High Protection Surgical - Mask V1.0 (HPS-M)

- The 3d printed surgical mask alternative with benefits -

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Figure 1. Image of HPS-M V1.0 after printing and assembly.

Table of Contents:

1. Disclaimer (Correct Usage Notice)
2. Mask Overview
    - 1.1. Brief Description
    - 1.2. Level of Protection
    - 1.3. Fitting and Sizing
3. Recommended Materials
    - 3.1. Filter Material
    - 3.2. Materials in Contact with the Face
        - 3.2.1. Mask Body and Front Cap Material (Printable Plastics)
        - 3.2.2. Strap Material
        - 3.2.3. Optional Materials to Improve Comfort and Seal
4. Recommendations for the Printing Process
5. Assembly Instructions
6. Cleaning and Disinfection

1. Disclaimer (Correct Usage Notice)

This 3d printed mask has been designed to aid the mask shortages found worldwide due to the current SARS-CoV-2 (COVID-19) pandemic. This mask is intended to aid those who lack the necessary personal protective equipment (PPE). **This mask is intended as a surgical mask alternative** with several added benefits. This includes increased splash protection, a better seal compared to conventional surgical masks, the ability to utilize one surgical mask to provide filters for 5 individual High Protection Surgical – Masks (HPS-M), the ability to be printed using widely available conventional Fused Deposition Modeling (FDM) printers, and the ability to be disinfected and reused thus decreasing infectious waste. As described by the Food and Drug Association (FDA) in the following document (https://www.fda.gov/media/136449/download), this mask is designed to be categorized as a "surgical mask intended to provide liquid protection". However, based on the common types of plastics used in FDM printing, this mask is **NOT** recommended for use in the presence of high intensity heat sources or flammable gas.

This mask, in its current iteration, is **NOT an alternative for n95 masks, Powered Air Purifying Respirators (PAPR), or any other masks intended for use in aerosol generating procedures. This mask does NOT meet airborne precautions and should not be used in settings with high risk of infection. This design is ONLY intended as a surgical mask alternative for places with PPE shortages.** This mask has undergone **expedited** testing procedures in order to provide hospitals and individuals suffering from extreme shortages of masks during the COVID-19 pandemic and has not undergone typical PPE testing protocols. As per the FDA, alternative approaches for typical PPEs, including the current iteration of this mask, is intended to be used **ONLY** during the duration of the COVID-19 emergency as declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

The information included in this document is intended as a guideline for those using this mask design. The recommended instructions regarding assembly

and cleaning/disinfection included in this document should be followed or improved upon such that best results are achieved without compromising the mask. **Improper usage and handling of the mask may lead to negative consequences.** Before usage, one must carefully consider the possible drawbacks of using a 3d printed mask over its commercial/conventional counterparts.

2. Mask Overview

1.1. Brief Description

This is an attempt to supply individuals with alternatives to commercial PPEs that are in limited supply in light of the current COVID-19 pandemic. This is, however, not a particulate mask (ex. N95), but is instead a surgical mask alternative meant to be produced using common FDM 3d printers (refer to disclaimer for more details). The HPS-M (version 1.0) shown in Figure 1 and Figure 2. is optimized to overcome certain hurdles involved in PPE production using 3d printers, such as improving the comfort, seal and ease of use.

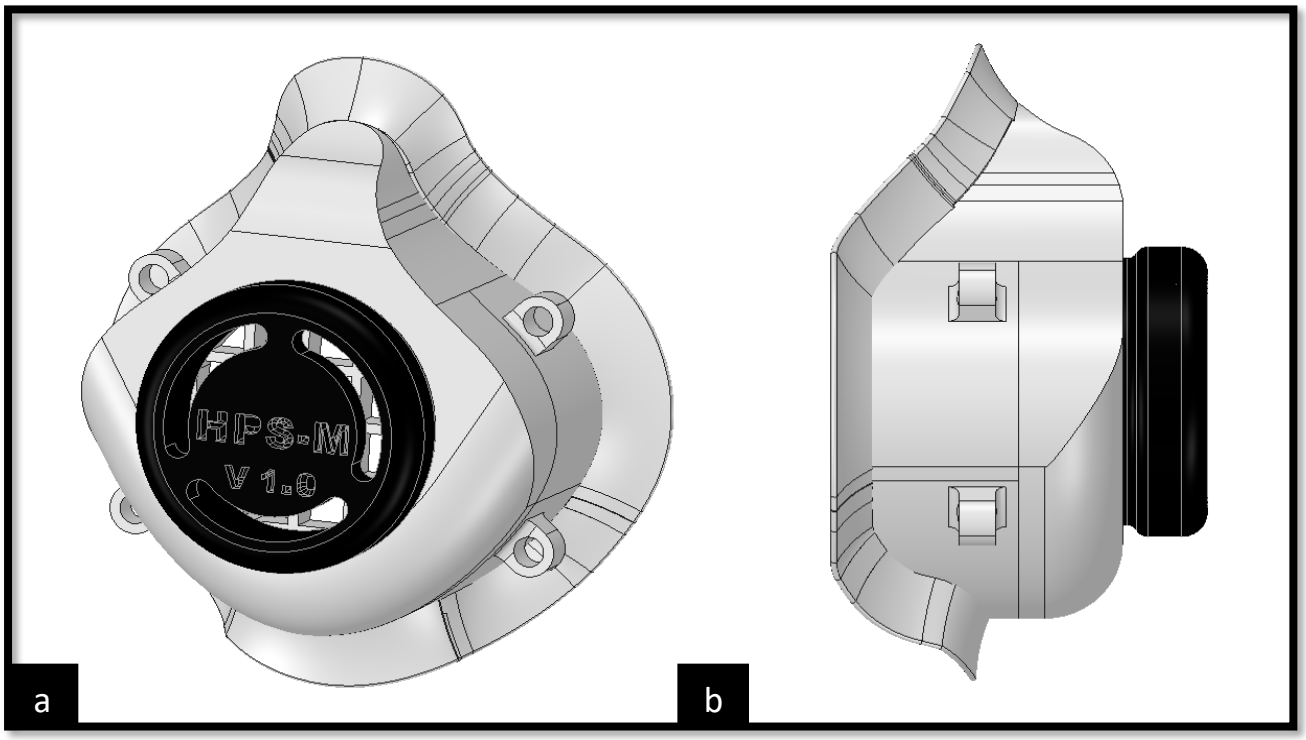

Figure 2. 3d renders of the HPS-M v1.0. a) Anterior view. B) Lateral view.

1.2. Level of Protection

The HPS-M is not a particulate mask replacement, and as such, is not intended to provide protection against airborne particles or pathogens. Instead this mask is intended to provide improved splash and liquid protection compared to some commercial surgical masks.

1.3. Fitting and Sizing

If a 3d printed mask is to contain thin borders, this may lead to an uncomfortable user experience. In an attempt to increase comfort and improve fitting of the HPS-M, it was fitted with elongated curved lips along the entire circumference of the mask which provide a comfortable fit by means of increasing the contact area of the mask with the wearers skin. As such, an effort to avoid prominent pressure points on the nose, cheeks, and chin were made. Additionally, these lips help secure a better seal by wrapping around the skin of the face. In regard to the sizing of the HPS-M, the current iteration consists of a one size fits most design wherein the posterior aspect of the mask is graduated. As seen in Figure 3., the mask contains an outer brim connected to an inner brim at an angle. This means that if a user with a smaller face wears the HPS-M, their face will fit closer to the inner brim, and if a user with a larger face wears the same mask, their face would fit closer to the outer brim. Still, the mask may not fit all types or sizes of faces particularly the smaller sized faces. Therefore, a scaled down design may be required in the future.

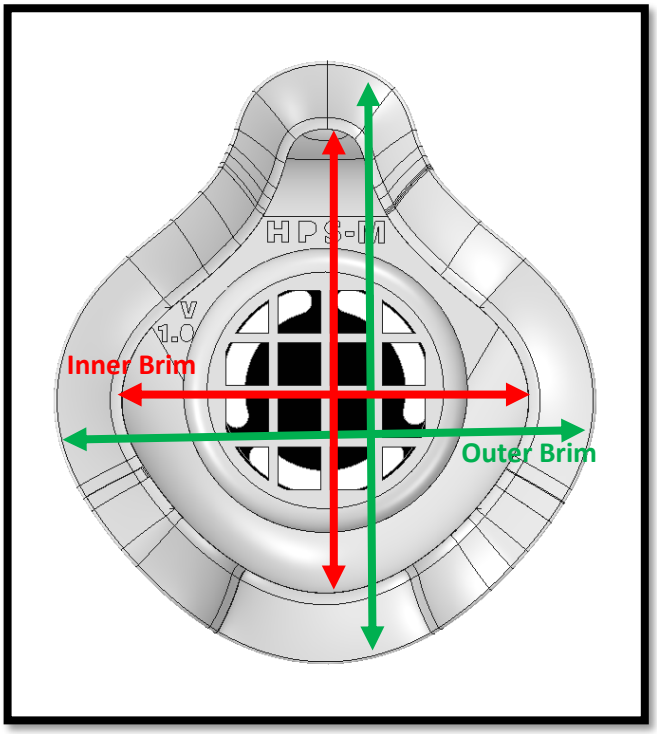

Figure 3. Image showing outer and inner brims.

3. Recommended Materials

3.1. Filter Material

The choice of filter material will, to some degree, affect the level of protection provided by the mask. This is why it is recommended to repurpose commercial surgical masks into filters for the HPS-M. A single surgical mask will provide enough filter material for about 5 individual HPS-Ms. Utilization of surgical masks in this fashion will reduce the amount of infectious waste whilst also providing a greater number of masks. Alternatively, filter materials of equivalent properties and filtering capabilities as surgical masks may be used **if** they have been deemed safe by relevant governing bodies. The filter should be removed after doffing the mask as part of the disinfection protocol.

3.2. Materials in Contact with the Face

3.2.1. Mask Body and Front Cap Material (Printable Plastics)

As this design is initially meant for use with FDM 3d printers, a great variety of possible plastics may be used in the manufacturing of this mask. The developers of HPS-M have conducted their tests on Polylactic acid (PLA) filament. It is of utmost importance to avoid hazardous plastics and ensure that an appropriate disinfection method is selected for the plastic being used.

3.2.2. Strap Material

It is possible to use both elastic and non-elastic straps with the HPS-M. These can be made out of fabric strips, or any other suitable material that does not contain a common allergen. Alternatively, straps from other available masks (ex. surgical masks) can be used as well. Ensure the material selected is durable enough and of appropriate length. These straps should be removed after doffing the mask as part of the disinfection protocol.

3.2.3. Optional Materials to Improve Comfort and Seal

For users who desire an improved seal or increased level of comfort, it is possible to purchase a number of products to place on the posterior aspect of the lips of the mask. The lips should provide ample room for attaching the selected material strip. This strip could be foam or some other material.

Ensure that the material does not contain any common allergens. Cut the material to length and use an adhesive to attach it to the mask. The strip of material should be removed after doffing the mask as part of the disinfection protocol.

4. Recommendations for the Printing Process

The HPS-M is optimized to be printed on accessible FDM 3d printers with standard PLA filament. The design should work with other types of filaments as well after adjusting the print settings accordingly, but this has not been tested yet. 3d printers can vary greatly in tolerances and precision. Thus, if the components of the mask, once printed, do not mesh properly, then it is recommended to ensure proper calibration of the printer and/or to scale up or down individual mask components to offset any inaccuracies. It is also recommended to print the mask body and front cap in the same orientation such that the logo of the mask body and front cap should both be facing the horizontal or vertical planes. This will also help with meshing of components. Occasionally, 3d prints may fail or show visible defects such as improper layer adhesion, warping, under extrusion, amongst others. Do **NOT** use or distribute the mask if there is any visible damage.

5. Assembly Instructions

Before assembly, ensure that any support material from the components have been removed with care if present. Additionally, if any abrasive edges were found on the posterior aspect of the mask, be sure to remove them. To ensure proper assembly of the HPS-M, please refer to the steps below:

a. Locate a clean environment to operate in.
b. Don a pair of new gloves.
c. Attachment of the straps will depend on the whether or not the straps are elastic in nature or not.
    - If the straps available are **elastic**, collect 2 strips approximately 14” in length. Take the first strip and tie it to the top left dedicated

strap hole on the mask body. More than 1 knot may be necessary. Once a secured knot is made, take the other end of the elastic strap and tie it to the top right strap hole. Ensure that the straps are indeed secure and leave some excess material as this may allow the user to re-tighten the knots if they become loose. The user may opt to cut excess material if there is too much. Repeat the aforementioned steps for the second elastic strap whilst attaching it to the bottom left and right strap holes on the mask body.

- If the straps available are **not-elastic**, collect 4 strips approximately 16” in length. Take the 4 strips and allocate each one to a specific strap hole on the mask body. Attach an end of the first strap to the top left, the second strap to the top right, the third strap to the bottom left, and the fourth strap the bottom right. More than 1 knot may be necessary. Ensure that the straps are indeed secure and leave some excess material as this may allow the user to re-tighten the knots if they become loose. The user may opt to cut excess material if there is too much.

d. Take the front cap and orient it such that the printed text is oriented to the top. Then press the cap on the selected filter material and trace around the cap using it as a stencil, then cut the filter accordingly. See Figure 4.
e. Take the filter and place it on the grid located on the anterior surface of the exterior of the mask body. Make sure that the filter is covering the entire grid.
f. Press the front cap onto the filter material and into a groove on the anterior surface of the exterior of the mask body until some clicks are heard. Make sure the front cap is secured properly and do not attempt to twist the cap as this may damage the underlying filter.
g. Conduct a final inspection of the all components. If no damage is found and the item has not been dirtied in the assembly process, then the mask is ready to be used.

To ensure proper donning and doffing of the mask, refer to this guide published by the Center for Disease Control (CDC): (https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf).

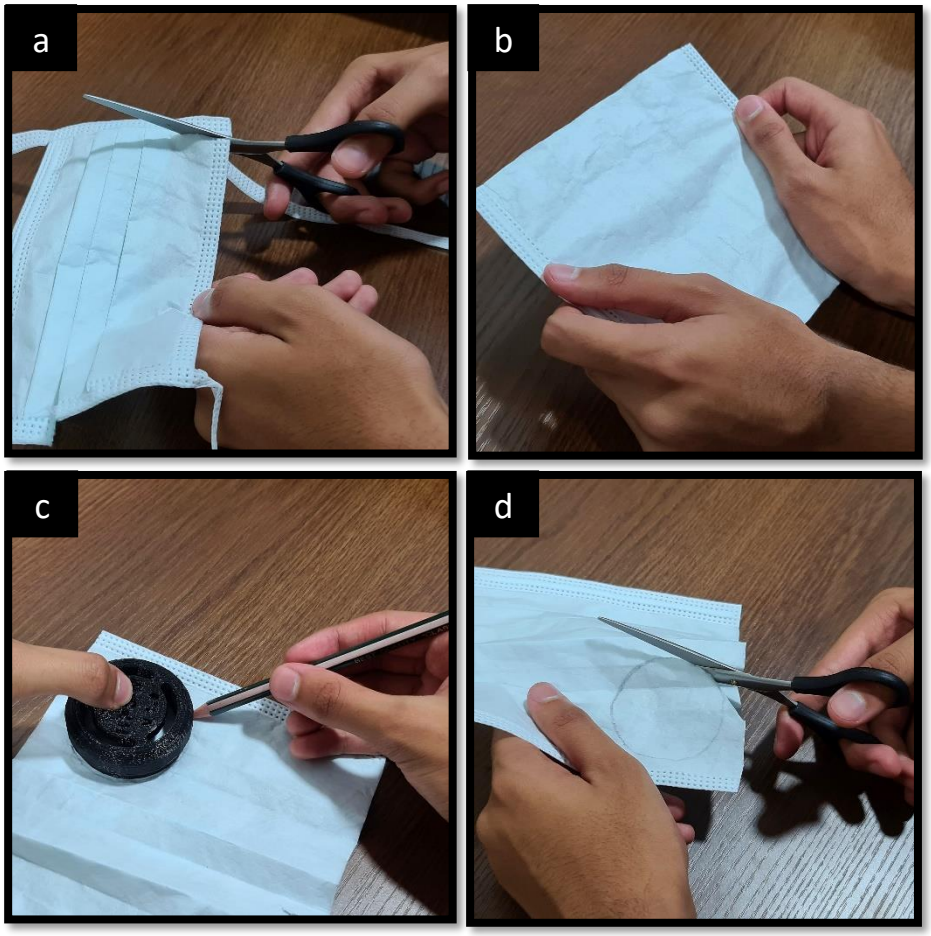

Figure 4. Utilizing a surgical mask to make 5 filters for the HPS-M v1.0. a) Cutting off the edges of surgical mask. b) Stretching open the mask to rid it of its folds. c) tracing a line around the front cap of the HPS-M. d) using scissors to cut the filters.

6. Cleaning and Disinfection

Recent studies indicate that COVID-19 may survive on plastic parts for prolonged periods of time. Hence, it is of utmost importance to properly handle and disinfect the HPS-M in order to avoid transmission of disease. The mask should be disassembled such that the straps, filter, and the optional comfort inserts be discarded safely and replaced later. It is recommended to abide by the protocols set by your institute for disinfection of PPEs bearing in mind that the disinfection method may differ based on the

plastic used to print the mask. In light of the recent COVID-19 pandemic, the CDC and the United States Environmental Protection Agency (EPA) have produced a list of appropriate disinfectants and protocols. Refer to the links below:

CDC:https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html

EPA:https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

Additionally, prior to the current pandemic, the World Health Organization (WHO) formulated a protocol for disinfection of respiratory PPEs (Not specific to COVID-19). Refer to the links below:

WHO: https://www.ncbi.nlm.nih.gov/books/NBK214361/