

ASTM PROTECTION VS. INTENDED USAGE

LEVEL 1 (LOW) BARRIER: 80 mm Hg	LEVEL 2 (MODERATE) BARRIER: 120 mm Hg	LEVEL 3 (HIGH) BARRIER: 160 mm Hg
Light / minimum BFE & PFE protection	High BFE & PFE protection	High BFE & PFE protection
Used for general procedures and respiratory etiquette	More breathable than high barrier mask	
Designed to resist a splash or spray at venous pressure	Designed to resist a splash or spray at arterial pressure	Highest fluid resistance – designed to resist a splash or spray during tasks like orthopedic surgery or trauma

ASTM F2100-11 (2011) REQUIREMENTS FOR MEDICAL FACE MASKS

TEST	LEVEL 1 (LOW) BARRIER: 80 mm Hg	LEVEL 2 (MODERATE) BARRIER: 120 mm Hg	LEVEL 3 (HIGH) BARRIER: 160 mm Hg
BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101	≥ 95%	≥ 98%	≥ 98%
PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299	≥ 95%	≥ 98%	≥ 98%
Delta P (Differential Pressure) MIL-M-36954C, mm H ₂ O/cm ²	< 4.0	< 5.0	< 5.0
Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg	80	120	160
Flame Spread 16 CFR part 1610	Class 1	Class 1	Class 1

ASTM standards are referenced by the Food and Drug Administration (FDA), as the endorsed standard in the United States. The current standard ASTM F2100-11 (2011) specifies the performance requirements for Medical Face Masks with five basic criteria

1. BFE (Bacterial Filtration Efficiency): BFE measures how well the medical face mask filters out bacteria when challenged with a bacteria-containing aerosol. ASTM specifies testing with a droplet size of 3.0 microns containing Staph. Aureus (average size 0.6-0.8 microns). In order to be called a medical/surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks must have bacterial filtration rates greater than 98%.

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.

2. PFE (Particulate Filtration Efficiency): PFE measures how well a hospital mask filters sub-micron particles with the expectation that viruses will be filtered in a similar manner. The higher the percentage, the better the mask filtration. Although testing is available using a particle size from 0.1 to 5.0 microns, ASTM F2100-11 specifies that 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.

3. Fluid Resistance: Fluid resistance reflects the surgical mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer 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. These pressures correlate to blood pressure: 80 mm Hg = venous pressure (Level 1), 120 mm Hg = arterial pressure (Level 2), and 160 mm Hg (Level 3) correlates to potential high pressures that may occur during trauma, or surgeries that include high pressure irrigation such as orthopedic procedures.

4. Delta P (Pressure Differential): Delta P measures the air flow resistance of the medical mask and is an objective measure of breathability. The Delta P is measured in units of mm H₂O/cm² and the lower the value the more breathable the mask feels. The ASTM standard requires that masks have a Delta P of less than 5.0 for moderate and high barrier masks, whereas low barrier masks must have a Delta P of less than 4.0.

5. Flame Spread: As hospitals contain sources of oxygen, heat, and fuel the ASTM F2100-11 standards include testing for flame resistance. Testing dictates that all hospital masks must withstand exposure to a burning flame (within a specified distance) for three seconds. All PRI-MED masks meet this requirement.

5.5 ISO Certification: In addition to the above tests, all medical face masks must be tested to an international standard (ISO 10993-5, 10) for skin sensitivity and cytotoxic tests to ensure that no materials are harmful to the wearer. Tests are conducted on materials used in construction of the mask which come in contact with the user's skin.