Designation: F 1862 – 00a

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 F 1862; 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 health care 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 face 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 synthetic blood under high velocity liquid contact with the medical face mask surface of a fixed volume over a relatively short period of time (0 to 2.5 s). 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 which may 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 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 values stated in each system may not be exact equivalents, therefore, each system shall be used independently of the other.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 1331 Test Methods for Surface and Interfacial Tension in Solutions of Surface-Active Agents[2]

[1] This test method is under the jurisdiction of ASTM Committee F-23 on Protective Clothing and is the direct responsibility of Subcommittee F23.40 on Biological Hazards.

Current edition approved ~~Jan.~~ July 10, 2000. Published ~~March~~ August 2000. Originally published as F 1862 - 98. Last previous edition F 1862 - ~~98.~~ 00.

E 105 Practice for Probability Sampling of Materials[3]
E 171 Specification for Standard Atmospheres for Conditioning and Testing Flexible Barrier Materials[4]
F 1494 Terminology Relating to Protective Clothing[5]
F 1670 Test Method for Resistance of Materials used in Protective Clothing to Penetration by Synthetic Blood[5]
F 1671 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[5]
2.2 *ANSI/ASQC Standard:*[6]
ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes
2.3 *ISO Standard:*[7]
ISO 2859-1 Sampling Plans for Inspection by Attributes
2.4 *Military Standards:*[8]
MIL-M-36954C Military Specification, Mask, Surgical, Disposable
MIL-STD-105 Sampling Procedures and Tables for Inspection by Attributes
2.5 *OSHA Standard*[9]
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 which 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 which 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*—any material or combination of materials used in an item of clothing for the purpose of isolating parts of the body from potential hazards.[5]
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 *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.
3.1.9.1 *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.
3.1.10 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F 1494.

4. Summary of Test Method

4.1 A specimen is supported on an apparatus that allows viewing from behind. A fixed volume of synthetic blood, simulating a given health care scenario, is aimed at the specimen and dispersed at a known velocity by a pneumatically controlled valve to simulate the impact (splatter) of blood or other body fluid onto the specimen. The speed and volume selected corresponds to a specific blood pressure spurting through a defined orifice size.
4.2 Any evidence of synthetic blood penetration on the viewing side of the medical face mask constitutes failure. Results are reported as *pass/fail*.

---

[2] *Annual Book of ASTM Standards*, Vol. 15.04
[3] *Annual Book of ASTM Standards*, Vol. 14.02
[4] *Annual Book of ASTM Standards*, Vol. 15.09
[5] *Annual Book of ASTM Standards*, Vol. 11.03
[6] Available from American Society for Quality Control, 611 E. Wisconsin Ave., Milwaukee, WI 53202.
[7] Available from American National Standards Institute, 11 W. 42nd Str., 13th floor, New York, NY 10036.
[8] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111–5094, Attn: NPODS.
[9] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

4.3 Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6, 16.0, and 21.3 kPa (80, 120, and 160 mm Hg). Test results are reported at each velocity 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 can be 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 can effect 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. The surface tension range for blood and body fluids (excluding saliva) is approximately 0.042 to 0.060 N/m **(1)**.[10] 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 may not 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 can be 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. A second factor is the size of the puncture, and a third factor is the distance from the puncture. Because only small punctures cause high velocity streams, 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 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 10.6 to 16.0 kPa (80 to 120 mm Hg) **(2)**. In this test method, medical face masks are tested at stream velocities corresponding to 10.6 kPa, 16.0 kPa, and 21.3 kPa (80 mm Hg, 120 mm Hg, and 160 mm Hg).

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 F 1670 by dispensing a stream of 2 mL of synthetic blood against the target area of a complete medical mask specimen whereas Test Method F 1670 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 F 1670 is at hydrostatic pressure of 13.8 kPa (2.0 psig). Test Method F 1670 is used for preliminary evaluation of protective clothing penetration resistance to synthetic blood in conjunction with Test Method F 1671 which 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 should 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 MSHA/NIOSH-certified respirator should be used. This test method can be used 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 25 + 3°C (77 ± 5°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 may be used in conjunction with this test method as described in 5.10. Professional health care 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 security. Consider tests which assess the impact of storage conditions and shelf life for disposable products, and the effects of laundering and sterilization for reusable products. The integrity of the protective clothing can also be compromised during use by such effects as flexing and abrasion **(3)**. It is also possible that

[10] The boldface numbers in parentheses refer to the list of references at the end of this standard.

pre-wetting by contaminants such as alcohol and perspiration also compromises the integrity of the protective clothing. If these conditions are of concern, evaluate the performance of protective clothing for synthetic blood penetration following an appropriate pretreatment technique representative of the expected conditions of use.

5.11 While this test method involves a qualitative determination of the medical face mask resistance to penetration by synthetic blood under specific test conditions, it is possible to use this test method as a material quality control or assurance procedure.

5.12 If this procedure is used for quality control, perform proper statistical design and analysis of larger data sets when more than the required specimens are tested. This type of analysis includes, but is not limited to, the number of individual specimens tested, the average percent passing or failing, or both, with a standard deviation. Data reported in this way help to establish confidence limits concerning product performance. Examples of acceptable sampling plans are found in references such as MIL-STD-105, ANSI/ASQC Z1.4, and ISO 2859-1.

5.13 In the case of a dispute arising from differences in reported results when using this test method for acceptance testing of commercial shipments, the purchaser and the supplier should conduct comparative tests to determine if there is a statistical bias between their laboratories. Competent statistical assistance is recommended for investigation of bias. As a minimum, the two parties should take a group of test specimens which are as homogeneous as possible and which are from a lot of the product of the type in question. The test specimens should then be randomly assigned in equal numbers to each laboratory for testing. The average results from the two laboratories should be compared using a non-parametric test for unpaired data and an acceptable probability level chosen by the two parties before testing is begun. If a bias is found, either its cause must be found and corrected or the purchaser and the supplier must agree to interpret future test results with consideration to the known bias.

6. Apparatus

6.1 *Test Apparatus*, to affix the specimen medical face mask and dispense synthetic blood at the target area of the specimen. The test apparatus consists of a specimen holding fixture, a fluid reservoir, a pneumatic-controlled valve and valve controller to dispense a specified volume of synthetic blood through a small diameter canula in a controlled amount of time, and a valve control switch. The configuration of the test apparatus is shown in Fig. 1. Dimensions for the specimen holding fixture are provided in Fig. 2. An overall photograph of the sample test apparatus is provided in Fig. 3. A parts list for the test apparatus is given in Table 1. Other specifications for the specimen holding fixture include as follows:

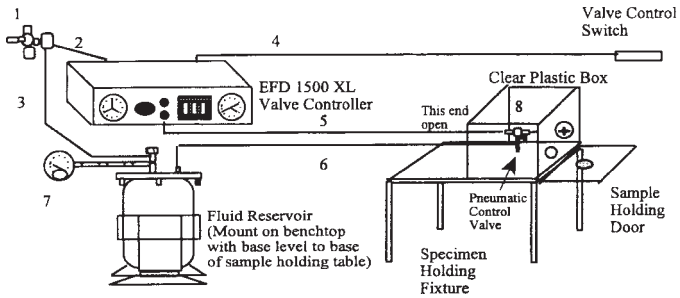
6.1.1 The height of the canula on the pneumatic valve is 420 mm (16.5 in.). This height corresponds to the height of the fluid reservoir.

6.1.2 The specimen holding fixture used to directly hold the specimen should be convex and apply only enough pressure to gently stretch the specimen while holding it firmly in place ~~38~~ 305 mm (12.~~5~~0 in.) from the tip of the canula on the valve. The specimen holder fixture may use metal clips to hold the specimen provided that these clips remain away from the target area and do not damage the specimen. A photograph of a specimen holding fixture is provided in Fig. 4.

NOTE 1—The specimen holding fixture illustrated in Fig. 2 consists of an aluminum table upon which is mounted a transparent plastic box. The table is fitted with a vertical ring clamp used to hold the pneumatic valve. The back of the box is open to allow access to the valve. The front of the box has a hole cut in it to fit the convex mounting fixture on the outer door where the specimens are positioned. The outer door is closed with the specimen in position and the specimen is held between the wall of the box and the door. The door is held closed by magnetic strips along the top of the box and the door. A hole is cut through the center of the convex specimen mounting fixture and the door to allow the test operator to visually note if any fluid penetrates to the inside layer of the specimen medical face mask. The top of the aluminum table is constructed to allow the test fluid to drain out through a hole drilled in the lowest portion of the table into a beaker or other suitable collection vessel.

6.2 *Air Pressure Source*, capable of providing air at a gage pressure of 700 ± 25 kPa (100± 5 psig).

6.3 *Graduated Cylinder*, calibrated and graduated to measure liquid with a precision of 0.1 mL.



NOTE 1—The following legend applies.

1–Filter/Regulator-Air supply
2–¼ ″ I.D. ½ ″ O.D. 150 psi, 193 cm air line to controller
3–Airline (¼ ″ plastic 300 cm)
4–Wire from controller to pedal switch-actives valve
5–Air line (¼ ″ plastic, 150 cm) to valve
6–Fluid feed (¼ ″ plastic, 94 cm) to valve
7–Reservoir pressure gage (conn. by 69 cm ¼ ″ plastic)
8–Valve mounted on ring-stand mount, 15 cm above Fixture, 42 cm elevation with canula

FIG. 1 Complete Test Apparatus

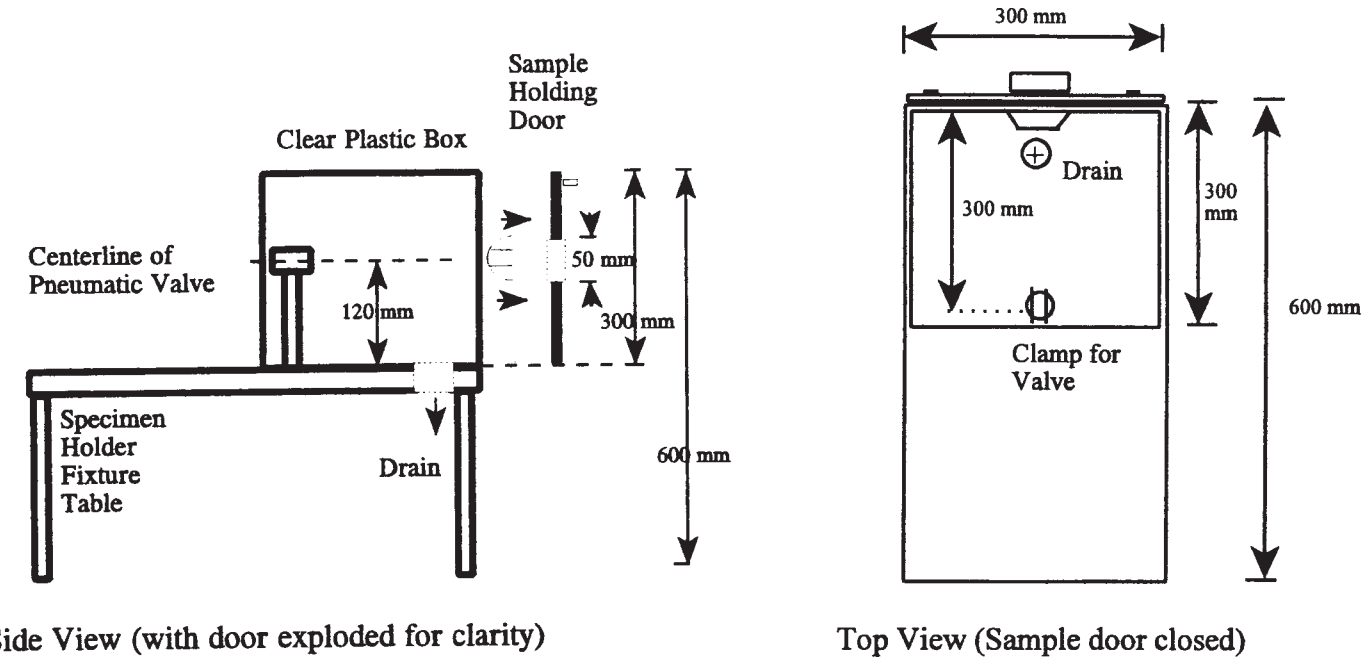


FIG. 2 Specimen Holding Fixture

NOTE 2—A 10 mL sized graduated cylinder with an expanded lip has been found to be a convenient size.

6.4 *Beaker*, 500 mL or larger, to collect runoff of synthetic blood from test apparatus.

6.5 *Temperature/Humidity Recorder*, to monitor ambient conditions during testing.

6.6 *Controlled Temperature and Humidity Chamber or Space*, capable of achieving and maintaining specified temperature and humidity conditions.

7. Reagents

7.1 *Synthetic Blood*[11]— If synthetic blood is not purchased, prepare using the following ingredients:

7.1.1 *High Performance Liquid Chromatography (HPLC)*, quality distilled water (1.0 L, pH 7.0 ± 0.5).

7.1.2 *Thickening agent*[11], 25.0 g.

7.1.3 *Red dye*[11], containing colorant and surfactant, 10.0 g.

7.1.4 To reduce biological contamination, boil the distilled water for 5 min and allow to cool to room temperature before mixing. Measure amount of distilled water at 20°C (± 1°C) after boiling.

7.1.5 Add the thickening agent to the distilled water and mix 45 min at room temperature on a magnetic stirring plate.

7.1.6 Add the red dye and mix 1 h or more.

NOTE 3—The red dye will stain skin, clothes, and work surfaces.

7.1.7 Determine the corrected surface tension of the solution using Test Method D 1331. The expected value of the corrected surface tension is 0.042 ± 0.002 N/m. Do not use synthetic blood solutions unless within the specified range of surface tension.

7.1.7.1 The amount of surfactant in the red dye may vary significantly causing unacceptable surface tension variability from batch to batch. If the corrected surface tension is too high, discard the batch of prepared synthetic blood. If the corrected surface tension is too low, remove excess surfactant from the red dye by mixing 25 g of red dye with 1 L of 90 % isopropanol, decant 80 % of the tainted alcohol, and discard or save for distillation. Pour dye - alcohol solution into an evaporation dish, spread thin, and cover with filter paper to allow residual alcohol to completely evaporate. The red dye is ready for use when dry.

7.1.7.2 Remove excess surfactant from the synthetic blood by allowing the mixture to settle for 24 h and then by carefully decanting the top 10 % of the mixture.

7.1.8 Store synthetic blood in a clear glass container at room temperature.

7.1.9 Shake synthetic blood well before using to prevent its separation.

7.1.10 Discard the solution if a gel-like precipitate forms.

7.2 *Isopropanol*, laboratory grade, for cleaning of circular test head.

---

[11] This test method is under the jurisdiction of ASTM Committee F23 on Protective Clothing and is the direct responsibility of Subcommittee F23.40 on Biological Hazards.

Current edition approved July 10, 2000. Published August 2000. Originally published as F 1862 - 98. Last previous edition F 1862 - 00.

FIG. 3 Photograph of Test Apparatus

8. Hazards

8.1 Because the synthetic blood readily stains clothing, wear a laboratory coat or similar cover during testing. Wear safety glasses with side shields if standing behind the test specimen for observing its performance.

9. Test Specimens

9.1 Use complete medical face masks as the test specimen.

9.1.1 If in the design of a medical face mask, different materials or thicknesses of material are specified at different locations, test each area of the specimen separately.

9.1.2 If in the design of a medical face mask, seams are claimed to offer the same protection as the base materials, test these areas of the face mask separately.

9.2 Test a sufficient number of specimens taken at random for each type, design, or lot of medical face mask to achieve an acceptable quality limit (AQL) of 4.0 %, as defined in ANSI/ASQC Z1.4, at each selected test pressure. Random specimens may be generated as described in Practice E 105..

NOTE 4—A single sampling plan providing an AQL of 4.0 % would require 32 specimens.

9.3 If warranted, use other pretreatment options, such as prewetting, to assess possible degradation mechanisms of medical face masks (5.10).

10. Conditioning

10.1 Condition each specimen for a minimum of 4 h by exposure to a temperature of 21 ± 5°C (70 ± 10°F) and a relative humidity of 85 ± 5 % as described in Specification E 171 using a controlled temperature and humidity chamber or space. Test specimens within 1 min of removal from the conditioning chamber, or alternatively keep conditioned specimens in a portable, closed container with an atmosphere representative of the specified conditioning environment prior to testing.

TABLE 1 Parts List for Test Apparatus

Quantity	Description
1	"Piggy back" style air filter/regulator, rated to withstand 7000 kPa (100 psi), with one input and two output connectors (EFD Part No. 2000F755 with air tree Part No. 1116)[A]
1	Air input hose (EFD part No. 2310S)[A]; item 5 in Fig. 1
1	Fluid reservoir liner and cover (EFD Part No. 615DRL)[A]
1	Reservoir stand (EFD part No. 61520)[A]
1	Fluid reservoir (EFD part No. 615DT)[A,B]
1	Pressure gage, calibrated and rated to a maximum pressure of 105 kPa (15 psig); item 7 in Fig. 1
1	Dip tube, for inside reservoir (EFD Part No. 61521)[A]
1	Fluid feed line (EFD part No. 2025)[A]; item 6 in Fig. 1
1	EFD Model 1500XL or equivalent value controller, mounted 430 mm (17 in.) above the bench top upon which the reservoir is positioned[A]
1	EFD Model 725D pneumatic fluid dispensing valve[A]
1	Hand or foot activated switch
10	18 gage, 12.7 mm (0.5 in.) type canulas with internal diameter of 0.85 mm (0.033 in.) EFD Part No. 5118-B, general purpose precision tips[C]
1	Sample holding fixture (see Fig. 2)

[A] Available from EFD, 977 Waterman Ave., East Providence, RI 02914.
[B] For increased accuracy in small pressure measurements, the pressure gage supplied with the EFD reservoir unit should be replaced with a larger gage.
[C] While only one tip is required to perform testing, it is recommended that a good supply of replacements be on hand in case of clogging or loss.

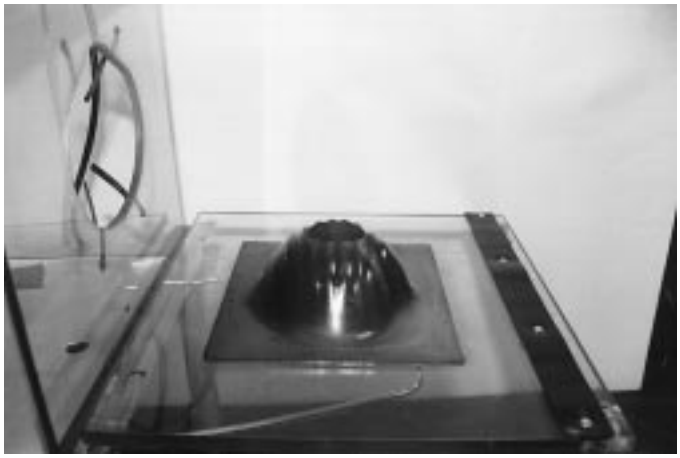


FIG. 4 Photograph of Test Apparatus of Specimen Holder Fixture

11. Preparation and Cleaning of Test Apparatus

11.1 Install a clean diameter canula on the front of the pneumatic-controlled valve.

11.2 Fill the reservoir with new synthetic blood (approximately 1 L).

11.3 Select the velocity needed and set the valve time for delivering 2 mL of flow using Eq 1 and Eq 2. Select the blood pressure needed and use Eq 1 to determine the stream velocity. From Eq 2 using the stream velocity, calculate the valve time setting.

$$[v = ((2.0081 \times 10^6)\, P)^{0.5}] \quad (1)$$

where:
P = blood pressure, mm Hg, [kPa] and
v = stream velocity, in./s. [mm/s]

$$[t = 3620/v] \quad (2)$$

where:
t = time for delivery of 2 mL, s.

See Appendix X1 for a derivation of the equations for stream velocity and time for delivery.

11.3.1 For the purposes of this test method, evaluate three different sets of specimens at stream velocities corresponding to blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa (80 mm Hg, 120 mm Hg, and 160 mm Hg).

11.3.2 If specimens are tested at higher stream velocities and show no penetration at an acceptable quality limit of 4.0, then testing of other specimens at lower stream velocities is not required.

11.4 Adjust the reservoir pressure as needed to achieve a flow of 2 mL for the selected valve time.

11.4.1 For a delivering a volume of synthetic blood other than 2 mL, refer to Appendix X1.

11.5 Verify the amount of synthetic blood delivered to be 2 mL by conducting trials into a graduated cylinder.

11.6 After every eight specimens, ensure that the test apparatus is delivering 2 mL of synthetic blood by following the method calibration steps as directed in 11.4 and 11.5.

11.7 If the canula is left for 1 h or more without use after passing synthetic blood during testing, replace with a clean canula and clean the used canula.

11.7.1 Clean the canula by immersing in isopropanol for 24 h and rinsing with distilled water.

11.8 Following testing, clean system lines and the reservoir with distilled water. Do not use isopropanol or other solvents on the valve or system lines as the valve may be damaged.

12. Procedure

12.1 Place a small droplet (approximately 0.1 mL) of the synthetic blood on the normal inside surface of an extra medical face mask. The droplet must remain easily visible to ensure that a droplet penetrating the material will be seen. If not, use talcum powder on the normal inside surface of the medical face mask to enhance droplet visibility.

12.2 Mount a specimen on the specimen holding fixture and position the specimen for impact of the synthetic blood to occur in the target area.

12.2.1 If the face mask contains pleats, spread the pleats out when mounting the face mask onto the test fixture to present a single layer of material as the target area. Use the center of the specimen as the target area.

12.2.2 Position the end of the pneumatic-controlled valve at a distance of ~~300~~ 305 mm (12.0 in.) from the target area onto the specimen.

12.3 Dispense the synthetic blood onto the specimen medical face mask. Ensure that the synthetic blood hits the target area of the medical face mask.

12.4 Inspect the viewing side of the specimen for synthetic blood within 10 s of dispensing the synthetic blood against the target area. Using suitable lighting note whether any synthetic blood, or other evidence of wetness, or both, appears on the viewing side of the specimen.

12.4.1 Use a cotton absorbent swab or similar item to lightly daub the target area, if doubt exists for visible penetration of the synthetic blood.

12.5 Test the remaining specimens at each of the pressures specified in 11.3.1.

13. Report

13.1 State that the test was conducted as directed in Test Method F 1862. Describe the medical face mask tested and the method of sampling used.

13.1.1 Report the materials of construction (for example, fiber type), supplier, lot number, and date of receipt for the medical face mask tested.

13.2 Report the following information for each of the specified test conditions and other test conditions selected for the evaluation of the medical face masks:

NOTE 5—The specified test conditions include stream velocities corresponding to blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa (80 mm Hg, 120 mm Hg, and 160 mm Hg) and a test volume of 2 mL.

13.2.1 The selected test blood pressures, and volumes and velocities of synthetic blood used, if different from that specified in this test method.

13.2.2 Description of target area(s) tested, if different from that specified in this test method.

13.2.3 The distance of the face mask target area surface from the tip of the canula and the angle of the pneumatic valve with respect to the face mask target area, if different from that specified in this test method.

NOTE 6—The specified distance of the medical face mask target area surface to the tip of the canula is 305 mm (12.0 in.) at an angle normal to the medical face mask target area surface.

13.2.4 A description of any technique used to enhance visual detection of synthetic blood penetration.

13.2.5 The temperature and relative humidity for both conditioning and testing.

13.2.6 A description of any pretreatment techniques used.

13.2.7 The *pass* or *fail* for each specimen at each test pressure.

13.3 Report the highest pressure corresponding to a stream velocity for which the medical face mask demonstrates an acceptable quality limit of 4.0 %.

NOTE 7—An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show *pass* results.

14. Precision and Bias

14.1 *Precision and Bias*—No information is presented about either the precision or bias of Test Method F 1862 for measuring

the synthetic blood penetration resistance of medical face masks because the test result is non-quantitative.

15. Keywords

15.1 blood; blood-borne pathogens; body fluids; medical face masks; penetration; synthetic blood

APPENDIX

(Nonmandatory Information)

X1. DERIVATION OF EQUATIONS FOR STREAM VELOCITY AND TIME OF DELIVERY

X1.1 The equations for calculating stream velocity and the time of delivery for synthetic blood in this test method are based on the Bernoulli equation which describes the conditions of a flowing fluid at two or more points along a flow line:

$$\frac{P_1}{\delta_1} + \frac{v_1^2}{2g} + z_1 = \frac{P_2}{\delta_2} + \frac{v_2^2}{2g} + z_2 + h_L \tag{X1.1}$$

where P_1 and P_2 are the pressures of the two fluid streams, v_1 and v_2 are the stream velocities, z_1 and z_2 their respective height above a defined plane, δ_1 and δ_2 are the densities of the fluid, g is the gravitational constant and h_L is the head loss.

X1.2 In defining the blood splatter threat, several assumptions were made and incorporated into the Bernoulli equation. If the flow of blood through a blood vessel (Location 1) is assumed to be slow compared to the flow out of the puncture hole (Location 2), then the term v_1 can be neglected and taken as zero. Likewise, since the height of the blood vessel and the exiting stream are the same, the terms for height (z_1 and z_2) can be neglected. The heat loss term can be neglected because there is very little opportunity for frictional losses between the inside and outside of the blood vessel.

X1.3 The pressure in a free stream of fluid is zero. This fact taken together with the assumptions in X1.2 reduce the Bernoulli equation to the following:

$$\frac{P_1}{\delta_1} = \frac{v_2^2}{2g} \tag{X1.2}$$

X1.4 The following equation can then be solved for velocity.

$$v_2 = \sqrt{\left(\frac{2g}{\delta_1}\right) P_1} \tag{X1.3}$$

X1.5 For the purpose of this test method, the constant K_A can be defined as follows:

$$K_A = \frac{2g}{\delta_1} = 413.95 \tag{X1.4}$$

using the gravitational constant and fluid densities for blood for calculating a stream velocity, v, in units of in/s and using pressures, P, in units of mm Hg. When calculating a stream velocity v, in units of mm/s and using pressures, P, in units of kPa, $K_A = 2.0082 \times 10^6$.

X1.6 The time of delivery can be determined using the velocity calculated in Eq X1.3 and the volume of synthetic blood which must pass through orifice size of the canula as shown in Eq X1.5.

$$t = \frac{4V}{\pi d^2 v} \tag{X1.5}$$

where V is the volume of synthetic blood and d is the diameter of the canula. For 2 mL of synthetic blood and canula diameter of 0.84 mm (0.033 in.), the equation becomes:

$$t = 142.64/v \text{ for } V \text{ (in./s)} \tag{X1.6}$$
$$= 3620/V \text{ for } V \text{ (mm/s)}$$

REFERENCES

(**1**) 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.
(**2**) Barach, P. G., Cullen, B.F., and Stoelting, R. K., *Handbook on Clinical Anesthesia*, Appendix A, J. B. Lippincott Co., Philadelphia, 1994.
(**3**) Telford, G. L. and Quebbeman, E. J., "Assessing the Risk of Blood Exposure in the Operating Room," *American Journal of Infection Control*, Vol 21, No. 6, December 1993, pp. 351-356.