

ADDITIVELY MANUFACTURED FACE MASKS

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U.S. Food and Drug Administration (FDA)

~10-12 minutes

InfoClear DAM-5668

Similar 1463, 1433, 2026,
2029, 5522

February 23, 2022



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Introduction

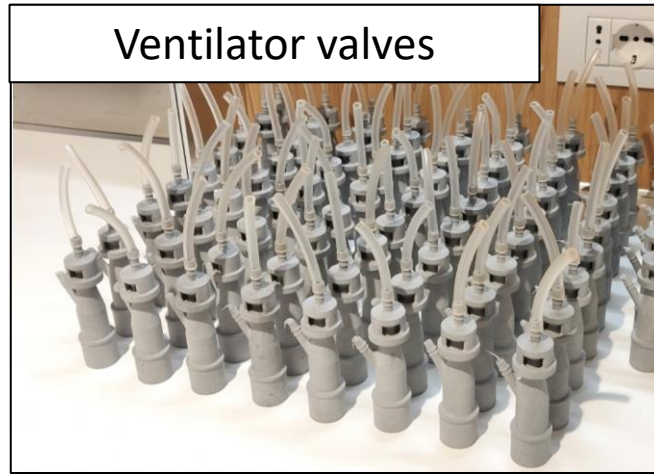
- Pandemics may create increased need to utilize personal protective equipment (PPE) for numerous people.
 - Example: COVID-19 type situations.
- In mid-late March 2020, device shortages were a serious issue, projected shortage of 1 billion face masks by June.



AM History During COVID

- Shortages required stopgap measures.
- Many different ideas came about.
- Some sparked thoughts on constructability of PPE in problematic supply logistic situations.

Ventilator valves



<https://www.medicaldevice-network.com/news/3d-printed-valves-covid-19-italy/>

Respirators



<https://www.defense.gov/News/News-Stories/Article/Article/2474314/dod-uses-3d-printing-to-create-n95-respirators/>

Face shields



3DPX-014383

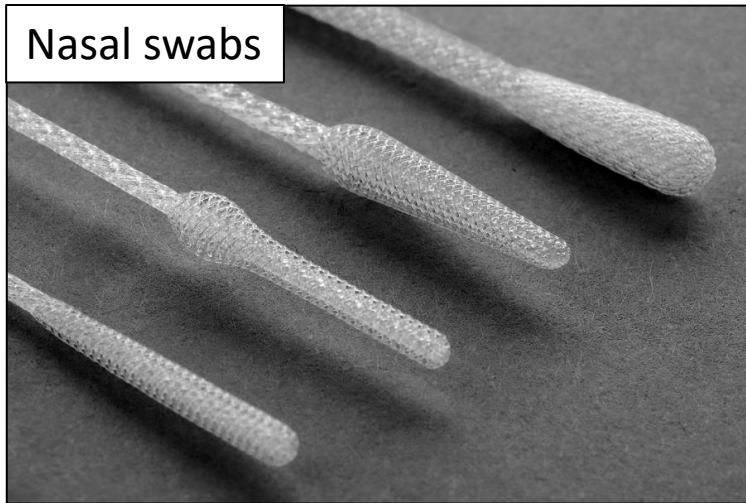


Welch Allyn Panoptic Shield

<https://3dprint.nih.gov/discover>

BCPLemanski

Nasal swabs



<https://news.mit.edu/2021/opt-industries-swab-0408>

Face masks

COVID-19 MASK v2 (Fast print)

COVID-19 MASK v2
3D PRINTABLE

1-2 HOURS TO PRINT
NO SUPPORT REQUIRED

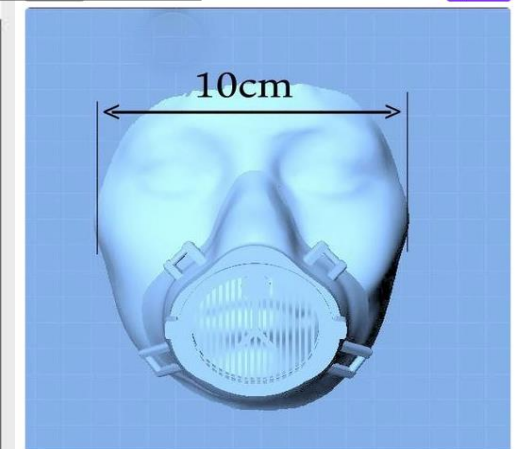
www.factoria3D.com

Collect Thing

<https://www.thingiverse.com/thing:4225667>

2020_08_05

9840



<https://cults3d.com/en/3d-model/tool/masque-facial-de-protection-enfant>

2020_08_05

Initial response – March 26th, 2020

FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic



<https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic>

- FDA’s general AM recommendations
- 3D Printing of PPE
 - Can it be done?
 - Can I use it?
 - What level of protection does it offer?
- Can components or parts of devices be printed?
- Can entire devices be printed?
- FDA’s efforts to combat shortages

AM Face Masks

- Numerous face mask designs are created, modified, updated, uploaded, and shared.
- Many different suggestions on:
 - What filter materials to use?
 - What printing material is best to use?
 - How to improve the fit?
 - How to wash the mask frames and components?
 - And more...

NIH Print Exchange Metrics

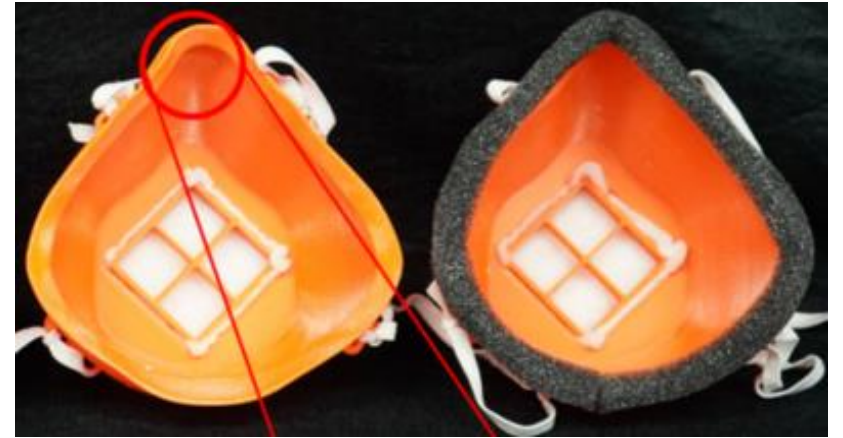
Top 10 Most downloaded in COVID collection

March 28, 2020 through September 29, 2020

	Page Title	Total Events
1	Surgical Mask Tension Release Band for Ear Comfort & Extended Use NIH 3D Print Exchange	22,409
2	Stopgap Surgical Face Mask (SFM) NIH 3D Print Exchange	18,775
3	DtM-v3.1 Face Shield PPE, 3D printable headband NO LOGO NIH 3D Print Exchange	10,569
4	Maker Mask V.4.6 3D Printable Respirator Style Mask NIH 3D Print Exchange	5,873
5	3DVerkstan 3D printed face shield head band NIH 3D Print Exchange	5,398
6	DtM-v3.0 Face Shield PPE, 3D printable headband NIH 3D Print Exchange	4,516
7	Surgical Mask Strap Clip - Ear Saver NIH 3D Print Exchange	4,459
8	IC3D Budmen Face Shield NIH 3D Print Exchange	3,735
9	Custom Fit Mask Ear Saver NIH 3D Print Exchange	2,689
10	Face Shield NIH 3D Print Exchange	2,525

Goals & Methods

- Investigate the potential performance of additively manufactured face masks.
 - Measure leakage using dry NaCl aerosols.
 - Measure pressure drop (breathability).
 - As-printed frames.
 - Post-processing / modifications.
 - cursory look into pediatric mask performance.
 - Initial investigation into washing the frames.



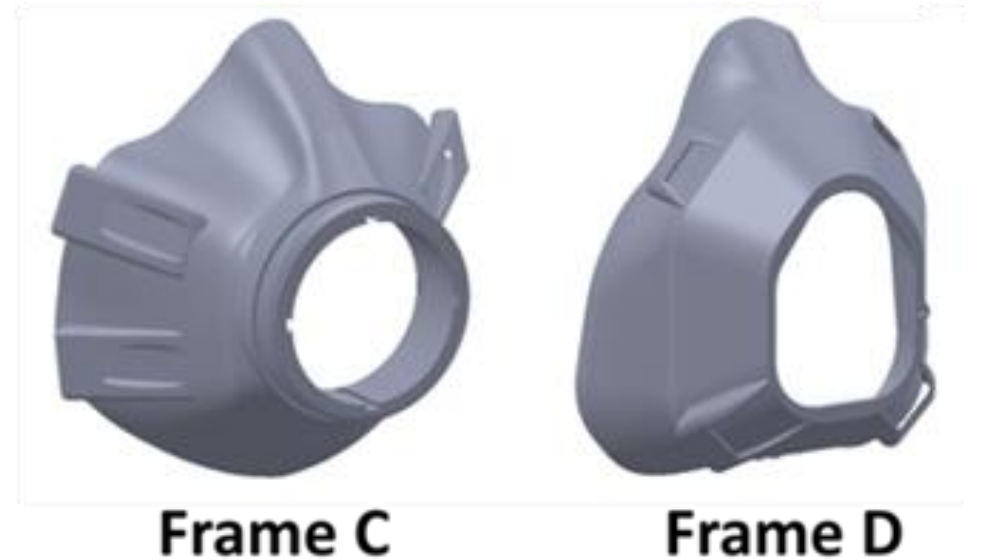
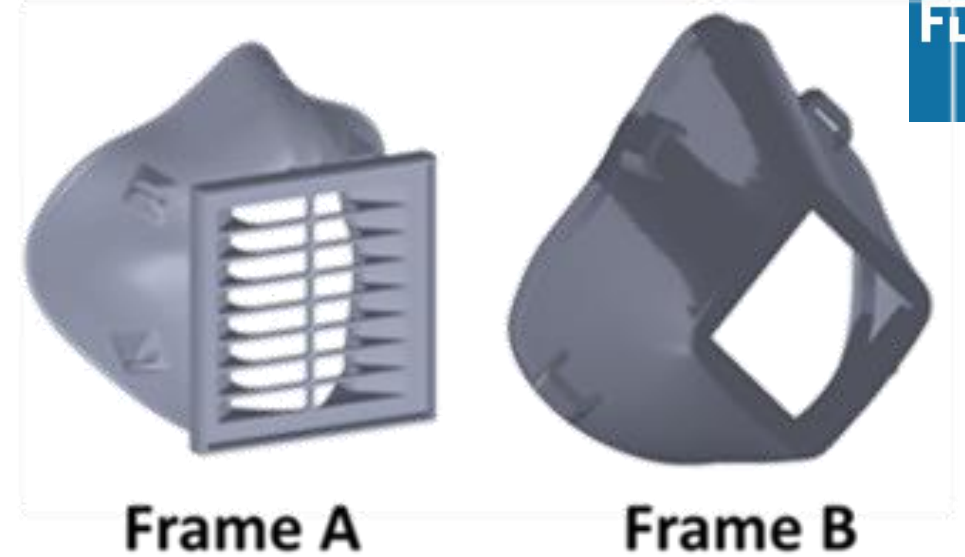
Adding foam strips



Hot water face forming

Frame Specimens

- **A**
 - NIH Print Exchange, 3DPX-014168, <https://3dprint.nih.gov/discover/3dpx-014168>, VHA Innovation Ecosystem
- **B**
 - NIH Print Exchange, 3DPX-014173, <https://3dprint.nih.gov/discover/3dpx-014173>, Matthew Fiedler
- **C**
 - Prusaprinters, 26047, <https://www.prusaprinters.org/prints/26047-coronavirus-covid-reusable-washable-face-respirator>, 3DP
- **D**
 - NIH Print Exchange, 3DPX-013607, <https://3dprint.nih.gov/discover/3dpx-013607>, GarrLarson



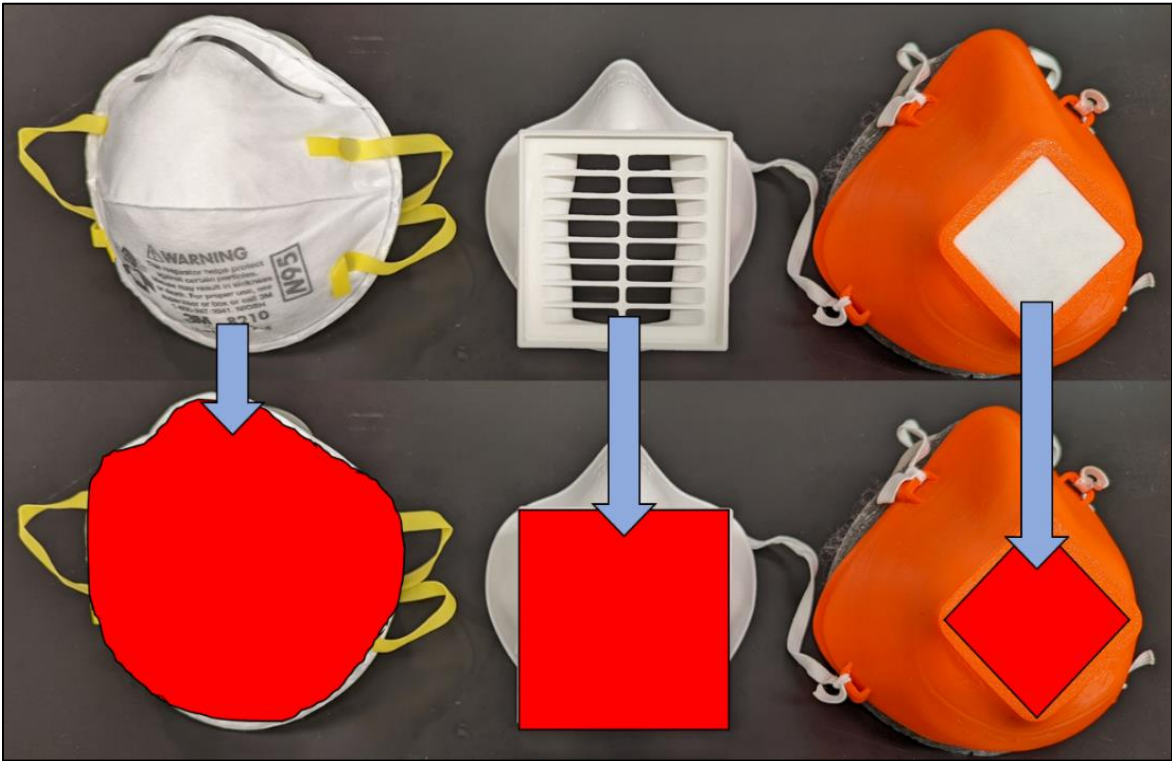
Experimental Method

Experimental Chamber



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Observations



N95 (3M 8210) and AM Face Mask filter area differences highlighted in red



Print flaws

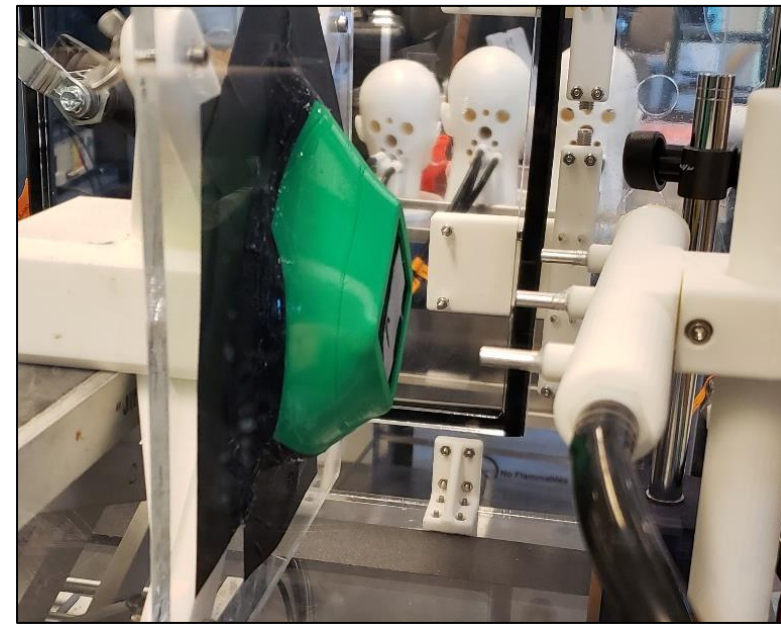
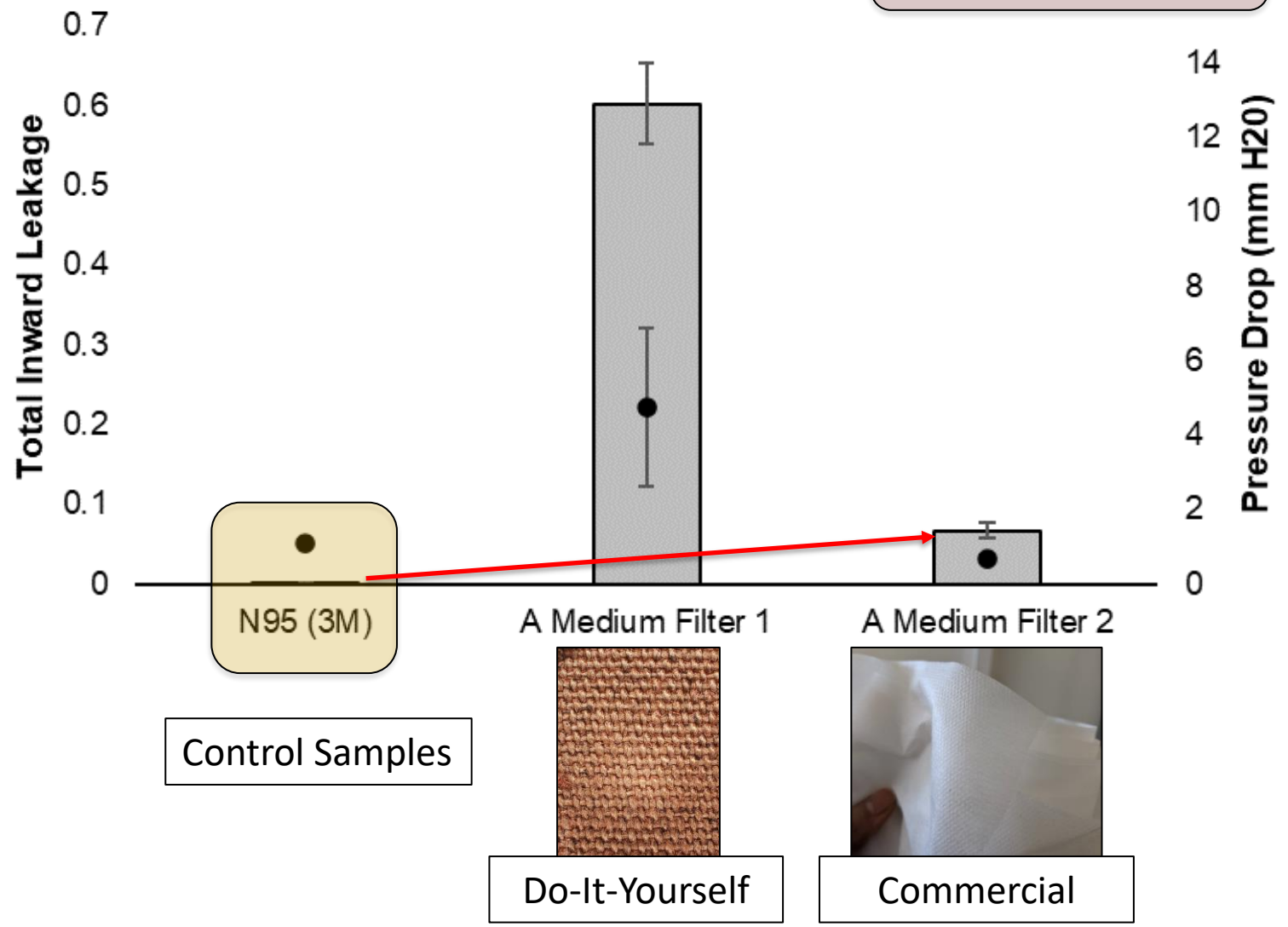
Observations

9 LPM
50 mg / 100 mL NaCl (dry aerosol)
Medium StopGap Mask



Baseline Test

□ TIL ● Pressure



Thank You For Your Attention

FDA

Questions



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