



## Face Masks

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The ADA has created some guidelines for mask usage. There have been no mandates when relating to mask usage. One thing is clear is that goggles or face shields are highly recommended during the pandemic. If you wear loupes, goggles are not an option. Therefore, you will be wearing a face shield for any aerosol generating procedures.

### Mandatory

1. Aerosol Generating Procedure: N95 or KN95 – rationale for fit testing is because this class of mask is considered best fitting and rated for protection of inspiration of viral aerosols. Recognize if fit is improper protection that is no better than surgical masks. The fit test enforcement requirement is temporarily lifted due to the pandemic.
2. Non-Aerosol Generating Procedure: Surgical mask type 3 are acceptable for non-aerosol generating procedures.

### Highly Recommended

1. Aerosol Generating Procedure: N95 or N95 equivalent. Fit tested.
2. Non-Aerosol Generating Procedure: Surgical mask type 3 for non-aerosol producing procedure.

### Citations

1. N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial. Radonovich et al. JAMA. 2019;322(9):824-833.
2. Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis. Smith et al. CMAJ. 2016 May 17; 188(8): 567–574.

Summary of the Citations: Although N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings, our meta-analysis showed that there was insufficient data to determine definitively whether N95 respirators are superior to surgical masks in protecting health care workers against transmissible acute respiratory infections in clinical settings. N95 respirators were associated with less filter penetration, less face-seal leakage and less total inward leakage under laboratory experimental conditions, compared with surgical masks. Procedures that generate an aerosol require additional respiratory tract protection and should be of the highest level available and worn by all staff in the immediate treatment vicinity.



## Mask Types

N95: An N95 respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. N95 fits very snug and makes a face seal.

The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles BFE. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. However, even a properly fitted N95 respirator does not completely eliminate the risk of illness or death.

### Seal Test

A user seal check is a procedure conducted by the respirator wearer to determine if the respirator is being properly worn. The user seal check can either be a positive pressure or negative pressure check.

During a positive pressure user seal check, the respirator user exhales gently while blocking the paths for air to exit the facepiece. A successful check is when the facepiece is slightly pressurized before increased pressure causes outward leakage.

During a negative pressure user seal check, the respirator user inhales sharply while blocking the paths for air to enter the facepiece. A successful check is when the facepiece collapses slightly under the negative pressure that is created with this procedure.

### Fit Test

A fit test should not be confused with a user seal check. A fit test is conducted to verify that a respirator is both comfortable and correctly fits the user. Fit test methods are classified as either *qualitative* or *quantitative*. A qualitative fit test is a pass/fail test that relies on the individual's sensory detection of a test agent, such as taste, smell, or involuntary cough (a reaction to irritant smoke\*). A quantitative fit test uses an instrument to numerically measure the effectiveness of the respirator.

*Qualitative fit testing* is a pass/fail test method that uses your sense of taste or smell, or your reaction to an irritant in order 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 you detecting leakage of the test substance into your facepiece. There are four qualitative fit test methods accepted by OSHA:

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

Qualitative fit testing is normally used for half-mask respirators—those that just cover your mouth and nose. Half-mask respirators can be filtering facepiece respirators—often called "N95s"—as well as elastomeric respirators.



## *Quantitative fit testing*

This test uses a machine to measure the actual amount of leakage into the facepiece and does not rely upon sense of taste, smell, or irritation in order to detect leakage. The respirators used during this type of fit testing will have a probe attached to the facepiece that will be connected to the machine by a hose. There are three quantitative fit test methods accepted by OSHA:

- Generated aerosol;
- Ambient aerosol; and
- Controlled Negative Pressure.

Quantitative fit testing can be used for any type of tight-fitting respirator.

Many workers need to wear prescription glasses or personal protective equipment, such as safety goggles or earmuffs, while performing a job. If you fall into this category, then you must wear these items during the fit test to be sure they don't interfere with the respirator's fit.

You must be fit tested before you use a respirator in the workplace, and you must be retested at least every 12 months to make sure that the respirator you use still fits you. You must be fit tested with the specific make, model, style, and size of respirator that you will be using.

Facial hair, like a beard or mustache, can affect your respirator's ability to protect you. Anything that comes between your face and the respirator's seal or gets into the respirator's valves can allow contaminated air to leak into the respirator facepiece and you will not be protected. For example, if you have long hair, make sure it doesn't get between the respirator seal and your face because this can allow contaminated air to leak into the respirator.

Fit testing can be done by your employer or an outside party, including a union, an apprenticeship program, a contractor's association, or a past employer. Your current employer is permitted to accept fit testing you have received from an outside party (such as a former employer) within the last 12 months, as long as you use the same respirator make, model, style, and size at your new worksite. This is known as "fit testing portability."

Advantages of qualitative fit testing:

- Low equipment cost
- Simple pass/fail results

Disadvantages of qualitative fit testing:

- Chance of employee deception or bluffing
- Limited protection-factor verification (maximum fit factor of 10)



Advantages of quantitative fit testing:

- No protection-factor limit
- Documentation of numerical results
- No chance of employee deception or bluffing

Disadvantages of quantitative fit testing:

- Expensive up-front equipment costs
- Requires probed face piece or probe adapter
- Annual recalibration of equipment is suggested

Level 1: low barrier protection for general use for low-risk, nonsurgical procedures and exams that do not involve aerosols, sprays and fluids. An ear loop mask is a level 1 mask. ASTM level 1 masks are the general standard for both surgical and procedural use. Fluid resistance= 80 mmHg, BFE > 95% at 3 microns, PFE ≥ 95% at 0.1 micron

Level 2: moderate barrier protection for low-to-moderate levels of aerosols, sprays and fluids. Fluid Resistance =120 mmHg, BFE >98% at 3 microns, PFE > 98% at 0.1 micron

Level 3: maximum barrier protection for any situation that has the potential for exposure to heavy levels of aerosols, sprays and fluids. Fluid Resistance= 160 mmHg, BFE > 98% at 3 microns, PFE > 98% at 0.1 micron

The five performance metrics for masks and their related tests are:

#### Fluid Resistance Test

This test evaluates the resistance of a medical face mask to penetration by a small volume (~2 mL) of synthetic blood at a high velocity (80 mmHg, 120 mmHg, or 160 mmHg). The mask either passes or fails based on visual evidence of synthetic blood penetration.

#### Breathability Test

This test determines the face mask's resistance to airflow. A controlled flow of air is driven through the mask, and the pressure before and after is measured. The difference in pressure is divided by the surface (in cm<sup>2</sup>) of the sample. A lower breathing resistance indicates a better comfort level for the user.

#### Bacterial Filtration (BFE) Test

This test measures the percentage of bacteria larger than 3 microns filtered out by the mask. The challenge material used is *Staphylococcus aureus*.

#### Particulate Filtration (PFE) Test

This test measures the percentage of particles larger than 1 micron filtered out by the mask. The challenge material used consists of latex aerosol concentrations in a controlled airflow chamber.



## Summary Items of Masks

Surgical mask type 1-3 and every class up is 25% more fluid resistance. This is a test for moisture penetration (waterproofness). There is relatively little difference in the bacterial filtration (bugs to pass thru fabric).

Expect a roughly 20% cost increase for level 3 compared to level one.

## Face Shield

**Mandatory:** To be used in all aerosol generating appointments. Goggles are a suitable alternative, but goggles cannot accommodate loupes.

**Recommended:** To be used in all aerosol generating appointments. The face shield also protects the mask from being soiled. Face shield should be reusable and easily disinfecting.

### Disinfecting Face Shield:

RECOMMENDED METHODS			
METHOD	CONDITIONS	EFFECTIVE AGAINST	VERIFICATION STATUS
Hot Air Dryer	65 °C (149 °F), 60 mins	bacteria, viruses	Verified by <a href="#">SYNLAB<sup>1</sup></a>
WHO Handrub disinfection*	75% IPA, 5 mins	bacteria, viruses	Verified by <a href="#">UCT<sup>2</sup></a>
Isopropanol (IPA)	96%, 5 mins	bacteria, viruses	Verified by <a href="#">UCT<sup>2</sup></a>
Isopropanol (IPA)	75%, 5 mins	bacteria, viruses	Verified by <a href="#">Labtech<sup>3</sup></a>
Sodium Hypochlorite (household bleach)	min. 0.01 % of hypochlorite (e.g. SAVO 1:10), 2 mins+	bacteria, viruses	Verified by <a href="#">Labtech<sup>3</sup></a> , <a href="#">SYNLAB<sup>1</sup></a>
UV-C	radiation, 30W, wavelength below 280 nm, 15 mins	bacteria, viruses	Verified by <a href="#">SYNLAB<sup>1</sup></a>
Ethanol	70-80% max**, 5 mins	bacteria, viruses	Verified by <a href="#">UCT<sup>2</sup></a> , <a href="#">Labtech<sup>3</sup></a>
IPA steam (70 %, 30 % water)	45-65 °C (113-149 °F), 30-90 mins, <a href="#">patent info</a>	bacteria, viruses	verification in progress
PVP-I (iodine disinfection)	4%, 5 mins	bacteria, viruses	verification in progress
Hydrogen Peroxide	25%, 5 mins	bacteria, viruses	Verified by <a href="#">ZUUSTI<sup>5</sup></a>
Soap water	repeated washing, 5 mins	bacteria, viruses	verification in progress
Ozone	strong oxidating effects, depends on the chamber	bacteria, viruses	verification in progress
Gamma radiation	strong ionizing radiation, depends on the chamber	bacteria, viruses	verification in progress

1: accommodation of loupes with lights based on the style of the major manufacturers: Oroscoptic, Designs for Vision, Suritel, SheerVision

> 2] Distortion effect on loupes: perhaps thickness of face shield related

2: Disposable vs Reusable

4: if reusable: how are they cleaned and how long do they last

5: Cost and availability

- \$3 for disposable to several hundred dollars for high end reusable.
- Increased cost does improve features for fit and adjustability.
- I have ordered the op-d-op; they are \$63 and are at least 3 weeks out.