



MEDICAL FACE MASKS

ASTM STANDARDS



GENERAL USES

Surgical and procedure masks are generally used to reduce the risk of pathogen transfer between people. They can be used as protection for asymptomatic individuals or to help contain droplets from symptomatic individuals. Masks accomplish this by covering the mucous membranes of the nose and mouth with filtering materials. Masks with attached visors also provide protection for the eyes.



No mask completely eliminates the risk of exposure to blood or bodily fluids.

MEDICAL FACE MASK STANDARDS AND REGULATIONS

Specifications developed by the American Society of Testing and Materials (ASTM) are referenced by the FDA as the required standard in the USA. The current standard ASTM F2100 specifies performance requirements for medical face masks with five basic criteria:

TEST	LEVEL 1	LEVEL 2	LEVEL 3
BFE (Bacterial Filtration Efficiency) <i>at 3.0 micron ASTM F2101</i>	≥ 95%	≥ 98%	≥ 98%
PFE (Particulate Filtration Efficiency) <i>at 0.1 micron ASTM F2299</i>	≥ 95%	≥ 98%	≥ 98%
Delta P (Differential Pressure) <i>EN 14683 (Annex C)</i>	< 5.0	< 6.0	< 6.0
Fluid Resistance to synthetic blood <i>ASTM 1862</i>	80 mm Hg	120 mm Hg	160 mm Hg
Flame Spread <i>16 CFR part 1610</i>	Class 1	Class 1	Class 1

In addition to the above tests, all face masks must be tested to an international standard (ISO 10993-5, 10) for skin sensitivity and cytotoxic tests to ensure no materials are harmful to the wearer. Tests are conducted on all materials used in construction of the mask, including the ties, elastic ear loops, anti-fog strips, visor shields, and any piping materials that may be used to hold the side pleats together.

BACTERIAL FILTRATION EFFICIENCY (BFE)

Measures a mask's ability to filter bacteria. ASTM specifies testing by aerosol with a droplet size of 3.0 microns containing *Staphylococcus aureus* (average size 0.6-0.8 microns). To be called a medical or surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks require bacterial filtration rates of greater than 98% to greater than 99%.



Some manufacturers use the Modified Greene & Vesley method to determine the BFE rating. This method is NOT recommended by ASTM for product comparison or evaluating consistency.

PARTICULATE FILTRATION EFFICIENCY (PFE)

Measures a mask’s ability to filter sub-micron particles with the expectation that viruses will be filtered in a similar manner. The higher the percentage, the more efficient the mask is at filtering particulates. Although testing is available using a particle size from 0.1 to 5.0 microns, ASTM F2100 specifies a particle size of 0.1 micron be used.



When comparing test results, it is important to note the size of the test particles used, as use of a larger particle size will produce a misleading PFE rating.

FLUID RESISTANCE

Reflects a mask’s ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer of the mask as the result of a splash or spray. ASTM specifies testing with synthetic blood at pressures of 80, 120, or 160 mm Hg to qualify for low, medium, or high fluid resistance.



80mm Hg

ASTM LEVEL 1
Used for general procedures, minimally invasive surgery, ophthalmology and respiratory etiquette. Designed to resist a splash or spray at venous pressure.



120mm Hg

ASTM LEVEL 2
Moderate fluid resistance for procedures such as general surgery and endoscopy. Designed to resist a splash or spray at arterial pressure.



160mm Hg

ASTM LEVEL 3
Highest fluid resistance — designed to resist a splash or spray during tasks like orthopedic surgery or trauma.

DELTA P (PRESSURE DIFFERENTIAL)

Measures how light and breathable a mask feels. A controlled flow of air is driven through a mask and the pressure on either side of the mask is determined. The difference in pressure is measured and divided by the surface area (cm²) of the mask segment tested. The higher the Delta P value, the more difficult it is for the wearer to breathe. The Delta P is measured in units of mm H₂O/cm². The ASTM standard requires that masks have a Delta P of less than 6.0, as a higher value would be considered too "hot" for general medical or surgical use. Masks with a Delta P of less than 5.0 are considered acceptable, while masks with a Delta P less than 2.0 would be considered "cool".

FLAME SPREAD

Measures a mask's ability to withstand exposure to flame. Operating rooms contain sources of oxygen and other gases used for anesthesia, and there are potential fire hazards from electrosurgical procedures such as lasers or cautery equipment. All products used within the operating room, including face masks, are tested for flame resistance. As part of ASTM F2100 testing, masks must withstand exposure to a burning flame (within a specified distance) for three seconds.

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