COSMIC PPE Snorkel Mask

The COVID-19 pandemic has led to a global shortage of Personal Protective Equipment (PPE) for healthcare providers (HCP). Many hospitals in various countries are facing shortages of surgical masks, face shields and N95 respirators. 3D printing technology is being widely used to print face shields and components of respirators.

Our team has modified a DasMeer full face snorkel mask by adding a 3D printed, custom fit adapter to the top outlet that will allow the mask to be connected to a hospital-grade, high efficiency particulate air (HEPA) filter with 99.99% bacterial and viral filtration efficiency. The purpose of the mask is to provide protection against airborne particles and to provide droplet protection, thus functioning like a reusable combination of N95 respirator and face shield.

Unfiltered air is drawn through a hospital grade HEPA filter at the top of the mask then respired air is expelled out through a check valve on the lower front of the mask. Some respired air may also be expelled up through the air filter on the top of the mask however the bulk of the expelled air will be expelled through the lower front check valve.

The intended user populations include health care providers, including, but not limited to, doctors, nurses, first responders, and respiratory therapists, who are in close contact with patients who may be carriers of the COVID-19 virus. The device is intended to be used in hospitals or in the field of work, as is the case for first responders.

These retrofitted respirators have NOT received regulatory approval. Appropriate use, decontamination, and regulatory approval of the design should be directed through your local health authority.

Device Description and Components

The COSMIC PPE Snorkel Mask is composed of 3 pieces:

1) Full-face snorkel mask
2) 3-D printed filter adapter
3) High Efficiency Particulate Air (HEPA) filter

The **full-face snorkel mask** is available commercially for non-medical use. Numerous brands are available. Our adapter was retrofitted for the DasMeer Snorkel Mask which can be purchased from Amazon.

The **HEPA filter** is commercially produced for use in anesthetic machines and breathing circuits. It has 99.99% bacterial and viral filtration efficiency. These filters are part of the hospital supply chain and can be ordered through an affiliation with a hospital. Unlike filters for existing reusable full and half-face respirators which are in high demand, these are not routinely used in respirators and should be readily available. It has a 22mm diameter that will interface with the 3D printed adapter.

The **3D-printed adapter** is engineered to fit the DasMeer Snorkel Mask top outlet. The CAD file is available on GitHub. The adapter can be reusable after decontamination. However, during testing, we have found that the fit of the **adapter loosens after repeated use.** We encourage all users to examine the adapter and fit before each use. A negative pressure seal check should also be performed as per our donning/doffing instructions. The adapter should be discarded and replaced regularly, if possible.

- Printing Instructions for STL file:
    - This version should accommodate a standard 22mm diameter HEPA filter
    - Suggested print settings: PLA, 100% infill and print orientation should be such that the 22.4mm diameter hole is in the +Z direction (facing up)
- We acknowledge that each printer is different and the design may need to be adapter for an appropriate fit.
- More information on 3D printing PPE in response to COVID-19
    - FDA FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic
    - 3D printing and other manufacturing of personal protective equipment in response to COVID-19

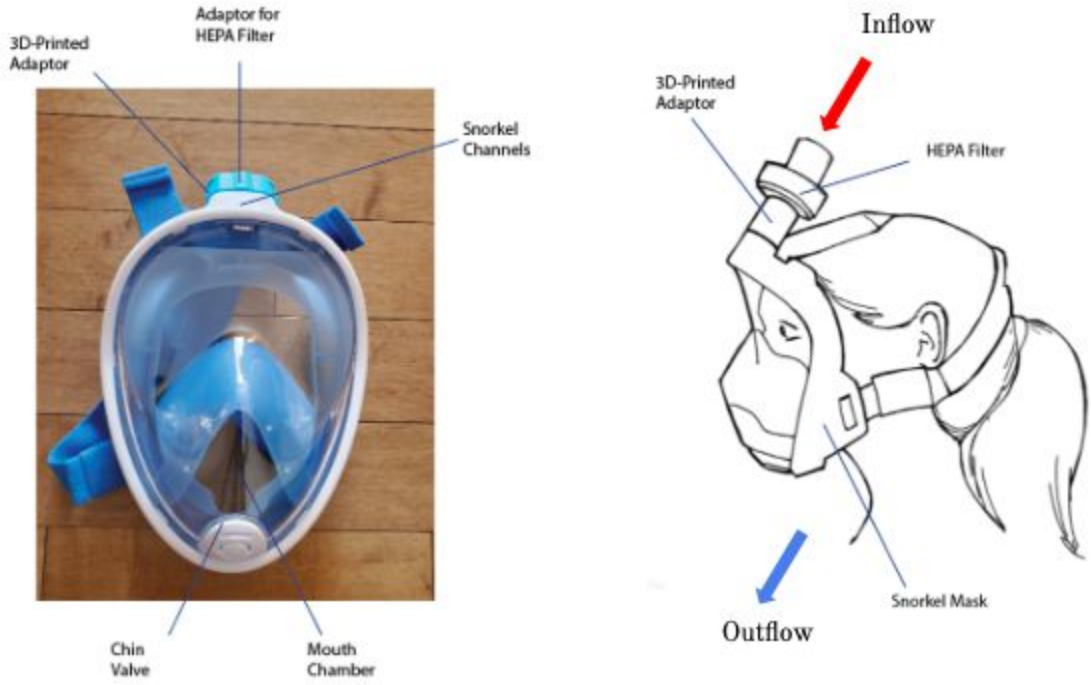

Figure 1: Labelled COSMIC PPE Snorkel Mask Components

Figure 2: Adapter Connections to Filter and Mask

Testing

The following tests are recommended to be performed before use:

1. Quantitative fit testing:
    a. This test is used to assess the fit of a respirator on an individual's face by measuring the amount of leakage into the respirator. **ALL PROVIDERS** should be fit tested before use. See detailed report on fit testing.
2. Decontamination testing:
    a. Please refer to your local hospital/health authority for appropriate decontamination guidelines.
    b. Reference: OSHA decontamination protocol for respirator.

The following tests have been performed by our team to assess safety and effectiveness of the design:

3. CO2 accumulation testing:
    a. We have monitored for CO2 accumulation at rest and during active phase for short term wear of up to 2 hours. Our tests have found no significant CO2 accumulation.
4. Biocompatibility testing:
    a. NO biocompatibility testing has been performed.

Donning and Doffing Guide

SNORKEL MASK VISUAL GUIDE

COSMIC MEDICAL

Assembly

1. Insert the filter adapter onto the oval inlet port on the top of the snorkel mask. The mating interface will need to be appropriately tight so some force may be required to insert the filter adapter onto the snorkel mask.
   NOTE: a click should be heard when the filter adapter is fully engaged onto the snorkel mask.
2. Insert the air filter into circular opening on the filter adapter. The mating interface will need to be appropriately tight so some force may be required to insert the filter into the filter adapter.
3. Check that the filter is in good alignment with the filter adapter. If the filter is angled or appears misaligned, remove the filter and reinsert it into the filter adapter with better alignment.

Bad alignment | Good alignment

4. Check that the filter adapter is in good alignment with the snorkel mask. If the filter adapter is not fully seated on the mask inlet, apply force to the side not fully seated until the entire filter adapter appears aligned with the mask inlet.

Bad alignment | Good alignment

Donning

1. Loosen the straps on either side of the snorkel mask.

2. Pull the strap bundle up and out of the mask slightly and insert the mask onto your face.

3. Pull the strap bundle up and over the top of your head and allow the strap bundle to rest of the back of your head.

4. Adjust the mask so that the internal silicone divider rests on the bridge of the nose. Adjust it so that there is no gap between your face and the divider.
   This prevents fogging.

5. Adjust the straps for comfort but make sure the straps are appropriately tight to allow the mask to maintain an appropriate seal around your face.
6. **Mask Seal Check #1:** run your index fingers along the periphery of the silicone seal contacting your face to feel for any obstructions such as clothing or hair that may be between the mask seal and your face. If you feel any obstructions attempt to remove them before proceeding.
7. **Mask Seal Check #2:** firmly cover the inlet of the air filter at the very top of the assembled Snorkel Mask HCP PPE with your hand then attempt to gently inhale. A slight vacuum should be formed inside the mask.

8. **Mask Seal Check #3:** take a slow deep breath in then firmly cover the inlet of the air filter at the very top of the assembled Snorkel Mask HCP PPE with your hand then attempt to exhale. All the exhaled breath should be expelled through the lower front check valve on the mask.

Doffing

1. Loosen the straps on either side of the snorkel mask.

2. Place your hands on either side of the mask and lift the mask off your face without touching your face.

Sizing Chart

The snorkel mask comes in two sizes: S/M and L/XL.