



Mk1 FACE SHIELD MANUFACTURING INSTRUCTIONS

APRIL 2020

⚠ WARNING
<p>Do not use near flame or intense heat Not tested to ANSI Standards</p>

⚠ CAUTION
<p>Does not provide liquid barrier Use with surgical mask/respirator</p>

<p>PAN-FAB Faceshield 1.0 Fabricated April, 2020 Not FDA cleared Use only when FDA cleared products not available</p>

This face shield was designed, manufactured and tested by the Greater Boston Pandemic Fabrication Team (PanFab), a group of volunteer engineers, clinicians, scientists and concerned citizens for use by health care providers during the COVID-19 Pandemic. All associated designs, clinical testing criteria and data are freely available for reuse. We do ask that users provide feedback so that we can further improve the design.

Purpose

This document provides recommendations for manufacturers about fabrication, packing and assembly of the BWH/PanFab supplementary face-shield. It must be distributed in association with an appropriate label, which is found at the end of this document.

Appropriate Use Criteria

This supplementary face shield was created as an emergency action in effort to protect people by providing backup Personal Protective Equipment (PPE) options if the standard PPE has become unavailable. This device has not gone through the same regulatory approval process as standard PPE but has gone through a special verification process expedited strictly for the response to the COVID-19 pandemic. The use of this supplementary face shield should always come secondary to existing PPE equipment, standards, and protocol options if available. The decision to implement this device should be made after careful consideration of risks and benefits and following consultation with an institution’s occupational health and infection control departments.

The information included in this document provides a best-effort protocol to minimize the risk of viral transmission during assembly and delivery, as well as produce face shields whose quality is as consistent as possible.

LEGAL DISCLAIMER

THIS FACE SHIELD DESIGN AND SPECIFICATIONS (THE “**DESIGN**”) IS PROVIDED “AS IS” AND BRIGHAM AND WOMEN’S HOSPITAL, INCLUDING ANY AND ALL OF ITS AFFILIATED INSTITUTIONS (“**BWH**”), IS NOT RESPONSIBLE FOR ENSURING THAT ONE’S USE OF THE DESIGN WILL BE CLINICALLY SOUND, WITHOUT ERROR, OR OTHERWISE SUCCESSFUL. THE DESIGN HAS NOT BEEN TESTED OR APPROVED FOR USE IN A HEALTHCARE SETTING AND THE DESIGN IS NOT APPROVED BY ANY REGULATORY BODY. IF YOU CHOOSE TO USE THE DESIGN, YOU ASSUME ALL RISK AND BEAR ALL RESPONSIBILITY AND LIABILITY, INCLUDING BUT NOT LIMITED TO, THE RESPONSIBILITY FOR ANY FEDERAL, STATE OR OTHER APPLICABLE REGULATORY REQUIREMENTS THAT APPLY TO THE MANUFACTURE, DISTRIBUTION, AND USE OF FACE SHIELDS. BWH SPECIFICALLY DISCLAIMS ALL WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT.

Overview of the design

This emergency face shield consists of five (5) components: the headband, the bottom support, the transparent visor, and a foam pad for comfort.

This design is a remix of the Prusa design and aims to:

- provide a transparent face shield that limits aerosol and splatter exposure from in front and above
- provide ear-to-ear protection without obstructing hearing, nor access to ears with a stethoscope
- provide top ventilation and prevent fogging
- be re-usable for a single user following appropriate decontamination
- be comfortable enough to be worn all day by healthcare workers

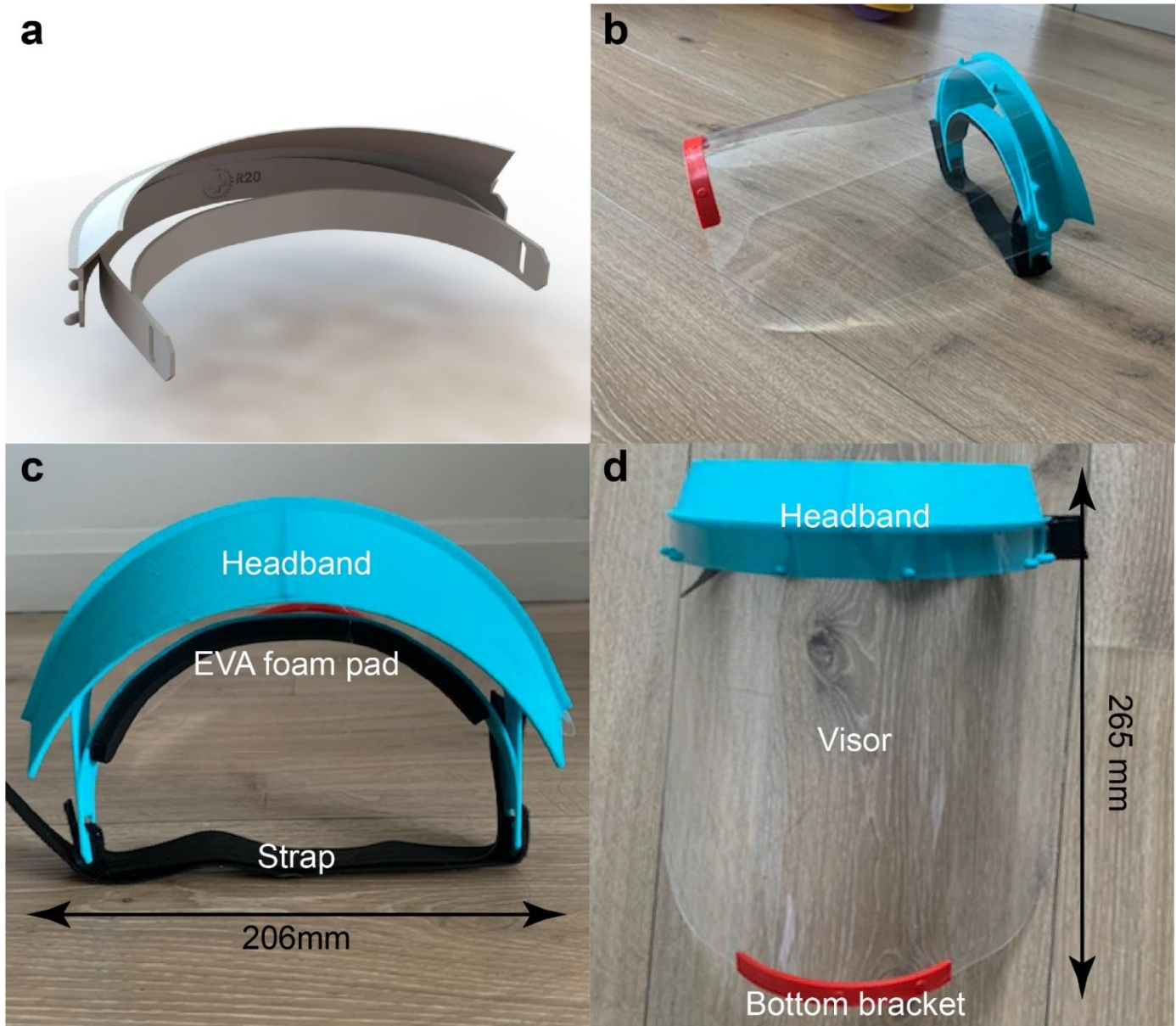


Figure 1: A) Headband CAD image B) final face shield prototype C) headband, foam pad, and hook and loop strap image with dimensions D) headband, visor, and bottom bracket image with dimensions.

Bill of Materials (all files can be downloaded from <https://www.panfab.org/>)

- The headband - 3D printed
 - Part Name: "PanFab-FaceShield-Headband.stl"
 - PLA preferred, other recommended materials PETG, Nylon, PEI
- Bottom bracket - 3D printed
 - Part Name: "PanFab-FaceShield-Headband-Bottom_reinforcement.stl"
 - PLA preferred, other recommended materials PETG, Nylon, PEI
- Transparent shield - can be either laser-cut or rotary die cut
 - Part Name: "PanFab-FaceShield-Transparent Shield.dxf"
 - PET, BoPET (Mylar) and PETG are preferred, PMMA can be accepted as an alternative
 - Thickness between 0.2-0.7mm is preferred
- Foam for comfort - can be either laser-cut, or cut to length directly from a foam tape
 - If using a foam tape
 - ~20mm wide, ~6mm thick adhesive-backed foam tape is recommended, cut 190mm long
 - Preferred material: EVA or closed cell neoprene foam. Polyurethane foam as an alternative
 - If laser-cutting the foam
 - Part Name: "PanFab-FaceShield-HeadBuffer Foam.dxf"
 - Preferred material: EVA or closed cell neoprene foam. Polyurethane foam as an alternative
 - Thickness: ~6mm
- Hook and loop strap:
 - 0.5 or 0.75 inch wide hook and loop strap recommended, cut to 330 mm in length

3D printing of the head-band and the bottom bracket.

The following settings are recommended to 3D-print the head band and the bottom bracket. These settings were optimized for fused filament fabrication (FFF) on an Ender 3 Pro (Creality), and should be adjusted depending on the 3D printer used.

- Print materials: PLA
- Print speed: 90mm/s
- Layer height: 0.2mm
- Infill: 15%
- Infill pattern: Gyroid
- Shell->3 perimeters, 1.2mm, 3 lines
- Top/bottom fill parameters: 0.8mm 2 layers
- Temperature: Printer - 185-200C, Bed - 60-70C

Laser cutting the transparent visor and the foam pad.

The following settings are recommended to laser cut the transparent visor and the foam pad. These settings were optimized on a GlowForge and GlowForge Pro and should be adjusted depending on the laser cutter used.

- Transparent visor
 - Material: BoPET
 - Thickness: 0.007 in
 - 1 Pass
 - Speed setting: 500
 - 40% power
 - Focus height: 0.178mm

- Foam pad
 - Material: EVA
 - Thickness: 6mm
 - 1 Pass
 - Speed setting: 155
 - 30% power
 - Focus height: 6.13mm

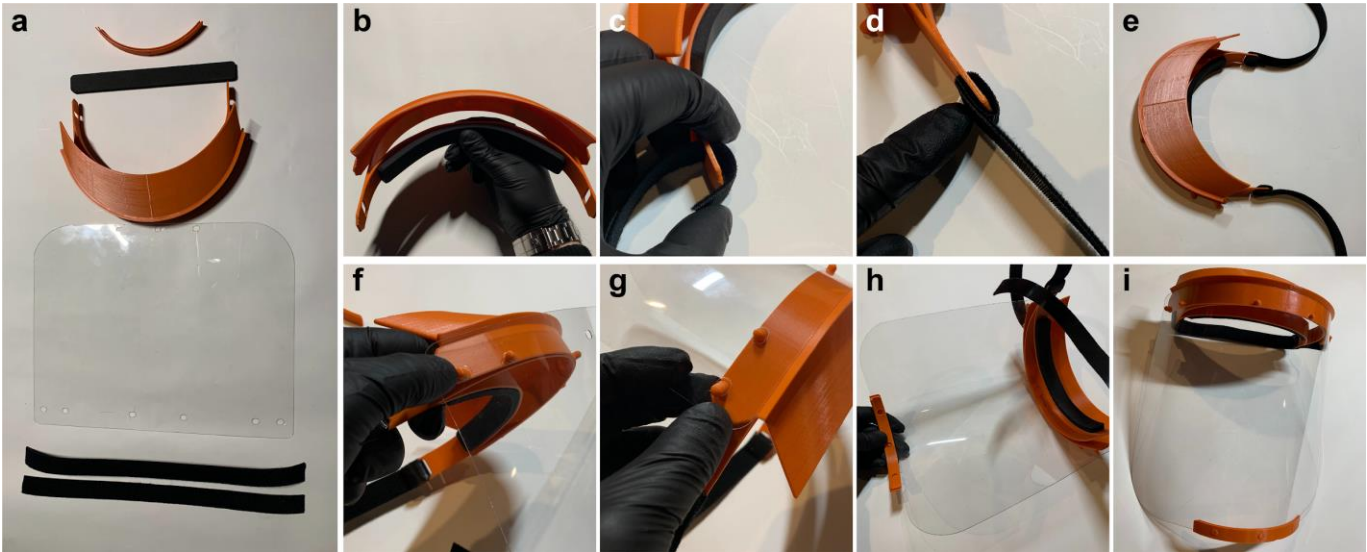


Fig 2: **A)** Individual component of the shields **B)** installation of the foam pad on the headband. **C-E)** hook and loop strap attachment on the headband **F-G)** Visor installation. **H)** Bottom bracket installation. **I)** Assembled face shield.

Preparatory steps at the manufacturing site

1. Disinfect your workplace and use good hand hygiene.
2. Don a pair of clean gloves
3. Prepare a box or a large bag that will be used for transportation of the finished prints.
4. In this box or large bag, prepare an additional hermetic plastic bag (poly-ethylene bag preferred) that will be used to “double-bag” the printed parts. The parts should be batched in groups of 20-50.
5. On the attached “FACE SHIELD LABEL AND ASSOCIATED WARNINGS” at the end of this document fill the “Manufacturer Information” section.
6. In each batch, place the “FACE SHIELD LABEL AND ASSOCIATED WARNING” and “INSTRUCTIONS OF USE” documentation.

Assembly Instructions at the manufacturing site or site of use

1. Disinfect your workplace and your hands.
2. Don a pair of clean gloves
3. Visually inspect laser cut and 3d printed parts, look for possible printing or cutting errors and sharp edges.
4. Attach the foam pad to the inner band of the headband using super glue (fig 2b)
5. Secure the hook and loop straps onto the headband by passing the straps inside the hole at the posterior side of the headband, and attaching it onto itself. In order to prevent hairs from being stuck onto the straps while wearing the face shield, make sure to keep the loop side of the strap towards the center of the headband. (fig 2c-e)

6. Secure one of the outer holes of the visor onto the corresponding outer peg on the headband (fig 2f)
7. Pull the visor across the headband so that each visor hole is aligned with the corresponding peg of the headband.
8. For the final visor hole/headband peg, some additional force might be required to pull the visor over the peg, the visor will then snap itself in place on the headband. (fig 2g)
9. Align the pegs of the bottom brackets with the corresponding holes of the bottom parts of the visor. Push the pegs in place. (fig 2h)
10. Clean the face shield following recommendation steps below

Donning and Doffing

Follow CDC guidelines for how to don and doff a face-shield.

Donning - https://www.cdc.gov/vhf/ebola/hcp/ppe-training/n95respirator_coveralls/donning_01.html

Doffing - https://www.cdc.gov/vhf/ebola/hcp/ppe-training/n95respirator_coveralls/doffing_08.html

Recommended cleaning methods

Warning: The following instructions represent recommendations for how to clean the face-shield. Hospitals and other medical workplaces should follow their institution's OSHA guidelines. A test on a single shield is recommended to verify possible damage of any sterilization method. A list of EPA-registered hospital disinfectant solutions recommended for COVID-19 is available at <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>. The following list of disinfectants has been used on the face-shield to date and did not cause any visible damage. Other disinfectants may work as well but have not been evaluated.

1. Super Sani-Cloth
2. Isopropyl Alcohol, 75%, 1min+
3. 10% chlorine bleach solution

Cleaning procedures.

These recommendations are based on the CDC's strategy to reuse PPE -

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html>

1. While wearing gloves, carefully wipe the inside, followed by the outside of the face shield or goggles using a clean cloth saturated with neutral detergent solution or cleaner wipe.
2. Carefully wipe the outside of the face shield or goggles using a wipe or clean cloth saturated with EPA-registered hospital disinfectant solution.
3. Wipe the outside of the face shield or goggles with clean water or alcohol to remove residue.
4. Fully dry (air dry or use clean absorbent towels).
5. Remove gloves and perform hand hygiene.

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MATERIALS IN DIRECT CONTACT WITH SKIN (full information available at PanFab website)

The headband, the foam pad, and the hook and loop strap will be in direct contact with the user's skin.

- Headband material(s): This component is 3D printed. Material selection will be subject to availability at each printing location. Polylactic Acid (PLA) is recommended as it is widely available, PETG or ABS can be used as a replacement
- Hook and loop strap material(s): Polyethylene hook and nylon loop (typically Velcro Brand)
- Foam pad Materials(s): Ethylene-Vinyl Acetate (EVA) closed cell foam
- This ~~PRODUCT~~ ~~product~~ contains no latex

WARNING

- This face shield helps protect against liquid splashes but does not eliminate exposure to or the risk of contracting any disease or infection. Misuse may result in sickness or death. In instances where aerosolization of body fluids of infectious individuals is likely to occur, this face shield must be used in conjunction with a respirator (e.g. a N95 filtering facepiece respirator - FFR - at a minimum). For proper use, see the attached documentation.
- Unlike other face shields you may have used, this PRODUCT has not been tested to ANSI/ISEA Standards (for optical clarity, impact protection etc).
- Do not use this PRODUCT near flame or intense heat
- This PRODUCT has not been FDA cleared or approved; use only when other FDA cleared products are not available.
- This PRODUCT is authorized for distribution under FDA enforcement discretion only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PRODUCTS under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Manufacturer information (this information is provided by individual fabricators)

- Manufacturer Name:
- Manufacturer Address:
- Manufacturer Phone number:
- Manufacturer Website:



Full information is available [at-on](#) our Website



Please help - take our survey