Designation: F 2100 – 01

Standard Specification for Performance of Materials Used in Medical Face Masks[1]

This standard is issued under the fixed designation F 2100; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers testing and requirements for materials used in the construction of medical face masks that are used in providing health care services such as surgery and patient care.

1.2 This specification provides for the classification of medical face mask material performance. Medical face mask material performance is based on testing for bacterial filtration efficiency, differential pressure, sub-micron particulate filtration efficiency, resistance to penetration by synthetic blood, and flammability.

1.3 This specification does not address all aspects of medical face mask design and performance. This specification does not specifically evaluate the effectiveness of medical face mask designs as related to the barrier and breathability properties. This specification does not also apply to respiratory protection, which may be necessary for some health care services.

1.4 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.5 The following precautionary caveat pertains only to the test methods portion, Section 9, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 1215 Test Method for Determining the Initial Efficiency of a Flatsheet Filter Medium in an Airflow Using Latex Spheres[2]

F 1494 Terminology Relating to Protective Clothing[3]

F 1862 Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)[3]

F 2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*[3]

2.2 *ANSI/ASQC Standard:*[4]

ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes

2.3 *ISO Standard:*[5]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *Military Standard:*[6]

MIL-M-36954C Military Specification, Mask, Surgical, Disposable

2.5 *Federal Standards:*[7]

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

29 CFR Part 1910.1030 Occupational Exposure to Bloodborne Pathogens: Final Rule

42 CFR Part 84 Approval of Respiratory Protective Devices

3. Terminology

3.1 *Definitions:*

3.1.1 *bacterial filtration efficiency (BFE), n*—the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria; expressed in the percentage of a known quantity that does not pass the medical face mask material at a given aerosol flow rate.

3.1.2 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.2.1 *Discussion*—In this specification, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

3.1.3 *body fluid simulant, n*—a liquid which is used to act as a model for human body fluids.

3.1.4 *differential pressure, n*—the measured pressure drop across a medical face mask material.

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[1] This specification is under the jurisdiction of ASTM Committee F23 on Protective Clothing and is the direct responsibility of Subcommittee F23.40 on Biological.

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[2] Discontinued; see *1999 Annual Book of ASTM Standards*, Vol 14.04.

[3] *Annual Book of ASTM Standards*, Vol 11.03.

[4] Available from American Society for Quality Control, 611 East Wisconsin Ave., Milwaukee, WI 53202.

[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[6] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[7] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

3.1.4.1 *Discussion*—In this specification, differential pressure is expressed as a pressure per unit area.

3.1.5 *flammability*, *n*—those characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain combustion.

3.1.6 *penetration*, *n*—in a protective clothing material or item, the flow of a chemical on a non-molecular level through closures, porous materials, seams and pinholes or other imperfections in protective clothing.

3.1.6.1 *Discussion*—In this specification, blood or body fluids replace the term chemical and the specific penetration liquid is synthetic blood, a body fluid simulant.

3.1.7 *protective clothing*, *n*—a product which is specifically designed and constructed for the intended purpose of isolating parts of the body from a potential hazard.

3.1.7.1 *Discussion*—The primary purpose of protective clothing is to act as a barrier for the wearer to a hazard. However, the product may also offer protection as a barrier which prevents the body from being a source of contamination.

3.1.8 *medical face mask*, *n*—an item of protective clothing designed to protect portions of the wearer's face, including at least the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures.

3.1.9 *sub-micron particulate filtration efficiency*, *n*—the efficiency of the filter material in capturing aerosolized particles smaller than one micron; expressed as the percentage of a known number of particles that does not pass the medical face mask material at a given flow rate.

3.1.10 *synthetic blood*, *n*—a mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

3.1.10.1 *Discussion*—The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids, for example, polarity (wetting characteristics), coagulation, content of cell matter.

3.2 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F 1494.

4. Significance and Use

4.1 This specification covers the minimum performance requirements for materials used in the construction of medical face masks.

4.2 This specification provides classification of performance for a range of medical face mask materials. The list of specified properties represents industry practices for characterizing material performance, but does not include all aspects of performance that may be necessary to protect health care workers. Therefore, this specification does not cover medical face masks for all possible use situations. For example, the Center for Disease Control and Prevention (CDC) specifically requires NIOSH respirators that are at least 95 % efficient for tuberculosis exposure control.

NOTE 1—This specification does not provide specific criteria for demonstrating medical face mask protection of the patient.

NOTE 2—The level of protection provided by medical face masks depends on several factors not considered in this specification. Examples include facial fit, material degradation from wearer challenges (perspiration, talking, sneezing and the length of time the medical face mask is worn).

4.3 Users of this specification are cautioned that improved resistance of medical face masks to penetration by synthetic blood can cause a reduction in medical face mask breathability. In general, increasing synthetic blood penetration resistance (and bacterial filtration efficiency and sub-micron particulate filtration efficiency) results in increasing pressure drop or reduction of breathability for medical face masks of the same design.

4.4 This specification or its requirements does not evaluate medical face masks for regulatory approval as respirators. It specifically only evaluates the materials used in the construction of the medical face mask and not the seal of the medical face mask against the wearer's face or other design features that determine its effectiveness of preventing particle or liquid exposure to the wearer. If respiratory protection for the wearer is needed, a NIOSH-certified respirator, meeting the requirements of 42 CFR Part 84, should be used.

5. Classification

5.1 Medical face mask materials covered under this specification shall be designated as one or more of the following performance classes: General Use, Sub-micron Filtering, or Fluid Resistant.

5.1.1 General use medical face mask materials are evaluated for bacterial filtration efficiency and differential pressure.

5.1.2 Submicron-filtering medical face mask materials are evaluated for their ability to capture sub-micron particles and are evaluated for bacterial filtration efficiency, and differential pressure. Medical face masks using submicron-filtering materials do not provide respiratory protection to the wearer.

5.1.3 Fluid resistant medical face mask materials are evaluated for resistance to penetration by synthetic blood, submicron particulate filtration, bacterial filtration efficiency, and differential pressure.

6. Requirements

6.1 The properties of the medical face mask material shall conform to the specifications requirements in Table 1, as tested in accordance with Section 9.

NOTE 3—Medical face mask materials comprise specimens taken from manufactured medical face masks, with all layers arranged in proper order.

6.2 Materials used in the construction of medical face masks shall meet the requirements for Class 1, normal flammability specified in 16 CFR Part 1610.

7. Sampling

7.1 Testing shall be performed on materials taken from

TABLE 1 Medical Fask Mask Material Requirements by Performance Class

Characteristic	General Use	Sub-Micron Filtering	Fluid Resistant
Bacterial filtration efficiency, %	>95	>98	>98
Differential pressure, mm H_2O/cm^2	<5.0	<5.0	<5.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	Not required	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	Not required	Not required	120
Flame spread	Class 1	Class 1	Class 1

manufactured medical face masks.

7.2 An acceptable quality limit of 4 % shall be used for all required testing to establish conformance of medical face masks to a specific performance class.

7.3 Examples of acceptable sampling plans are found in ANSI/ASQC Z1.4 and ISO 2859-1.

8. Number of Tests

8.1 A sufficient number of medical face masks shall be evaluated for each test to achieve the established acceptable quality limit or confidence level.

9. Test Methods

9.1 *Bacterial Filtration Efficiency*—Determine the bacterial filtration efficiency as directed in Test Method F 2101.

9.2 *Differential Pressure*—Determine breathing resistance or differential pressure as specified in paragraph 4.4.1.2 of MIL-M-36954C.

NOTE 4—This test method provides a measurement of pressure per unit area of material specimen tested.

9.3 *Sub-Micron Particulate Filtration*—Determine particulate filtration efficiency as directed in Test Method F 1215.

9.4 *Resistance to Penetration by Synthetic Blood*—Determine synthetic blood penetration resistance as specified in Test Method F 1862.

9.5 *Flammability*—Determine flammability as specified in 16 CFR Part 1610.

10. Report

10.1 When requested by the purchaser, a report shall be provided with the following information:

10.1.1 Manufacturer name.

10.1.2 Manufacturer address and phone number.

10.1.3 Product or style name.

10.1.4 The performance class as classified by this specification.

10.1.5 The results of each test used for classifying the medical face mask material to this specification.

10.1.6 An optional statement indicating compliance of the medical face mask materials with this specification, including the number, year or issue, and revision letter.

11. Keywords

11.1 bacterial filtration efficiency; differential pressure; fluid resistance; general use; medical face masks; particle filtration efficiency; sub-micron filtration