

SLUHN FI 3D Mask TEST REPORT

Rev: 6.10.20

Fluid Resistance

This mask meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F186218 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

Procedure: (approximating ASTM F1862)

1. Use 2mL of synthetic blood
2. Use a 3mL syringe with a ½" long 18-gauge tapered needle
3. Dispense the blood at the mask at a distance of 12 inches over ½ seconds
4. Determine if any synthetic blood passes through to the clean side of the mask within 10 seconds

Results: Mask Passed for Fluid Resistance

Flammability of the Mask Assembly

The Mask Assembly

Procedure: The Mask Assembly passed through a >800°C (+/- 50°C) flame with a speed of 6 cm/s.

Results: After passing through the flame the mask self-extinguished. The filter alone was also tested in this way and self-extinguished.

Elastic strap CPSC CS -191-53 Flammability Test Method (16 CFR 1610) Standard for flammability of Clothing Textiles.

Procedure: Initiate flame on the sample

Results: Flame did not climb to the top of the test specimen in 3.5 seconds.

Bio-Compatibility - Skin contacting components are listed in the Bill of Materials

Bacteria Barrier – Per the Infectious Control Coordinator, SLUHN, the reusable/ subitizable portions of the mask (Mask body and Grill Cover) are non-porous and con-conducting, and therefore do not harbor bacteria. The mask does not, however, include any antimicrobial or antiviral treatment for infection prevention.

Adequate Air Exchange

Tested in real-time scenarios:

- Worn by users for two continuous hours
- Worn by male and female users during 2-minute sessions of CPR chest compressions on a mannequin
- Health care providers have worn the masks during shifts and rated the breathability as adequate.

N95 Fit Testing

Multiple sizes of mask were fit tested on various individuals, to provide evidence that the SLUHN-FI 3d Mask would be able to be worn appropriately by many individuals

A “fit test” tests the seal between the respirator's facepiece and the users face. It takes about fifteen to twenty minutes to complete and is performed at least annually. After passing a fit test with a respirator, the user must use the exact same make, model, style, and size respirator on the job.

Qualitative fit testing is a pass/fail test method that uses the sense of taste or smell, or the reaction to an irritant to detect leakage into the respirator facepiece. Qualitative fit testing does not measure the actual amount of leakage. Whether the respirator passes or fails the test is based simply on detecting leakage of the test substance into the facepiece. There are four qualitative fit test methods accepted by OSHA:

- Isoamyl acetate, which smells like bananas;
- Saccharin, which leaves a sweet taste in the mouth;
- Bitrex, which leaves a bitter taste in the mouth; and
- Irritant smoke, which can cause coughing.

Procedure:

1. The user dons the mask appropriately
2. The user dons the Fit Test hood
3. The facilitator injects the desired compound into the Fit Test hood.
4. The user tries to determine if the smell or taste is present.
5. The user moves about as appropriate and talks and moves the head side to side.
6. The Fit test is successful if the smell or taste is not detected by the user.

Results:

Multiple users (>75) were successfully fit tested with a SLUHN-FI 3d Mask