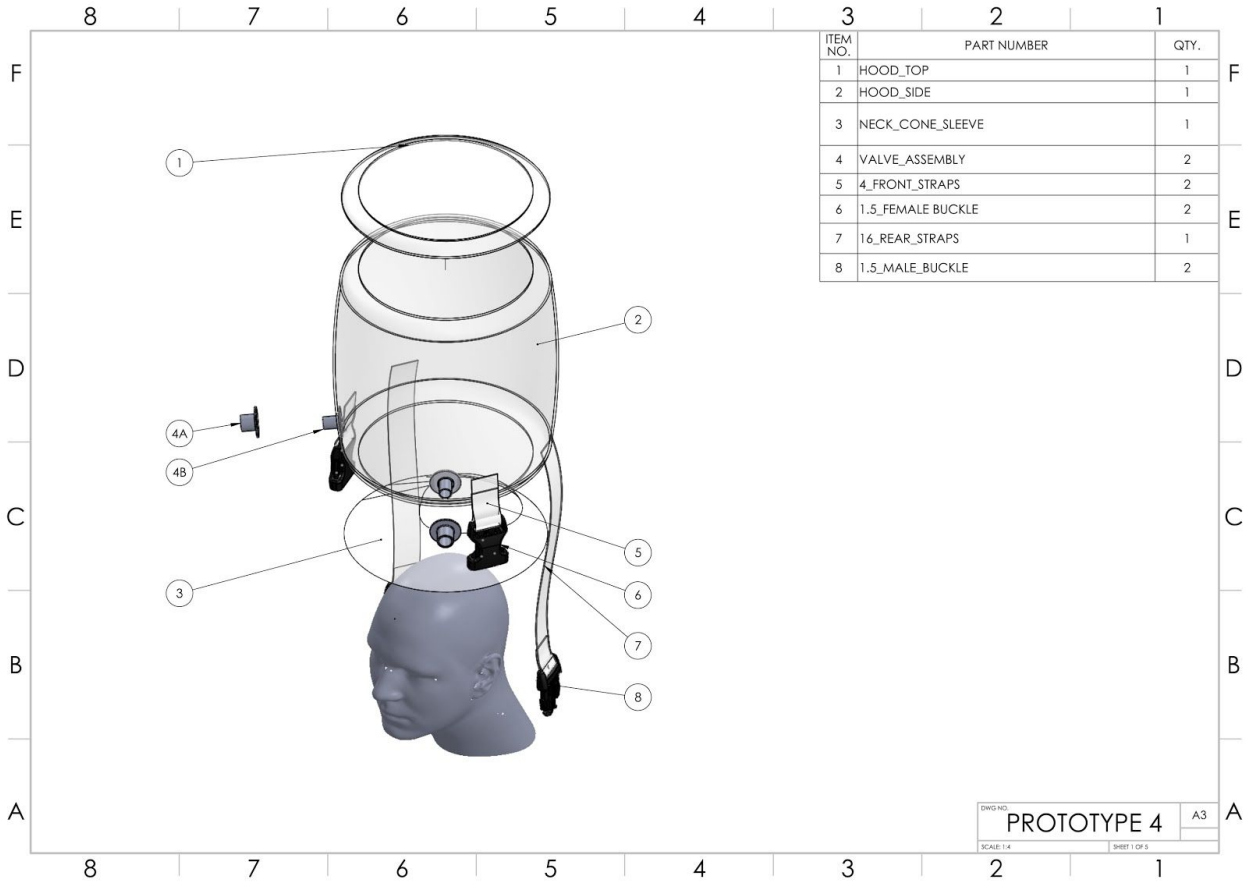



*Figure 1: CAD rendering of a disassembled Bubble Helmet with numbered components*

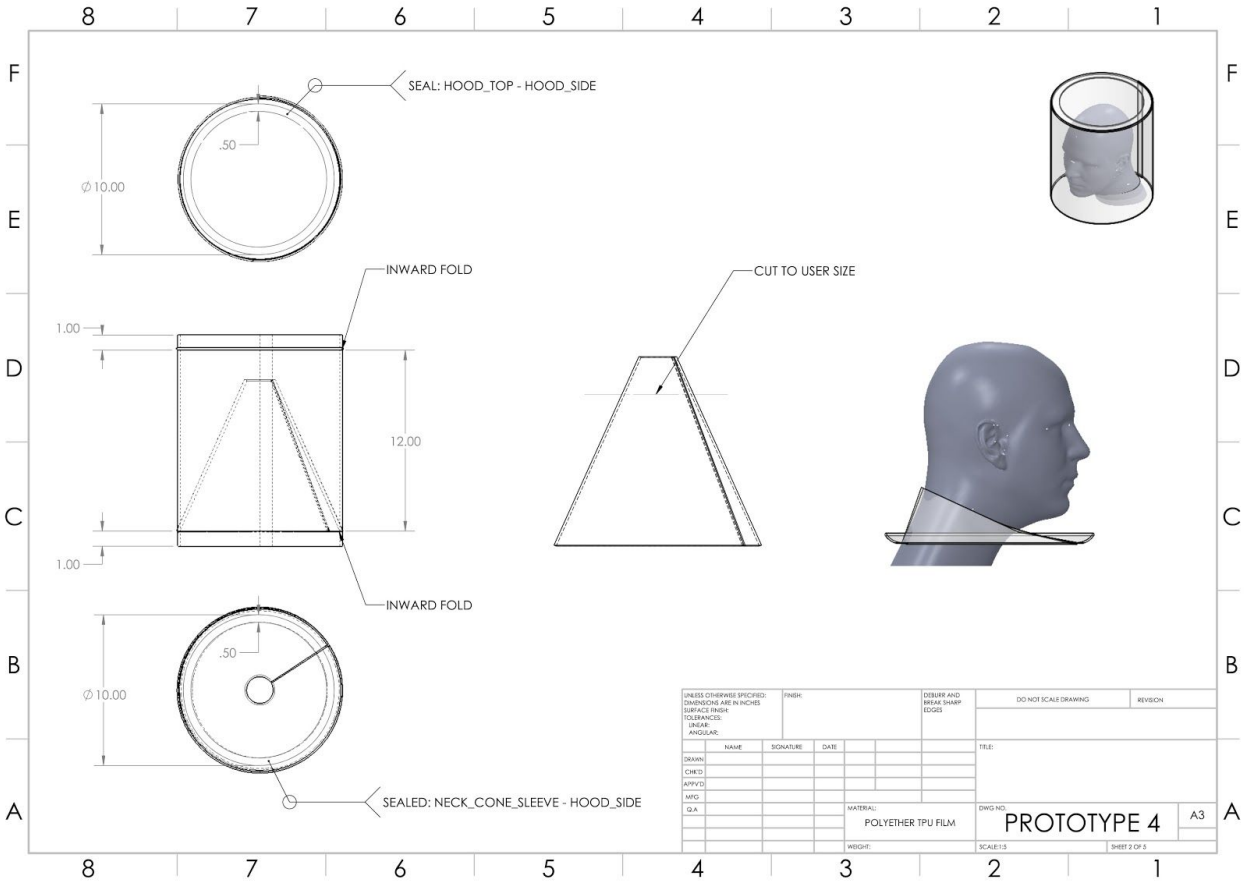



*Figure 2: CAD rendering of connection between hood and neck seal*

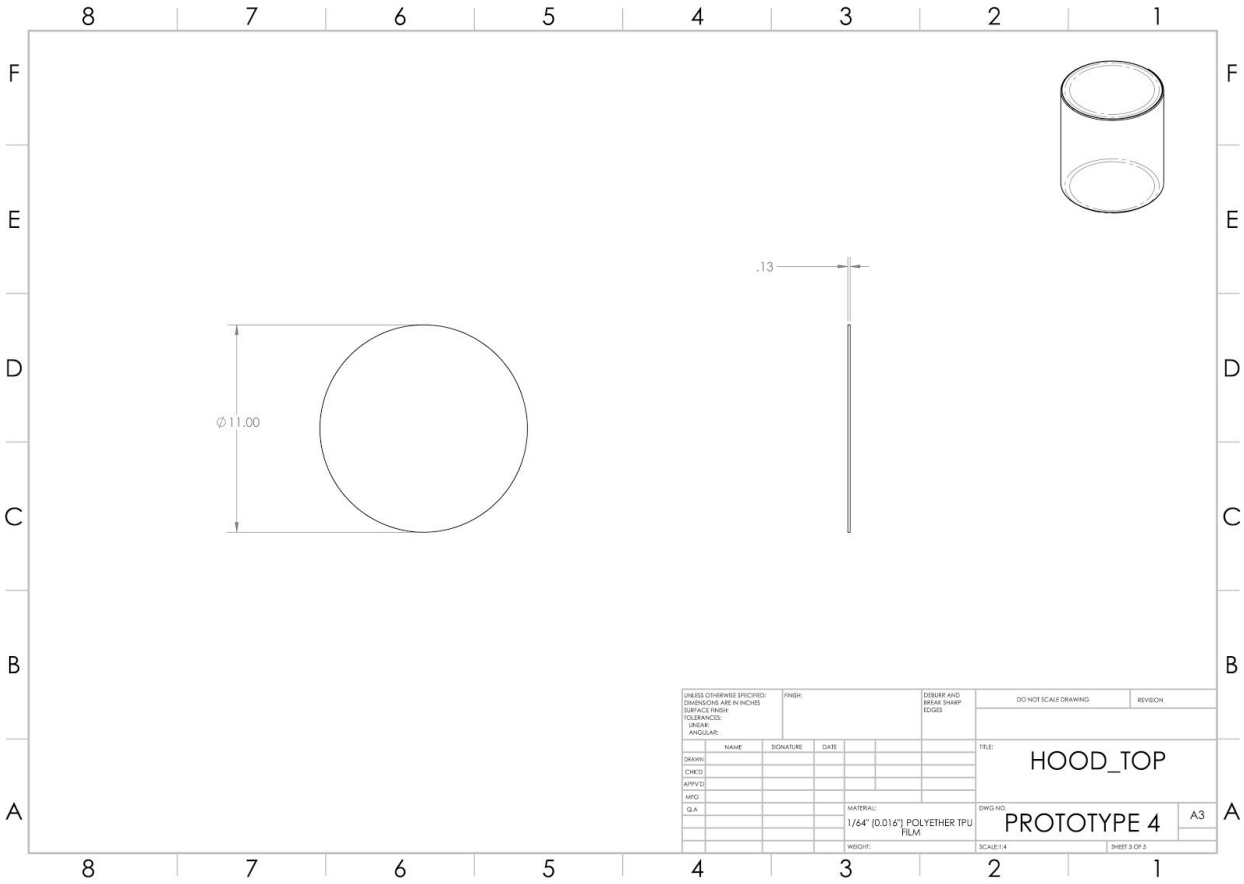



*Figure 3: Design drawing for hood top manufacturing*

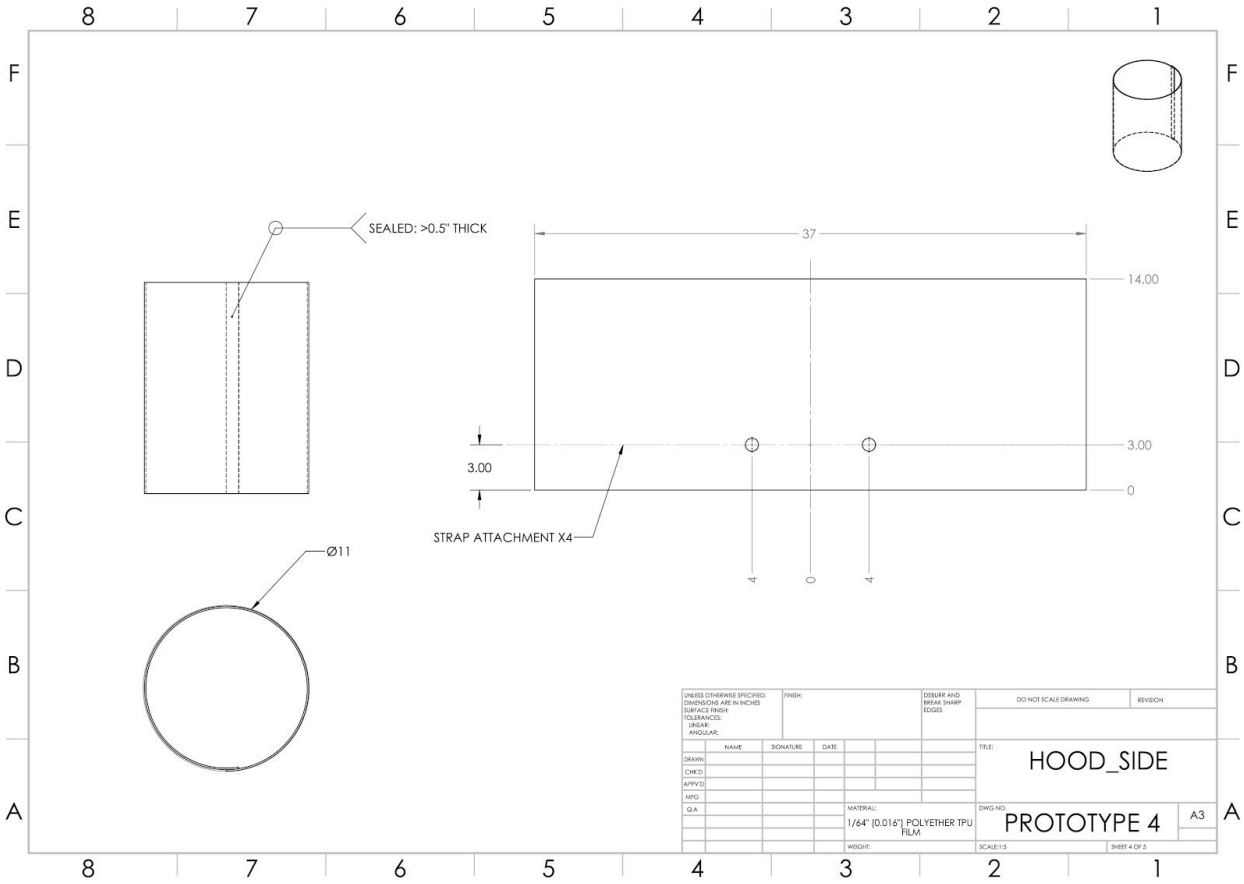



*Figure 4: Design drawing for hood body manufacturing*

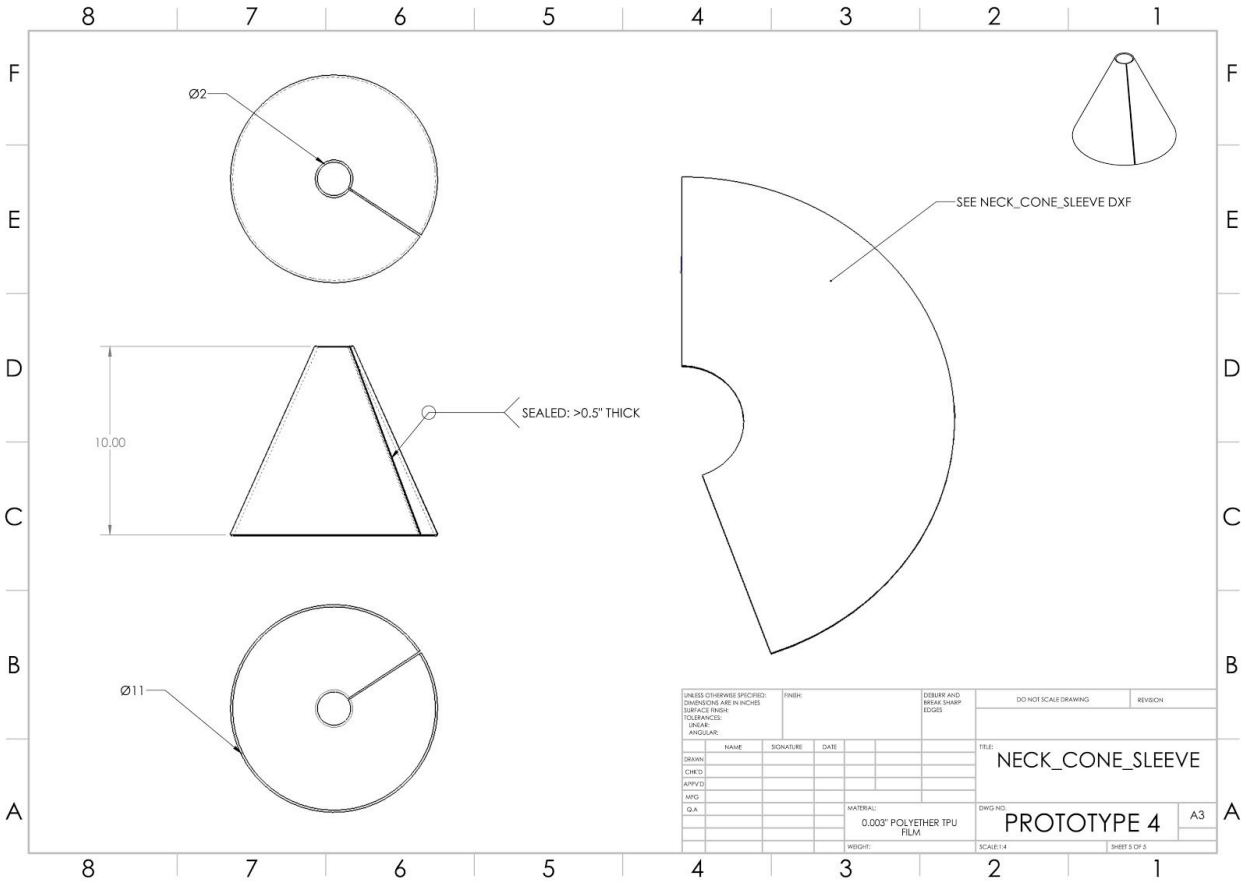



*Figure 5: Design drawing for neck seal manufacturing*