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Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

Vêtements de protection contre les agents infectieux — Masques faciaux médicaux — Méthode d'essai de la résistance à la pénétration par un sang synthétique (volume fixe, projection horizontale)



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22609 was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*. It is based on ASTM F1862-00a^[4].

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 that cause hepatitis [Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)] and acquired immune deficiency syndrome (AIDS) [Human Immunodeficiency Virus (HIV)]. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact through the use of protective clothing that resists penetration. 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.

The test method is intended to evaluate the protection of the health care provider's face from exposure to blood and body fluids. It is used to evaluate the resistance of medical face masks to penetration by synthetic blood under high-velocity liquid contact with the medical face mask surface of a fixed volume over a relatively short period of time (0 s to 2,5 s). Medical face mask "pass/fail" determinations are based on visual detection of synthetic blood penetration.

NOTE 1 Medical face masks are intended to resist liquid penetration from the splatter or splashing of blood, body fluids, and other potentially infectious materials. Many factors can 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. The surface tension range for blood and body fluids (excluding saliva) is approximately 0,042 N/m to 0,060 N/m^[1]. To help simulate the wetting characteristics of blood and body fluids, the surface tension of the synthetic blood is adjusted to approximate the lower end of this surface tension range. The resulting surface tension of the synthetic blood is (0,042 ± 0,002) N/m.

NOTE 2 During a medical procedure, a blood vessel can be punctured resulting in a high-velocity stream of blood impacting a protective medical face mask. The impact velocity depends on several factors, the most important being the blood pressure of the patient. A second factor is the distance from the puncture. The velocity of larger punctures drops because the pressure in the blood vessel drops quickly. Because only small punctures cause high-velocity streams, large punctures were not used to model the range of blood-splatter velocities considered in this test. Furthermore, this test method is based on the assumption that the medical face mask will be in close proximity to the puncture area. This test method is therefore based on the impact velocity of a stream of fluid that corresponds to the target blood pressure.

NOTE 3 The mean human blood pressure generally varies over a range of about 10,6 kPa to 16,0 kPa (80 mm Hg to 120 mm Hg)^[2]. In this test method, medical face masks are tested at stream velocities corresponding to 10,6 kPa, 16,0 kPa, and 21,3 kPa (80 mm Hg, 120 mm Hg, and 160 mm Hg, respectively). 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.

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

This International Standard 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, interfaces or other factors which may affect the overall protection offered by the medical face mask and its operation (such as filtration efficiency and pressure drop).

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 as protection against contamination via airborne exposure pathways or in the prevention of the penetration of aerosolized body fluids deposited on the medical face mask.

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NOTE 4 Users of this test method should realize that certain tradeoffs exist between improved resistance of medical face masks to penetration by synthetic blood and in pressure drop across mask materials which is an indicator of the breathability of the face mask. 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.

NOTE 5 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, an approved respirator should be used. This test method can be used to evaluate the resistance of a respirator to penetration by synthetic blood, if warranted.

Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

1 Scope

This International Standard describes a laboratory test method for measuring the resistance of medical face masks to penetration by a splash of synthetic blood.

This International Standard 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, interfaces or other factors which may affect the overall protection offered by the medical face mask and its operation (such as filtration efficiency and pressure drop).

This test method does not evaluate the performance of medical face masks as a protection against contamination via airborne exposure pathways or in the prevention of the penetration of aerosolized body fluids deposited on the medical face mask.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 304, *Surface active agents — Determination of surface tension by drawing up liquid films*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

aerosolized body fluids

body fluids which have been dispersed into air as very small liquid droplets

3.2

airborne exposure pathways

inhalation routes of exposure to the medical face mask wearer

NOTE Inhalation routes of exposure do not include streams of blood or body fluid that may be expelled from a wound.

3.3

blood-borne pathogen

any infectious secreted or excreted bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids

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3.4

body fluid

any liquid produced (secreted or excreted) by the body

NOTE For the purpose of this International Standard, body fluids include those 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.

3.5

body-fluid simulant

liquid which is used to act as a model for human body fluids

3.6

medical face mask

item of protective clothing designed to protect portions of the wearer's face, including at least the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures

3.7

penetration

flow of particles or liquids through closures, porous materials, seams and holes or other imperfections in a protective clothing material

NOTE In this International Standard, the penetration liquid is synthetic blood.

3.8

protective clothing

any material or combination of materials used in an item of clothing for the purpose of isolating parts of the body from contact with a potential hazard

NOTE For the purpose of this International Standard, the potential hazard of contact with blood or other body fluids is simulated.

3.9

synthetic blood

mixture of amaranth dye, surfactant, thickening agent, inorganic salts and distilled water having a surface tension representative of blood and some other body fluids

NOTE The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids. For example, this synthetic blood does not simulate polarity (wetting characteristics), coagulation, or content of cell matter.

4 Principle

A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario.

Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail".

Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10,6 kPa, 16,0 kPa, and 21,3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4,0.

NOTE This test method differs from ISO 16603 by dispensing a stream of 2 ml of synthetic blood against the target area of a complete medical mask specimen whereas ISO 16603 involves the continuous contact of a specimen of protective clothing with synthetic blood over the period of an hour. The exposure time of 1 min in ISO 16603 is at a hydrostatic pressure of 13,8 kPa. ISO 16603 is used for preliminary evaluation of protective clothing penetration resistance to synthetic blood in conjunction with ISO 16604, which uses a microbiological challenge. Both procedures are intended for assessment of protective clothing that has the potential to contact blood or other body fluids for extended periods of time, and under pressure.

5 Apparatus and materials

5.1 Equipment

5.1.1 Test apparatus, capable of affixing the specimen medical face mask and dispensing synthetic blood at the target area of the specimen and consisting of a specimen-holding fixture, a fluid reservoir, a pneumatic-controlled valve and valve controller to dispense a specified volume of synthetic blood through a small-diameter canula in a controlled amount of time, and a valve control switch as shown in Figure 1.

Dimensions for the test apparatus are provided in Figure 2. A parts list for the test apparatus is given in Annex A. Alternative designs are permitted as long as the same operational characteristics are achieved.

Dimensions for the specimen-holding fixture are provided in Figure 3. It should be convex and apply only enough pressure to gently stretch the specimen while holding it firmly in place 300 mm from the tip of the canula on the valve. Metal clips or an elastic cuff may be used to hold the specimen against the fixture provided they remain away from the target area and do not damage the specimen.

NOTE The specimen-holding fixture illustrated in Figures 2 and 3 consists of a platform on which is mounted an open-ended transparent plastic box. The platform is fitted with a vertical ring clamp used to hold the pneumatic valve. The front of the box has a hole cut in it to fit the convex mounting fixture on the outer door where the specimens are positioned. The outer door is closed with the specimen in position and the specimen is held between the wall of the box and the door. The door is held closed by magnetic strips along the top of the box and the door. A hole is cut through the centre of the convex specimen-mounting fixture and the door to allow the test operator to visually note if any fluid penetrates to the inside layer of the specimen medical face mask.

5.1.2 Air-pressure source, capable of providing air at a gage pressure of (700 ± 25) kPa.

5.1.3 Graduated cylinder, calibrated and graduated to measure liquid with a precision of 0,1 ml.

NOTE A 10 ml graduated cylinder with an expanded lip has been found to be a convenient size.

5.1.4 Balance, calibrated and with a precision of at least 0,01 g.

5.1.5 Temperature/humidity recorder, capable of monitoring the ambient temperature (to $\pm 0,5$ °C) and humidity (to ± 1 %) during testing.

5.1.6 Controlled temperature and humidity chamber or space, capable of maintaining the specified temperature and humidity conditions for preconditioning of specimens.

5.1.7 Targeting plate, a recommended addition to the test apparatus, consisting of a plate with a 0,5 cm hole as shown in Figures 3 and 4, which can be positioned so that the hole is centred approximately 1 cm in front of the specimen mask, between the mask and the canula, such that the fluid stream passing through the hole impacts the centre of the specimen mask. The targeting plate blocks the high pressure leading edge of the stream and allows only the steady-state stream to impact the mask, thus increasing the accuracy and repeatability of the velocity of the stream which impacts the specimen masks. Subclause 7.3 should be used for setting the test pressure when using the targeting plate.

The splatter of fluid hitting the targeting plate can be contained by using a disposable plastic cup with the appropriately sized hole punched in the bottom as the targeting plate. The cup is mounted horizontally with the opening facing the nozzle by any convenient method. The cup in Figure 4 is supported by a sheet of lexan. The cup fits in a hole in the lexan that is the diameter of the base of the cup. The lexan is set in a notched

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stand to hold it upright. A second cup placed below the lip of the targeting cup can be used to collect the run-off.

5.2 Reagents

5.2.1 Synthetic blood, prepared as described in Annex B.

NOTE Because the synthetic blood readily stains clothing, wear a laboratory coat or similar cover during testing. Wear a face shield or use a fixed shield if standing behind the test specimen for observing its performance.

5.2.2 Isopropanol, of laboratory grade, for cleaning the canula and surfaces contacted by the synthetic blood.

6 Specimens

Use complete medical face masks as the test specimen.

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. 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.

Test a sufficient number of specimens taken at random for each type, design, or lot of medical face masks to achieve an acceptable quality limit (AQL) of 4,0 %, as defined in ISO 2859-1, at each selected test pressure.

NOTE A single sampling plan providing an AQL of 4,0 % requires 32 specimens.

If warranted, use other pre-treatment options, such as pre-wetting, to assess possible mechanisms which degrade the effectiveness of medical face masks.

Testing without including degradation by physical, chemical, and thermal stresses that could negatively impact the performance of the protective barrier, might lead to a false sense of security. Consider tests that assess the impact of storage conditions and shelf life for disposable products, and the effects of laundering and sterilization for reusable products. The integrity of the protective clothing can also be compromised during use by such effects as flexing and abrasion^[3]. It is 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 pre-treatment technique representative of the expected conditions of use.

Condition each specimen for a minimum of 4 h by exposure to a temperature of $(21 \pm 5) ^\circ\text{C}$ and a relative humidity of $(85 \pm 5) \%$ using a controlled temperature and humidity chamber or space.

This test method involves the preconditioning of specimen medical face masks in a relatively high humidity environment $(85 \pm 5) \%$ relative humidity at $(21 \pm 5) ^\circ\text{C}$ 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 pre-treatment techniques may be used in conjunction with this test method. Professional health care providers recommend that medical face masks be replaced when saturation occurs from breathing or from contact with other liquids.

7 Procedure

7.1 Preparation and cleaning of test apparatus

NOTE 1 An alternative test set-up procedure is provided in 7.3 that utilizes a targeting plate to ensure a more accurate and uniform velocity of fluid to the specimen mask.

Prepare and clean the test apparatus using the following steps.

- a) Install a clean 12,7 mm long canula with an inside diameter of 0,84 mm on the front of the pneumatic-controlled valve.
- b) Fill the reservoir with new synthetic blood (approximately 1 l).
- c) Set the valve time corresponding to the blood pressure being assessed in accordance with Table 1. If non-standard pressures, fluid volumes (2 ml) or canula sizes (0,084 cm ID) are employed, the valve time should be calculated using Equations (C.4) and (C.7) in Annex C.

Table 1 — Valve times for standard test pressures

Pressure (kPa)	Velocity (cm/s)	Valve time for standard apparatus and fluid (s)
10,6	450	0,80
16,0	550	0,66
21,3	635	0,57

NOTE 2 For the purposes of this test method, as a minimum three different sets of specimens at stream velocities corresponding to blood pressures of 10,6 kPa, 16,0 kPa, and 21,3 kPa are evaluated.

- d) Adjust the reservoir pressure as needed to achieve a flow of 2 ml for the selected valve time.
- e) Verify the amount of synthetic blood delivered to be 2 ml by conducting trials into a graduated cylinder.

Alternatively, the volume of synthetic blood can be measured by determining the mass using a balance. For the standard fluid, with a specific gravity of 1,005, the 2 ml of fluid would weigh $(2,010 \pm 0,040)$ g.
- f) After every 16 specimens, ensure that the test apparatus is delivering 2 ml of synthetic blood by following the method calibration steps as directed in 7.1 d) and 7.1 e).
- g) If the canula is left unused for 1 h or more after synthetic blood has passed through it during testing, replace it with a clean canula and clean the used canula.
- h) Clean the canula by immersing in isopropanol for 24 h and rinsing with distilled water.
- i) Following testing, clean the system lines and the reservoir with distilled water. Do not use isopropanol or other solvents on the valve or system lines as the valve may be damaged.

7.2 Test procedure

Use the following steps to evaluate medical face masks.

- a) Conduct all testing in an environment having a temperature of (21 ± 5) °C and a relative humidity of (85 ± 10) %.
- b) 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 shall be easily visible to ensure that any droplet that penetrates the material will be seen. If not, use talcum powder on the normal inside surface of the medical face mask to enhance droplet visibility.
- c) Remove a specimen from the conditioning chamber. Mount the specimen on the specimen-holding fixture and position the specimen for impact of the synthetic blood to occur in the target area.

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 centre of the specimen as the target area.

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Position the end of the pneumatic-controlled valve at a distance of (300 ± 10) mm from the target area from the specimen.

- d) Squirt the synthetic blood onto the specimen medical face mask. Ensure that the synthetic blood hits the target area of the medical face mask. Conduct the test within 60 s after removal from conditioning chamber.
- e) Inspect the viewing side of the specimen for synthetic blood (10 ± 1) s after squirting the synthetic blood against the target area. Note whether any synthetic blood or other evidence of wetness, or both, appears on the viewing side of the specimen using suitable lighting.

Use a cotton absorbent swab or similar item to lightly daub the target area if there is any doubt regarding the visible penetration of the synthetic blood.

- f) Test the remaining specimens.

7.3 Alternative test set-up using a targeting plate

The following procedure improves the accuracy of the velocity of the stream hitting the target mask. Once the valve opens, the pressure of the fluid at the tip drops as frictional losses build as the fluid flows through the tubing, valve and canula. The net result is that the pressure of the initial portion of the stream can be two to three times the target pressure. This procedure blocks this high-pressure stream and allows only the fluid travelling at the target velocity to hit the mask.

- a) Set the valve time to 0,5 s.
- b) Collect and weigh the amount of fluid delivered from the nozzle.
- c) Set the valve time to 1,5 s.
- d) Collect and weigh the amount of fluid delivered from the nozzle.
- e) Calculate the difference in mass of the two spurts. For a test fluid with a specific gravity of 1,005, Table 2 gives the target difference in mass plus lower and upper limits for a velocity range within 2 % of the target. See Annex B to determine the target mass differences for other velocities, canula sizes or fluids with other specific gravities.

Table 2 — Weight differences for test method fluid pressures and target velocities

Fluid pressure		Target velocity (cm/s)	Mass difference for 1 s difference in spurt duration		
(kPa)	(mmHg)		Minimum (g)	Target (g)	Maximum (g)
10,6	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

- f) Adjust the reservoir pressure as necessary and repeat steps 7.3 a) through 7.3 e) until the mass difference is within the target range.
- g) Once the reservoir pressure has been set, do not change the relative height of the reservoir and nozzle.
- h) The targeting plate should be placed approximately 1 cm away from the mask and be located such that the fluid passing through the hole in the targeting plate hits within 0,6 cm of the centre of the hole in the specimen holding form.

- i) Adjust the aim of the valve assembly such that the steady-state portion of the stream passes cleanly through the targeting hole. The initial portion of the stream should hit above the hole.
- j) Set the valve time to 0,5 s.
- k) Collect and weigh the amount of fluid passing through the targeting hole.
- l) Set the valve time to 1,5 s.
- m) Collect and weigh the amount of fluid passing through the targeting hole.
- n) The difference in mass between the 0,5 s and 1,5 s deliveries through the targeting plate hole should be within $\begin{matrix} +2\% \\ -5\% \end{matrix}$ of the difference in mass from the nozzle [7.3 f)].
- o) If the differential mass through the hole is less than 95 % of the mass difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.
- p) If the mass differential is more than 102 % of the mass difference exiting the nozzle, repeat the collecting and weighing process in 7.3 a) to 7.3 f).
- q) Adjust the timer setting 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 should weigh 2,01 g.
- r) Record the timer setting to use as the starting point for subsequent testing.

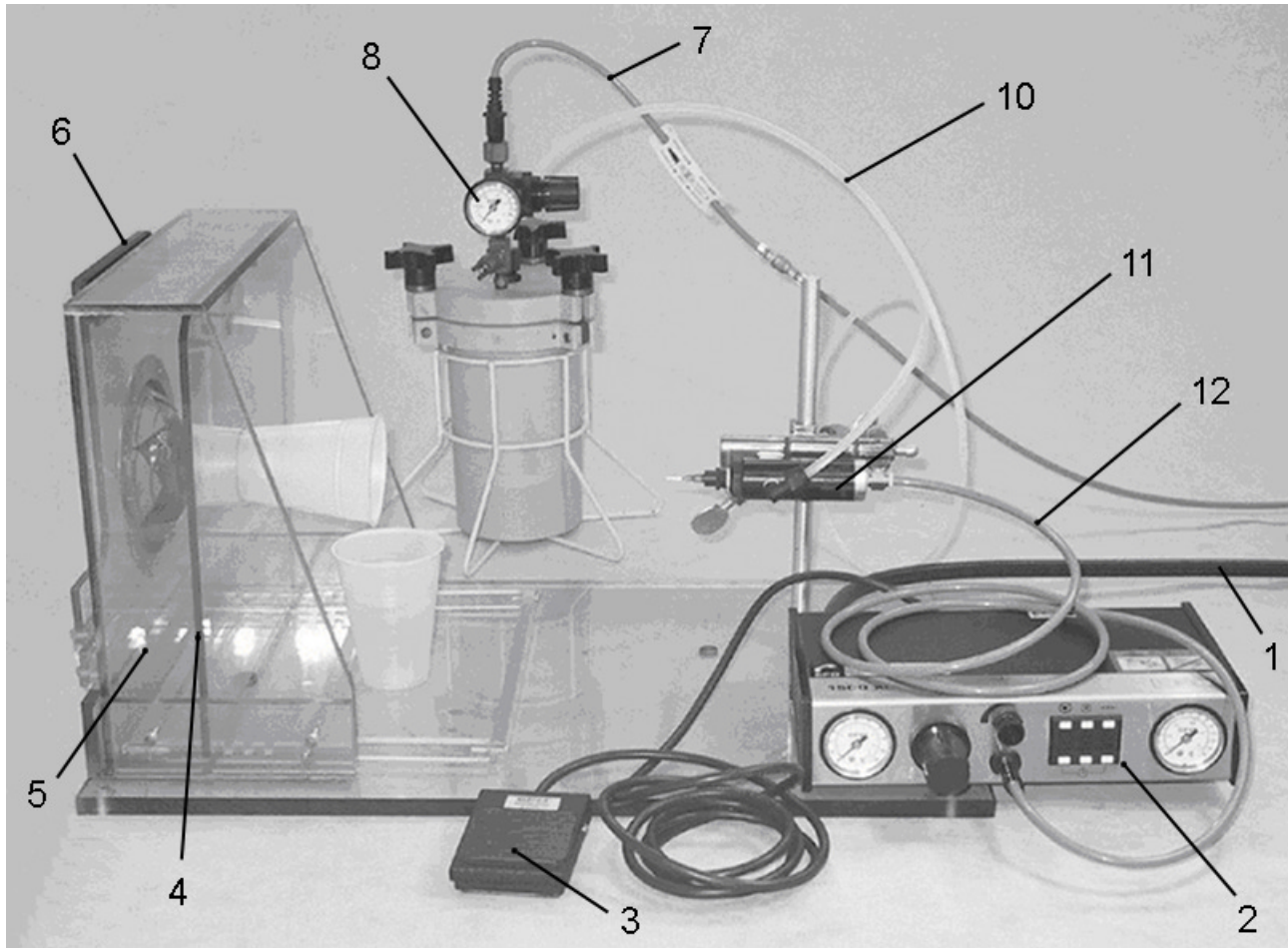
8 Report

For each test, report the following:

- a) that the test was carried out in accordance with this International Standard;
- b) identification of the medical face mask and the medical face mask material tested;
- c) selected test blood pressures and volumes, and velocities of synthetic blood used, if different from those specified in this test method;
- d) description of target area(s) tested;
- e) distance of the face mask target area surface from the tip of the canula and the angle of the pneumatic valve with respect to the face mask target area, if different from those specified in this test;
- f) description of any technique used to enhance visual detection of synthetic blood;
- g) temperature and relative humidity for both conditioning and testing;
- h) description of any pre-treatment techniques used;
- i) “pass” or “fail” for each specimen at each test pressure;
- j) highest pressure corresponding to a stream velocity for which the medical face mask demonstrates an acceptable quality limit of 4,0 %;
- k) whether the targeting-plate method was used.

NOTE 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.

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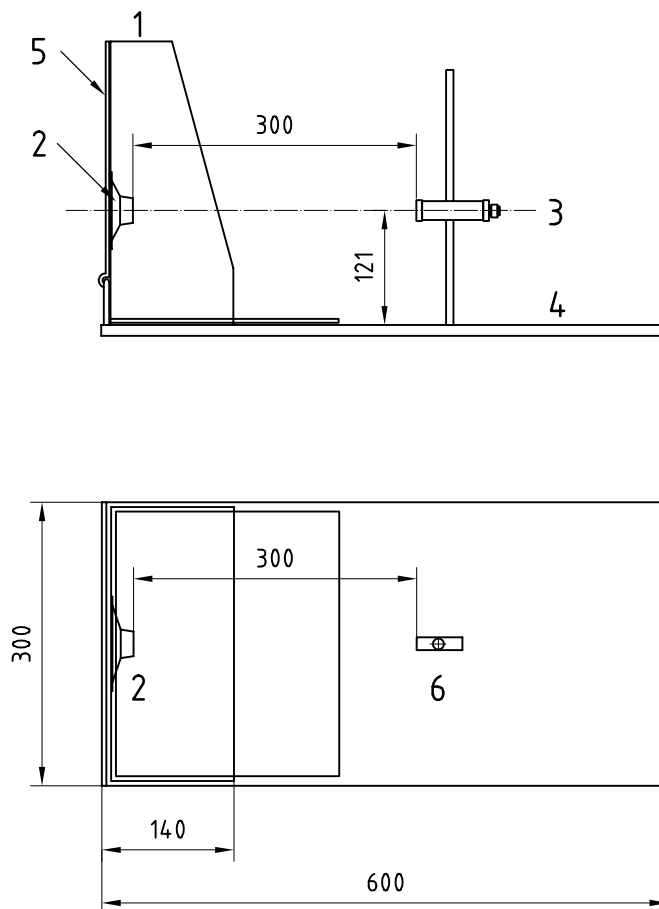


Key

- 1 air line from supply to controller (6 mm ID, 12 mm OD, 1,9 m long tube rated for 1 000 kPa)
- 2 EFD 1500 XL valve controller
- 3 valve control switch
- 4 targeting plate (see Figure 4)
- 5 transparent plastic box (see Figure 2)
- 6 hinged door with sample holding fixture (see Figure 3)
- 7 air line from supply to fluid reservoir (6 mm internal diameter, plastic, 3 m long)
- 8 fluid reservoir pressure gauge (connection at 6 mm internal diameter, 0,7 m long)
- 9 fluid reservoir (mount on bench top with base level to base of sample holding table)
- 10 fluid feed from reservoir to valve (6 mm internal diameter, plastic, 1,5 m long)
- 11 valve mounted on ring stand mount, with canula
- 12 air line from controller to valve (6 mm internal diameter, plastic, 1,5 m long)

Figure 1 — Complete test apparatus

Dimensions in centimetres



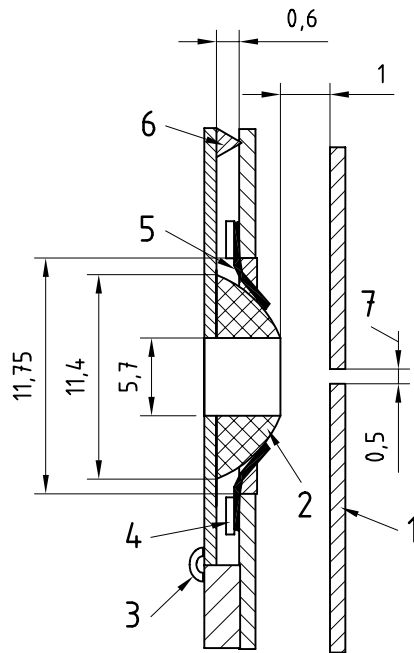
Key

- 1 transparent plastic box
- 2 specimen-holding fixture
- 3 centreline of pneumatic tube
- 4 test apparatus table
- 5 hinged door
- 6 clamp for valve

Figure 2 — Test apparatus

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Dimensions in centimetres



Key

- | | | | |
|---|-----------------|---|----------------|
| 1 | targeting plate | 5 | rubber cuff |
| 2 | backing form | 6 | magnetic latch |
| 3 | hinge | 7 | hole |
| 4 | retaining ring | | |

Figure 3 — Specimen-holding fixture (detail view)

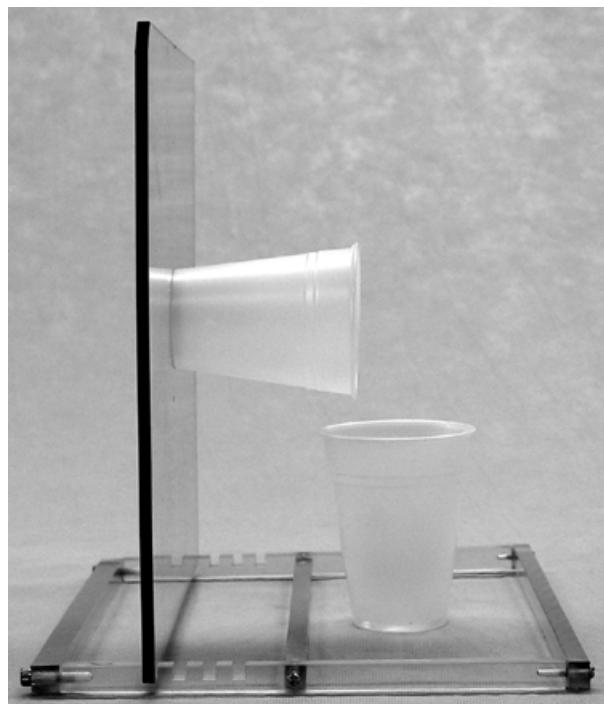


Figure 4 — View of targeting plate with collection cup

Annex A (informative)

Parts list for test apparatus

Quantity	Description	Part number ¹⁾	Notes
1	“piggy back” style air filter/regulator, rated to withstand 7 000 kPa, with one input and two output connectors	EFD Part No. 2000F755 with air tree Part No. 1116	a
1	air input hose	(EFD part No. 2310S)	a
1	fluid reservoir liner and cover	(EFD Part No. 615DRL)	a
1	reservoir stand	(EFD Part No. 61520)	a
1	fluid reservoir	(EFD Part No. 615DT)	a, b
1	pressure gauge, calibrated and rated to a maximum pressure of 105 kPa	—	—
1	dip tube, for inside reservoir	(EFD Part No. 61521)	a
1	fluid feed line	(EFD Part No. 2025)	a
1	EFD Model 1500XL or equivalent valve controller, mounted 420 mm above bench top upon which reservoir is positioned	—	a
1	EFD Model 725D pneumatic fluid dispensing valve	—	a
1	hand or foot activated switch	—	
10	18 gauge, 12,7 mm type canulas with internal diameter of 0,84 mm; general purpose precision tips	(EFD Part No. 5118-B)	a, c
1	sample holder fixture (see Figures 1 and 2)	—	—
<p>^a Available from EFD, 977 Waterman Avenue, East Providence, RI 02914 USA.</p> <p>^b For increased accuracy in small pressure measurements, the pressure gauge supplied with the EFD reservoir unit should be replaced with a larger gauge.</p> <p>^c While only one tip is required to perform testing, it is recommended that a good supply of replacements be on hand in case of clogging or loss.</p>			

1) This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the products named. Equivalent products may be used if they can be shown to lead to the same results.

Annex B (normative)

Preparation of synthetic blood

B.1 Reagents

Prepare 1 l of synthetic blood using the following reagents:

— high-performance liquid-chromatography (HPLC) quality distilled water (pH $7,0 \pm 0,5$)	up to 1 l
— thickening agent	25,0 g
— red dye containing colorant and surfactant distilled water	10,0 g

NOTE 1 Acrysol G 110²⁾ is a suitable thickening agent and is available from Rohm and Haas Company, Independence Mall West, Philadelphia, PA 19105 USA (Phone ++1-215-592-3000).

NOTE 2 Prepared synthetic blood meeting this specification, and small quantities of Direct Red 081²⁾, CI #28160 (Morfast Red 8BL²⁾) are available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906 USA (++1-507-252-1766).

B.2 Preparation procedure

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

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

Add the red dye and mix 15 min more.

B.3 Surface tension, adjustment, storage and use

Measure the corrected surface tension of the solution in accordance with ISO 304. The expected value of the corrected surface tension is $(0,042 \pm 0,002)$ N/m. Do not use synthetic blood solutions unless the surface tension falls within the specified range.

Excessive oil in the red dye often causes unacceptable variations in synthetic blood surface tension. Remove excess oil from the red dye by mixing 25 g of the dye with 1 l of 90 % isopropanol, decant 80 % of the tainted alcohol, and discard or save for distillation. Pour the dye-alcohol solution into an evaporation dish, forming a thin layer, and cover with filter paper to allow residual alcohol to completely evaporate. The red dye is ready for use when dry.

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.

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

Shake the synthetic blood well before using to prevent its later separation.

Discard the solution if a gel-like precipitate forms.

2) Acrysol G 110, Direct Red 081, and Morfast Red 8BL are examples of suitable product available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of these products.

Annex C (informative)

Derivation of equations for stream velocity and time of delivery

C.1 The velocity of the fluid stream at impact with the mask is the key variable in this test method. The Bernoulli equation (C.1) can be used to describe the conditions of a flowing fluid at two or more points along a flow line. Thus, Equation (C.1), where subscripts 1 and 2 refer to location 1 (inside the blood vessel) and location 2 (at the exit of the blood vessel), respectively, can be used to estimate the velocity of blood exiting an artery in a clinical setting.

$$\frac{p_1}{\rho_1} + \frac{v_1^2}{2g} + z_1 = \frac{p_2}{\rho_2} + \frac{v_2^2}{2g} + z_2 \quad (\text{C.1})$$

where

- p_1 is the fluid pressure inside the blood vessel;
- p_2 is the fluid pressure at the exit of the blood vessel;
- v_1 is the fluid velocity inside the blood vessel;
- v_2 is the fluid velocity at the exit of the blood vessel;
- z_1 is the height above a defined plane inside the blood vessel;
- z_2 is the height above a defined plane at the exit of the blood vessel;
- ρ_1 is the density of the fluid inside the blood vessel;
- ρ_2 is the density of the fluid at the exit of the blood vessel;
- g is the acceleration due to gravity, equal to 980,67 cm/s².

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

- a) 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.
- b) Likewise, since the height of the blood vessel and the exiting stream are the same, the terms for height (z_1 and z_2) can be neglected.
- c) There is little opportunity for frictional losses between the inside and outside of the blood vessel, so no term for head loss term is included in Equation (C.1).
- d) 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.

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

$$\frac{p_1}{\rho_1} = \frac{v_2^2}{2g} \quad (\text{C.2})$$

C.4 Equation (C.2) can then be rearranged as Equation (C.3) to solve for velocity of blood exiting a puncture:

$$v_2 = \sqrt{[(2g / \rho_1) \times p_1]} \quad (\text{C.3})$$

which reduces to Equation (C.4):

$$v_2 = 137.59 \sqrt{p_1} \quad (\text{C.4})$$

when p_1 is expressed in kilopascals (with a conversion factor of 1 kPa = 10,197 g/cm²), ρ_1 is set equal to 1,056 5 g/cm³ (the density of whole blood^[1], not the density of the test fluid) and g is as defined for Equation (C.1).

Table C.1 — Velocities for specific pressures

Pressure (kPa)	Velocity (cm/s)	Velocity rounded to nearest 5 cm/s (cm/s)
10,6	447,96	450
16,0	550,36	550
21,3	635,00	635

NOTE 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.

C.5 In the test method, the pressure in the test apparatus is set to produce the desired exit velocity. As the velocity at the exit is difficult to measure directly, it is determined from a calculation of the volume of fluid produced over a known time through an orifice of known area using Equation (C.5):

$$v = \frac{Q}{t \times A} \quad (\text{C.5})$$

where

v is the flow velocity;

Q is the volume;

t is the duration of the flow;

A is the cross-sectional area of the orifice.

C.6 The cross-sectional area of a round orifice can be calculated from the orifice diameter using Equation (C.6):

$$A = \frac{\pi \times d^2}{4} \quad (\text{C.6})$$

where d is the inside diameter of the orifice.

C.7 Equations (C.5) and (C.6) can be combined and rearranged in the form of Equation (C.7) to solve for the duration of flow, or valve-open time:

$$t = \frac{4Q}{v \times \pi \times d^2} \quad (\text{C.7})$$

When v is in units of centimetres per second and the following standard conditions

$$Q = 2 \text{ ml of fluid,}$$

$$d = 0,084 \text{ cm,}$$

$$\pi = 3,1416,$$

are used, Equation (C.7) reduces to Equation (C.8):

$$t = \frac{360,98}{v} \quad (\text{C.8})$$

For the standard test pressures, the valve times are given in Table C.2:

Table C.2 — Valve times for standard test pressures

Fluid velocity (cm/s)	Equivalent blood pressure (kPa)	Valve time for standard apparatus and fluid (s)
450	10,6	0,80
550	16,0	0,66
635	21,3	0,57

If the density or specific gravity of the fluid is known, the spurt can be more conveniently measured by mass using Equation (C.8), rather than by volume using Equation C.7:

$$m = Q \times \rho \quad (\text{C.8})$$

where

m is the mass of the spurt;

Q is the volume of the spurt;

ρ is the density of the test fluid.

Assuming a density of 1,005 g/cm³ for the test fluid, the weight of a 2 ml spurt would be 2,010 g.

C.8 It is important to note that Equation (C.8) and Table C.2 assume that the velocity of the fluid is constant during the entire spurt, as stated in C.2 c). This is a valid assumption for blood spurting out of a vessel where the distance travelled is only the thickness of the wall of the blood vessel. It is not a good assumption for the test apparatus, where the blood flows through a long tube, then through a valve and the canula as frictional drag forces are generated during this flow. So, while the pressure in the reservoir is held constant by a regulator, the pressure at the exit of the canula drops until a steady-state flow rate is reached. This takes about 0,1 s. This behaviour 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 more than a centimetre higher than the impact of the steady-state flow.

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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 in diameter) in a plate between the canula and the mask. If the stream is aimed such that the steady-state flow passes through the hole, the higher-velocity part of the stream will be blocked, as it will hit the plate above the hole.

Equation (C.7) can be combined with Equation (C.8) in the form of Equation (C.9) and used to estimate the velocity of the steady-state flow:

$$m_2 - m_1 = \frac{1}{4} (v \times \rho \times d^2) (t_2 - t_1) \quad (\text{C.9})$$

where

m_1 is the mass of fluid delivered in time t_1 ;

m_2 is the mass of fluid delivered in time t_2 ;

t_1 and t_2 are times long enough to ensure the flow has reached steady state ($> 0,1$ s).

Equation (C.9) can be rewritten as Equation (C.10):

$$(m_2 - m_1) = \frac{v(t_2 - t_1)}{C} \quad (\text{C.10})$$

where

$$C = \frac{4}{\rho \times \pi \times d^2} \quad (\text{C.11})$$

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

When m is expressed in grams and v in centimetres per second and the following standard conditions

$$d = 0,084 \text{ cm},$$

$$\rho = 1,005 \text{ g/cm}^3 \text{ (the density of the test fluid not whole blood),}$$

are used, then $C = 179,55$.

The value of C should be recalculated for fluids with specific gravities less than 0,995 or more than 1,015 (1 %); or for canula with an inside diameter other than 0,084 cm.

Equation (C.11) and the appropriate value for C can then be used to build a table of targets and limits for the differential spurt masses for specified velocities using the standard apparatus (see Table 2).

C.9 In practice, the pressure of the fluid reservoir is adjusted until the differential mass 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 the stream is properly aimed.

C.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 g/cm³, 2,01 g of fluid should pass through the targeting plate.

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