Designation: F2100 – 11

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

This standard is issued under the fixed designation F2100; 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 are to be regarded as standard. No other units of measurement are included in this standard.

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:*[2]

F1494 Terminology Relating to Protective Clothing

F1862 Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

F2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*

F2299 Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

2.2 *ANSI/ASQC Standard:*[3]

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

2.3 *ISO Standard:*[4]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *Military Standard:*[5]

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

2.5 *Federal Standards:*[6]

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

29 CFR Part 1910.1030 Occupational Exposure to Blood-borne 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,

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

Current edition approved April 1, 2011. Published April 2011. Originally approved in 2001. Last previous edition approved in 2007 as F2100 – 07. DOI: 10.1520/F2100-11.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] Available from Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, http://dodssp.daps.dla.mil.

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

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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.

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

3.1.6.1 *Discussion*—Examples of medical face masks include surgical masks, procedure masks, isolation masks, laser masks, dental masks, and patient care masks.

3.1.7 *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.

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

3.1.8 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

3.1.8.1 *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.

3.1.9 *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 F1494.

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. Medical face mask performance classes are based on the barrier performance properties of the medical face mask materials (fluid resistance, bacterial filtration efficiency, and sub-micron filtration efficiency). 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.

4.5 The selection of the appropriate medical face mask must be governed by the potential exposure hazards based on the specific areas of performance associated with class of medical face masks. General use masks provide minimal fluid resistance and are suitable for situations such as in isolation settings and for certain types of patient care. Where procedures involve the generation of sub-micron particles, such as in laser or electrocautery surgery, sub-micron filtering masks are appropriate. Where procedures involve the probability or likely exposure to blood or body fluids, select fluid-resistant medical faces masks.

5. Classification

5.1 Medical face mask materials covered under this specification shall be designated as one or more of the following performance classes as based on the barrier performance

properties of the materials used in medical face masks: Level 1 Barrier, Level 2 Barrier, and Level 3 Barrier.

5.1.1 Level 1 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles, resistance to penetration by synthetic blood at the minimum velocity specified in Test Method F1862, bacterial filtration efficiency and differential pressure.

5.1.2 Level 2 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles and are evaluated for resistance to penetration by synthetic blood at the middle velocity specified in Test Method F1862, bacterial filtration efficiency, and differential pressure.

5.1.3 Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the maximum velocity specified in Test Method F1862, sub-micron 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 manufactured medical face masks.

TABLE 1 Medical Face Mask Material Requirements by Performance Level

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	<4.0	<5.0	<5.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

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 F2101.

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 F2299.

9.4 *Resistance to Penetration by Synthetic Blood*—Determine synthetic blood penetration resistance as specified in Test Method F1862.

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

10. Report

10.1 The primary package containing the medical face masks, which meet this specification shall be prominently labeled with the following information:

10.1.1 Manufacturer name,

10.1.2 Product or style name,

10.1.3 Product lot,

10.1.4 A graphic representation indicating the performance level met in Table 1 with the technical requirements of the indicated performance level. The graphic representation shall include a prominent visual indication of the performance level.

11. Keywords

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

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