

# INSTRUCTIONS FOR USE | DtM FACE SHIELD



This design has undergone review in a clinical setting and is recommended when fabricated as instructed.

## Indications for Use

The DtM Face Shield is intended for multiple uses by the same user in medical use applications. Face shields may be effective at preventing healthcare practitioner (HCP) exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19.

## Limitations / Appropriate Use Criteria

The use of this DtM 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 consultation of the corresponding institution's occupational health and infection control departments and in line with CDC Strategies for Optimizing the Supply of Eye Protection (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html>)

## FDA Emergency Use Authorization (EUA)

This device is being offered for the duration of the FDA Emergency Use Authorization for Face Shields (9 April, 2020). This product is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner. It is not an FDA-registered or approved product, nor is it manufactured under a quality systems manufacturing process compliant with 21 CFR Part 820. See FDA EUA: (<https://www.fda.gov/media/136842/download>)

## Recommended by the U.S. National Institutes of Health

The DtM-v4 has gone through a verification process expedited strictly for the response to the COVID-19 pandemic leading to its recommendation by the U.S. National Institutes of Health. Learn more about this effort by viewing the 31 March 2020 release: FDA Efforts to Connect Manufacturers and Health Care Entities: The FDA, Department of Veterans Affairs, National Institutes of Health, and America Makes Form a COVID-19 response Public-Private Partnership. (<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/fda-efforts-connect-manufacturers-and-health-care-entities-fda-department-veterans-affairs-national>) See the DtM-v4 design for injection molding here: <https://3dprint.nih.gov/discover/3dpx-013830>

## Device Overview

This face shield consists of three (3) components: the HEADBAND FRAME, the TRANSPARENT SHIELD, and the HEADBAND STRAP as seen in Figure 1.

This face shield is designed to be compatible with an extra-large TRANSPARENT SHIELD as well as a standard US Letter-sized report cover (or similar transparent sheet) that can be attached and secured by using the geometry found in a standard 3-hole punch.

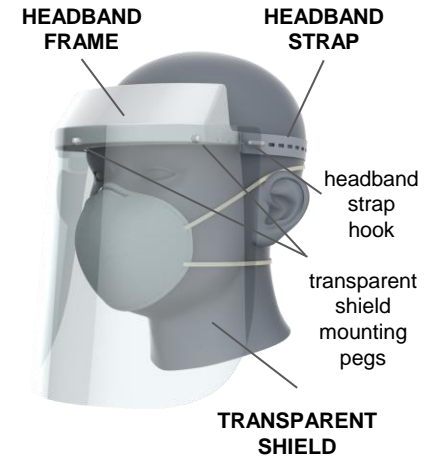


Figure 1

Components to be disinfected and reused for multiple uses by the same user as long as proper disinfectant protocol is followed and there is no visible damage to parts (See Appendix A for disinfecting solutions recommended for this device).

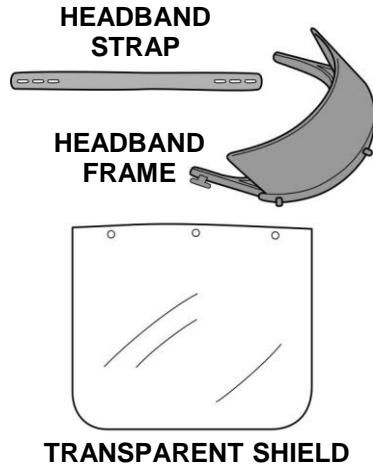


If the face shield is not properly cleaned before first use and before reuse, there is a risk of infectious material deposited on the shield during manufacturing or during use to infect the wearer or other people that come in contact with the face shield.

Tool Gauge  
4315 S Adams St  
Tacoma, WA 98409, USA  
[www.toolgauge.net](http://www.toolgauge.net)

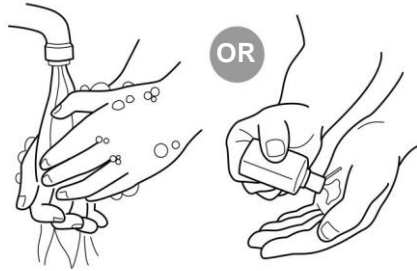


# ASSEMBLY STEPS D1M FACE SHIELD



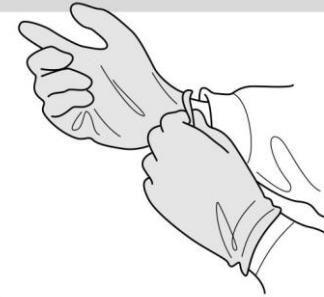
## 1 Hand hygiene

Wash hands OR apply hand sanitizer



## 2 Don gloves

Don a new pair of gloves



## 3 Clean & disinfect

Before use of a new or used face shield, clean and/or disinfect all components as described in Recommended Cleaning



Recommended cleaners and disinfectants



Our facility will use these disinfectants or cleaners (refer to Appendix A for recommendations compatible with face shield materials):

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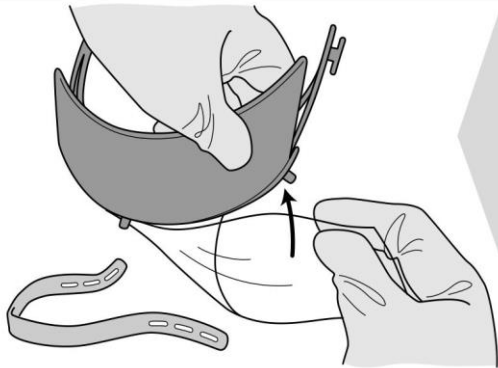
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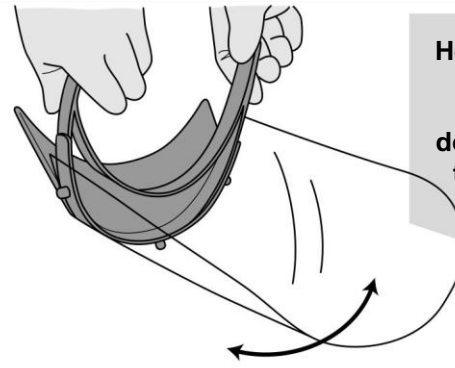
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## 4 Attach shield



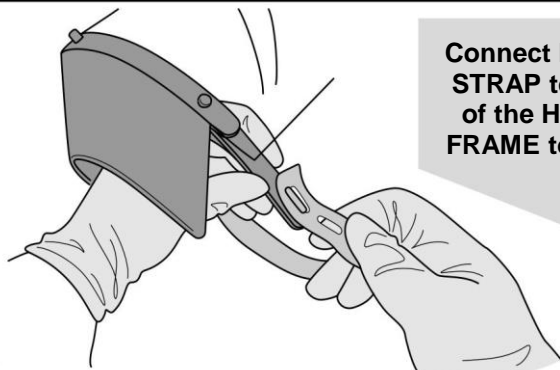
Press the holes of the TRANSPARENT SHIELD onto the pegs of the HEADBAND FRAME

## 5 Check connection



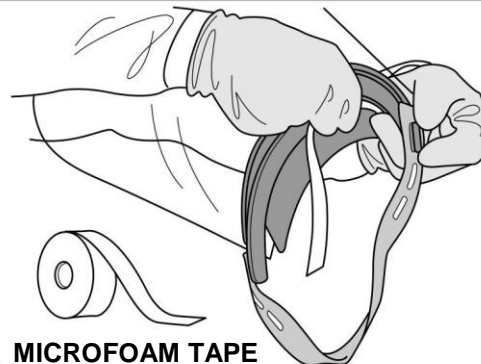
Hold assembly with TRANSPARENT SHIELD facing down; gently shake to ensure secure connection

## 6 Connect headband strap



Connect HEADBAND STRAP to each side of the HEADBAND FRAME to fit to head

## 7 Optional padding

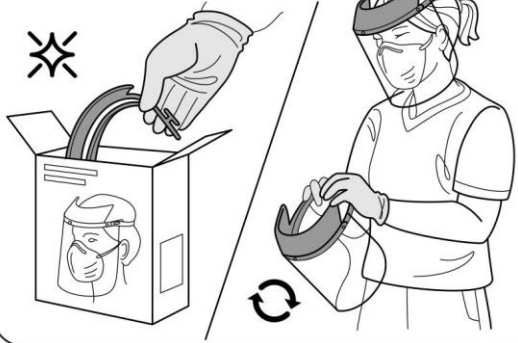


OPTIONAL:  
Place a strip of microfoam surgical tape on the inside edge of the HEADBAND FRAME to increase comfort on forehead

# RECOMMENDED CLEANING D<sub>t</sub>M FACE SHIELD

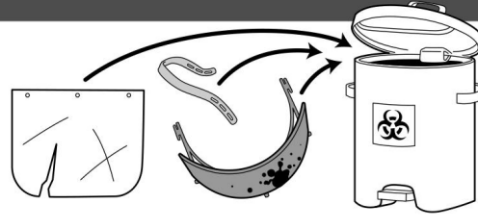
## When to clean

Before first use / After use



## Proper disposal

Properly dispose of any components deemed uncleanable; discard any DIY padding such as foam tape from the headband



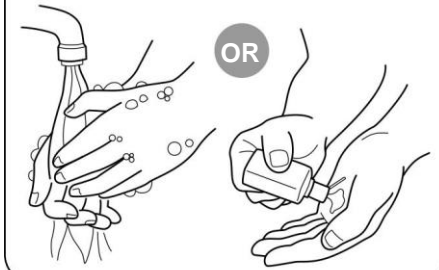
## Don PPE

Used shield? Wear a face mask and a clean face shield if available



## 1 Hand hygiene

Wash hands OR apply hand sanitizer



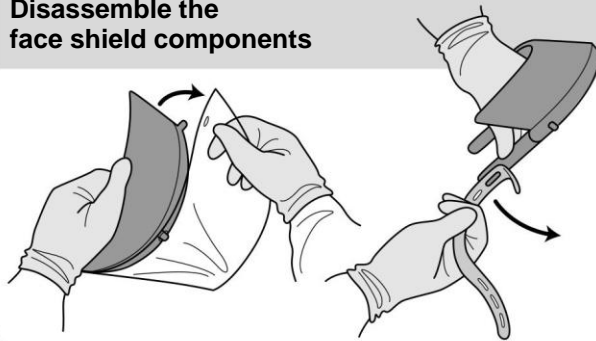
## 2 Don gloves

Don a pair of clean gloves



## 3 Disassemble

Disassemble the face shield components



## 4 Use cleaner

Select a recommended disinfecting product from list in Appendix A



Our facility will use these disinfectants or cleaners (refer to Appendix A for recommendations compatible with face shield materials):



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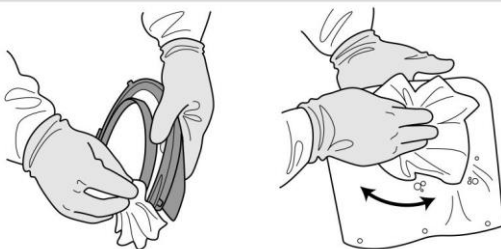
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## 5 Clean components

Wipe down and disinfect all faces and features on HEADBAND FRAME & TRANSPARENT SHIELD



## 6 Assemble

After dry, follow steps in ASSEMBLY section



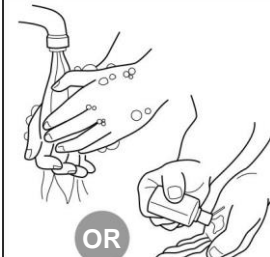
## 7 Doff

Doff gloves



## 8 Hygiene

Perform hand hygiene procedures



More information about cleaning Face Shields can be found in CDC *Strategies for Optimizing the Supply of Eye Protection*:  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html>



Scan this QR code to visit the CDC Recommendations for Cleaning Face Shields



# INSTRUCTIONS FOR USE | DtM FACE SHIELD

## Appendix A: Recommended Disinfectants

From FDA guidelines on Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency released March 2020, it is recommended that “this policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act)”.

(<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease>)

The policy recommends to use an approved disinfection agent as it should “minimize the viability of SARS-CoV-2” on the surface of the components of the face shield.

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>)

and American Chemistry list of Novel Coronavirus (COVID-19)—Fighting Products (<https://www.americanchemistry.com/Novel-Coronavirus-Fighting-Products-List.pdf>).

Based on the testing done on TRANSPARENT SHIELD, HEADBAND FRAME, and HEADBAND STRAP, it is recommended to use the following disinfection or cleaning agents for the Recommended Cleaning procedures of the face shield. Other disinfectants may work as well but have not been evaluated.

Note: the following list of disinfection or cleaning products are listed in preferential order and have been tested with this device.

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

In addition, all parts can be submerged in disinfectants in keeping with recommended exposure times in EPA-List N for full disinfection against COVID-19. (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>)

## Appendix B: Device Materials

Materials for face shield components are listed below. All materials in contact with the body have been noted.

**HEADBAND FRAME:** Polypropylene copolymer, natural color  
Note, this material will be in direct contact with skin.

**TRANSPARENT SHIELD:** Clear polycarbonate, 0.060” Thick

In addition, the following clear report covers obtainable through office supply stores could be used as a replacement for the manufacturer-provided TRANSPARENT SHIELD, listed in preferential order:

- GBC ClearView Presentation Covers (polypropylene) (P/n: GBC 2000041)
- Avery (P/n: 16741)
- Office Depot Binding Covers (polypropylene) (P/n 459-207)

**HEADBAND STRAP:** Monprene® TPE  
Note, this material will be in direct contact with skin.



**This product is latex free.**



**Do not use in the presence of high intensity heat source or flammable gas**

### Need Help?

For questions or to report any issue, please contact the Tool Gauge Customer Care Service Center at 253-722-0330, or [Atronca@toolgauge.net](mailto:Atronca@toolgauge.net). Hours of operation are M-F, 08:00-17:00.