



Designation: F1862/F1862M – 17

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

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 ( $\epsilon$ ) 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 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 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*

<sup>1</sup> 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:<sup>2</sup>

- 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:<sup>3</sup>
- ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes
- 2.3 ISO Standard:<sup>4</sup>
- ISO 2859-1 Sampling Plans for Inspection by Attributes
- 2.4 Military Standards:<sup>5</sup>
- MIL-M-36954C Military Specification, Mask, Surgical, Disposable
- 2.5 OSHA Standard:<sup>6</sup>
- 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.

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

<sup>3</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

<sup>4</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

<sup>5</sup> Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

<sup>6</sup> Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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*.



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.<sup>7</sup> 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  $0.042 \pm 0.002$  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 corre-

sponding 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).<sup>8</sup> 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 ( $85 \pm 5$  % relative humidity at  $21 \pm 5$  °C [ $70 \pm 10$  °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

<sup>7</sup> 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.

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



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 is occasionally compromised during use by such effects as flexing and abrasion.<sup>9</sup> It is also possible that 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 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, conduct comparative tests between the purchaser and supplier to determine if there is a statistical bias between their laboratories. Competent statistical assistance is recommended for investigation of bias. At minimum, 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. Randomly assign test specimens in equal numbers to each laboratory for testing. Compare the average results from the two laboratories 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 dispense a specified volume of synthetic blood through a small diameter cannula over a controlled amount of time at a specimen mask a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable cannula, and a valve controller. A permitted optional design for the test apparatus includes a base for more convenient mounting of the components and a hood or other components to contain or control the splash. A photograph of a typical sample test apparatus is

provided in Fig. 1(a). Fig. 1(b) provides an example of an alternative apparatus with the addition of a funnel to collect excess liquid so that the level in the reservoir can be estimated to help prevent running out of synthetic blood in the middle of a test lot. Fig. 1(c) and Fig. 1(d) show the incorporation of X-Y-Z axis slides for easy, smooth fine-tuning of cannula position that also helps keep pneumatic valve steady to reduce the risk of accidentally bumping it out of adjustment. Other specifications for the specimen holding fixture include as follows:

6.1.1 *Specimen Holding Fixture*, to support the specimen mask during the test. The design and construction of the specimen holding fixture has a significant impact on the outcome of the test. The specimen holder and supporting frame must be sufficiently stiff and rigid that the energy of the impact of the spurt is absorbed solely by the specimen mask. The specimen holder and frame must not deform, flex, or bend during a test. If necessary, alter the fixture design details from that described below, in order to provide appropriate specimen presentation while maintaining the intent of the method described herein.

6.1.1.1 The standard backing form for the specimen holder is a solid section of a 12.7-cm [5-in.] diameter sphere. Use a form made of a material with a Shore A hardness of at least 40. (See Note 1.) The form has a 5.7-cm [2.25-in.] diameter viewing hole through its center as shown in Fig. 2 and Fig. 3.

NOTE 1—A backing form can be made from liquid polyester resin (found at home improvement centers or auto parts stores), a 5-in. ball candle mold (candle supply companies such as genwax.com), and a 2-in. PVC tubing union (2.25 in., 5.7 cm outside diameter, found at home improvement centers). Mark a ring around the outside of the union 1 1/8 in. [3.0 cm] from one end. This will indicate the proper depth to fill the form to fit the apparatus described in this method. The depth can be adjusted to accommodate variations in the design of the specimen mask holder. The key element is to maintain the diameter of the form at the plane of the cuff at 4.125 in. [10.5 cm]. Using plumber's putty on the end of the union opposite the depth mark, seal the union to the inside of one half of the ball mold. Set the mold in the mold stand. Rest a level on the union to ensure the hold is horizontal in all directions. Mix about 12 oz of resin and 25 drops of hardener in a well-ventilated area. Carefully pour the resin into the mold outside of the union, making an annular form. Fill the mold up to the line on the union, taking into account the meniscus of the fluid. Once hardened, remove the form from the mold and the union from the mold. The use of a short piece of 2-in. PVC tubing is suitable to carefully knock the union out of the mold. Sand the base of the mold such that the surface is flush. Drill and tap mounting holes into the mold.

6.1.1.2 The backing form is mounted to a plate which is hinged<sup>10</sup> to the specimen holder frame so there is a 0.6-cm [0.25-in.] gap between the plate and the frame, as in Fig. 2. The frame contains an 11.75-cm [4 5/8-in.] hole to receive the backing form.

6.1.1.3 A rubber cuff which partially covers the hole is secured to the frame. The cuff draws the specimen mask across the backing form. Use a cuff made from 0.08-cm [1/32-in.]

<sup>9</sup> 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.

<sup>10</sup> A continuous plastic hinge provides a little more give than a rigid piano hinge. Reference McMaster Carr 11195A41. McMaster-Carr Supply Company, Atlanta, Georgia.

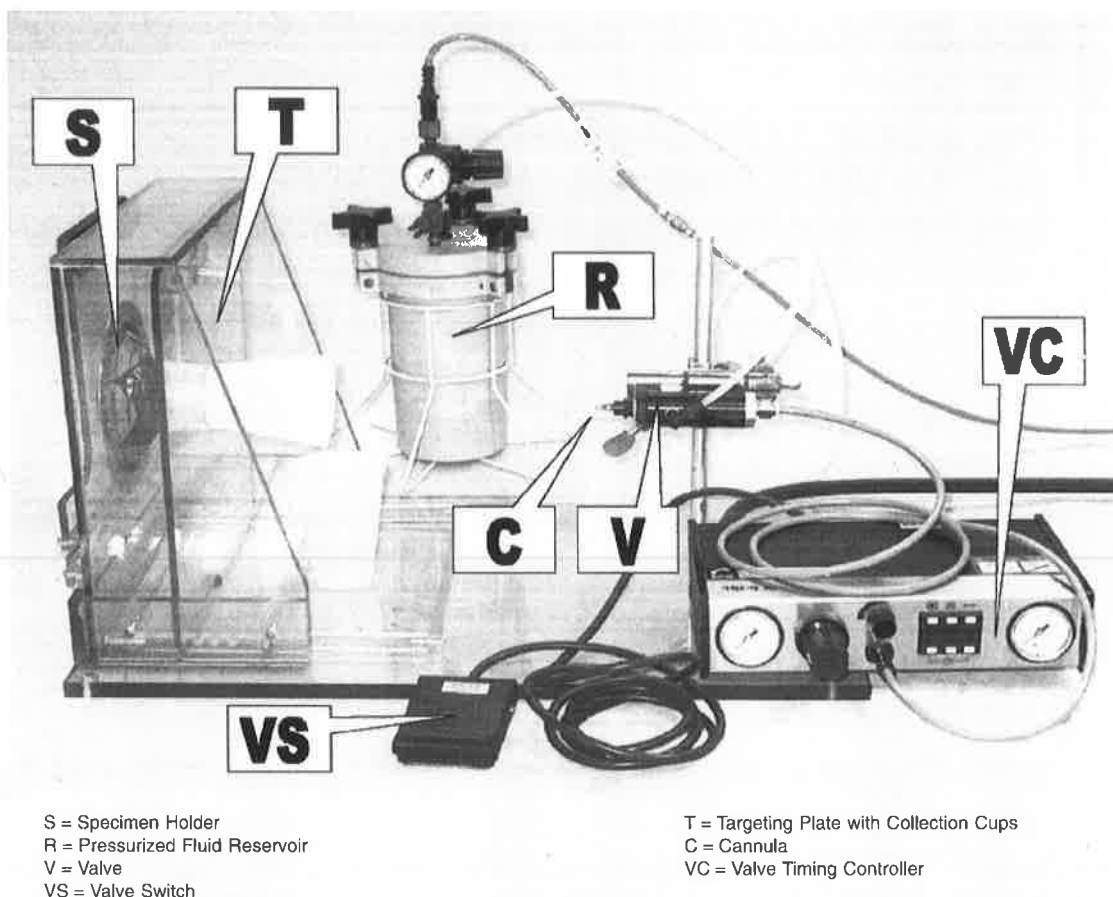


FIG. 1 (a) Test Apparatus

buna-N gasket material with a Shore A hardness of 70.<sup>11</sup> The dimensions of the six-point star-shaped opening in the cuff are detailed in Fig. 4.

6.1.2 *Targeting Plate*, to block the high-velocity leading edge of the fluid stream and to provide a means of ensuring the fluid stream hits the target area of the specimen mask. The plate contains a  $\frac{3}{16}$ -in. diameter hole. Ensure that the thickness of the targeting plate at the hole does not exceed  $\frac{3}{16}$  in. beyond the hole and is made of clear plastic. The plate is configured upright and placed approximately  $\frac{1}{2}$  in. in front of the specimen mask, between the mask and the cannula, such that the stream impacts the center of hole in the mask supporting form.

6.1.2.1 A suitable method for containing the splatter of fluid hitting the targeting plate uses a disposable plastic cup with a hole larger than  $\frac{3}{16}$  in. diameter cut out of the bottom.<sup>12</sup> The cup is mounted horizontally with the opening facing the nozzle by any convenient method. The run-off is suitably collected by a second cup placed below the lip of targeting cup, as shown in Fig. 1.

6.1.3 *Pneumatically Actuated Valve*,<sup>13</sup> shall be mounted on a stiff support, such as a ring stand. The valve support shall not flex when the valve is actuated. The valve shall be positioned so that the exit of the cannula is 30.5 cm [12.0 in.] from the point of impact on the specimen mask.

6.1.3.1 *Valve Maintenance*—Periodically disassemble and clean the pneumatically actuated valve with isopropanol to prevent interference with the valve mechanism or plugging of the cannula, which can lead to inconsistent valve performance.

6.1.4 *Valve Controller*,<sup>14</sup> to set the duration of the fluid spurt. Use a valve controller with a resolution and accuracy of at least  $0.01 \pm 0.005$  s.

6.1.5 *Cannula*,<sup>15</sup> which attaches to the exit of the valve. The standard for this method is a 1.27-cm [0.5-in.] long, 18 gauge stainless steel cannula with an internal diameter of 0.084 cm [0.033 in.].

6.1.5.1 Deviations from the standard cannula must be noted in the test report.

<sup>11</sup> Reference McMaster-Carr item 8635K161 - 12 in. by 12 in. sheets of 70A hardness  $\frac{1}{2}$  in. thick Buna-N gasket material. McMaster-Carr Supply Company, Atlanta, Georgia.

<sup>12</sup> Reference McMaster-Carr 3427A57 -  $\frac{3}{16}$ -in. Arch Punch for making the targeting plate holes in soft materials. McMaster-Carr Supply Company, Atlanta, Georgia.

<sup>13</sup> Reference EFD Model 725D pneumatic fluid dispensing valve or equivalent. EFD, 977 Waterman Ave, East Providence, RI 02914.

<sup>14</sup> Reference EFD 1500D controller or equivalent. A remote hand or foot actuated switch can also be used with the 1500D controller. EFD, 977 Waterman Ave. East Providence, RI 02914.

<sup>15</sup> Reference EFD Part Number 5118-B. EFD, 977 Waterman Ave, East Providence, RI 02914.

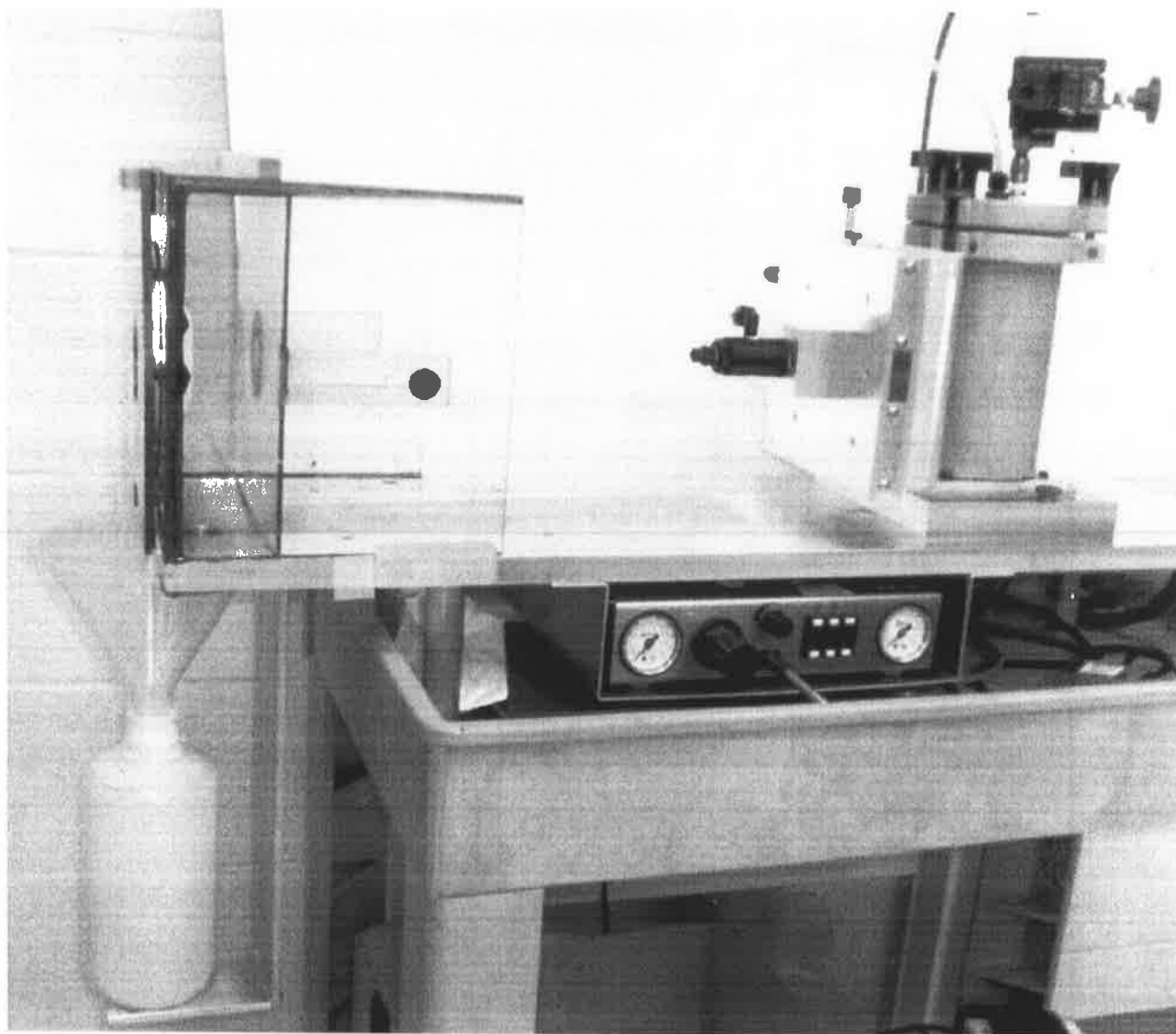


FIG. 1 (b) Test Apparatus (continued)

6.1.6 *Pressure-Regulated Fluid Reservoir*, to contain the synthetic blood for delivery to the nozzle.<sup>16</sup>

6.2 *Air Pressure Source*, capable of providing air at a gauge pressure recommended by manufacturer of valve controller.

6.3 *Balance*, calibrated to measure weight with a precision of at least 0.01 g.<sup>17</sup>

6.4 *Beaker or Cup*, to collect the synthetic blood discharged from the nozzle and cannula.

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.

<sup>16</sup> Reference EFD parts: 615DTH fluid reservoir; 615DRL fluid reservoir cover and liner; 61520 reservoir stand; 2000f755 air filter and regulator; 1116 air tree EFD, 977 Waterman Ave. East Providence, RI 02914.

<sup>17</sup> Weighing the fluid output is faster and more accurate than measuring the fluid volume.

## 7. Reagents

7.1 *Synthetic Blood*<sup>18</sup>—If synthetic blood is not purchased, prepare using the following ingredients:

7.1.1 *High Performance Liquid Chromatography (HPLC)*, quality distilled water (0.975 L, pH  $7.0 \pm 0.5$ ).

7.1.2 *Acrysol G111 Thickening Agent*, 50.0 g.

7.1.3 *Red Dye*, 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  $20 \pm 1^\circ\text{C}$  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 2—The red dye will stain skin, clothes, and work surfaces.

<sup>18</sup> Prepared synthetic blood meeting this specification, and small quantities of Direct Red 081, CI No. 28160 (Morfast Red 8BL) are available from JM & Co., 507-208-6390. Acrysol G111 is available from Dow Chemical Company.

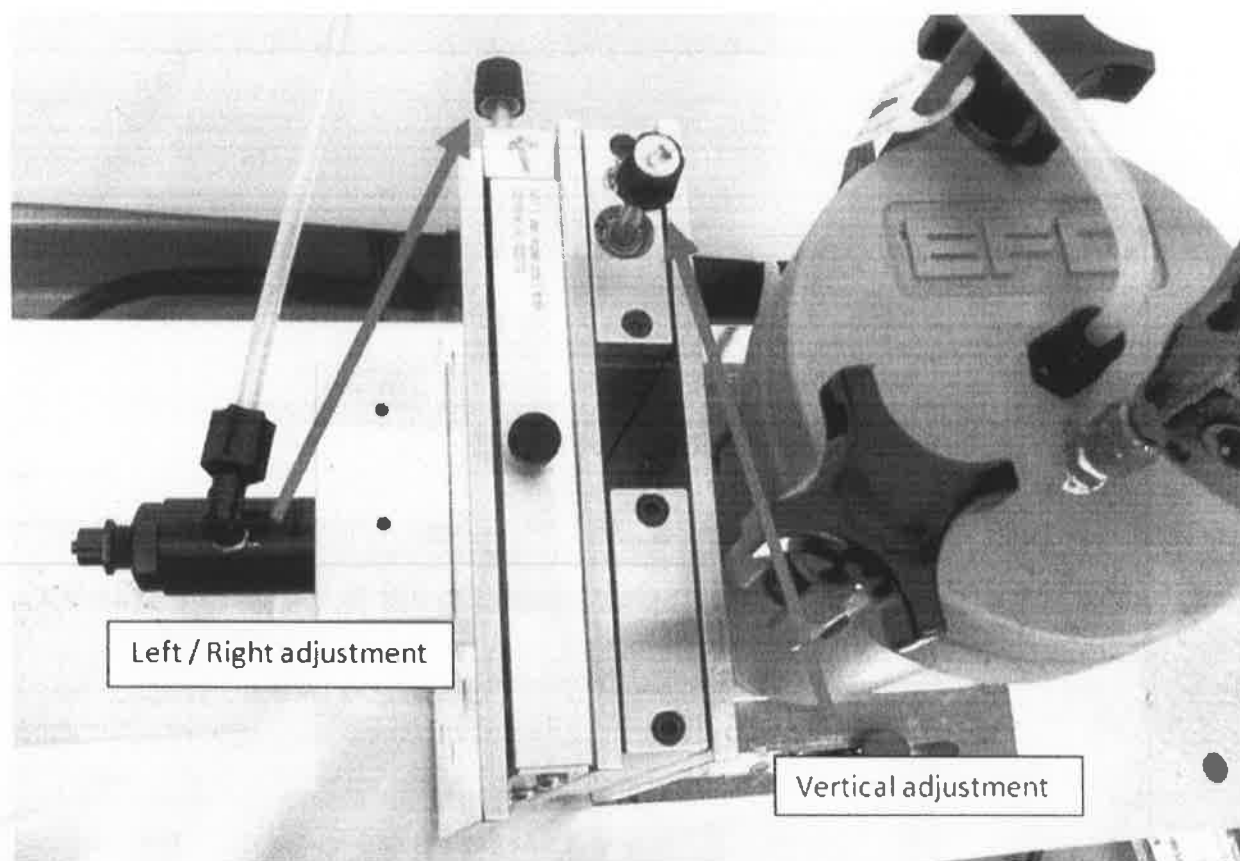


FIG. 1 (c) Left/Right and Vertical Adjustment (continued)

7.1.7 Measure the surface tension of the solution using Test Methods D1331, DuNouy ring (Method A). The surface tension measurement declines over time in an undisturbed dish. After filling the sample container using the mixing method in 7.1.10, let the solution sit for 20 min before beginning the surface tension measurement procedure. The surface tension, measured by ring after 20 min, shall be  $40 \pm 5$  dyn/cm.

7.1.7.1 An alternate check of surface tension may be performed with a capillary tube. The expected surface tension in a capillary tube is  $61 \pm 1$  dyn/cm and is not significantly affected by time.<sup>19</sup>

7.1.7.2 Do not use synthetic blood solutions unless within the specified range of surface tension.

NOTE 3—Exposure to atmosphere causes the difference in surface tension between the ring and capillary methods. Because the ring method exposes the synthetic blood to the atmosphere, the surface tension declines rapidly until reaching equilibrium. In contrast, the capillary method protects the synthetic blood from the atmosphere, which provides an elevated but stable measurement. Both the ring and capillary methods are acceptable to validate the fluid for testing.

7.1.7.3 Excessive oil in the red dye generally causes the unacceptable variations in synthetic blood surface tension. Remove excess oil 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 onto 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.

7.1.7.4 Remove excess oil in 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 Determine the specific gravity of the solution using a hydrometer or pycnometer in accordance with Test Methods D891.

7.1.8.1 If the specific gravity of the test solution is less than 0.995 or greater than 1.015 (1 % different from the specific gravity used in the derivations), recalculate the targets and limits for the amount of fluid discharged from the nozzle in accordance with Appendix X1.

7.1.9 When storing synthetic blood, limit exposure to air. Excess air in the vessel may alter the fluid properties over time. Store at room temperature. Do not freeze. Store in a glass vessel, if storing for more than one year. Do not store in low-density polyethylene.

7.1.10 Synthetic blood remains well mixed over time, however a thin layer of oil may rise to the surface. To mix before use, invert container and gently swirl. Do not shake, as shaking has been shown to affect the surface tension of the fluid for up to several days. After gently mixing, extract synthetic blood with syringe from mid depth to avoid skimming substance from the fluid surface.

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

<sup>19</sup> The capillary tube may be purchased from Fisher Scientific, Catalog #14-818, and the instructions and calculations are specified in the instruction manual.



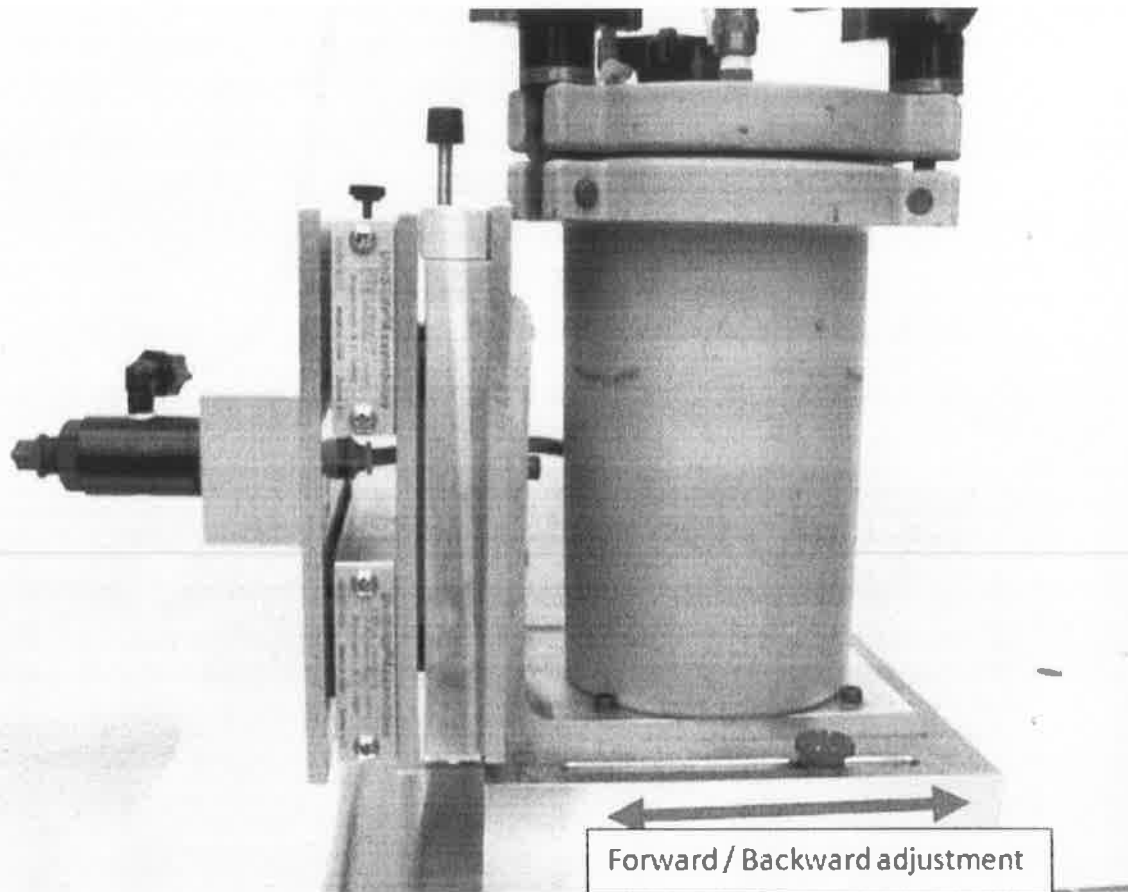


FIG. 1 (d) Forward and Backward Adjustment (continued)

7.2 Isopropanol, laboratory grade, for cleaning the 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. An acceptable procedure involves generating random specimens as described in Practice E105.

9.2.1 A single sampling plan providing an AQL of 4.0 % would require 32 specimens.

9.3 If warranted, use other pretreatment options, such as pre-wetting, 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  $21 \pm 5^\circ\text{C}$  [ $70 \pm 10^\circ\text{F}$ ] and a relative humidity of  $85 \pm 5\%$  as described in Practice E171/E171M 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.

## 11. Preparation and Cleaning of Test Apparatus<sup>20</sup>

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

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

<sup>20</sup> As the setup and calibration of the apparatus involve several repeated calculations, the use of a spreadsheet to aid in these calculations is recommended.



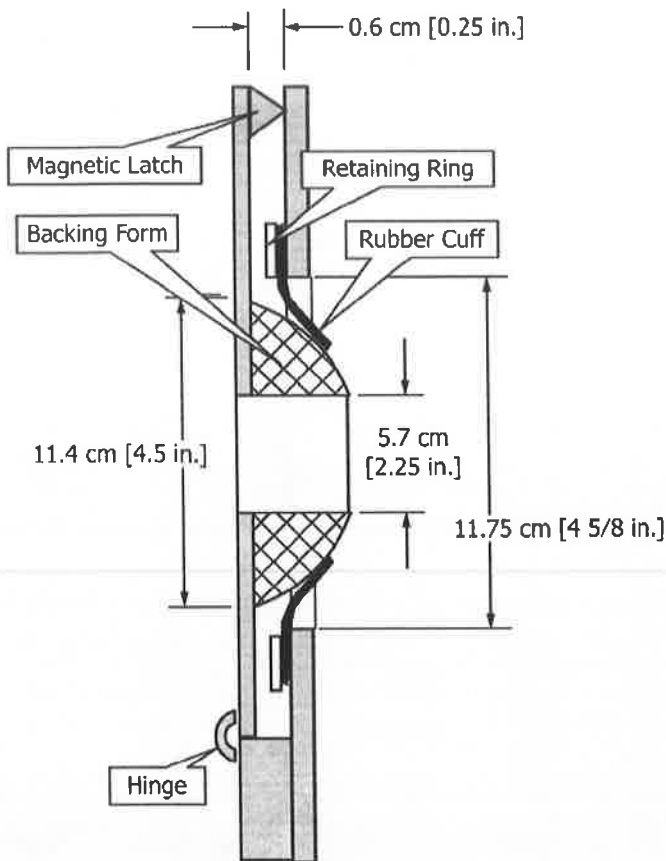


FIG. 2 Schematic of Specimen Holding Fixture

11.3 Adjust the reservoir pressure to deliver the desired steady-state fluid velocity.

11.3.1 Standard fluid velocities for this method are 450, 550, and 635 cm/s [177, 217, and 250 in./s] which correspond to blood pressures of 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg).

11.3.2 Set the reservoir pressure to the approximate pressure. The reservoir pressure used in previous testing is a good starting point.

11.3.3 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered over a 0.5-s spurt.

11.3.4 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered over a 1.5-s spurt.

11.3.5 Calculate the difference in weight of the two spurts. For a test fluid with a specific gravity of 1.005, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2 % of the target. See Appendix X1 to determine the target weight differences for other velocities, cannula sizes, or fluids with other specific gravities.

11.3.6 Adjust the reservoir pressure and repeat steps 11.3.3 – 11.3.5 until the weight difference is within the target range.

11.3.7 Record the weight difference for the spurts exiting the nozzle.



FIG. 3 Specimen Holding Fixture

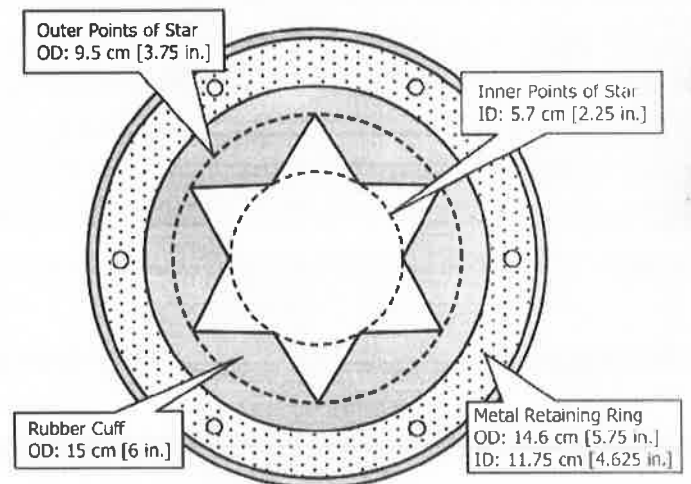


FIG. 4 Schematic of Specimen Retaining Cuff

11.3.8 Record the pressure in the reservoir. Use this as the initial reservoir pressure in subsequent testing to expedite setup.

11.3.9 Once the reservoir pressure has been set, do not change the relative height of the reservoir and nozzle.

11.4 Aim the nozzle so that the steady-state stream passes through the targeting plate.

11.4.1 Place the targeting plate approximately 1 cm [ $\frac{1}{2}$  in.] away from the mask and locate it such that the fluid passing through the hole in the targeting plate hits within 0.6 cm

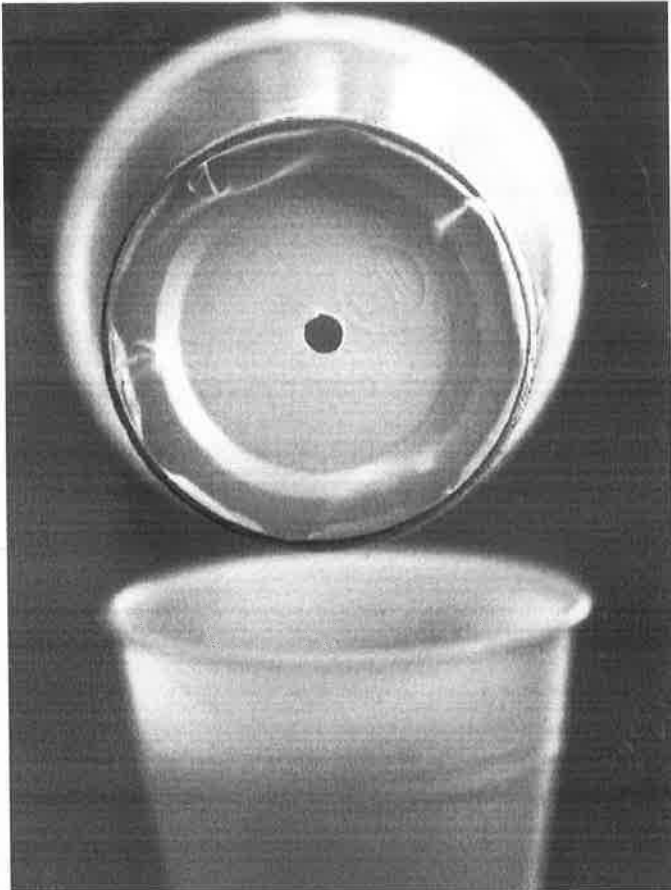


FIG. 5 Disposable Cup Targeting Plate

[1/4 in.] radius of the center of the hole in the specimen holding form as shown in Fig. 6.

11.4.2 Set the valve time to 0.5 s.

11.4.3 Adjust the aim of the valve assembly such that the steady-state portion of the stream passes cleanly through the targeting hole. Ensure that the initial portion of the stream hits above the hole.

NOTE 4—As a setup aid, an alignment rod will help set up the 12-in. distance between mask and cannula, and the 1/2-in. distance from target plate to mask. It will also help obtain a general aim.

11.4.4 Collect and weigh the amount of fluid passing through the targeting hole.

11.4.5 Set the valve time to 1.5 s.

11.4.6 Collect and weigh the amount of fluid passing through the targeting hole.

11.4.7 The difference in weight between the 0.5-s and 1.5-s deliveries through the targeting plate hole shall be within +2%, -5% of the difference in weight from the nozzle (see 11.3.7).

11.4.7.1 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

11.4.7.2 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 11.3.3 - 11.3.7).

11.5 Adjust the valve time to deliver 2 mL of test fluid to the mask through the targeting plate.

11.5.1 Adjust the timer duration until 2 mL of fluid passes through the hole for three spurts in a row. For a test fluid with a density of 1.005 g/cm<sup>3</sup>, the output shall weigh  $2.01 \pm 0.04$  g for each individual spurt.

11.5.1.1 For standard synthetic blood, the timer duration can be estimated using the formula:  $t = 0.5 + (2.01 \text{ g at } 0.5 \text{ s}) / (\text{g at } 1.5 \text{ s} - \text{g at } 0.5 \text{ s})$ .

11.5.2 Record the timer setting to use as the starting point for subsequent testing.

11.6 For the purposes of this test method, evaluate three different sets of specimens at stream velocities of 450, 550, and 635 cm/s, corresponding to blood pressures of 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg).

11.6.1 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.

11.7 After every 16 specimens, ensure that the test apparatus is delivering 2 mL of synthetic blood by collecting and weighing the output passing through the targeting hole. If the delivered output has shifted by more than 0.04 g (2 %), repeat the calibration procedure.

11.7.1 If the delivered output has shifted by more than 0.1 g (5 %), discount the results since the last calibration.

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

11.8.1 Clean the cannula by immersing in isopropanol for 24 h and rinsing with distilled water.

11.9 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 they have the potential to damage the valve.

## 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 mask on the specimen holding fixture and position the specimen so the impact of the synthetic blood occurs in the desired area of the mask and at the desired angle while ensuring a consistent tension across the target area.

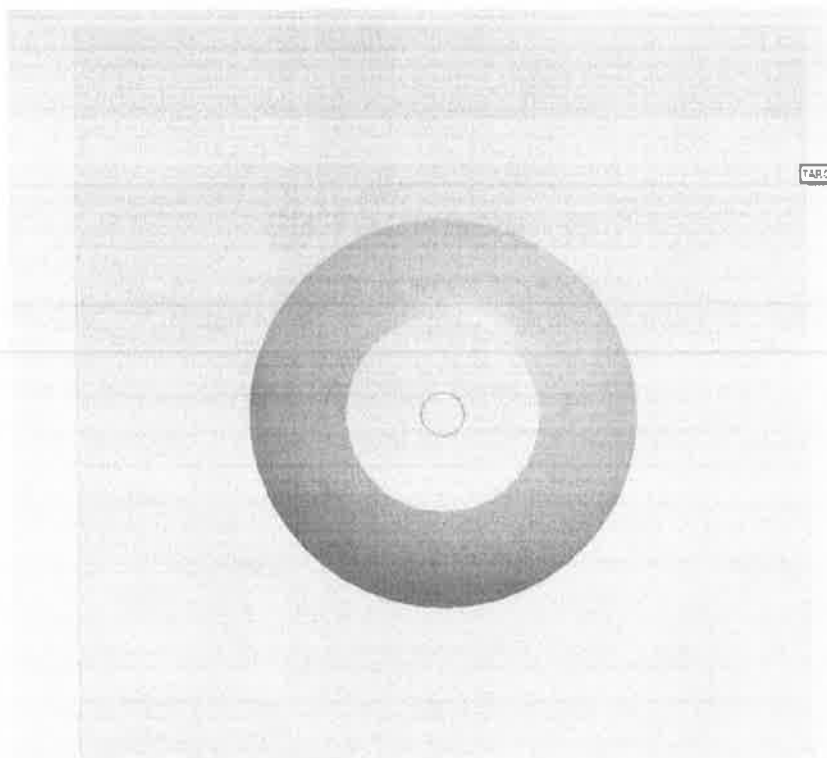
12.2.1 If the face mask contains pleats, spread the pleats out when mounting the face mask onto the test fixture to present a single layer of material as the target area. Use the center of the specimen as the target area.

12.2.2 If the specimen cannot be easily situated into the specimen holding fixture, secure the specimen in a manner that will maintain consistent tension without folding, wrinkling, or presenting the contact area in a manner that does not appropriately represent the intended presentation.



TABLE 1 Target Weight Differences

Fluid Pressure kPa	Fluid Pressure mmHg	Target Velocity cm/s	Weight difference, in grams, for 1-s difference in spurt duration		
			g, min	g, target	g, max
10.7	80	450	2.456	2.506	2.556
16.0	120	550	3.002	3.063	3.124
21.3	160	635	3.466	3.537	3.607



NOTE 1—The small circle is the hole in the targeting plate and the large circle shows a ¼-in. radius around the center of the specimen holding form. The synthetic blood stream needs to hit the test specimen within the large circle.

FIG. 6 Alignment Described in 11.4.1

12.2.3 Locate the exit of the cannula 30.5 cm [12.0 in.] from the target area of the specimen mask.

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 F1862. 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:

13.2.1 The selected fluid velocities and corresponding test blood pressures used, if different from that specified in this test method.

13.2.1.1 The specified test conditions include stream velocities of 450, 550, and 635 cm/s which correspond to blood pressures of 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg) and a test volume of 2 mL of synthetic blood.

13.2.2 The volume of fluid impacting the specimen masks, if different from that specified in this test method.

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

13.2.4 The specified distance of the medical face mask target area surface to the tip of the cannula is 30.5 cm [12.0 in.]

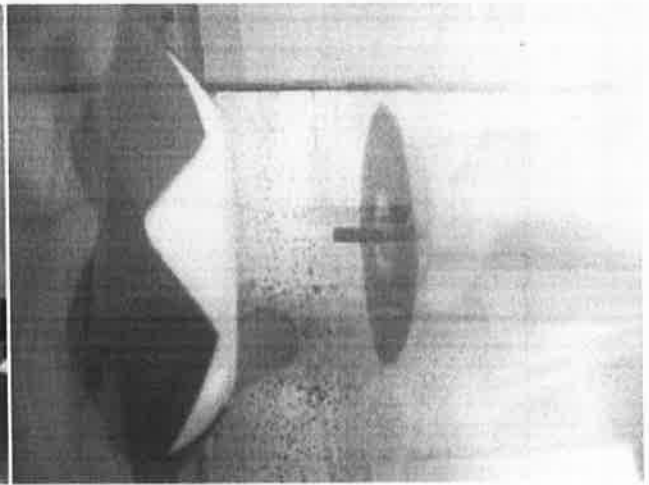
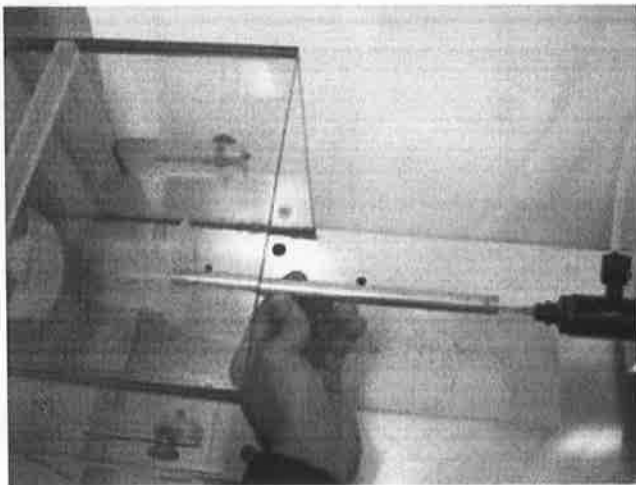
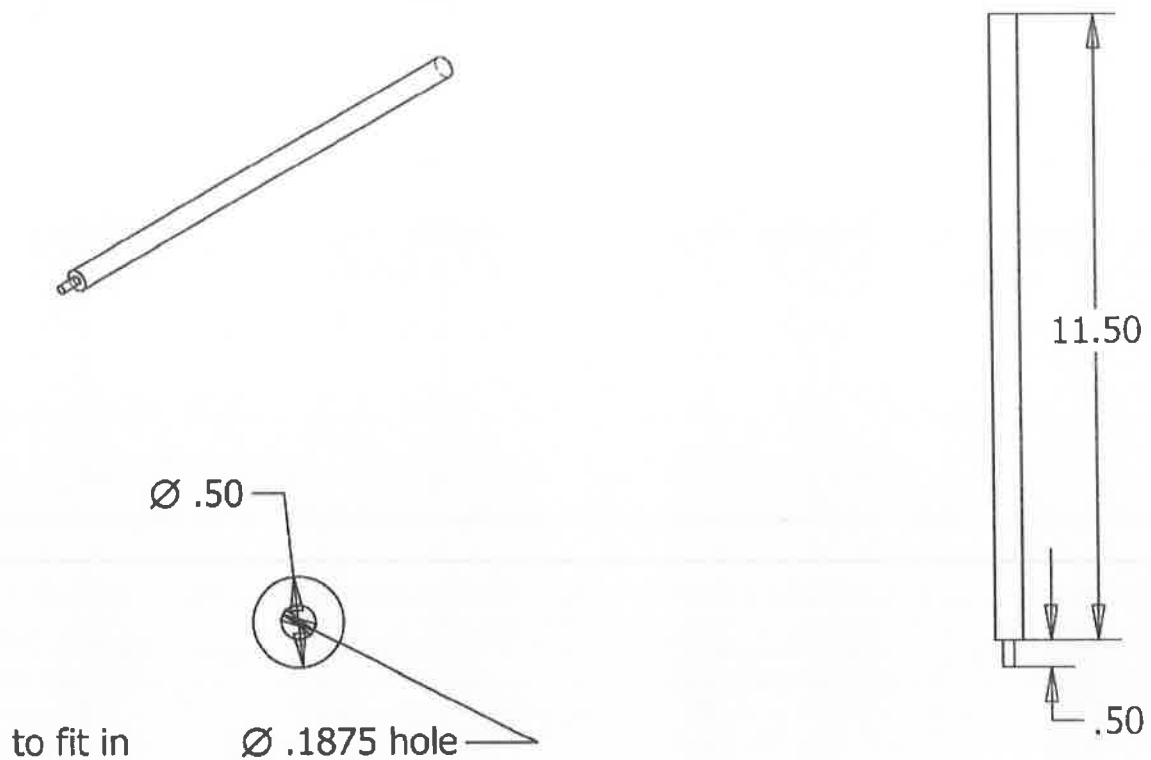


FIG. 7 Alignment Aid

with the impact of the spurt normal to the target area of the specimen medical face mask.

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

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

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

13.2.7 A description of any pretreatment techniques used.

13.2.8 Any other deviations from the stated method.

13.2.9 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 %.

13.3.1 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 No information is presented about either the precision or bias of Test Method F1862 for measuring Resistance of Medical Face Masks to Penetration by Synthetic Blood since the test result is nonquantitative.

## 15. Keywords

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

## APPENDIXES

### (Nonmandatory Information)

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

X1.1 The velocity of the fluid stream at impact with the mask is the key variable in this test method. The Bernoulli equation (Eq X1.1) can be used to estimate the velocity of blood exiting an artery in a clinical setting. The Bernoulli equation describes the conditions of a flowing fluid at two or more points along a flow line:

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

where:

Location 1 = in the blood vessel,  
 Location 2 = the exit of the blood vessel,  
 $P_1$  and  $P_2$  = the pressures at two points in the fluid stream,  
 $v_1$  and  $v_2$  = the stream velocities,  
 $z_1$  and  $z_2$  = the respective heights above a defined plane,  
 $\delta_1$  and  $\delta_2$  = the densities of the fluid,  
 $g$  = the acceleration of gravity, and  
 $h_L$  = the frictional head loss.

X1.2 Several assumptions were made in defining the blood splatter threat to simplify the Bernoulli equation and its application to this situation.

X1.2.1 The flow of blood through a blood vessel (Location 1) is assumed to be much slower than the flow exiting the puncture hole (Location 2). Thus, the term  $v_1$  approaches zero and can be neglected.

X1.2.2 Likewise, the height of the blood vessel and the exiting stream are essentially the same, so the terms for height ( $z_1$  and  $z_2$ ) can be neglected.

X1.2.3 There is little opportunity for frictional losses between the inside and outside of the blood vessel, so the head loss term can be neglected.

X1.2.4 The frictional loss of the stream in air over the short distance of the spurt is negligible, so the velocity at impact is assumed to be the same as the velocity exiting the blood vessel.

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

$$\frac{P_1}{\delta_1} = \frac{v_2^2}{2g} \quad (\text{X1.2})$$

X1.4 Eq X1.2 is then to be rearranged to solve for the velocity of blood exiting a puncture.

TABLE X1.1 Corresponding Blood Velocities

mmHg	kPa	in./s	cm/s
80		176.91	449.35
	10.7	177.06	449.74
120		216.67	550.34
	16.0	216.52	549.96
160		250.19	635.47
	21.3	249.82	634.54

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

which becomes:

$$v_2 \text{ (cm/s)} = 137.59 \sqrt{P_1 \text{ (kPa)}} \quad (\text{X1.4})$$

or

$$v_2 \text{ (in./s)} = 19.779 \sqrt{P_1 \text{ (mmHg)}} \quad (\text{X1.5})$$

when using:

$\delta_1$  = 1.0565 g/cm<sup>3</sup> (density of whole blood),<sup>21</sup>  
 $g$  = 980.67 cm/sec<sup>2</sup>,  
 kPa = 10.197 g/cm<sup>2</sup>, and  
 mmHg = 1.3595 g/cm<sup>2</sup>.

X1.4.1 The velocity of blood exiting a puncture hole (Location 2) can then be determined for specific pressures. (See Table X1.1.)

X1.4.2 Rounding the target velocities to the nearest 5 cm/s results in velocities that correspond to blood pressures that are within 1 % of the target pressures using either English or SI units. As such, testing a particular velocity can be referenced in either pressure units. (See Table X1.2.)

X1.5 In the test method, the pressure in the test apparatus is set to produce the desired exit velocity. As the velocity of the stream exiting the test apparatus is difficult to measure directly, it must be deduced from the volume of a stream produced over a known time through an orifice of known area using:

$$v = \frac{Q}{tA} \quad (\text{X1.6})$$

<sup>21</sup> Lentner, C., ed., *Geigy Scientific Tables*, Vol 3 - Physical Chemistry, Composition of Blood, Hematology, Sonotometric Data, Medical Education Div., Ciba-Geigy Corp., West Caldwell, NJ, 1984.



TABLE X1.2 Target Velocities and Pressures

mmHg	kPa	cm/s	in./s	kPa	mmHg
80	10.7	450	177.17	10.697	80.232
120	16.0	550	216.54	15.979	119.85
160	21.3	635	250.00	21.300	159.76

where:

$v$  = flow velocity,  
 $Q$  = flow volume,  
 $t$  = duration of the flow, and  
 $A$  = cross sectional area of the orifice.

X1.6 The cross sectional area of a round orifice can be calculated from the orifice diameter using:

$$A = \frac{\pi d^2}{4} \quad (\text{X1.7})$$

where:

$d$  = orifice diameter.

X1.7 As it may be easier and more accurate to measure the weight rather than the volume of the spurt, Eq X1.8 may be used to determine the weight of fluid for a given volume.

$$\omega = Q\delta \quad (\text{X1.8})$$

where:

$\omega$  = weight of the spurt,  
 $Q$  = volume of the spurt, and  
 $\delta$  = density of the test fluid.

Assuming a density of 1.005 g/mL for the test fluid, the weight of a 2-mL spurt would be 2.010 g.

X1.8 Eq X1.6, Eq X1.7, and Eq X1.8 can be combined and rearranged to solve for the duration of flow, or valve open time, for a given target velocity and spurt volume.

$$t = \frac{4\omega}{v\delta\pi d^2} \quad (\text{X1.9})$$

X1.8.1 It is important to note that equation Eq X1.9 assumes that the velocity of the fluid is constant during the entire spurt, as in assumption X1.2.3. This is not a good assumption with the test apparatus. Frictional drag forces are generated as the test fluid flows through the tubing, valve, and cannula. So, while the pressure in the reservoir is held constant by a regulator, the pressure at the exit of the cannula drops until a steady-state flow rate is reached. This takes about 0.1 s. This behavior can be observed subjectively by noting that the vertical position of the impact of the stream changes during the spurt. The initial impact can be over a centimeter higher than the impact of the steady-state flow. The frictional losses can also be determined quantitatively by plotting the velocity (or weight/valve time) for a range of spurt durations for a constant reservoir pressure, as in Fig. X1.1.

X1.8.2 The change in the height of the impact during the spurt can be used to ensure that only the steady-state flow impacts the specimen mask by aiming the stream through a small hole (0.5-cm [ $\frac{3}{16}$ -in.] diameter) in a plate blocking the mask. If the stream is aimed such that the steady-state flow

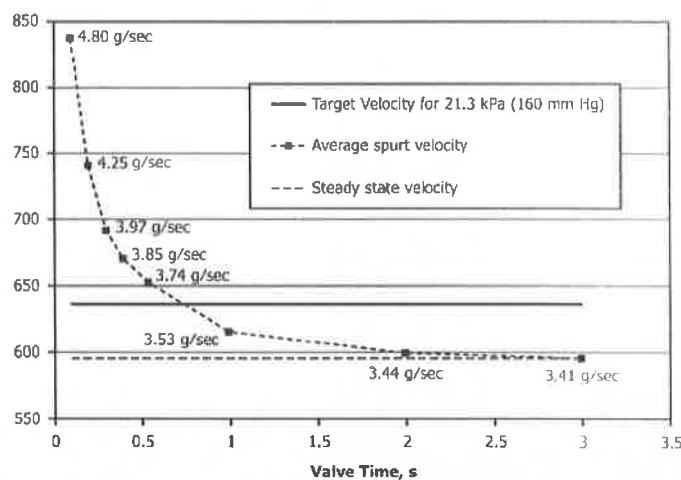


FIG. X1.1 Velocity Versus Valve Time

passes through the hole, the higher velocity part of the stream will be blocked as it will hit the plate above the hole.

X1.8.3 Eq X1.10 can be used to estimate the steady-state velocity. This is equation Eq X1.9 applied to the steady-state flow.

$$(\omega_2 - \omega_1) = v \frac{\pi \delta d^2}{4} (t_2 - t_1) \quad (\text{X1.10})$$

where:

$\omega_1$  = the mass of fluid delivered in time  $t_1$ ,  
 $\omega_2$  = the mass of fluid delivered in time  $t_2$ ,  
 $t_1$  = long enough to ensure the flow has reached steady state ( $>0.1$  s),  
 $t_2$  =

X1.8.4 Eq X1.10 can also be represented as:

$$(\omega_2 - \omega_1) = \frac{v(t_2 - t_1)}{C} \quad (\text{X1.11})$$

where:

$$C = \frac{4}{\pi \delta d^2} \quad (\text{X1.12})$$

Note that from a practical standpoint, the application of these equations is further simplified if  $t_2$  is set to 1 second greater than  $t_1$ . In which case, the time portion drops out as  $t_2 - t_1 = 1$ .

X1.8.5 If the standard conditions in this method are applied, where:

$d$  = 0.084 cm cannula inside diameter, and  
 $\delta$  = 1.005 g/cm<sup>3</sup> density of the test fluid,

then:

$C$  = 179.55 for  $\omega$  in grams and  $v$  in cm/s,  
 $C$  = 70.689 for  $\omega$  in grams and  $v$  in in./s,  
 $C$  = 2004.0 for  $\omega$  in ounces and  $v$  in in./s,

using:

$\pi$  = 3.1416,  
Inch = 2.5400 cm, and  
Ounce = 28.350 g.



TABLE X1.3 Target Weight Differences

Fluid Pressure kPa	Fluid Pressure mmHg	Target Velocity cm/s	Weight difference, in grams, for 1-s difference in spurt duration		
			g, min	g, target	g, max
10.7	80	450	2.456	2.506	2.556
16.0	120	550	3.002	3.063	3.124
21.3	160	635	3.466	3.537	3.607

The constant  $C$  shall be recalculated for fluids with specific gravities less than 0.995 or more than 1.015 (1 %); or for cannula of with inside diameters other than 0.084 cm.

X1.8.6 Eq X1.11 and the appropriate value for constant  $C$  can then be used to build a table of targets and limits for the differential spurt weights for specified velocities using the standard apparatus. Table X1.3 includes weight limits for and velocities  $\pm 2\%$  from the target velocity. Note again, that the duration of both spurts for the determining the differential spurt weights must be long enough to ensure steady-state flow. As steady state is reached in about 0.1 s, spurts of at least 0.25 s are recommended.

X1.9 In practice, the pressure of the fluid reservoir is adjusted until the differential weight of the spurts is within the limits for the desired velocity. The steady-state stream is then aimed through the hole in the targeting plate. The differential weight of the stream passing through the hole is also checked against the limits to ensure that stream is properly aimed.

X1.10 The amount of fluid reaching the mask through the targeting plate is then set by weighing the fluid passing through the targeting plate and adjusting the valve timer to achieve the target volume. For 2 mL of a test fluid with a density of  $1.005 \text{ g/cm}^3$ , 2.01 g of fluid shall pass through the targeting plate.

## X2. EXAMPLE SETUP WIZARD SPREADSHEET

X2.1 Fig. X2.1 is an example of a Microsoft Excel spreadsheet used to aid in the calibration calculations for this method.

The five framed text cells (B7:C8 and F18) are for input from the tester. Cells G6:G15 are white text on a green background indicating the pressure is acceptable for the 120-mmHg target. Cell C9 is red text and cells B10:C10 are blue on red, indicating that not enough of the spurt is getting through the targeting hole and either the stream needs to be re-aimed or the cannula replaced to try to reduce the spread of the droplets.

Conditional formatting has been used to aid in identifying in- or out-of-target conditions. In this example, the green cells (G6:G15) indicate that the pressure is within range for the 120-mmHg target. The red cells (C9 and B10:C10) indicate that not enough fluid is getting through the targeting hole, suggesting the aim is off or the cannula has is producing too wide of a spray pattern.

X2.2 Figs. X2.2-X2.4 show the formulas used in this spreadsheet.

X2.3 Conditional formatting of some of the cells can help. The following conditional formatting in Fig. X2.5 is for cell F6. The formatting for this cell can be copied to cells F6:H15. The conditional format is set to bold white text on a green background.

X2.4 If the steady-state pressure is between target pressure ranges, the spurt weight (B9) and the appropriate limit cells (F:13:H13 and F15:H15) can be with conditional formatting, as shown in Fig. X2.6, to show up as bold black font on a yellow background.





Microsoft Excel - Book1										
File Edit View Insert Format Tools Data Window Help Adobe PDF										
Type a question for help										
A1 ASTM F-1862-03 Calibration Spreadsheet										
	A	B	C	D	E	F	G	H	I	J
1	ASTM F-1862-03 Calibration Spreadsheet									
2	Enter data in the blue boxes for calibration.									
3	Maroon boxes are for reference to aid in									
4										
5	21-Jan-05 3:27 PM									
6		Spurt weight in grams (Before hole)	Spurt weight in grams (After hole)		mmHg	80	120	160		
7	1.5 s	4.78	4.44	g	Target vel.	450	550	635	cm	Target stream velocities
8	0.5 s	1.7	1.6	g						
9	difference	3.08	2.84	g	Tank Pr	4.95	6.5	8.3	psi	Approximate tank pressure for reference
10		92.2%			wt @1.5s	3.82	4.73	5.52	g	Approximate spurt weight for 1.5s for reference
11										
12	Approximate time for 2ml spurt through hole:						OK			
13		0.64 sec			Upper Limit	2.58	3.12	3.61	g	Weight limits for 2% velocity range
14	Steady state pressure and velocity of this spurt.				Target	2.51	3.06	3.54	g	
15		121.2	mmHg		Lower Limit	2.48	3	3.47	g	
16		553.0	cm/sec							
17					C	179.55	velocity to time conversion factor			
18						1.005	Specific gravity of the synthetic blood being used.			
19							(Must be updated if fluid s.g. is <0.995 or >1.015)			
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										
F1862 Calibration										

FIG. X2.1 Spreadsheet Example to Aid Calibration Calculations



Microsoft Excel - Book1				
File Edit View Insert Format Tools Data Window Help Adobe PDF				
B13      fx = (2*F18-C8)/C9+0.5				
	A	B	C	D
1	ASTM F-1862-03 Calli			
2	Enter data in the blue boxes for calibration			
3	Maroon boxes are for reference to aid in subsequent calibrations			
4				
5	=NOW()			
6		Spurt weight in grams (Before hole)	Spurt weight in grams (After hole)	
7	1.5 s	4.78	4.44	g
8	0.5 s	1.73	1.4	g
9	difference	=B7-B8	=C7-C8	g
10		=C9/B9		
11				
12	Approximate time for 2			
13		=(2*F18-C8)/C9+0.5 sec		
14	Steady state pressure and velocity of this spurt:			
15		=12.773*(B9)^2	mmHg	
16		=SQRT(B15)*18.779*2.54	cm/sec	
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
Ready      F1862 Calibration				

FIG. X2.2 Formulas Used for Spreadsheet, Part 1

Microsoft Excel - Book1		
File Edit View Insert Format Tools Data Window Help Adobe PDF		
E1		
	E	G
1		
2		
3		
4		
5		
6	mmHg 80	120
7	Target vel 450	550
8		
9	Tank Pr 4.95	6.5
10	wt @ 1.5s 3.82	4.73
11		
12	=IF(AND(\$B\$9<=F13,\$B\$9>=F15),"OK","")	=IF(AND(\$B\$9<=G13,\$B\$9>=G15),"OK","")
13	Upper Limit =ROUND(1.02*F7/\$F\$17.2)	=ROUND(1.02*G7/\$F\$17.2)
14	Target =+ROUND(F7/\$F\$17.2)	=+ROUND(G7/\$F\$17.2)
15	Lower Limit =ROUND(0.98*F7/\$F\$17.2)	=ROUND(0.98*G7/\$F\$17.2)
16		
17	C = 180.45/\$F\$18	velocity to time conversion factor
18	1.005	Specific gravity of the synthetic blood being used (Must be updated if fluid s.g. is <0.995 or >1.015)
19		
20		
21		
22		
23		
F1862 Calibration		
Ready NUM		

FIG. X2.3 Formulas Used for Spreadsheet, Part 2



Microsoft Excel - Book1			
File Edit View Insert Format Tools Data Window Help Adobe PDF			
Type a question for help			
E1			
	H	I	J
1			
2			
3			
4			
5			
6	160		
7	835	cm/s	Target stream velocities
8			
9	8.3	psi	Approximate tank pressure for reference
10	5.52	g	Approximate spurt weight for 1.5s for reference
11			
12	=IF(AND(\$B\$9<=H13,\$B\$9>=H15),"OK",")		
13	=ROUND(1.02*H7/\$F\$17,2)	g	Weight limits for 2% velocity range
14	=+ROUND(H7/\$F\$17,2)	g	
15	=ROUND(0.98*H7/\$F\$17,2)	g	
16			
17			
18			
19			
20			
21			
22			
23			
24			
F1862 Calibration			
Ready			
NUM			

FIG. X2.4 Formulas Used for Spreadsheet, Part 3



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F6 80

	E	F	G	H
1				
2				
3				
4				
5				
6	mm-Hg	80		
7	Target vel.	450		
8				
9	Tank Pr.	4.95		
10	w. @1.5s	3.82		
11				
12		=IF(AND(\$B\$9<=F13,\$B\$9>=F15),"OK",")		
13	Upper Limit	=ROUND(1.02*F7/\$F\$17,2)	=ROUND(1.02*G7/\$F\$17,2)	=ROUND(1.02*H7/\$F\$17,2)
14	Target	=+ROUND(F7/\$F\$17,2)	=+ROUND(G7/\$F\$17,2)	=+ROUND(H7/\$F\$17,2)
15	Lower Limit	=ROUND(0.98*F7/\$F\$17,2)	=ROUND(0.98*G7/\$F\$17,2)	=ROUND(0.98*H7/\$F\$17,2)
16				
17	C	=180.45/\$F\$18		
18		1.005		
19			velocity to time conversion factor	
20			Specific gravity of the synthetic blood being used.	
21			(Must be updated if fluid s.g. is <0.995 or >1.015)	
22				
23				
24				
25				
26				
27				
28				
29				

Conditional Formatting

Condition 1

Formula is: =F\$12="OK"

Preview of format to use when condition is true: AaBbCcYyZz

Format...

Add >> Delete... OK Cancel

Ready

NUM

FIG. X2.5 Conditional Formatting for Spreadsheet

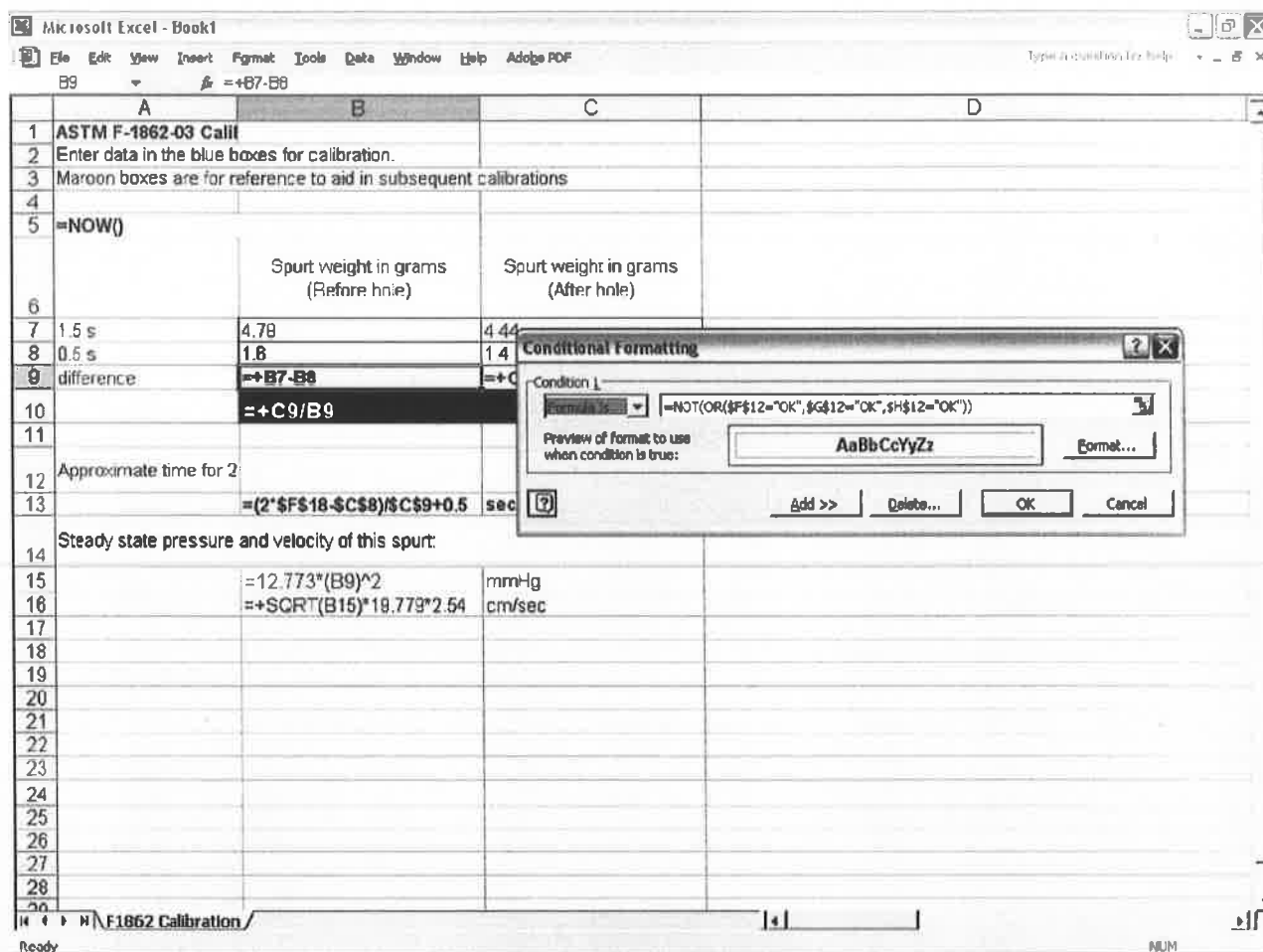


FIG. X2.6 Conditional Formatting Example

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