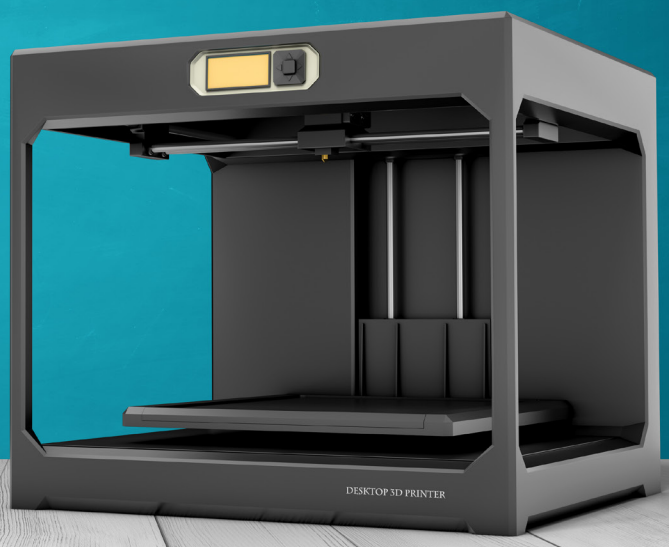
MAKE THE MASKS

The Montana Mask: PPE Solution

Prepared By: **Make the Masks**
Delivered on: **April 3, 2020**

A rapidly deployable solution for states and local entities to maximize their supplies of surgical-grade and N95 masks for healthcare providers and first responders during the COVID-19 pandemic.



INTRODUCTION

Hospitals in Montana are multiplying (by at least four) their existing supply of surgical-grade and N95 masks for healthcare professionals, hospital workers and first responders. They are doing this by employing an innovative reusable mask design (the Montana Mask) and rapidly producing those masks at a local level. **This is a replicable model that can and should be deployed by other states and counties to provide facemasks to frontline healthcare workers.**

A Three-Part Model

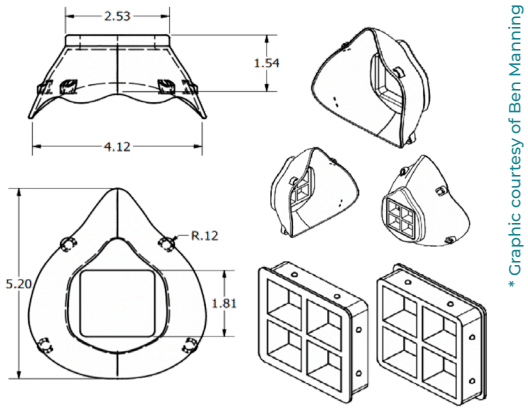
Part 1: Mask Design - the Montana Mask
Part 2: Mask Production - Make Locally
Part 3: Hospital Implementation/Use

PART 1: MASK DESIGN - THE MONTANA MASK

The Montana Mask is a reusable, sanitizable medical mask. It uses a 2.5"x2.5" patch at the front of the mask to filter out particulate matter. The level of protection correlates with the filter material used. **The small filter patch size means one standard disposable surgical mask can be cut to make six patches for use in six Montana Masks and one standard disposable n95 mask can be cut to make four patches for use in four Montana Masks.**

This mask was developed as a public service by three inventors in Billings, MT: Dusty Richardson, MD. Spencer Zaugg, D.D.S., and Colton Zaugg. They have made the Montana Mask design files available for unlimited free public use.

Although this mask is not FDA approved, it is on a short list for approval by the National Institute of Health (https://3dprint.nih.gov/discover/3dpx-013312). Under the current CDC and FDA guidelines, the Billings Clinic in Montana has approved this mask for use by its healthcare workers, allowing the Clinic to protect itself against worldwide facemask shortages (https://bit.ly/2xQmtdl).



* Graphic courtesy of Ben Manning

Clinical Tests

When tested at the Billings Clinic, a gasket-lined, PLA mask** fitted to Dr. Richardson's face passed both quantitative and qualitative OHSA fit tests. These tests were conducted with N95 material as a filter, indicating that the mask will take on the same level of filtration as the filter that is installed. Summary of Montana Mask test results *(see appendix for full test results and discussion)*:

- Passed quantitative and qualitative OSHA Fit Tests for standard n95 mask
- No CO2 buildup or drop in O2 levels for the wearer
- No microbe growth at 72hr bacterial study after being sanitized with Sani-wipe or bleach solution (indicates the mask can be easily and safely sanitized in between uses)

Filters

By utilizing these masks, N95 grade melt blown material could be ordered per yard from manufacturers without having to wait for the process to be fitted into a disposable respirator. This could greatly shorten the timeline of getting PPE.

The most effective material for filtration against viruses is an N95 rated material. As these masks become more scarce and are not readily available to some clinics and first responders, surgical masks are often used instead.

Dr. Richardson has begun testing alternate options for filters for use in the Montana Mask, and found that filters made from Halyard H600 (a material readily available at most US hospitals) had a protective rating higher than standard surgical masks.

Montana Mask 3-D printed in PLA with gasket and N95 filter.

PART 2: PRODUCING THE MASK

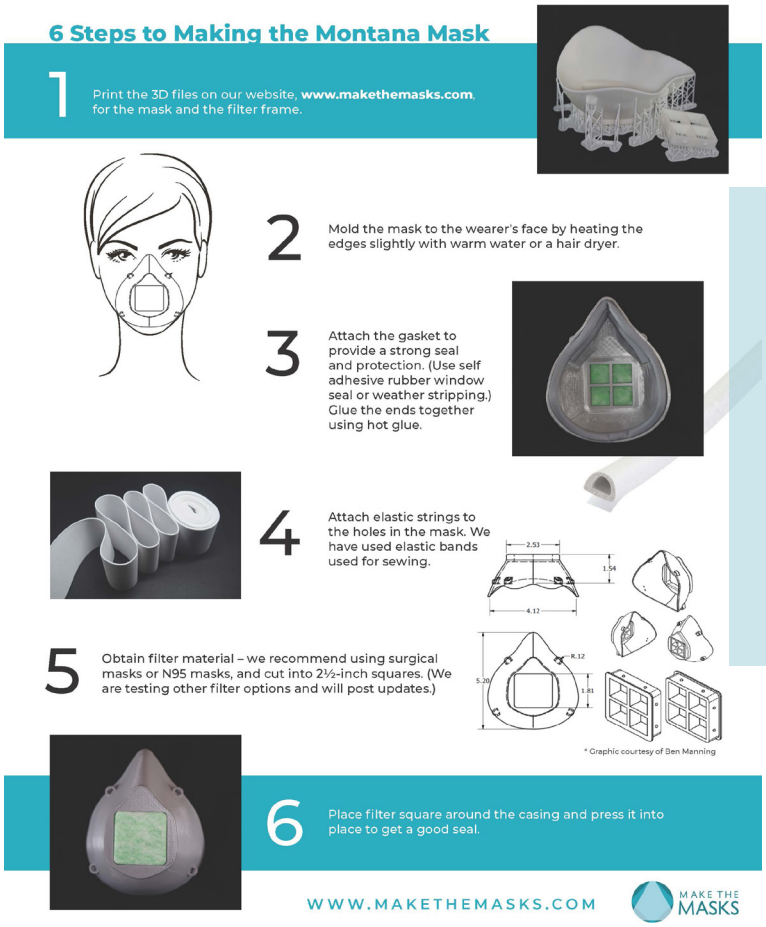
Montana hospitals rapidly scaled Montana Mask production for local needs via 3D printers and injection molding machines.

The Montana Mask can be printed on any 3D printer using PLA 3D printing filament, and assembled using weatherstripping and elastic bands.

Total cost to produce one mask (without filters) is between $1-3.

PLA (Poly Lactic Acid) is a 3-D printing filament that is readily available, inexpensive and easy to use. The mask size can be adjusted using the print scale. Once printed, mask fit can be improved by placing it in warm water and then molded to the face. To achieve a tight seal, a gasket made of weatherstripping is placed on the inside edge of the mask.

Simple instructions for printing and assembly can be found at: https://bit.ly/makingthemask.



Materials Needed for Production:

1. 3D Printer
2. Filament
3. Weatherstripping
4. Elastic Bands

Total Cost Per Mask
$1-3

Leverage the Public

3D printing efforts can be scaled by fully utilizing community resources such as 3D printers at libraries, colleges, public schools, dental offices, dental labs, local businesses and hobbyists. The most basic 3-D printer can generate 2-5 masks per day, with larger models creating up to 50 per day. When a community is at full printing capacity, thousands of masks could be made in a single day.

Montana hospitals controlled for quality by having volunteers drop off printed masks at a closed business building, then assembled them (gasket and elastic bands) at the hospital with a small team.

The most effective way to scale production, is to allow production to travel at the speed of information. Montana used the traditional media as well as social media to put out a call to the public and set several public drop-of locations at temporarily closed businesses. The public responded rapidly by downloading the mask files, printing masks and dropping them at designated locations.

Volunteer Grassroots Effort

There are countless efforts being made around the world to help with the shortage of PPE, but legal and manufacturing constraints are hindering wide-scale distribution and production of the Montana Mask by a large manufacturer. After consulting with several large medical distributors, its been confirmed that there is simply too much red tape and too much time required to scale production by a large company. Also, PPE assistance at the federal level does not and cannot adequately keep up with rapidly-changing local demands. These obstacles can be overcome and shortages can be addressed most quickly by leveraging the public and local companies to produce and distribute on the local level. This mode of local production is viable and will save lives now. Volunteers have joined with MaketheMasks to become “Local Coordinators” and serve as the point of contact for their communities. They help facilitate, mask creation, conversations with makers and donations to hospital-designated off-site drop-off locations. Without the help of volunteers on a local level, immediate PPE needs will not be effectively met, especially in rural areas where federal supplies and assistance are not being prioritized.

Injection Molding

Montana Masks can also be created via injection molding. Many local manufacturers have the capability to produce via injection molds. With a CAD file design, these companies can create the necessary tooling to produce a Montana Mask in as little as two days. **CAD files are available for free and can be accessed at (makethemasks.com). Average output of a small plant could be 400-1,000 masks/day and some can produce up to 10,000/week.**

Injection mold produced masks can be fitted with elastic bands and function as a surgical mask using a surgical mask patch as a filter. To achieve a tighter face seal, more consistent

with an n95 mask fit, a weather stripping gasket can be applied to the edge of the mask, using the same assembly process as the 3D printed version.

Local Montana snowboard binding producer, Spark R&D, is manufacturing these masks for Montana hospitals at a cost of $2-3/mask. If local producers in your area cannot create the necessary tooling to produce a Montana Mask via injection mold, tooled molds in two sizes can be purchased at cost of production from Spark R&D and shipped immediately.

Makethemasks.com has received interest from small, local manufacturers all over the country who are producing Montana Masks via injection molding, making this option viable in nearly all parts of the US. It is possible that a local manufacturer is already tooling molds to produce this mask on their own accord.

PART 3: IMMEDIATE DEPLOYMENT/HOSPITAL USE

In order for this mask design to be utilized and deployed immediately, governments at the local and state levels need to:

1. Make their local hospitals aware of the most recent FDA and CDC guidelines allowing for alternate PPE usage during “crisis level” PPE shortages (https://bit.ly/cdcstrategies & https://bit.ly/2xQmtdl)
2. Arrange for a 3D Montana Mask to be printed, assembled, and delivered to the PPE decision-maker at each hospital in your area for testing and approval.
3. Strongly encourage hospitals to test the masks for approval for immediate usage, or for usage when PPE levels his “Crisis Level” amounts.
4. Direct public and private entities to 3D print masks now so that masks will be available when PPE levels become critical (if they are not already).
5. Employ local companies that produce any products via injection molding to download the free Montana Mask CAD files and begin production (or purchase a tooled mold at cost from Spark R&D or any local source that can produce tooled molds).

How Government Leaders Can Help

- Ensure all hospitals in your area receive a mask and conduct fit tests (masks can be provided by MaketheMasks.com and overnighted to you)
- Provide FDA guidance to hospitals on using 3D printed masks
- Encourage medical facilities to implement usage now
- Facilitate and rally local printing efforts for immediate public and private response

FDA Guidance

As information and momentum for 3D printing has grown over the last week, the FDA has released an FAQ regarding printed material. Hospitals in local areas should be appraised of this most recent information and allow it to guide their decisions when determining if they will accept 3D printed PPE, like the Montana Mask (https://bit.ly/2xQmtdl).

Q. What should health care providers do if using a 3D-printed mask?
A. Health care providers should:

- Check the 3D-printed mask's seal for leaks
- Confirm that they can breathe through any makeshift Filter materials
- Exercise caution in surgical environments where the need for liquid barrier protection and flammability is a concern
- Recognize that the mask may not provide air filtration enough to prevent transmission of infectious agents
- Safely dispose of infectious materials and disinfect any part they intend to reuse

Using the CDC guidelines for optimizing face mask supplies will also help hospitals best utilize mask and filter materials for each patient encounter (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html).

HOSPITAL USE GUIDELINES

Immediacy

These masks should ideally be implemented before hospitals have exhausted their supply of n95 masks and surgical masks. This strategy works best when its used to extend low supplies.

Sanitization/Sterilization

Ideally, each provider would utilize two fitted masks, enabling a process of sterilizing one while the other is in use, therefore cutting down the wait time between encounters. 3D printed masks can be sanitized using a bleach solution, a Sani-wipe, or similar sanitizing wipe. Depending on the material, injection molded masks can be sterilized.

Donning/Doffing Procedures

Each medical facility should develop and implement donning and doffing procedures to ensure proper usage and eliminate risk of cross contamination as the mask has reusable components. Here are videos with donning and doffing procedures adopted by the Billings Clinic: https://bit.ly/PPEWalkthrough.

Use with FDA-Approved Options

The FDA recently approved technology from non-profit Batelle, that can sterilize disposable n95 masks, allowing them to safely be reused up to 20 times. If Batelle sterilizing machines are used to sterilize Montana Mask n95 patches, those patches could then be reused up to 20 times. This process requires a 2.5hr sterilizing process using specialized equipment at a Batelle facility and is most likely to be deployed only in areas of highest need (https://bit.ly/2R8A32S).

Overall Benefits

- Inexpensive to produce
- Multiplies existing supply of n95 and surgical masks by four
- Can be quickly and locally produced
- Fills immediate needs efficiently
- Production can begin immediately
- Can be deployed by city, state or region
- Travels as fast as information as free source file

Overall Potential Risks

- 3D printers must print exact files provided or risk mask performance issues
- Printing errors can cause irregularities, if specific instructions aren't followed
- Improper cleaning or usage of the mask can occur, if hospitals don't adopt robust procedures
- Improper assembly of gasket can cause lack n95 level seal, and must be inspected for quality control
- Misinformation and stigma to crisis level alternative options creates barriers to considering 3D printed solutions

A NOTE FROM THE AUTHORS AND VOLUNTEERS AT MAKETHEMASKS.COM

We respect the outsized and critical challenge the COVID-19 pandemic presents to you as an official. We implore you to act bravely, and boldly RIGHT NOW to solve this critical PPE shortage. In countries with large COVID-19 outbreaks, such as Italy, the mortality rate for frontline healthcare workers has been disproportionately high. We believe one of the critical contributing factors is a lack of appropriate PPE. Your decisions to deploy solutions now, will make the difference between nurses, doctors and EMT's becoming infected with and potentially succumbing to COVID-19. Many of us have spouses who are frontline healthcare workers. Please protect them by acting now.

Makethemasks.com is an all-volunteer effort of people across the US in all fields who came together and are volunteering their time with one goal: to get PPE to frontline healthcare workers now. No one is paid, all information on the website and files are free and no one at makethemasks.com is profiting from this endeavor. Spark R&D, a company referenced in this document, is producing masks and tooled molds at cost and is simply listed as a potential resource currently being used by hospitals in Montana.

** The mask tested was created on a machine using 25% infill and .15mm layers on a specific machine. Every mask produced must undergo a thorough inspection and fit test for a specific provider before being used in a setting where N95 filtration is required. Masks produced out of different materials, assembled differently, or printed to different specifications will produce a different result. These masks will provide some measure of protection, but will not yield the same results.*

*** Makethemasks.com does not speak on behalf or represent nor is it affiliated with the Billings Clinic or the Billings Clinic Foundation.*

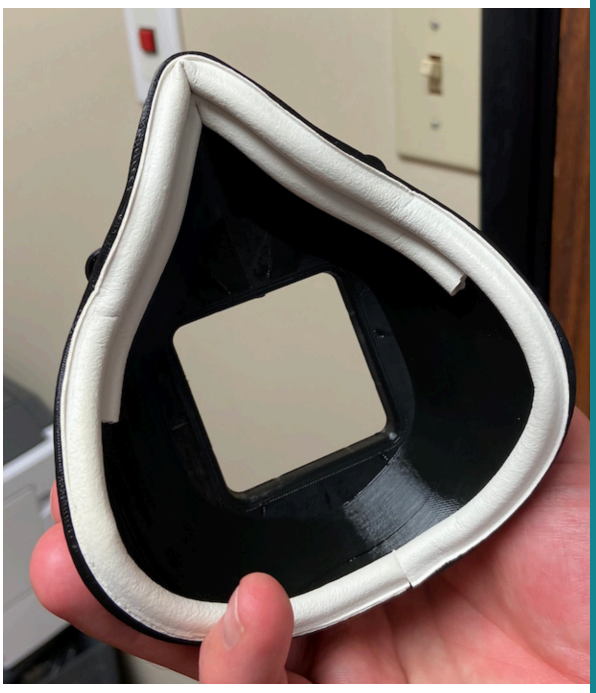
APPENDIX

Discussion of Test Results for “Montana Mask”

March 25, 2020

MAKE THE MASKS

WWW.MAKETHEMASKS.COM



Mask was printed using PLA polymer on a 3D printer. A gasket was fitted using MD rubber weather stripping around the face seal area, with a second row around the nasal bridge for comfort. Three different filtration patches were cut into 2.5 x 2.5 inch squares from the following materials:

- MN95 mask
- surgical mask
- MERV 16 rated air filter
  (procured from High-Tech filters in Billings, Montana)

The MERV 16 filter is commonly used in hospital HVAC units. It is meant to filter out 95% of 0.3 micron particles. It is a blended media of a synthetic product and wet laid fiberglass covered by a scrim. We are continuing to test other filter materials.

METHODS

Three types of tests were conducted

1. A **respiratory test** was performed on 3/25/2020 to measure oxygen, carbon dioxide an heart rate while breathing open air, then with the Montana Mask with a surgical mask patch, then an N95 patch.

2. **Quantitative fit testing** was performed on 3/24/2020 using OSHA 29CFR1910.134 protocol using a TSI PortaCount. This protocol measures the amount of leakage on nanoparticles into the facepiece. A score of 200+ indicates the mask has an excellent seal and no detectable leakage of particles through the filtration media.

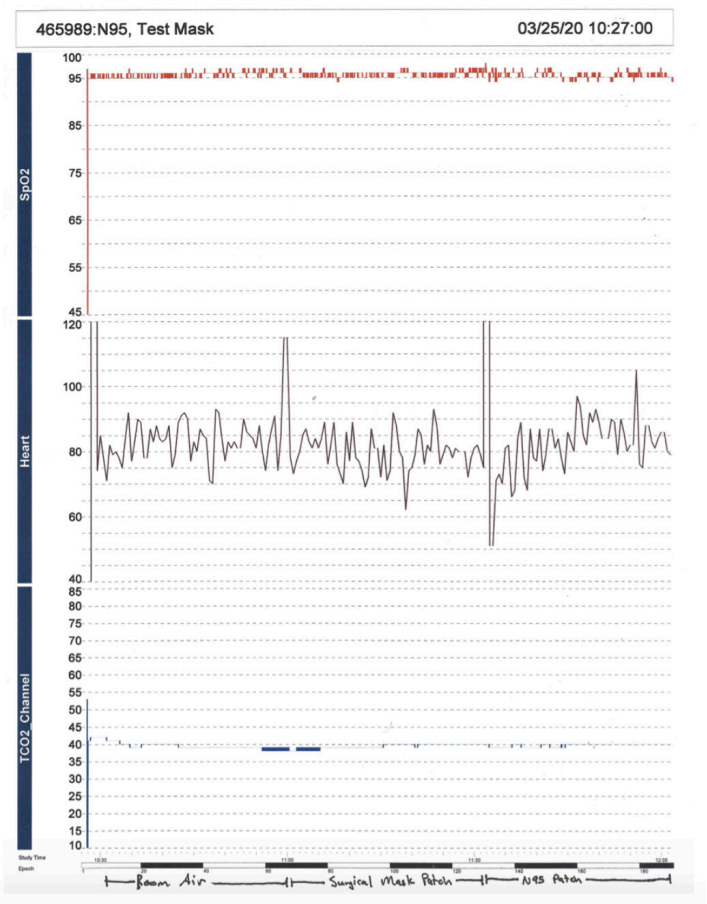
3. A **sanitization test** using auger plates were used to show microbial culture pre and post sanitization using either a Sani-wipe or bleach solution.

RESULTS

1. **Respiratory test results:** Oxygen saturation, heart rate and CO2 levels remained consistent and stable during breathing open air, then through the Montana mask with both the surgical patch and then the N95. The wearer reported breathing is easy with no shortness of breath.

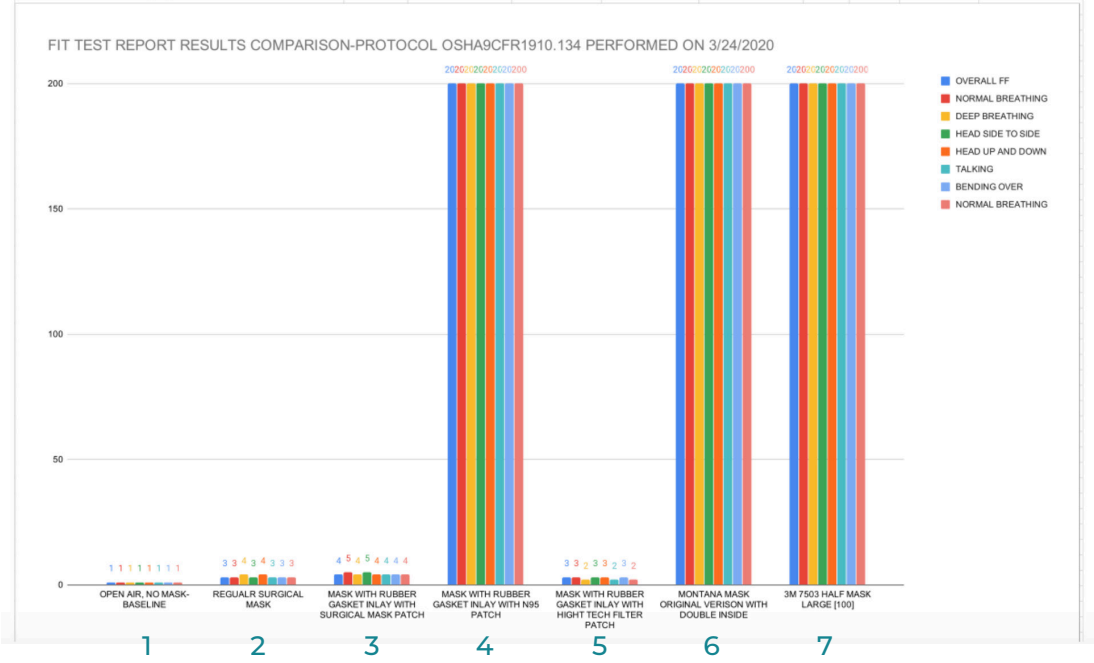
NAME:	N95, Test Mask			**PHY:**	
ID:	465989			**ROOM:**	
DATE:	3/25/2020			**AGE:**	0
HEIGHT:	in cm	**WEIGHT:**	lbs kg	**SEX:**	

Epoch	Technote
7	10:31:05 - On room air sitting at rest mask off
67	11:00:52 - N95 mask on with surgical mask filter
71	11:03:06 - Breathing is easy not short of breath
130	11:32:34 - switching to N95 filter
161	11:47:40 - Breathing is easy not short of breath
163	11:48:41 - Talking with mask on no problem TCO2 is stable



2. Quantitative Fit test results:

MASK	OVERALL FF	NORMAL BREATHING	DEEP BREATHING	HEAD SIDE TO SIDE	HEAD UP AND DOWN	TALKING	GRIMACE	BENDING OVER	NORMAL BREATHING
OPEN AIR, NO MASK-BASELINE	1	1	1	1	1	1	EXCL.	1	1
REGUALR SURGICAL MASK	3	3	4	3	4	3	EXCL.	3	3
MASK WITH RUBBER GASKET INLAY WITH SURGICAL MASK PATCH	4	5	4	5	4	4	EXCL.	4	4
MASK WITH RUBBER GASKET INLAY WITH N95 PATCH	200	200	200	200	200	200	EXCL.	200	200
MASK WITH RUBBER GASKET INLAY WITH HIGHT TECH FILTER PATCH	3	3	2	3	3	2	EXCL.	3	2
MONTANA MASK ORIGINAL VERISON WITH DOUBLE INSIDE	200	200	200	200	200	200	EXCL.	200	200
3M 7503 HALF MASK LARGE [100]	200	200	200	200	200	200	EXCL.	200	200



Column 1: Negative control- Open air: score or 1 shows essentially no filtration or seal as expected.

Column 2: Regular surgical mask- score of 3 indicates no seal or filtering of aerosolized particles, as expected since a surgical mask is not designed as a filtration respirator

Column 3-5: All show the same Prototype 3D printed mask with gasket specified above. Only the type of filter was changed between tests

Column 3: Surgical mask filter patch. Score of 4 indicates low filtration capabilities of this filter type. This is expected since surgical grade masks are not intended as a respirator.

Column 4: N95 mask patch: score of 200+ indicates excellent seal and filtration.

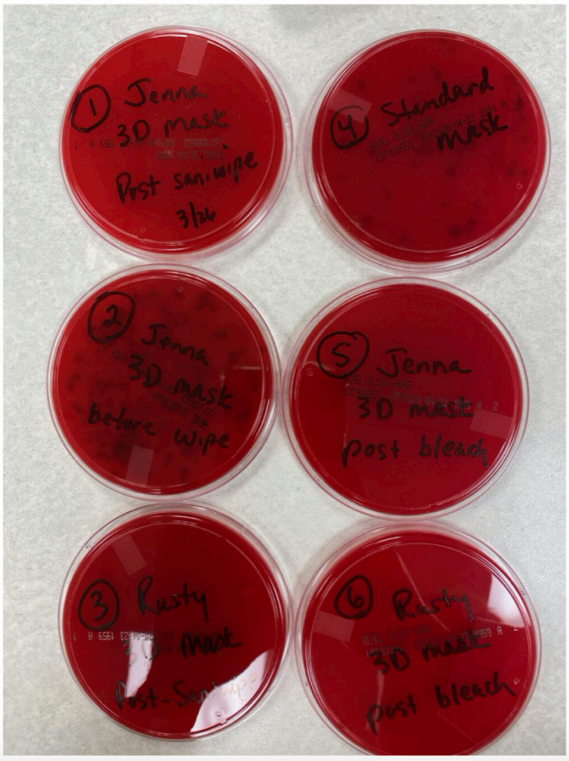
Column 5: MERV 16 rated air filter patch: score or 3 indicates low filtration capabilities of this filter type as an N95 comparable material.

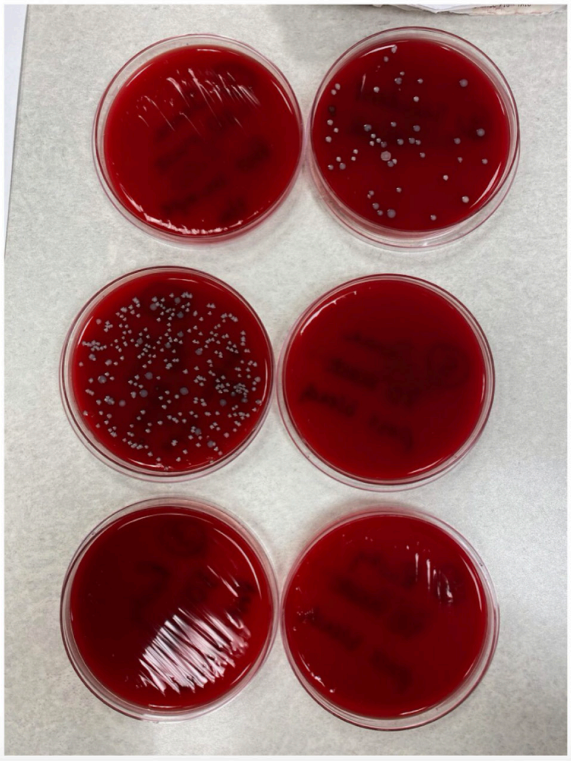
Column 6: Used the original Montana mask 3D design with same gasket material with an N95 respirator patch. Score of 200 indicates that this mask has excellent seal. We did this extra test to prove that both 3D designs were comparable to N95 standards when an N95 patch was used as the filter.

Column 7: Positive control using the highly effective 3M brand 7503 Half mask respirator. Score of 200 indicates excellent seal and filtration.

3. Sanitization tests:

The re-usability of this mask hinges on its ability to be sanitized between patient encounters. Masks before any sanitization showed significant microbial count. Those after sanitization using bleach solution or sani-wipes showed no microbial colonies.





CONCLUSION

These test results demonstrate that the Montana Mask design with gasket appears to perform at a similar level as a high level respirator such as the 3M 7503 when used in conjunction with a piece of N95 filtration media. Since a single N95 disposable mask can be cut into 4 or 5 squares at the necessary 2.5" size, this solution essentially multiplies a hospital's current stock of N95s by at least four.

Additionally, this mask can be used to augment the supply of surgical masks by inserting a HEPA filter (MERV 16) or a patch from a surgical mask. Since one surgical mask can be cut into six filters, this essentially multiplies your existing supply of surgical masks by six.

Masks were able to be sterilized after use, including the weather stripping attaches as a gasket.

DISCUSSION

Every end user must be instructed that this mask's ability to work depends on the robustness of the filter. Because the amount of filter material used in each patient encounter is a fraction of what is currently used, this mask can extend current supply. Use of CDC guidelines to optimize the supply of masks by utilizing surgical masks unless N95 masks are necessary can allow the user to place the type of filter needed for the type of procedure they will be doing.

Of note is the reusability of this mask, each provider can have a mask specially fitted to their face shape. Ideally, two masks can be fitted so one can be sterilized while the provider is seeing a patient, cutting down the waiting time to sterilize between encounters. UV light sterilization, a bleach bath, and moist heating are also viable options for sterilization depending on the melting point of the polymer used by the 3D printer.

By utilizing these masks, N95 grade melt blown material could be ordered per yard from manufacturers without having to wait for the process to be fitted into a disposable respirator. This could greatly shorten the timeline of getting PPE.

For more information please visit **http://www.makethemasks.com**
or email **makethemasks@gmail.com**