

Supplemental COVID Face Shield – Quality Control Protocol

This quality control protocol corresponds to V1 of the **CVHCS COVID-19 Face Shield**. The revision of the corresponding Face Shield can be found on the inside edge of the shield.

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 with careful consideration and under the consultation of the corresponding institution's occupational health and infection control departments.

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

Manufacturing Protocol

This supplementary Face Shield (Figure 1.) consists of three (3) components: the Shield, the Frame (frame, H-clip, and nosepiece), and an adjustable Strap. The shield and strap can be purchased off-the-shelf, however, the frame must be locally manufactured. This protocol assumes the frame will be manufactured via laser cutting.



Figure 1 Face shield components.

Laser Cutting Steps

Each laser cutter, all of the parts that it produces, and each sheet of plastic used for that printer should only be handled by one person. This is to reduce the risk of transmission via shared surface contact.

1. Prior to cutting, obtain a clean bag or box to place finished prints inside. The container must be able to be closed.
2. Take a new, clean piece of paper and write your initials on it, leaving room for several other handlers' initials. This will be known as the **Handler Tracking Sheet**.
3. Securely tape the Handler Tracking Sheet to the outside of the container.
4. Once a newly cut batch of frames has cooled, it should immediately be placed in the container. Do not place any frames from another handler's machine in that same container.
5. When the container is full, close it and prepare a new container.

Laser Cutter Settings

The following settings are recommended when laser cutting the frame. This ensures that each batch is of a consistent build regardless of laser cutter and allows the build to be distributed across multiple partners. All settings listed or not should be adjusted according to the specific laser cutting platform utilized to ensure a structurally sound part. The following settings worked well for a Universal Laser Systems VLS4.60 Laser platform

- Polypropylene (copoly) 3/16" thickness
 - 10.6µm CO2 laser, 60 watts
 - 100% power
 - 3.1% speed
 - Compressed air source with Manual and Lateral gas assist
- PET-G up to .016" thickness
 - 10.6µm CO2 laser, 60 watts
 - 26% power
 - 24% speed
 - Compressed air source with Manual and Lateral gas assist

Laser Cutting Steps

Exact cutting steps will vary by specific laser cutter used. Follow manufacturer's instructions. The PET-G typically has a single side coated with a protective plastic, this can be left on during cutting (on bottom of cutting surface) and removed prior to assembly or usage. The polypropylene (copoly) typically also has one side covered in protective plastic. This should be removed or placed on the bottom of the cutting service depending on specific laser system. Based on the laser system used slight scraping or sanding will be required to remove debris from the polypropylene parts before washing or assembly.

Assembly Protocol

Preparatory Steps

1. Disinfect the work environment.
2. Perform hand hygiene procedures.
3. Don a clean pair of gloves.
4. Prepare a clean bag or box to contain the fully assembled parts.
5. Take one container of manufactured frames and remove the Handler Tracking sheet.
6. Add your initials to the **Handler Tracking Sheet** and tape the sheet to the outside of the new bag or box.

Assembly Steps

1. Take a single set of frame, H-clip, and nosepiece (Figure 2.)
2. Clip nosepiece into H-clip. The H-clip is symmetrical, so orientation does not matter.
3. Clip the nosepiece assembly into the frame, note orientation. The assembly should angle in towards open "U" area of main frame. (Figure 2.)



Figure 2 frame, H-clip, and nosepiece assembly

4. The Clear PET-G Shield will snap into place on the frame with little effort. If the shield is forced it might crack. Holding the Frame in your non-dominant hand, slide one back edge of the shield under the rear most Peg A (Figure 3, Step 1) and gently wrap shield around frame while snapping into place on next 3 Pegs B,C, and D (Figure 3, Step 2). Slide opposite back edge of shield behind diagonal Peg F, (Figure 3, Step 3). While gently holding shield in place over Peg E with dominate hand open the ear pieces of the main frame until the shield snaps into place over Peg E (Figure 3, Step 4).

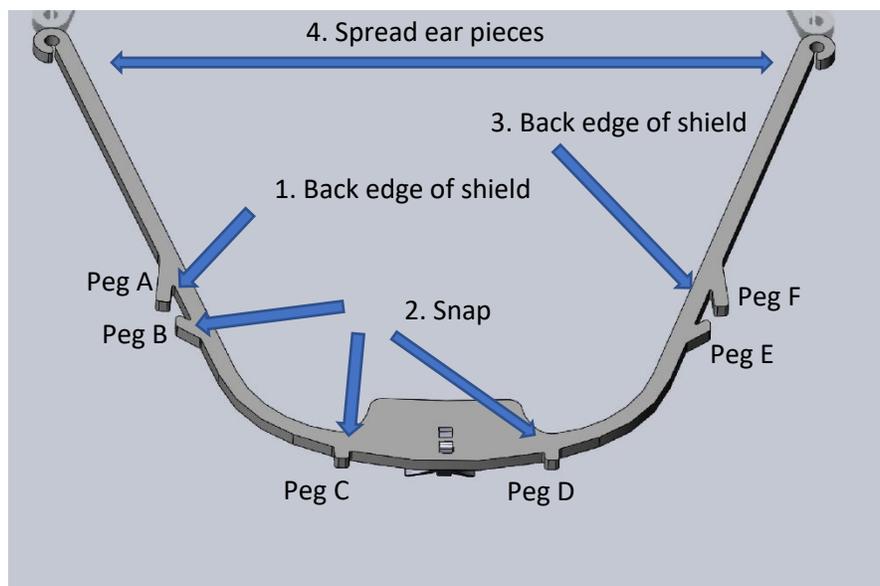


Figure 3 Shield attachment

5. Do a final inspection of the mask with all components assembled to ensure nothing is damaged and everything has been assembled properly.
6. Disinfect via the Disinfecting Steps below.
7. Repeat for the next Frame in the same container as this one. If the container is empty, follow the Interstitial Steps outlined below.

NOTE: If assembly permits deliver pre-made Shields separately in a sealed container such as a bag with a knot and zip-tie or equivalent.

Interstitial Steps

Each time assembly has been completed for a single container of manufactured parts, complete the following steps.

1. Seal the filled container of newly assembled face shields. Options include either double bagging assembled face shields with a knock on both bags and a zip-tie on the outer bag or putting a single bag knot and a zip-tie into a box. Or an equivalent procedure.
2. Doff and carefully dispose of gloves.
3. Perform hand hygiene procedures.
4. Don a new pair of gloves.

5. Prepare a clean bag or box to contain the fully assembled parts.
6. Take one container of manufactured frames and remove the Handler Tracking Sheet from the outside.
7. Add your initials to the Handler Tracking Sheet and tape the sheet to the outside of the new bag or box.
8. Perform Assembly Steps above.

Disinfecting Steps

Using one of the recommended disinfecting products from the list outlined in **Appendix A**, prepare to perform the following steps.

1. Wipe down and disinfect the all faces and features on the Frame.
2. Wipe down and disinfect both sides of the clear plastic Shield.
3. Ensure the surface of the Shield is visibly wet with the disinfectant product for the duration of the contact time as defined by the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2 \(https://www.epa.gov/pesticide-registration/list-ndisinflectants-use-against-sars-cov-2\)](https://www.epa.gov/pesticide-registration/list-ndisinflectants-use-against-sars-cov-2).
4. Wipe any excess disinfectant and dry the face shield using a clean paper towel

Delivery Protocol

When delivering a container of Frames from a manufacturing unit to an assembly unit or when delivering a container of assembled face shields from the assembly unit to the final drop-off point, follow the steps outlined below.

Pick-up Steps

1. Once at the pick-up location, perform hand hygiene procedures.
2. Don a new pair of clean gloves.
3. Ensure that the container of parts is closed.
4. Add your initials to the Handler Tracking Sheet.
5. Load containers into the delivery vehicle, ideally using a trunk door.
6. Doff and dispose of gloves after all containers of parts from one location have been loaded into the vehicle, and before entering the vehicle.

Drop-off Steps

1. Once at the drop-off location, perform hand hygiene procedures.
2. Don a new pair of clean gloves.
3. Remove the containers and leave at the designated drop-off site.
4. Once all containers have been dropped-off, doff and dispose of gloves.
5. Perform hand hygiene procedures.

Appendix A: Recommended Disinfectants

From the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>), it is recommended to use the following four solutions for the disinfecting procedures of the face shield. Note: the following list is in preferential order and have been tested with this device.

1. Super Sani-Cloth
2. 10% chlorine bleach solution (*May fog Shield over time)
3. CaviWipes
4. Soap and water

Appendix B: Functional Testing of CVHCS COVID-19 Face Shield

The following test protocol has been followed to ensure the safety of healthcare professionals.

Donning & Doffing: Don and doff the face shield 10 times – **Pass** (The device should hold up well past this amount)

Splash Resistance: 20CC bolus of water delivered over 1 second at the center of the shield repeated 5 times –

Pass

Face Shield Securement & Range of Motion: With the face shield on, look left, right, up, down, and shake head yes and no - **Pass**



Figure 4 Splash Resistance Test



Figure 3: Range of Motion Test

Appendix C: Material Selection of CVHCS COVID-19 Face Shield Frame

Material- copolymer-polypropylene (Co-poly) has been chosen as the plastic sheet stock of choice as it is most readily available, has good material properties for this application and can be laser cut.

Intended Use- The frame sits on the care provider's forehead, provides a rigid structure to attach the shield, and prevents the shield from falling off the user's head/face.

Cleaning Method- Test cuts of co-poly frames were used for the following tests. Four cleaning products approved by the CDC were used to wipe down the surface of the part. These include: a soap and water solution, Super Sani-Wipes, a 10% bleach solution, and CaviWipes. Surfaces were wiped dry when testing with a water-based solution and left to air dry when using an alcohol-based solution. 10 cleaning and drying cycles were performed.

Observed Results- There were no observable changes to the surface finish, color, or strength of the co-poly frame and no degradation of the materials was observed.

Shield

Materials- two transparent plastics were tested. These include: PETG plastic and Apollo Transparency sheets.

Intended Use- The secured shield will aid in protecting healthcare professionals from potential fluid splashes. The shield portion of the PPE is considered semi-reusable. It should be disposed of if damaged.

Cleaning Method- Four cleaning products were tested on each of the four varieties of sheet plastic. Soap and water, Super Sani-Cloth wipes, water with a 10% bleach solution, and CaviWipes were tested. Both the front and back surfaces were tested to eliminate potential error introduced by unexpected manufacturing surface treatments of the plastic.

Observed Results- CaviWipes and soap and water were observed to have left a small amount of residue on the surface that would eventually cloud the transparent plastic and limit visibility for the user. The Isopropyl alcohol left little to no residue or cloudiness in the plastic.

Recommendations- While all four cleaning products successfully disinfect the face shield, due to the least observed changes in transparency and the ubiquity of Isopropyl alcohol in clinical spaces it is recommended to use this product if available.

Handler Tracking Sheet

Name

Initial

Date

Assembly

Delivery
