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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)

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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

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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].

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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 $(0,042 \pm 0,002)$ N/m.

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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.

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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)

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.

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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.

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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

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

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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.

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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.

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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 ± 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.

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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 ± 5) °C and a relative humidity of (85 ± 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 ± 5) % relative humidity at (21 ± 5) °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.

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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.

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e) Verify the amount of synthetic blood delivered to be 2 ml by conducting trials into a graduated cylinder.

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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 ± 0,040) g.

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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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