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# Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)[1]

This standard is issued under the fixed designation F1862/F1862M; 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.

## INTRODUCTION

Workers, primarily those in the healthcare profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis (hepatitis B virus (HBV) and hepatitis C virus (HCV)) and acquired immune deficiency syndrome (AIDS) (human immunodeficiency virus (HIV)). Because engineering controls can not eliminate all possible exposures, attention is placed on reducing the potential of direct skin and mucous membrane contact through the use of protective clothing that resists penetration (29 CFR Part 1910.1030). This test method was developed for ranking the synthetic blood penetration resistance performance of medical ace masks in a manner representing actual use as might occur when the face mask is contacted by a high-velocity stream of blood from a punctured wound.

## 1. Scope

1.1 This test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume (~2 mL) of a high-velocity stream of synthetic blood. Medical face mask *pass/fail* determinations are based on visual detection of synthetic blood penetration.

1.2 This test method does not apply to all forms or conditions of blood-borne pathogen exposure. Users of the test method must review modes for face exposure and assess the appropriateness of this test method for their specific application.

1.3 This test method primarily addresses the performance of materials or certain material constructions used in medical face masks. This test method does not address the performance of the medical face mask's design, construction, or interfaces or other factors with the potential to affect the overall protection offered by the medical face mask and its operation (such as filtration efficiency and pressure drop). Procedures for measuring these properties are contained in Test Method F2101 and MIL-M-36954C.

1.4 This test method does not address breathability of the medical face mask materials or any other properties affecting the ease of breathing through the medical face mask. This test method evaluates medical face masks as an item of protective clothing. This test method does not evaluate the performance of medical face masks for airborne exposure pathways or in the prevention of the penetration of aerosolized body fluids deposited on the medical face mask.

1.5 The values stated in SI units or inch-pound units are to be regarded separately as standard. The pressure values stated in each system are not exact equivalents. However, as the corresponding velocities are within 1 % of each other, (see X1.4.2), reporting of the results in either units is permitted.

1.6 *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.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the*

[1] This test method 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.

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*Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D891 Test Methods for Specific Gravity, Apparent, of Liquid Industrial Chemicals

D1331 Test Methods for Surface and Interfacial Tension of Solutions of Paints, Solvents, Solutions of Surface-Active Agents, and Related Materials

E105 Practice for Probability Sampling of Materials

E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging

F1494 Terminology Relating to Protective Clothing

F1670/F1670M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

F1671/F1671M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

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

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 Standards:*[5]

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

2.5 *OSHA Standard:*[6]

29 CFR Part 1910.1030 Occupational Exposure to Blood-borne Pathogens: Final Rule, *Federal Register*, Vol 56, No 235, Dec. 6, 1991, pp. 64175–64182

## 3. Terminology

3.1 *Definitions:*

3.1.1 *aerosolized body fluids, n*—body fluids that have been dispersed into air as very small liquid droplets.

3.1.2 *airborne exposure pathways, n*—inhalation routes of exposure to the medical face mask wearer.

3.1.3 *blood-borne pathogen, n*—an infectious bacterium or virus, or other disease-inducing microbe carried in blood or other potentially infectious body fluids.

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

3.1.4.1 *Discussion*—In this test method, 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).

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

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.

3.1.7 *penetration, n— for biological protective clothing*, the flow of a body fluid 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 test method, the 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*—In this test method, medical face masks are evaluated. The potential hazard of contact with blood or other body fluids is being simulated.

3.1.9 *spurt, n*—a short duration gush or volume of fluid.

3.1.9.1 *Discussion*—In this test method, a spurt refers to the volume of fluid disbursed from the apparatus at the sample mask. It can also refer to the volume of fluid ejected from a punctured blood vessel.

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, and content of cell matter.

3.1.11 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F1494.

## 4. Summary of Test Method

4.1 A volume of synthetic blood is disbursed at a specimen mask by a pneumatically controlled valve from a set distance to simulate the impact (splatter) of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given healthcare scenario.

4.2 Any evidence of synthetic blood penetration on the inner facing of the medical face mask (side contacting the wearer's face) constitutes a failure. Results are reported as *pass/fail*.

[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.

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

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

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

4.3 Specimen medical face masks are evaluated at velocities of 450, 500, and 635 cm/s. These correspond to the velocity exiting a small arterial puncture at human blood pressures of 10.7, 16.0, and 21.3 kPa (80, 120, and 160 mmHg). Test results are reported at each velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

## 5. Significance and Use

5.1 This test method offers a procedure for evaluating medical face mask resistance to synthetic blood penetration that is useful in establishing claims for penetration resistance performance of medical face masks and ranking their performance. However, this test method does not define acceptable levels of penetration resistance because this determination must be made by each responsible user organization based on its own specific application and conditions. Therefore, when using this test method to make claims for the performance of medical face masks, the specific conditions under which testing is conducted must be described.

5.2 Medical face masks are intended to resist liquid penetration from the splatter or splashing of blood, body fluids, and other potentially infectious materials. Many factors affect the wetting and penetration characteristics of body fluids, such as surface tension, viscosity, and polarity of the fluid, as well as the structure and relative hydrophilicity or hydrophobicity of the materials and the design of the mask itself. The surface tension range for blood and body fluids (excluding saliva) is approximately 0.042 to 0.060 N/m.[7] To help simulate the wetting characteristics of blood and body fluids, the surface tension of the synthetic blood is adjusted to approximate the lower end of this surface tension range. The resulting surface tension of the synthetic blood is 0.042 ± 0.002 N/m.

5.3 The synthetic blood mixture is prepared with a red dye to aid in visual detection and a thickening agent to simulate the flow characteristics of blood. The synthetic blood will not always duplicate the polarity, and thus the wetting behavior and subsequent penetration, of real blood and other body fluids through protective clothing materials.

5.4 During a medical procedure, a blood vessel is occasionally punctured resulting in a high velocity stream of blood impacting a protective medical face mask. The impact velocity depends on several factors, the most important being the blood pressure of the patient. Other factors include the size of the puncture and distance from the puncture. Because the pressure, and thus velocity drops quickly with large punctures, large punctures were not used to model the range of blood splatter velocities considered in this test. Furthermore, this test method is based on the assumption that the medical face mask will be in close proximity (within 300 mm or 12 in.) to the puncture area. The use of this test method is, therefore, based on selecting an appropriate blood pressure, finding the corresponding stream or impact velocity, and determining the valve time to create that stream velocity as shown in Appendix X1.

5.4.1 The mean human blood pressure generally varies over a range of about 10.7 to 16.0 kPa (80 to 120 mmHg).[8] In this test method, medical face masks are tested at stream velocities corresponding to 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg).

5.5 This test method permits the use of other non-standard test pressures, stream velocities, fluid volumes, and specimen orientations for evaluating medical face mask penetration resistance consistent with specific applications.

5.6 This test method differs from Test Method F1670/F1670M by dispensing a stream of 2 mL of synthetic blood against the target area of a complete medical mask specimen, whereas Test Method F1670/F1670M involves the continuous contact of a specimen of protective clothing with synthetic blood over the period of an hour. One minute of the exposure in Test Method F1670/F1670M is at hydrostatic pressure of 13.8 kPa [2.0 psig]. Test Method F1670/F1670M is used for preliminary evaluation of protective clothing penetration resistance to synthetic blood in conjunction with Test Method F1671/F1671M that uses a microbiological challenge. Both procedures are intended for assessment of protective clothing which has the potential to contact blood or other body fluids for extended periods of time, and under pressure.

5.7 Users of this test method must realize that certain tradeoffs exist between improved resistance of medical face masks to penetration by synthetic blood and in pressure drop across mask materials as an indicator of medical face mask breathability. In general, increasing synthetic blood penetration resistance for medical face masks results in increasing pressure drop or reduced breathability for medical face masks of the same design and fit of the individual wearer.

5.8 This test method evaluates medical face masks as an item of protective clothing and does not evaluate medical face masks as respirators. If respiratory protection for the wearer is needed, a NIOSH-certified respirator must be used. This test method is useful to evaluate the resistance of a respirator to penetration by synthetic blood, if warranted.

5.9 This test method involves the preconditioning of specimen medical face masks in a relatively high humidity environment (85 ± 5 % relative humidity at 21 ± 5 °C [70 ± 10 °F]) to simulate the conditions of use when the wearer creates high humidity conditions by breathing through the mask. This preconditioning does not account for saturation of the interior medical face mask layer. However, additional pretreatment techniques in conjunction with this test method as described in 5.10 are permitted. Professional healthcare providers recommend that medical face masks be replaced when saturation occurs from breathing or from contact with other liquids.

5.10 Testing prior to degradation by physical, chemical, and thermal stresses which could negatively impact the performance of the protective barrier, could lead to a false sense of

[7] Lentner, C., ed., *Geigy Scientific Tables*, Vol 1 – Units of Measurement, Body Fluids, Composition of Blood, Hematology, Somatometric Data, Medical Education Div., Ciba-Geigy Corp., West Caldwell, NJ, 1984.

[8] Barach, P. G., Cullen, B. F., and Stoelting, R. K., *Handbook on Clinical Anesthesia*, Appendix A, J. B. Lippincott Co., Philadelphia, 1994.