

# 3D Printed QuickPrint HEPA Filter Mask V6.5 and V7

## QuickPrint HEPA Filter Mask (HFM)- Instructions for Use

These instructions for use correspond to **Version 6.5 and V7** of the HEPA Filter Mask (HFM). Version 6.5 of the corresponding mask shown in Fig 1.

### Appropriate Use Criteria

This is a supplementary face mask and its intent is to be used as emergency backfill in the event of Personal Protective Equipment (PPE) shortages if/when the option of traditional PPE devices have become unavailable. Its original intent is to be used as a community mask, to be used by the general public to slow the spread of COVID19. This device has not gone through the same regulatory approval process as traditional PPE and should be regarded as emergency or supplemental use only.

Though this device is **not** suitable protection against airborne exposures and should **not** be used as a replacement for a N95 mask, PAPR device, or any other respirator device, HEPA filters are rated to filter airborne particulate matter down to .3 Micron. Per CDC Guidelines (42 CFR Part 84) N95 masks must meet test standards of filtering airborne aerosol with a mass median aerodynamic diameter particle of about 0.3  $\mu\text{m}$  which is the same requirement for HEPA filters. This supplementary face mask **DOES NOT MEET REQUIREMENTS FOR AIRBORNE PRECAUTIONS** and **SHOULD NOT BE USED DURING AEROSOL GENERATING PROCEDURES**. The supplementary mask should not be used in a clinical setting where the infection risk level through inhalation exposure is high.

This mask can however be used in situations where the risk of community spread is high, as a suitable alternative to a cloth mask or other types of face coverings which do not filter to the same requirements of an N95. Examples of community uses of this mask are but not limited to those in the mental health field, shop keepers, postal service workers, etc.

The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.

## Device Overview

The Quick Print V6.5 HEPA Filter Mask consists of three main components (the TPU mask flexible body, PLA/PETG hard shell and the HEPA filter w/ filter housing) and six supplementary components (the PLA/PETG strap clips and the two elastic straps, two pieces of ribbon, or two cords of 1.75mm TPU). A diagram of the components is shown below in Fig. 1.



Imaged (left to right):

TPU Soft Shell

Filter Housing and HEPA Filter

PETG/PLA Hard Shell and TPU straps w/  
clips

Fig 1. Diagram of the QuickPrint V7 HEPA Filter Mask components

This mask is designed to receive a 700 series iRobot Roomba vacuum HEPA Filter that can be inserted into the filter housing once removed from the originally manufactured housing. At this time it is recommended that the entire mask is decontaminated after use period (with the decontamination instructions provided in Appendix A). If alternate filter material is used with this supplemental mask please refer to CDC guidelines and other appropriate materials as these are updated almost daily at the time of writing this document. See Appendix B for known guidelines on filter material selection.

## Point of Care

### Disassembly and Assembly

For instruction on how to properly disassemble and Assemble QuickPrint face mask, please refer to the steps outlined below.

#### Assembly Steps

- 1.) (use of Roomba 700 filter) Carefully remove filter from manufactured housing with a pair of pliers or other device.
- 2.) Set filter material aside
- 3.) Insert TPU body into the face side of the PLA/PETG hardshell.



Ensure the brimmed lip of the TPU soft shell extends above the top lip of the PLA/PETG hard shell. ATTN: the seal of the tpu will still work if the brim has become loose or removed over time.

- 4.) Insert the filter material or filter into filter housing. If using the Roomba 700 this is a pressure fitting and will be a very tight connection (be sure to force the filter down as far as it will go -- it should be nearly flush with the 45° angle midway on the filter housing).
- 5.) Insert the filter housing into the hard and soft shell of the QuickPrint mask.



Ensure the brimmed portions of the filter housing are flush or nearly flush with the TPU brim. The filter housing should be snug in the connection port. If it does not refer to fitting instructions.

- 6.) If preparing for oneself -- at this point you may test the mask for an airtight connection, by placing your palm over the inlet for the mask and breathing in. This should make the face suck tight to your face. If not address air leaks accordingly. Some leaks may be caused by improper fitting of the mask to one's face or facial hair. In the event the mask does not fit to the face refer to fitting instructions.

- 7.) Attach straps to the connection points. This can be done in a variety of ways. In any case the mask should be easy to don and doff, but also sit tight enough to the user's face so that if you place a palm lightly over the air inlet the user can feel the face suck down to their face and achieve an airtight seal.



When using the TPU strap there are many different weaving options to anchor the strap. Above are a couple of those options.

- 8.) Adjust the straps to fit the user. The straps should be long enough to provide comfort to the user, as well as a tight seal to the face. If the mask leaves rings on the face after prolonged use loosen the straps accordingly.

### Fitting the QuickPrint HEPA Mask

The mask itself is printed in two types of thermoplastic (TPU and PLA/PETG). In order to have the best fit to one's face I recommend heat forming the TPU portion to the user's face but **THIS REQUIRES HEAT AND A USER MUST BE ABSOLUTELY SURE THE MASK IS NOT GOING TO BURN THEIR FACE WHEN ATTEMPTING THIS!**

- 1.) Prepare a pot of boiling water and set the mask away from the heat source.
- 2.) **Dip the face side of the mask into the water for approximately 5 seconds. Do not allow the hard shell to touch the water as you want that part to stay rigid and in its original form. DO NOT expose the mask for longer than 5 seconds as it will become too hot and you risk burn yourself when fitting.**
- 3.) Touch the warm portions of the mask to your wrist ensuring it is warm to the touch but not too hot (like a baby bottle). You want the mask to be about as hot as a hot cloth or hot bath.
- 4.) Press the warm mask to your face and wiggle it around.
- 5.) Repeat the above steps until you have a fitted mask.

### **Fit the hard shell to the filter housing (Do not attempt if not familiar with heat forming)**

- 1.) Prepare a pot of boiling water and set the mask away from the heat source.
- 2.) **Dip the connection port of the mask into the water for approximately 5 seconds with the filter and filter housing removed. DO NOT expose the mask for longer than 5 seconds as it will become too hot and you risk burn yourself when fitting.**
- 3.) Remove the warm mask from the water and insert the filter housing into the connection port.
- 4.) Press the warm mask to the filter housing.
- 5.) Repeat the above steps until you have fitted the hard shell to the filter housing. Be sure to remove the filter housing every time you reheat the mask.

### **Recommended Cleaning**

The recommended materials selected for making the reusable components of this supplemental face mask have a proven track record for remaining stable during and after the use of the list of disinfectants and sterilization process outlined in Appendix A. However, there has been no formal testing completed yet to support the claim that the use of disinfectants alone is a sufficient cleaning approach against the COVID19 virus specifically on the surface of this material.

Because of this, we recommend that the following disinfection and sterilization steps are performed after each user is finished using the supplemental mask and the user has followed the proper procedures for doffing the device.

1. Perform hand hygiene procedures and remove mask.
2. Submerge mask in unscented cleaning solution such as **COLD WATER** combined with hydrogen peroxide, bleach, iso-alcohol for a duration of 4 minutes (Ensure the mask is submerged for a duration of no less than 4 minutes as defined by the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2).
3. Remove mask from unscented cleaning solution and rinse with cold water.
4. Perform hand hygiene procedures again.
5. Wipe down the entire mask with sterile cotton cloth to dry.
6. Set the mask aside in a clean environment to dry completely
7. Once dry place the mask in a bag for storage for next use.

### **Optional Face Shield Attachment**

If attaching the optional face shield, fully assemble the face mask then slide the straps and TPU soft shell through the hole in the center of the shield. Make sure to line up the nose ;) You can glue this piece on but it does not really end glue.

# Appendix A: Recommended Disinfectants and Sterilization Methods

## Recommended Disinfecting Agents:

From the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#), it is recommended to use the following solutions for the disinfecting procedures of this device.

1. 10% chlorine bleach solution
2. Super Sani-Cloth
3. CaviWipes
4. Hydrogen peroxide
5. Soap and water

## Recommended Sterilization Method:

Below is a table outlining the sterilization parameters that are recommended to be used for autoclave sterilization processing.

Temperature (°C)	Minimum Exposure Time (min)	Drying Time (min)
132	5	30

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# Appendix B: Recommended Filter Materials

The level of protection provided by the supplementary mask will be determined in part by the filter material used. It is recommended that the user only use 700 series iRobot Roomba HEPA filters, as that the mask was only designed to nest with those parts.

# Appendix C: Materials in Direct Contact with Skin

Only two components will come into direct contact with the provider's skin (the elastic straps and the mask body).

## TPU straps

TPU with a low shore hardness is suitable for the straps, and can be attached to the mask with the provided strap clips.

## Materials for the Elastic Straps

It is recommended that the straps be made from 1/8" - 1" thick braided elastic strap material or something of similar material. As this component is disposable, its main purpose is providing enough tension to keep the mask on the face during use. Though the clips must be altered before printing.

### **Materials for the Mask Body**

Since the mask body component will be in direct contact with the user's skin for long durations of time, it is recommended that only materials and processes with existing examples of FDA cleared skin contacting applications should be used. Below are the materials that have been recommended in the manufacturing guidance document for manufacturing of the HEPA Filter Mask (HFM).

<b>Material</b>	<b>Manufacturer</b>
TPU	3D Systems
TPU	Gizmo Dorks
TPU	HP
TPU	EOS

## Appendix D: Special Printing Instructions (MAIN MASK BODY)

Because the overall objective of the HEPA Filter Mask is to mitigate the porousness of low cost FDM style printers for use in medical applications, it is **ONLY RECOMMENDED THE MASK BE PRINTED IN SPIRAL VASE MODE.**

**Hard Shell:** Print in vase mode with a 1mm nozzle -- single wall @ 1.2 width and .4mm layer height in PETG or PLA. Face side down with no brim.

**Soft Shell:** Print in vase mode 1mm nozzle -- single wall @ 1.2 width and .4mm layer height in TPU. Face side up with 2 brim lines for 2 layers (brim offset 0mm)

**Filter Housing:** Print in vase mode 1mm nozzle -- single wall @ 1.2 width and .4mm layer height in PETG or PLA. Narrow end up with 2 brim lines for 2 layers (brim offset 0mm)

**Filter Cover:** Print in normal mode .4 mm nozzle -- 0 top 2 side 0 bottom @ .48 mm width and .2 mm layer height in PLA or PETG. Print at 20% or less infill.

**Various Clips:** Print in normal mode .4 mm nozzle -- 2 top 2 side 2 bottom @ .48 mm width and .2 mm layer height in PLA or PETG.

**(Optional) Face Shield:** Cut from PETG/Lexan Sheet with a thickness no greater than 3.17mm. If cutting on CNC router/laser cutter you can leave tabs, which give a glue point in this version. I left tabs at 1.5mm thickness and then glued in the mask after production.

### Specifics of FDM Spiral Vase Prints

Nozzle Size	Extrusion Width	Layer Height
1 mm	1.2	.4 (or less)

First layer height: **.5 mm**

Platform additions: The Main Mask body **must be printed with a 2mm brim** which consists of 2 concentric lines. The brim acts as the gasket between the filter and the main mask body