DESIGN THAT MATTERS FACE SHIELD DTM-V3.0

Model ID 3DPX-013238

PRODUCT POINT-OF-VIEW

Healthcare workers responding to COVID-19 who face PPE supply gaps while waiting for domestic face shield production to catch up with demand NEED a transparent face shield that:

- limits aerosol and splatter exposure from in front and above, while providing top ventilation
- reduces aerosol and splatter exposure on N95 and other face masks
- is re-usable for a single user (can survive multiple daily washes; transparent visor can be replaced from readily sourced materials when worn out)
- is easy to fabricate within a few days of design approval (ie no complex supply chains or production bottlenecks)
- is comfortable to wear and easy to don and doff (as it will be taken on and off dozens of times in a twelve-hour shift)
- provides protection to broader area of face compared to standard safety goggles or glasses

BILL OF MATERIALS

- 3d-printed headband in PLA, roughly 50g/1.75oz per part. Outer envelope of 3d-printed headband is 191mm wide, 148.5mm long, and 52.5mm tall. Print time is roughly 3h15m per part on a Prusa i3 MK2S and a Lulzbot Taz 6 at 30% infill, no supports.
 - Acceptable alternate 3d printing materials include PETG, ABS, ASA, Nylon (Salmon PL recommends using PETG for easier and more effective sanitizing.)
 - .STL File included on site
- Elastic for the headband: could be 7"x1/8" rubber bands, 13" strip of 3/4" wide buttonhole elastic, coflex/coban tape
- A standard US letter-sized transparency or report-cover for the shield, 2-10mil (0.002-0.01", 0.05-0.25mm) thickness
 - Acceptable alternative materials include clear PETG, PMMA or mylar in the same thicknesses cut to 8.5" x 11" (215.9mm x 279.4mm). Dimensions for a US-style threehole-binder punch: three 6-8mm diameter holes with each center spaced 108mm apart. Do NOT cut PVC

See below for specific transparency recommendations.

Options:

- Clinicians and caregivers who have worn the device on service recommend the following additions to the headband to improve comfort: add a wrap of foam tape or "chest tube foam tape", tape layers of gauze or a folded paper towel on the headband; dispose as necessary
- Before hole-punching, add tape (duct tape, medical cloth tape, etc) to reinforce the holes at top of the transparency sheet during repeat use and washings. Remove and replace tape between patients as necessary.

INSTRUCTIONS FOR USE & ASSEMBLY

- 1. Punch holes in standard US letter-sized transparency (8.5x11 in) with a standard US three-hole-punch.
- 2. Attach transparency to headband on the three mounting pegs.
- 3. Attach elastic to headband with cleats near temples, adjust to fit. Some users may find 7" rubber band too tight, consider chaining elastic bands as necessary.
- 4. To clean, follow CDC recommendations in Strategies for Optimizing the Supply of Eye Protection - Selected Options for Reprocessing Eye Protection. DO NOT submerge or soak 3D-printed headband in cleaning solution as the headband may absorb the solution and leak it out onto the wearer's forehead over time.
- 5. Discard and replace the transparent visor as appropriate, after excessive wear or fogging.

FDA REFERENCES

- FDA 2017 Technical Considerations for Additive Manufactured Medical Devices
- FDA 2020 Personal Protective Equipment for Infection Control
- FDA 2020 Face Mask For General Public/Healthcare Personnel Per lie Guidance (product classification)
- FDA 2020 Coronavirus (COVID-19) Update: Daily Roundup March 26, 2020
- FDA 2020 FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic

CDC GUIDELINES

- <u>CDC Eye Infection Control Recommendations</u>
- <u>CDC Interim Infection Prevention and Control Recommendations for Patients with Suspected</u> <u>or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings</u>
- <u>CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities</u>
- <u>CDC PPE Donning and Doffing Sequence</u>
- <u>CDC 2020 Strategies for Optimizing the Supply of Eye Protection</u>
- <u>CDC 2020 Strategies for Optimizing the Supply of Face Masks</u>
- <u>CDC 2020 Strategies for Optimizing the Supply of N95 Respirators</u>
- <u>CDC 2020 Interim U.S. Guidance for Risk Assessment and Public Health Management of</u> <u>Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with</u> <u>Coronavirus Disease (COVID-19)</u>
- <u>CDC NIOSH 2009 Latex Allergies</u>

This design is a remix of the <u>Prusa Printers RC2 face shield</u>.

UPDATE ON TRANSPARENCIES 3/29/2020:

#1 BEST: Avery Clear Easy View Durable Plastic Dividers Item 16741 <u>https://www.amazon.com/Avery-Durable-Plastic-Dividers-16741/dp/B017ETNUTC</u>

#2 ALSO GOOD: Office Depot "clear gloss poly binding cover" Item 459-207 <u>https://www.officedepot.com/a/products/459207/Office-Depot-Brand-Binding...</u> Fellowes 52311 Crystals Presentation Covers with Round Corners, 8mil 11 1/4 x 8 3/4, Clear (Pack of 100)

https://www.amazon.com/Fellowes-52311-Crystals-Presentation-Corners/dp/B...

WORST: any kind of thin overhead transparency. Many have subtle textures that spoil visibility. They also tend to be so thin that they flutter.