

Innovations in PPE: Adapting Full-Face Snorkel Masks

N95 Working Group Report

The COVID-19 Healthcare Coalition is a collaborative private-industry response to novel coronavirus. Our mission is to save lives by providing real-time learning to preserve healthcare delivery and protect populations. (<https://c19hcc.org>)

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Summary

As the COVID-19 pandemic continues to impact the nation, and hospitals and healthcare workers grapple with a lack of FDA-authorized personal protective equipment (PPE), researchers have turned to creative solutions to address the issue.

The COVID-19 Healthcare Coalition has partnered with the Prakash Lab at Stanford, the first group to pioneer a stop-gap solution leveraging commercial snorkel masks. The innovative design consists of a commercial-off-the-shelf (COTS) snorkel mask, custom (3D-printed or injection molded) adapter, and COTS filter and cartridge (Figure 1) [1].

Over the past month, several other U.S. and international organizations—such as MasksOn, OceanReefGroup, Haagland Medisch Centrum (HMC), and True Health—have released similar snorkel mask designs [2,3,4]. These retrofitted snorkel mask technologies are aimed at doctors, nurses, and hospital staff who lack FDA-authorized PPE and have access to standard sterilization and disinfection infrastructure.

While no snorkel mask design has yet to receive FDA Emergency Use Authorization (EUA), this option can provide temporary protective solutions for frontline workers during this unprecedented time. *The inventors underscore that this technology should only be used when face shields and N95 or equivalent respirators are not available.*

Design and Components

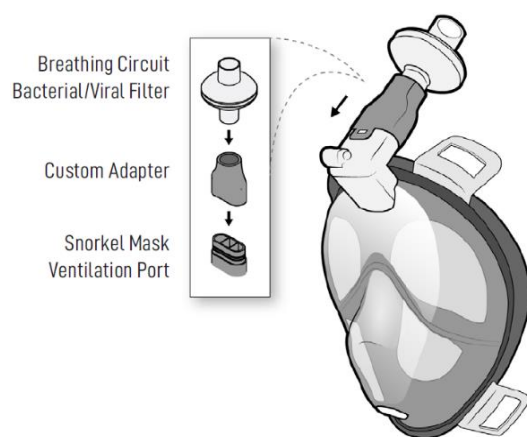


Figure 1. Pneumask components.

The snorkel mask design provides full-face coverage and air seal for the user while also allowing for the intake of filtered, breathable air provided by commercial medical or industrial filters. The recommended commercial filters are designed to capture even smaller particles than the N95 respirators.

Snorkel mask designs feature an adapter that can be attached to COTS snorkel masks and filter cartridges. Note that different manufacturers may have varying port sizes, therefore the adapters will need to be custom-fitted to the specific mask and filter. The [Pneumask](#), [MasksOn](#), and [OceanReefGroup](#) groups have compiled lists of

commercial snorkel masks and industrial and medical filters that are compatible with their adapter designs.

Use and Sterilization

As with other respirator-type PPE, proper fit is critical to taking advantage of the full safety capabilities of the snorkel mask designs. It is important that users wear masks that are suited for their individual face size and ensure that the fit of the mask is free from air gaps that can be identified during an initial respiration exercise.

Proper donning and doffing procedures have been described in detail on the Pneumask [website](#) [5]. As with any new technology, there are still kinks to be worked out. As of April 29, 2020, the HMC's COVID Lifesaver adapter design became unavailable due to concerns regarding inward leakage of the system. The HMC engineers are currently collaborating with the Prakash Lab before releasing future open-source adaptor designs [4].

Snorkel masks were designed for fast adoption to meet the critical needs of healthcare workers. For example, they leverage COTS components, like readily accessible filters. They can also be sterilized using disinfectants in standard supply and readily available at hospitals.

If used and sterilized properly, this technology can be reused for up to a year as long, as filter cartridges are replaced regularly, per manufacturer instructions. Additionally, the Pneumask and MasksOn teams have developed and tested cleaning protocols based on guidance from the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), and peer-reviewed literature regarding elastomeric respirators. These protocols involve standard autoclave systems and immersion in bleach or ethanol [2,5].

Medical Disclaimers

As of April 3, 2020, the Pneumask was classified as a Class 1 device (if considering only the mask and adapter components), which are *“not intended for use in supporting or sustaining life or of substantial importance to preventing impairment to human health”* [6]. The Class 1 designation of the Pneumask is intended to be comparable to wearing a face shield and surgical mask.

The inclusion of the filter upgrades the Pneumask to “improvised PPE,” at which point the clinician would be responsible for his or her own safety. This FDA classification applies to all snorkel mask designs. Even with these caveats, there are clinicians already using the masks in clinical settings around the world [7,8,9].

The Prakash team has submitted the Pneumask for FDA EUA to allow for its classification as a N95-equivalent respirator, which would include all components of the Pneumask (mask, adapter, and filter). As of April 14, the Pneumask design received approval by the National Agency for the Safety of Medicines and Health Products in France, which allows for increased production and distribution of the Pneumask design [7]. This approval puts the Pneumask at the forefront of authorization by national health agencies.

However, not all organizations are looking to receive FDA EUA for their products. For example, MasksOn states that their design is for “Investigational Use Only” (IUO), and they make no

claims regarding efficacy of the masks in clinical or surgical settings or of its antimicrobial effectiveness. HMC have not yet released any statements as to whether they intend to submit their design for FDA EUA.

Current Deployment

As of May 4, over 4,000 MasksOn mask kits and 42,600 Pneumasks have been deployed to clinicians around the world [9,10]. Internationally, 30,000 Pneumasks units are already in use in French hospitals and 10,000 units are being deployed to Belgium [11]. It is not clear how many times other open-source adapter designs have been fabricated and utilized in hospital or healthcare settings.

The Pneumask or MasksOn organizations are giving away their mask kits, building relationships with health centers to identify those in need and then distributing kits. *Please contact these organizations for more information.*

The Healthcare Coalition has been working closely with the Prakash team to identify hospitals and clinical care units that are in immediate need of PPE. For example, MITRE has acquired more than 1,000 Pneumasks to distribute to Mount Auburn Hospital in Cambridge, Massachusetts, and the University of Miami healthcare system. The primary goal of this alliance is to distribute Pneumasks as equitably as possible to healthcare workers who lack approved PPE and are thus most at risk of being infected.

References

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