



Designation: F1862/F1862M – 13

# 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 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 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 Methods 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.*

## 2. Referenced Documents

2.1 *ASTM Standards:*<sup>2</sup>

<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.

Current edition approved Dec. 1, 2013. Published December 2013. Originally approved in 1998. Last previous edition approved in 2007 as F1862 - 07. DOI: 10.1520/F1862\_F1862M-13.

<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.

- 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** Practice for Conditioning and Testing Flexible Barrier Packaging
- F1494** Terminology Relating to Protective Clothing
- F1670** Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- F1671** 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.
- 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).

<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.

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

3.1.10.1 *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.

3.1.11 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 health care 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 corresponding stream or impact velocity, and determining the valve time to create that stream velocity as shown in [Appendix X1](#).

5.4.1 The mean human blood pressure generally varies over a range of about 10.7 to 16.0 kPa (80 to 120 mmHg).<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 mm Hg, and 160 mm Hg).

<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.

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](#) by dispensing a stream of 2 mL of synthetic blood against the target area of a complete medical mask specimen whereas Test Method [F1670](#) 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](#) is at hydrostatic pressure of 13.8 kPa [2.0 psig]. Test Method [F1670](#) is used for preliminary evaluation of protective clothing penetration resistance to synthetic blood in conjunction with Test Method [F1671](#) 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.

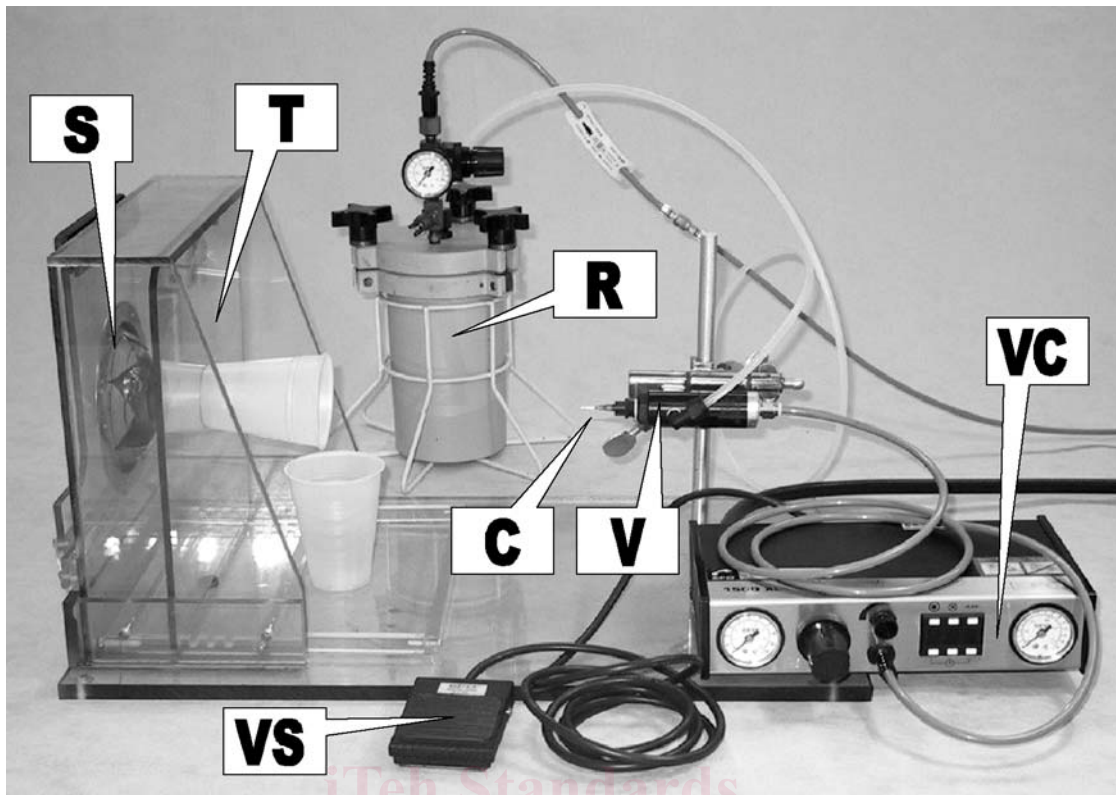
5.7 Users of this test method must realize that certain tradeoffs exist between improved resistance of medical face masks to penetration by synthetic blood and in pressure drop across mask materials as an indicator of medical face mask breathability. In general, increasing synthetic blood penetration 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  $21 \pm 5^\circ\text{C}$  [ $70 \pm 10^\circ\text{F}$ ]) 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 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 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

<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.



NOTE 1—

- |                                 |  |
|---------------------------------|--|
| S = Sample Holder               | T = Targeting Plate with Collection Cups |
| R = Pressurized Fluid Reservoir | C = Canula                               |
| V = Valve                       | VC = Valve Timing Controller             |
| VS = Valve Switch               |  |

FIG. 1 (a) Test Apparatus

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. As a 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 canula 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 canula 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

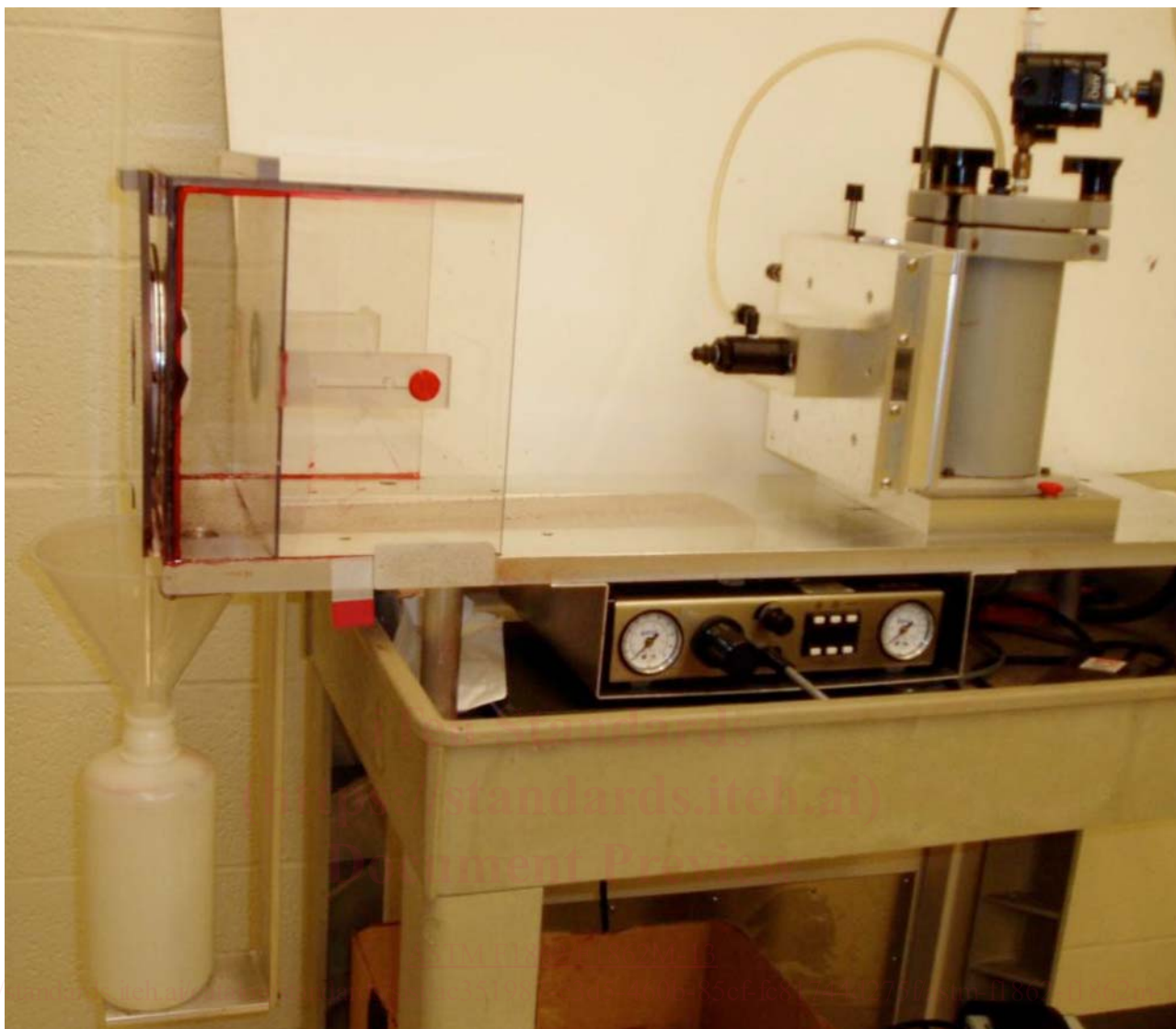


FIG. 1 (b) Test Apparatus (continued)

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 canula 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 sample 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 3/8 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 plumbers 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.

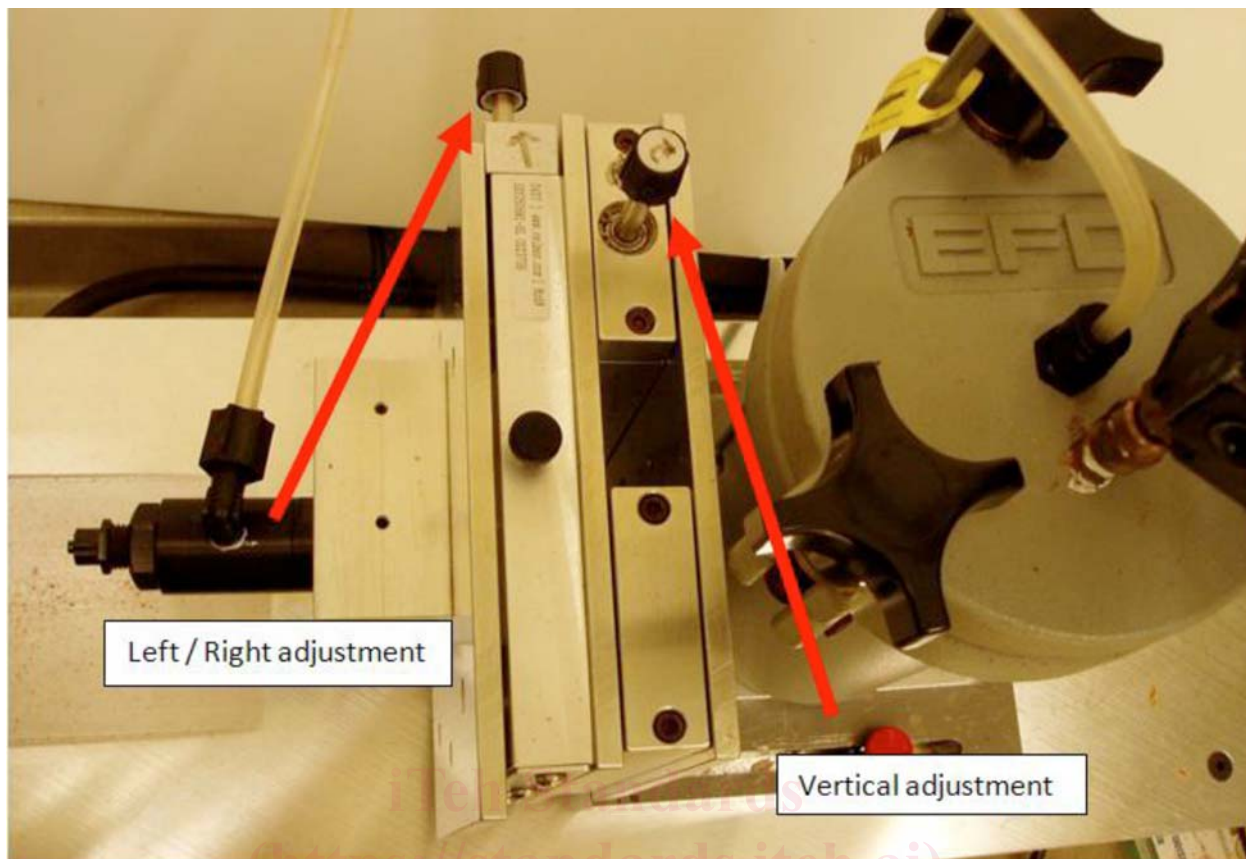


FIG. 1 (c) Left/Right and Vertical Adjustment (continued)

## Document Preview

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.] 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 3/16 in. diameter hole. Ensure that the thickness of the targeting plate at the hole does not exceed 3/16 in. beyond the hole and is made of clear plastic. The plate is configured upright and placed approximately 1/2 in. in front of the specimen mask, between the mask and the canula, 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 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 canula 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 canula, 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  $0.01 \pm 0.005$  seconds.

<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.

<sup>11</sup> Reference McMaster-Carr item 8635K161—12 in. by 12 in. sheets of 70A hardness 1/32 in. thick Buna-N gasket material. McMaster-Carr Supply Company, Atlanta, Georgia.

<sup>12</sup> Reference McMaster-Carr 3427A57—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

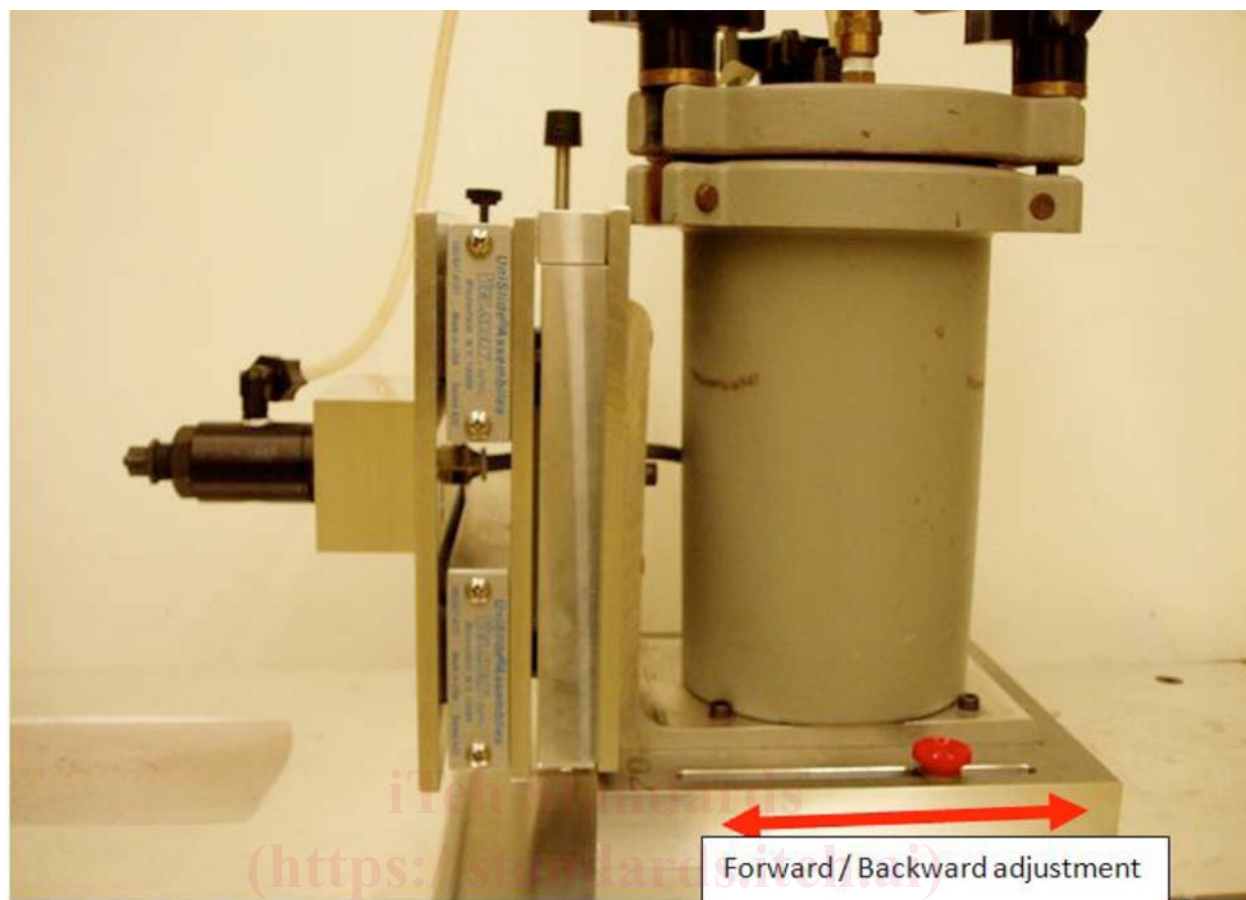


FIG. 1 (d) Forward and Backward Adjustment (continued)

6.1.5 *Canula*<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 canula with an internal diameter of 0.084 cm [0.033 in.].

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

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 grams.<sup>17</sup>

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

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*<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 (1.0 L, pH 7.0 ± 0.5).

7.1.2 *Thickening agent*, 25.0 g.

7.1.3 *Red dye*, containing colorant and surfactant, 10.0 grams.

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 ± 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.<sup>19</sup>

NOTE 2—The red dye will stain skin, clothes, and work surfaces.

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

<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.

<sup>18</sup> Prepared synthetic blood meeting this specification, and small quantities of Direct Red 081, CI No. 28160 (Morfast Red 8BL) and Acrysol G110 are available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.

<sup>19</sup> The red dye will stain skin, clothes, and work surfaces.

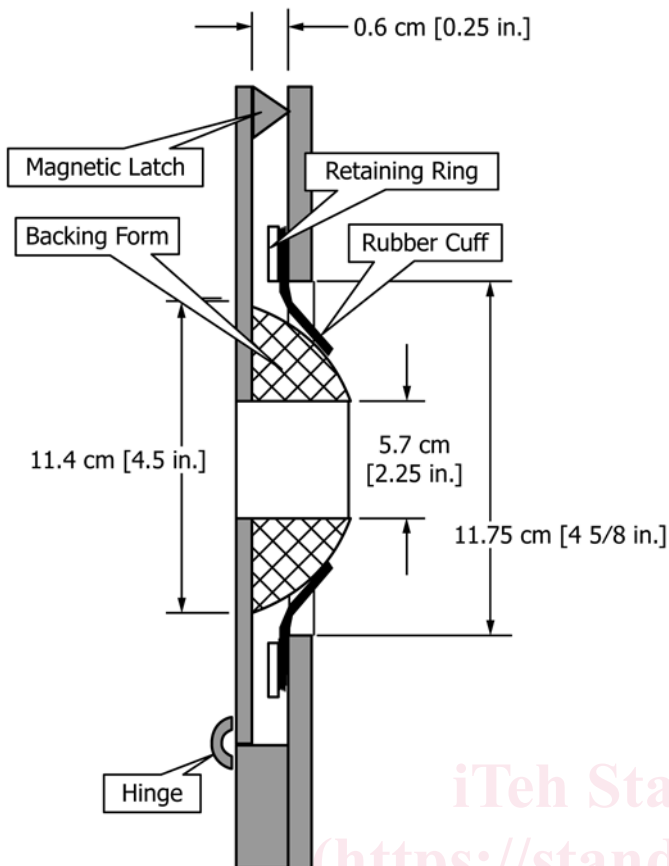


FIG. 2 Schematic of Specimen Holding Fixture



FIG. 3 Specimen Holding Fixture

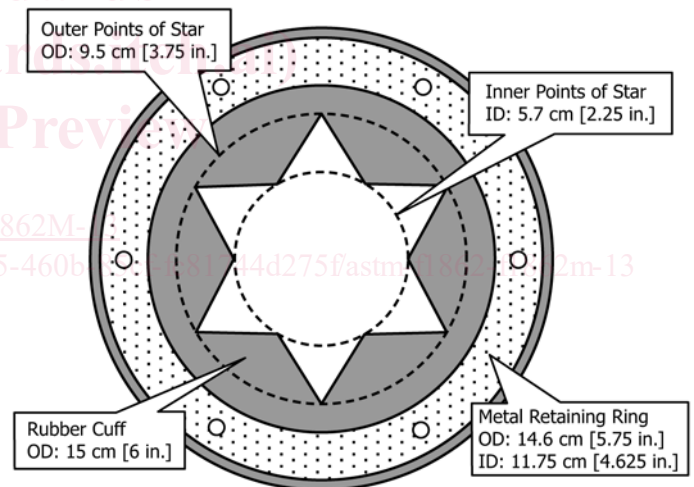


FIG. 4 Schematic of Specimen Retaining Cuff

7.1.7 Determine the corrected surface tension of the solution using Test Method D1331. The expected value of the corrected surface tension is  $0.042 \pm 0.002$  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, which varies batch to batch, affects the surface tension. 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 Determine the specific gravity of the solution using a hydrometer or pycnometer in accordance with Test Method 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 Store synthetic blood in a plastic or glass container at room temperature.

7.1.10 Ensure that the synthetic blood is thoroughly mixed before using.

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

7.2 Isopropanol, laboratory grade, for cleaning the apparatus.



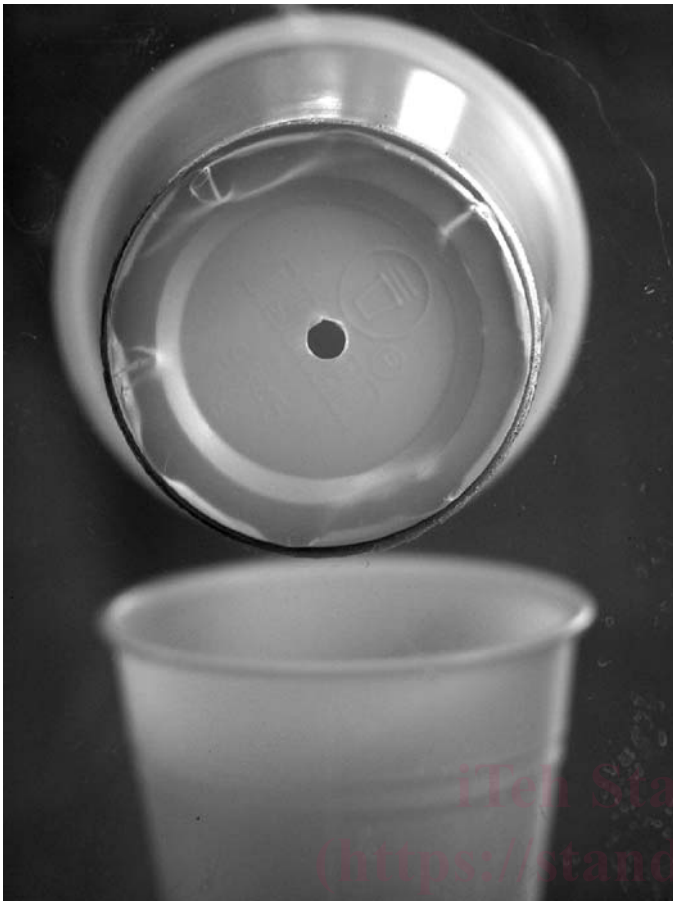


FIG. 5 Disposable Cup Targeting Plate

## 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 Specification E171 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 canula on the front of the pneumatic-controlled valve.

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

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 mm Hg, 120 mmHg, and 160 mm Hg).

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 seconds. Collect and weigh the amount of fluid delivered over a 0.5-s spurt.

11.3.4 Set the valve timer to 1.5 seconds. 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, canula sizes or fluids with other specific gravities.

11.3.6 Adjust the reservoir pressure and repeat steps 11.3.3 to 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.

11.3.8 Record the pressure in the reservoir. Use this as the initial reservoir pressure in subsequent testing to expedite set-up.

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 [ $\frac{1}{4}$  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 seconds.

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

**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**

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 3—As a setup aid, an alignment rod will help setup the 12 in. distance between mask and canula, and the ½ 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 seconds.

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 second and 1.5 second 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 to 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 ± 0.04 g for each individual spurt.

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

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).