



Designation: F1862/F1862M – 24

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

This standard is issued under the fixed designation F1862/F1862M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Workers, primarily those in the healthcare profession involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis (hepatitis B virus (HBV) and hepatitis C virus (HCV)) and acquired immune deficiency syndrome (AIDS) (human immunodeficiency virus (HIV)). Because engineering controls cannot 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 assessing the synthetic blood penetration resistance performance of medical face masks in a manner representing actual use as might occur when a high-velocity stream of blood from a punctured artery hits the face mask.

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 is primarily intended to address the performance of finished medical face masks. While this test method may also be used to assess performance of materials or certain material constructions used in medical face masks, it is important to note the performance of finished medical face masks may be impacted by the interaction of the materials used and how they have been assembled. Results can differ depending on testing a final finished medical face mask or materials taken from manufactured medical face masks.

1.4 This test method does not address 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).

1.5 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.

1.6 The values stated in SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the 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.

1.7 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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

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1.8 This international standard was developed in accordance with internationally recognized principles on standardization established in the *Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee*.

2. Referenced Documents

2.1 ASTM Standards:²

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

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

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

F2100 Specification for Performance of Materials Used in Medical Face Masks

2.2 ANSI/ASQC Standards:³

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

ANSI/ASQC Q3 Sampling Procedures and Tables for Inspection of Isolated Lots by Attributes

2.3 ISO Standards:⁴

ISO 28590 Sampling Procedures for Inspection by Attributes—Introduction to the ISO 2859 Series of Standards for Sampling for Inspection by Attributes

ISO 2859-1 Sampling Plans for Inspection by Attributes

ISO/TR 8550-1 Guidance on the Selection and Usage of Acceptance Sampling Systems for Inspection of Discrete Items in Lots—Part 1: Acceptance Sampling

ISO/TR 8550-2 Guidance on the Selection and Usage of Acceptance Sampling Systems for Inspection of Discrete Items in Lots—Part 2: Sampling by Attributes

2.4 OSHA Standard:⁵

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:

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

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

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

⁵ Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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

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

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

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

3.1.4.1 *Discussion*—In this test method, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

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

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

3.1.7 *penetration, n*—for biological protective clothing, the flow of a body fluid on a non-molecular level through closures, porous materials, seams, and pinholes, or other imperfections in protective clothing.

3.1.7.1 *Discussion*—In this test method, the penetration liquid is synthetic blood, a body fluid simulant.

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

3.1.8.1 *Discussion*—In this test method, medical face masks are evaluated. The potential hazard of contact with blood or other body fluids is being simulated.

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

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

3.1.10 *synthetic blood, n*—a mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

3.1.10.1 *Discussion*—The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids, for example, polarity (wetting characteristics), coagulation, and content of cell matter.

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

4. Summary of Test Method

4.1 A volume of synthetic blood is disbursed at a specimen mask 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, or 635 cm/s. These correspond to the velocity exiting a small arterial puncture at human blood pressures of 10.7, 16.0, or 21.3 kPa (80, 120, or 160 mmHg). Results are reported for each velocity or corresponding pressure tested.

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 may be 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.⁶ 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 40 ± 5 dyn/cm (0.040 ± 0.005 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).⁷ In this test method, medical face masks are tested at stream velocities corresponding to 10.7 kPa, 16.0 kPa, and 21.3 kPa (80 mmHg, 120 mmHg, and 160 mmHg).

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

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

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

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

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

⁶ 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.

⁷ Barach, P. G., Cullen, B. F., and Stoelting, R. K., *Handbook on Clinical Anesthesia*, Appendix A, J. B. Lippincott Co., Philadelphia, 1994.

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.⁸ 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 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 to determine the required number of specimens to be tested. Sampling conducted in this way helps to establish confidence limits concerning product performance. The sampling plan or statistical approach selected should be designated or approved by the relevant responsible authority. Examples of acceptable sampling plans are found in references such as the ISO 2859 series of standards for inspection by attributes and ANSI/ASQC Z1.4 and ANSI/ASQC Q3.

NOTE 1—Guidance on the selection of acceptance sampling plans can be found in references such as ISO/TR 8550-1 and ISO/TR 8550-2.

NOTE 2—Subject to the purpose of testing the relevant responsible authority may be a first, second, or third party. Further information about responsible authorities in the context of acceptance sampling plans (including examples, duties, and functions) can be found in references such as 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

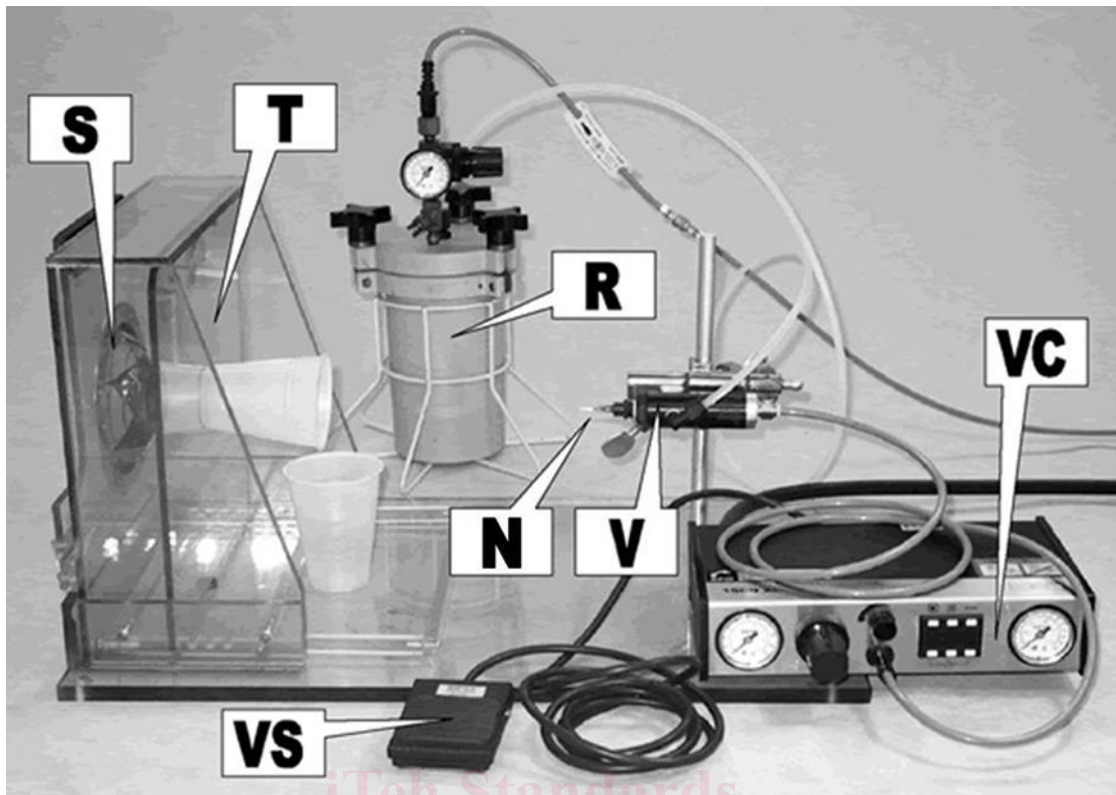
6.1 *Test Apparatus*, to dispense a specified volume of synthetic blood through a small diameter nozzle over a controlled amount of time at a specimen mask a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a valve, delivery nozzle, 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 the nozzle position and also helps keep the 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 3.) The form has a 5.7 cm [2.25 in.] diameter viewing hole through its center as shown in Figs. 2 and 3.

NOTE 3—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), and a 2 in. PVC tubing union (5.7 cm [2.25 in.] outside diameter, found at home improvement centers). Mark a ring around the outside of the union 3.0 cm [1³/₈ in.] 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 10.5 cm [4.125 in.]. 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 355 mL [12 fl 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

⁸ 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.



S = Specimen Holder
R = Pressurized Fluid Reservoir
V = Valve
VS = Valve Switch

T = Targeting Plate with Collection Cups
N = Nozzle
VC = Valve Timing Controller

FIG. 1 (a) Test Apparatus

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 hinged⁹ 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 [4⁵/₈ 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 70.¹⁰ 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 0.48 cm [³/₁₆ in.] diameter hole. Ensure that the thickness of the targeting plate at the hole does not exceed 0.48 cm [³/₁₆ in.] beyond the hole and is made of clear plastic. The plate is configured upright and placed approximately

⁹ A continuous plastic hinge provides a little more give than a rigid piano hinge. Reference McMaster Carr 11195A41. McMaster-Carr Supply Company, Atlanta, Georgia.

¹⁰ 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.

1.27 cm [¹/₂ in.] in front of the specimen mask, between the mask and the nozzle, 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 0.48 cm [³/₁₆ in.] diameter cut out of the bottom.¹¹ 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*,¹² 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 nozzle 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 nozzle, which can lead to inconsistent valve performance.

¹¹ Reference McMaster-Carr 3427A57 – ³/₁₆ in. Arch Punch for making the targeting plate holes in soft materials. McMaster-Carr Supply Company, Atlanta, Georgia.

¹² Reference NORDSON EFD LLC, 725D pneumatic fluid dispensing valve or equivalent. NORDSON EFD LLC, 40 Catamore Blvd. East Providence, RI 02914.

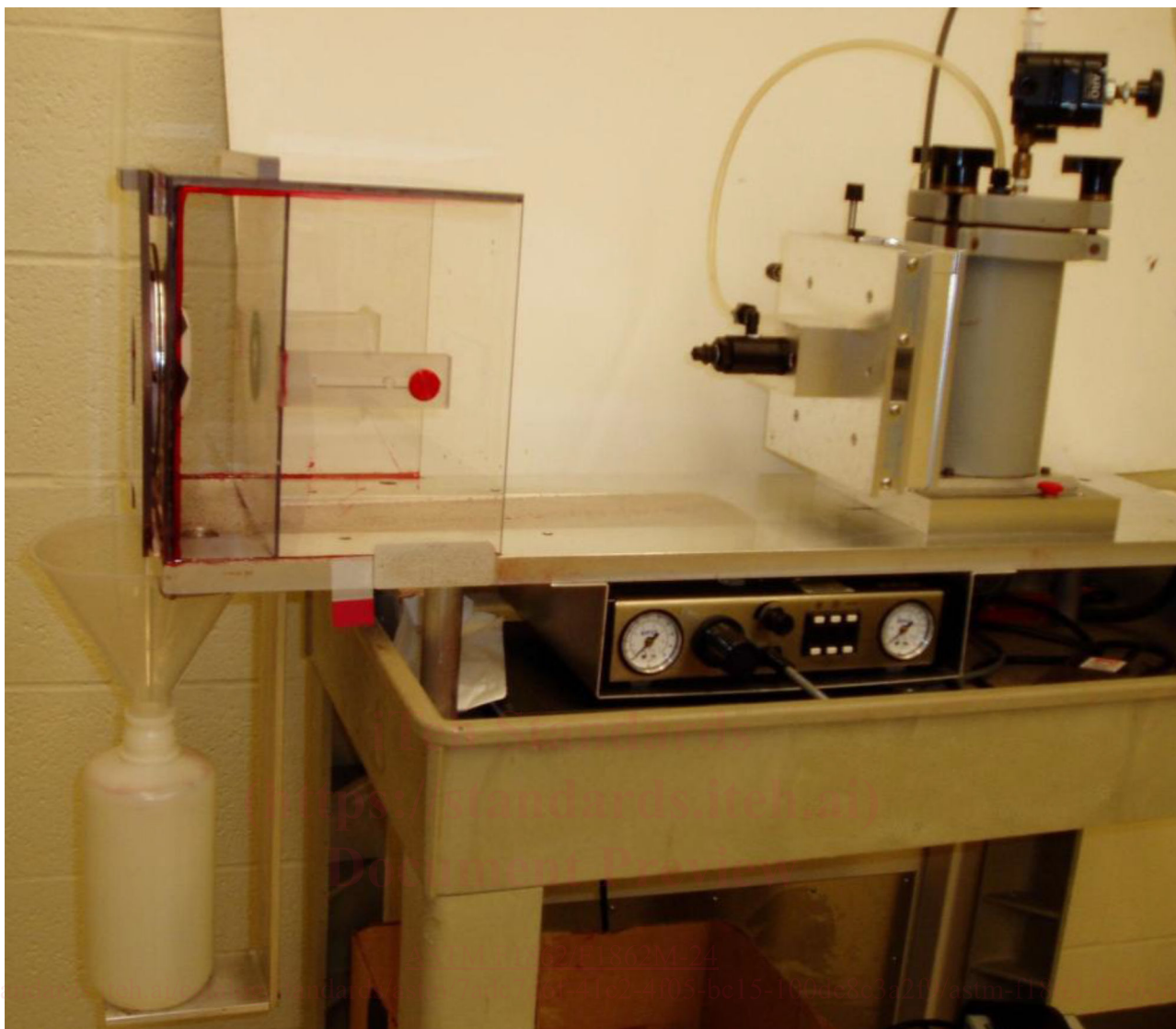


FIG. 1 (b) Test Apparatus (continued)

6.1.4 *Valve Controller*,¹³ to set the duration of the fluid spurt. Use a valve controller with a resolution and accuracy of at least 0.01 ± 0.005 s.

6.1.5 *Nozzle*,¹⁴ which attaches to the exit of the valve for delivering the spurt. The standard for this method is a 1.27 cm [0.5 in.] long, 18 gauge stainless steel cylindrical tube cannula with an internal diameter of 0.084 cm [0.033 in.].

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

6.1.6 *Pressure-Regulated Fluid Reservoir*, to contain the synthetic blood for delivery to the valve/nozzle assembly.¹⁵

¹³ Reference NORDSON EFD LLC, 1500D controller or equivalent. A remote hand or foot actuated switch can also be used with the 1500D controller. NORDSON EFD LLC, 40 Catamore Blvd. East Providence, RI 02914.

¹⁴ Reference NORDSON EFD LLC, Part Number 5118-B. NORDSON EFD LLC, 40 Catamore Blvd. East Providence, RI 02914.

¹⁵ Reference NORDSON EFD LLC, parts: 615DTH fluid reservoir; 615DRL fluid reservoir cover and liner; 61520 reservoir stand; 2000f755 air filter and regulator; 1116 air tree. NORDSON EFD LLC, 40 Catamore Blvd. East Providence, RI 02914.

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.¹⁶

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

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*¹⁷—If synthetic blood is not purchased, prepare using the following ingredients:

¹⁶ Weighing the fluid output is faster and more accurate than measuring the fluid volume.

¹⁷ Acrysol G111 is available from Dow Chemical Company.

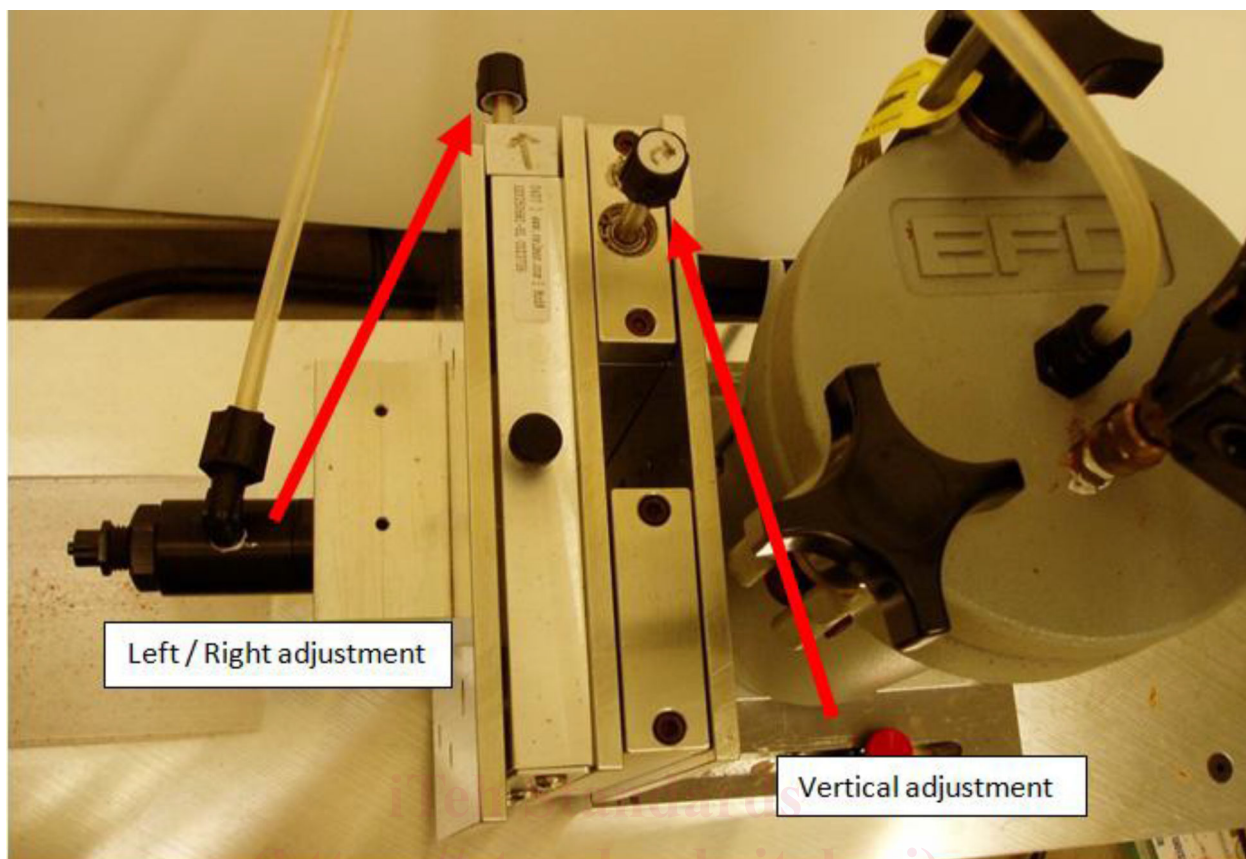


FIG. 1 (c) Left/Right and Vertical Adjustment (continued)

7.1.1 High Performance Liquid Chromatography (HPLC) Quality Distilled Water, 0.975 L, pH 7.0 ± 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 ± 1 °C after boiling.

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

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

NOTE 4—The red dye will stain skin, clothes, and work surfaces.

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 ± 5 dyn/cm (0.040 ± 0.005 N/m).

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 ± 1 dyn/cm and is not significantly affected by time.¹⁸

¹⁸ The capillary tube may be purchased from Fisher Scientific, Catalog #14-818, and the instructions and calculations are specified in the instruction manual.

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

NOTE 5—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 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.

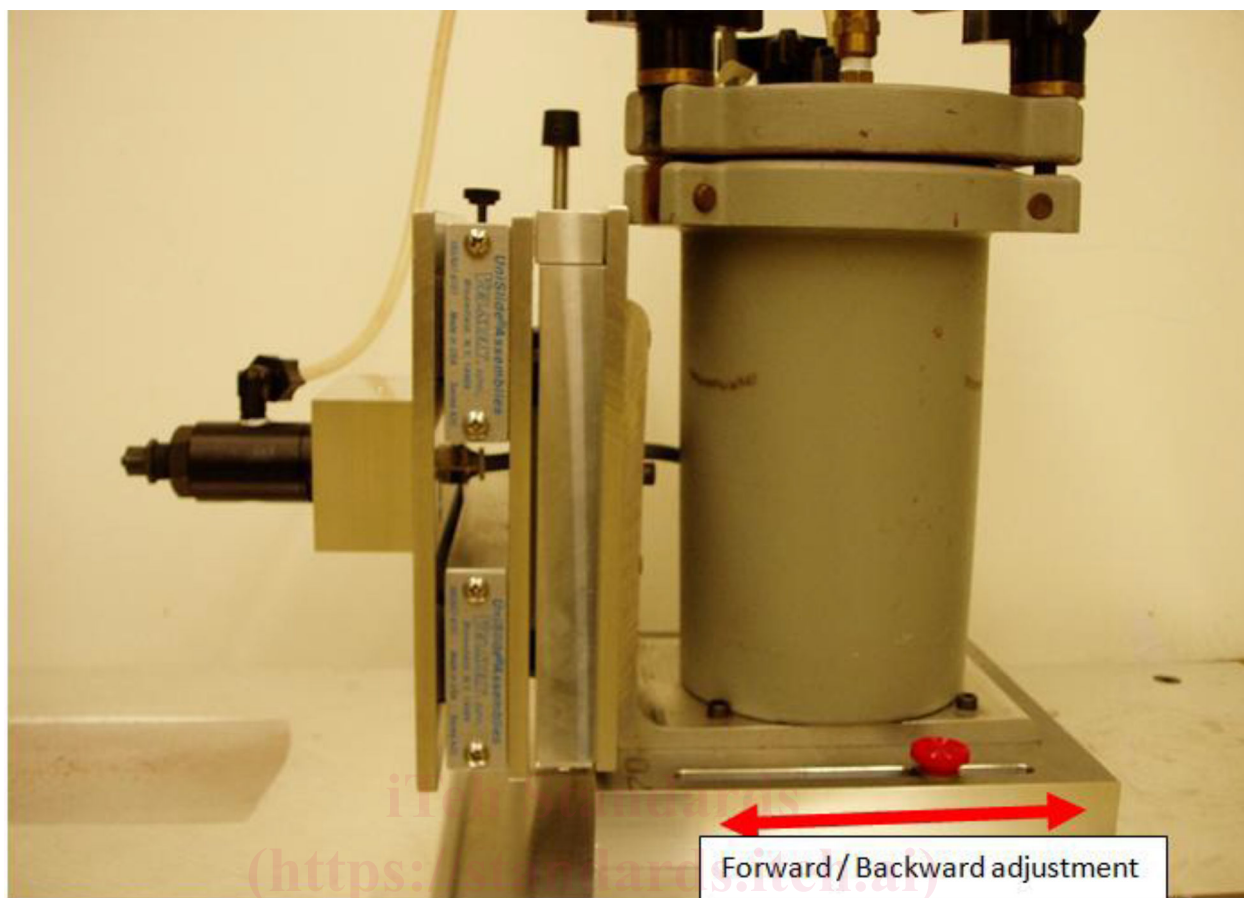


FIG. 1 (d) Forward and Backward Adjustment (continued)

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.

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 minimum of 32 specimens at the selected test pressure.

NOTE 6—The number of specimens to test and the number of failures allowed are typically dictated by other product specifications or standards such as applicable regulatory requirements or guidances, consensus standards such as Specification F2100, or the manufacturer's internal specifications and quality control plan.

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 ± 5 °C [70 ± 10 °F] and a relative humidity of 85 ± 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

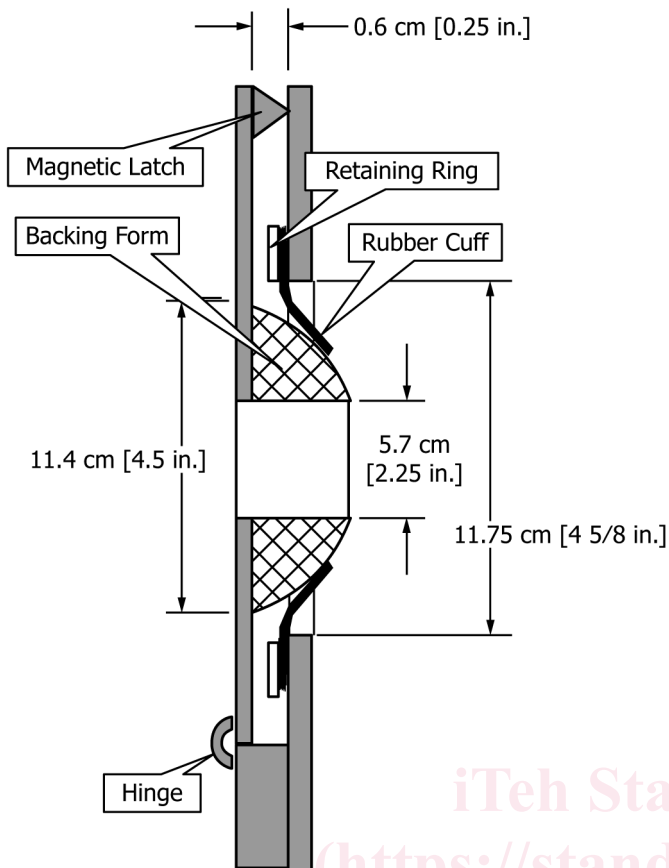


FIG. 2 Schematic of Specimen Holding Fixture



FIG. 3 Specimen Holding Fixture

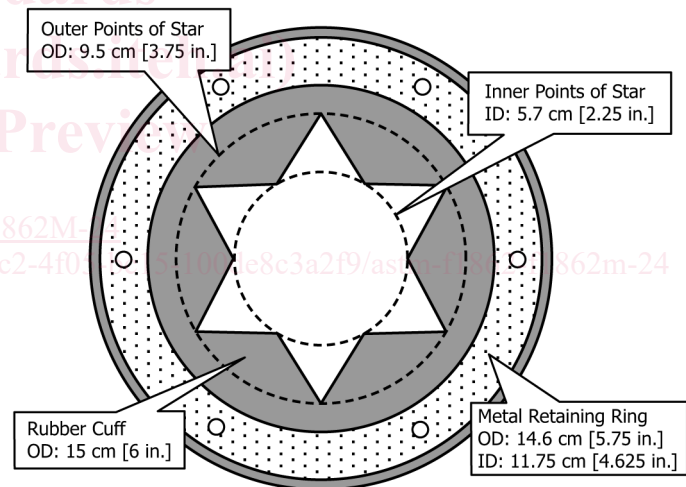


FIG. 4 Schematic of Specimen Retaining Cuff

atmosphere representative of the specified conditioning environment prior to testing.

11. Preparation and Cleaning of Test Apparatus¹⁹

11.1 Install a clean nozzle 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 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.

¹⁹ As the setup and calibration of the apparatus involve several repeated calculations, the use of a spreadsheet to aid in these calculations is recommended.

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, nozzle 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.



FIG. 5 Disposable Cup Targeting Plate

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 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 1.27 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 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 7—As a setup aid, an alignment rod will help set up the 30.5 cm [12 in.] distance between mask and nozzle, and the 1.27 cm [$\frac{1}{2}$ 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/cm³, 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: $t = 0.5 + (2.01 \text{ g at } 0.5 \text{ s}) / (\text{g at } 1.5 \text{ s} - \text{g at } 0.5 \text{ s})$.

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 specimens at stream velocities of 450, 550, or 635 cm/s, corresponding to blood pressures of 10.7 kPa, 16.0 kPa, or 21.3 kPa (80 mmHg, 120 mmHg, or 160 mmHg).

11.6.1 If specimens are tested at higher stream velocities and meet pass criteria for sampling applied, 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 nozzle is left for 1 h or more without use after passing synthetic blood during testing, replace with a clean nozzle and clean the used nozzle.

11.8.1 Clean the nozzle 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