

Moldable Mask

A 3D printable mask that can be molded to the user's face using hot water. Intended for use during the COVID-19 pandemic in cases where there is a shortage of N95 respirator masks.

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Moldable Mask - Instructions for Use

These instructions for use correspond to **Revision (1)** of the Moldable Mask.

Appropriate Use Criteria

This supplementary 3D printable N95 mask, with moldable capabilities was created as an emergency action in effort to provide protection as a backup Personal Protective Equipment (PPE) option if the traditional PPE devices have become unavailable. This device has not gone through the same regulatory approval process as traditional PPE but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic.

This device is intended to be used only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act). The decision to implement this device should be made with careful consideration and under the consultation of the corresponding institution's occupational health and infection control departments.

This device, called the "Moldable Mask" consists of two 3D printed parts, a mask body and filter cage and requires two additional materials, strap material and N95 filter material. An optional other material is rubber stripping which can be added for comfort and improved fit. The advantage of this mask is that when produced in PLA or ABS, the edges of the mask can be easily molded to the user's face using hot water. The FDA's guidance for 3D printing medical devices was consulted as well as the newly issued "FAQ on 3D Printing of Medical Devices ...During the COVID-19 Pandemic". The links to each are listed below.

[Technical Considerations for Additive Manufactured Medical Devices](#)
[FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic](#)

Please note that this 3D printed mask is not intended to replace FDA approved and tested personal protective equipment such as an N95 mask. It is intended to help address the shortage of personal protective equipment during the COVID-19 pandemic. The designer does not assume any liability and makes no representations, warranties or guarantees regarding the safety or efficacy of the device. Use of this device is at the user's risk.

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

Device Overview

This device is a 3D printable N95 respirator mask called the Moldable Mask. It consists of two 3D printed parts and requires additional materials in the form of strap material and filter material. Optionally, the user can add rubber weather stripping to increase comfort. The 3D printed parts are the mask body and the filter cage. The mask assembly can be seen in Figure 1. The separate body and filter components are shown in Figure 2. The contour and filter elements of this mask as well as the use of weather rubber stripping are based on the Montana Mask (makethemasks.com/). Many other elements of the mask, including filter use and sanitization are also based on the Montana Mask. The nose area of the mask is based on the shape of popular fabric masks such as the one shown in Figure 3.

The key differentiating feature of this mask is that when produced in a plastic with a low melting point (such as PLA), hot water can be used to mold the edges of the mask to each individual user. The user simply submerges the edge of the mask in hot water until the plastic becomes pliable and can then place it on their face and use their fingers to adjust the contour to fit their face. The shape and thickness of the mask is designed to make contouring easier.

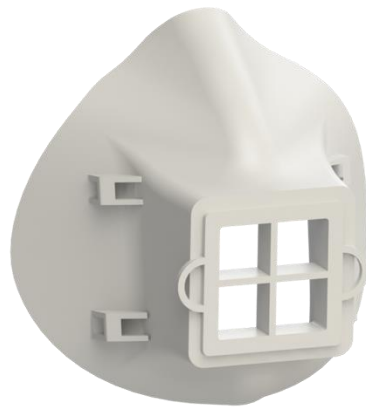


Figure 1. 3D printable components of mask

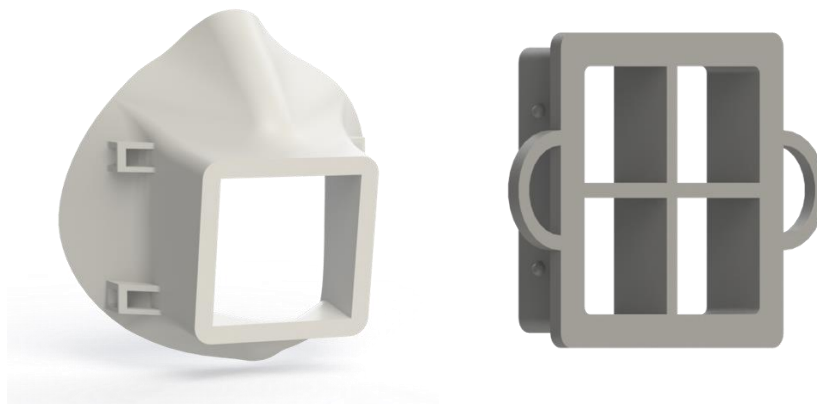


Figure 2. Mask body (left), filter cage (right)



Figure 3. Fabric mask that nose contour is based on

(<https://www.craftpassion.com/wp-content/uploads/2013/08/face-mask-with-nose-wire.jpg>)

Device assembly is simple. The additional materials needed are some form of tie such as elastic (1/2" or less is best), string, cord or any other material that can be used as a strap. Additionally, the user needs filter material. Links to possible strap and filter materials are in Table 1. The user can fit the straps to their own head shape and desired tightness. The filter material is taken from N95 surgical masks by cutting out a 4.5 cm square piece of filter material that can be taken from a soft N95 mask or from a roll of N95 filter material. Optionally, the user can attach self-adhesive rubber stripping around the edge of the mask for added comfort and improved seal.

Table 1. Strap and filter materials with links

Product	Description	Link
Elastic Cord	¼" braided elastic	https://www.amazon.com/70-Yards-Braided-Elastic-Stretch-Measure/dp/B06XXH8KQQ
Elastic Cord	½" braided elastic	https://www.amazon.com/Braided-Elastic-144-Yards-White/dp/B06XGNZ767
Filter Material	N95 Mask - folded	https://www.usamedicalsurgical.com/dukal-n95-mask-surgical-mask-n95-respirator/
Rubber for comfort	Rubber weather stripping 5/16"	https://www.lowes.com/pd/M-D-17-ft-x-5-16-in-White-Window-Seal-Rubber-Window-Weatherstrip/1010041

If produced in PLA material, the 3D printed parts of the device should be able to be disinfected using a hospital grade disinfectant wipe or sani-wipe. These are the sanitization suggestions of the Montana Mask made with PLA material. THIS HAS NOT BEEN TESTED ON THE MOLDABLE MASK.

See Appendix A for recommended disinfecting solutions and sterilization methods for this device.

See Appendix B for guidelines on material selection. The Moldable Mask should be made with a low-melting point plastic such as PLA or ABS.

Components to be disposed of after every use or immediately after potential contamination by bodily fluids:

- Filter material
- Straps
- Rubber stripping

Components to be disinfected and reused:

- Mask body
- Filter cage

Manufacturing Instructions

3D Printing Instructions

The suggested 3D printing instructions are included below for the printer used for test prints of the mask. No support material is needed to print the Moldable Mask. Please note that the large size mask does not fit on the small print bed of the printer that was used during testing.

Printer: [Monoprice MP Select Mini 3D Printer V2](#)

Equipment Settings

Extruder Temperature: 200 C

Platform Temperature: 60 C

Layer thickness: 0.175 mm

Material: PLA

Filament diameter: 1.75 mm

Infill: 25%

Supports: None

Build Time: 6 hours for mask, 1.5 hours for filter cage

Although the Monoprice MP Select Mini V2 was used for testing, any FDM printer that can print PLA or ABS material should also be able to print the mask. Some possible printers are:

- Any Ultimaker Printer
- Raise 3D Pro
- Lulzbot TAZ Workhorse
- Prusa i3 MK3s

A number of other FDM 3D printers should also be able to successfully print the mask. We recommend using the following settings.

Infill: 25 – 40%

Supports: None

Layer thickness: 0.1 – 0.2 mm

Post Processing

The mask body and filter cage should be post processed by sanding all edges with 200 grit or higher sandpaper. Particular care should be taken with the edge and inside face of the mask that contacts with the face to reduce the chance of skin abrasions or irritation. The 3D printed components should be sanitized before use according to the cleaning instructions given in the next section.

Point of Care Assembly and Cleaning Instructions

For instruction on how to properly assemble, clean, and reassemble for reuse of the Moldable Mask please refer to the steps outlined below.

Bill of Materials

Table 2 gives the bill of materials needed to assemble the mask. Starred items are optional

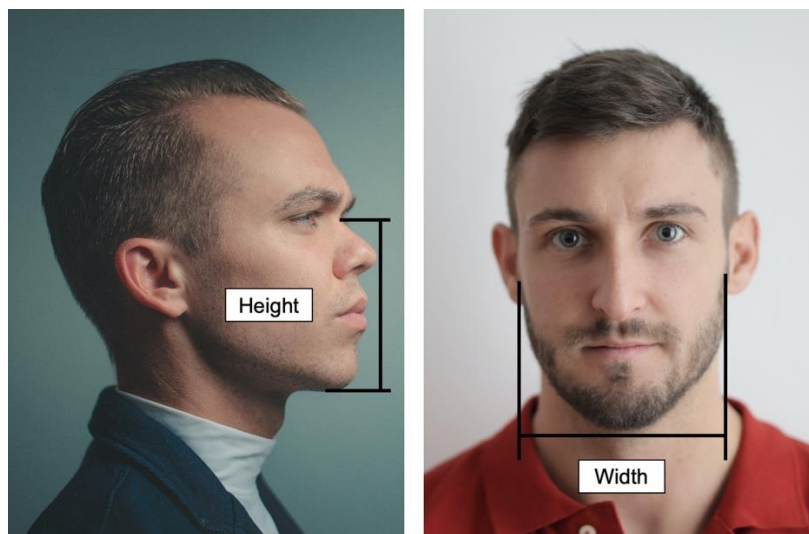
Table 2. Bill of materials for mask components

Part	Quantity	Supplier
Mask Body – PLA Filament	about 30 – 40 g	Overture PLA 1.75 mm
Filter Cage – PLA Filament	about 5-10 g	Overture PLA 1.75 mm
N95 Filter Material – N95 Surgical Mask Folded	can produce 3 Moldable Masks from one	USA Medical and Surgical Supplies
Strap Material – ¼” elastic	about 40-60 cm	Amazon
*Rubber tubing – about 5/16”	about 40 cm	Lowe's , Amazon
Hospital Grade Disinfectant Wipe	2+ (as needed)	
Marker or Pen	1	

Assembly Steps

BEFORE STARTING MAKE SURE THE MASK BODY YOU HAVE IS APPROPRIATELY SIZED.

Measure your face in the following way, then use the chart below to choose the appropriate size. Measure the height of your face by finding the distance from the bridge of your nose (between your eyes) to the bottom of your chin. Measure the width of your face, find the points on each side of your face where your jaw begins. You can find this by opening and closing your mouth and finding the movement point. Measurements do not have to be very accurate.



Height (mm)	Width (mm)	
	<110	<135
Small		Small-Wide
110-120	<140	>140
	Medium	Medium-Wide
>120	<145	>145
	Large	Large-Wide

Preparation

1. Prepare a clean environment or area to work in. This area should be free of aerosols and the surfaces you are working with should be sanitized.
2. Don a clean pair of disposable gloves.
3. Collect your supplies as described in the Bill of Materials (Table 2).
4. Sanitize the mask body and filter cage using a hospital grade disinfectant wipe. Set the filter cage aside.

Mask Fitting

1. Prepare hot water (not hot enough to be uncomfortable to the skin) and place in a vessel large enough to fit the diameter of the mask.



Figure 4. Hot water preparation

2. Dip or rest the edge of the mask in the hot water vessel until the plastic becomes pliable, about 30 seconds.



Figure 5. Dipping mask in hot water

- Using your fingers, press the edges of the mask into your face so that it conforms to your facial contour. You may need to dip the mask several times to adjust all elements of the mask. It also helps to do this step in front of a mirror so you can visualize the fit.



Figure 6. Using fingers to mold the mask

- Dry off the mask with a clean paper towel.

A comparison of the mask before and after contouring is shown in Figure 7, showing the improved conformance to the face. If the fit is satisfactory, these steps do not need to be repeated.



Figure 7. Mask before contouring (left), mask after contouring (right)

Straps

- Get your elastic and measure 2 pieces that can go around your head loosely.
- Attach the elastic to both top and bottom loops of one side of the mask by inserting the elastic and tying a knot to secure it.



Figure 8. Mask with loops on one side

3. Insert the free end of the elastic into the loops of the other side of the mask.
4. Pull the mask on over your head. The elastic should be long enough that it doesn't slide out of the loops as you do this.
5. Holding the mask in place on your face with one hand, pull the free elastics one at a time until you have a snug fit with no leaks. Use your pen to mark the location you desire.



Figure 9. Finding the right length of elastic

6. Take the mask off, tie off the elastic on the free ends tightly and cut off excess elastic. Check for fit and repeat steps if necessary

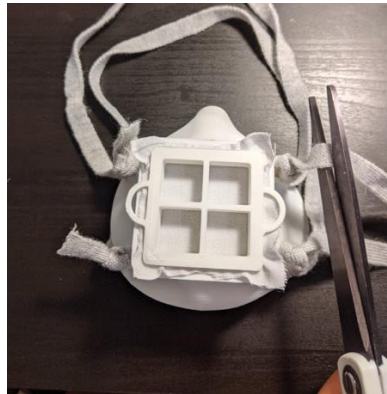


Figure 10. Cutting off excess elastic

Filter

1. Get your filter cage and place it on your filter material. Use the tabs as a guide to cut out a square of filter material that is larger than the cage.



Figure 11. Measuring filter material

2. Place the filter material on the mask.



Figure 12. Place filter material on mask

3. Press fit the filter cage in place.

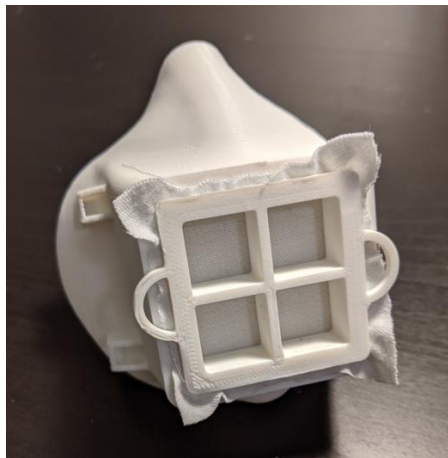


Figure 13. Filter cage in place

Rubber stripping around edge (optional but recommended)

1. Get your strip of self-adhesive rubber stripping.
2. Starting at the bottom of the mask, start adhering the rubber stripping around the edge of the mask. Ensure the loop of rubber stripping is closed well at the bottom to avoid leaks.
3. See [this video](#) from the Montana Masks for a clearer description.
4. Before use, sanitize all plastic portions of mask once again using a hospital grade disinfectant wipe. Do not remove the filter material

FDA guidance on using N95 respirator masks during the COVID-19 pandemic can be found [here](#).

Recommended Cleaning

The recommended materials selected for making the reusable components of this Moldable 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, it is recommended that the following disinfection and sterilization steps are performed after each user is finished using the Moldable Mask and the user has followed the proper procedures for doffing the device.

PLEASE NOTE THAT NO SANITIZATION PRODUCTS HAVE BEEN TESTED BY THE DESIGNERS OF THE MOLDABLE MASK. THESE ARE THE PRODUCTS SUGGESTED BY THE DESIGNERS OF THE MONTANA MASK.

1. Remove the mask at the end of use using gloved hands.
2. Cut off or untie the straps and set aside to dispose of or wash in a washing machine.
3. Remove the filter cage using the tabs and dispose of the filter material in an appropriate hazardous material trash can.
4. Using a sani-wipe or hospital grade disinfectant wipe, thoroughly wipe all surfaces of the mask body and filter cage.
5. Place in an area that will not be exposed to COVID-19 aerosols. Now the mask is ready to be re-assembled and re-used.

Preparing the Supplementary Mask for Reuse.

While not in use, the mask body and filter cage should be stored in a container or area that is protected from aerosols such as a clean plastic bag or box. A clean environment should be used when cleaning the mask as is described in the initial device assembly. When re-assembling, follow the same instructions described in the Assembly Steps, skipping the mask fitting process.

Appendix A: Recommended Disinfectants and Sterilization Methods

From FDA guidelines on [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#) released March 2020 it is recommended that “this policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)”. The policy recommends using an approved disinfection agent as it should “minimize the viability of SARS-CoV-2” on the surface of the Moldable Mask.

Recommended Disinfecting Agents:

The plastic parts of the Moldable Mask should be cleaned using a hospital grade disinfectant wipe or a sani-wipe. The designers of the Moldable Mask have not evaluated any disinfecting agents that can be used on the plastic elements of the Moldable Mask and therefore cannot recommend any specific disinfectants.

Appendix B: Recommended Materials

The recommended material to be used in manufacturing the Moldable Mask is PLA filament. ABS filament can also be used if PLA is not available. Table 3 gives the PLA filament used in the test print on the Monoprice MP Select Mini 3D Printer V2. An alternative ABS filament is also given. The appropriate filament diameter should be chosen for the printer being used.

Table 3. Recommended Filament

Material	Manufacturer	Link
PLA Professional, 1.75 mm	Overture	https://overture3d.com/collections/overture-pla-3d-printer-filament/products/overture-pla-professional-1-75mm
ABS, 1.75 mm	Hatchbox 3D	https://www.amazon.com/HATCHBOX-3D-Filament-Dimensional-Accuracy/dp/B00J0H6NNM

Appendix C: Materials in Direct Contact with Skin

The materials that can be in contact with the face are listed below:

- PLA
- ABS if PLA is not available
- Natural rubber or silicone rubber if rubber material around the edge is used.

PLA (polylactic acid) is a non-toxic, biodegradable plastic. In its solid form it is safe for contact with the skin and has no toxic or sensitive effects

(https://colorfabb.com/files/SDS_E%20Colorfabb_LW-PLA.pdf).

ABS (acrylonitrile butadiene styrene) is also non-toxic and suitable for skin contact.

Natural rubber is skin safe for those without a natural rubber allergy. Those with a natural rubber allergy can use silicone rubber instead which is inert and safe for skin contact. However, some individuals may also have a silicone allergy so it is important to test for allergic reactions before using these materials.