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Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

Vêtements de protection contre les contacts avec le sang et les fluides corporels — Détermination de la résistance des matériaux des vêtements de protection à la pénétration par le sang et les fluides corporels — Méthode d'essai utilisant un sang synthétique

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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 16603 was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*. It is based on ASTM F1670-98.

Introduction

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis [hepatitis B virus (HBV) and hepatitis C virus (HCV)] and acquired immune deficiency syndrome (AIDS) [human immunodeficiency viruses (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.

This International Standard is concerned with protective clothing and related protective devices designed to protect against the penetration of blood or body fluids. This test method addresses only the performance of materials or certain material constructions (e.g. seams) used in protective clothing. This test method does not address the design, overall construction and components, or interfaces of garments or other factors which can affect the overall protection offered by the protective clothing.

It is emphasized that the test does not necessarily simulate conditions to which clothing materials are likely to be exposed in practice. The use of test data should therefore be restricted to broad comparative assessment of such material according to their synthetic blood penetration resistance characteristics. 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. Tests which assess the impact of storage conditions and shelf life on the penetration resistance for disposable products, and the effects of laundering and sterilization on the penetration resistance for reusable products, should be considered. The integrity of the protective barrier can also be compromised during use by such effects as flexing and abrasion or pre-wetting by contaminating materials such as alcohol and perspiration. If these conditions are of concern, the performance of protective clothing materials for synthetic blood penetration should be evaluated following an appropriate preconditioning technique representative of the expected conditions of use.

Medical protective clothing materials are intended to be a barrier to blood, body fluids, and other potentially infectious materials. Many factors can effect 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.[2] In order 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, i.e. (0,042 $\pm$ 0,002) N/m.

Part of this method for exposing the protective clothing material specimens with synthetic blood involves pressurization of the test cell to 14,0 kPa (in Procedures A and B). This hydrostatic pressure has been documented to produce test results that correlate with a human factors validation.[3] Some studies, however, suggest that mechanical pressures exceeding 345 kPa can occur during actual use.[4] [5] Therefore, it is important to understand that this test method does not simulate all the physical stresses and pressures that are exerted on protective clothing in use. This test method can also be used as a screening test to determine which time and pressure protocol is appropriate for evaluating the viral-resistance-properties of protective apparel with a more sophisticated barrier test method as described in ISO 16604. Procedures C and D use a stepped pressurization approach with pressures up to 20,0 kPa. These procedures simulate a range of possible procedures for ranking material performance.

Given the variety of health care settings, activities, and the potential for exposure to blood or body fluids, the barrier requirements for protective clothing materials will change with the application. The choice of an appropriate test method depends on the specific application of protective clothing and its intended use. A risk assessment should be performed to determine the level of risk for determining the appropriate test method.[1]

Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

1 Scope

This International Standard describes a laboratory test method for measuring the penetration resistance of clothing materials to blood and body fluids. This test method uses a synthetic blood in continuous contact with the material specimen at specified set of conditions using the ISO 13994 test apparatus.

This test method is not always effective in testing protective clothing materials having thick, inner liners which readily absorb the synthetic blood.

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 3801, *Textiles — Woven fabrics — Determination of mass per unit length and mass per unit area*

ISO 5084, *Textiles — Determination of thickness of textiles and textile products*

ISO 13994, *Clothing for protection against liquid chemicals — Determination of the resistance of protective clothing materials to penetration by liquids under pressure*

3 Terms and definitions

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

3.1
blood-borne pathogen
infectious secreted or excreted bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids

3.2
blood-resistant material
material that restricts blood and body fluid penetration

3.3
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.

3.4
body fluid simulant
liquid which is used to act as a model for human body liquids

NOTE In this International Standard, synthetic blood is used as a body fluid simulant.

3.5
penetration
flow of a liquid through closures, porous materials, seams and holes or other imperfections in a protective clothing material on a non-molecular level

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

3.6
protective clothing
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

3.7
synthetic blood
mixture of an amaranth dye, surfactant, thickening agent, inorganic salts, and distilled water having a surface tension and viscosity representative of blood and some other body fluids

NOTE The synthetic blood in this International Standard does not simulate all of the characteristics of real blood or body fluids, for example, colour, coagulation and content of cell matter.

4 Principle

The resistance of a protective clothing material to penetration by blood and body fluids is determined by subjecting the material to synthetic blood as a body fluid simulant for a specified time and pressure sequence and observing if visible penetration of the liquid occurs.

In the penetration test apparatus, the clothing material acts as a partition separating the body fluid simulant from the viewing side of the test cell.

Any evidence of synthetic blood penetration constitutes failure. Results are reported as “pass/fail”.

5 Synthetic blood

The synthetic blood shall meet the following requirements:

— surface tension: $(0{,}042 \pm 0{,}002)$ N/m

— pH: $(7{,}3 \pm 0{,}1)$

— viscosity: $(2{,}7 \pm 0{,}3)$ mPa·s

— conductivity: $(12{,}0 \pm 1{,}2)$ mS/cm

NOTE A suitable method of preparation can be found in Annex A.

6 Apparatus

6.1 Penetration test cell, as specified in ISO 13994, to restrain the specimen during contact with the pressurized test synthetic blood.

In the test cell, the specimen acts as a partition separating synthetic blood from the view side of the test cell. It consists of a cell body that is fastened to a cell support. The cell body has a capacity of approximately 60 ml for synthetic blood. A flange cover, with an open area to allow visual observation and a transparent cover are included. The cell body has a top port for filling and a drain valve for draining the penetration test cell. Other items, such as a fitting to allow attachment of the air line to the top port in the cell body, gaskets, and the retaining screen are also required. A diagram of the penetration test cell and apparatus are shown in Figures 1 and 2. An alternative air pressure controller is listed in Annex B.

6.2 Retaining screen, comprising a smooth finish plastic or metal square mesh screen to support extensible or elastomeric materials, meeting the following specifications:

a) open area of > 50 %;

b) deflection of the test specimen is limited to $\leqslant 5{,}0$ mm.

6.3 Air pressure source, capable of providing air at $\left(20{,}0^{+2}_{0}\right)$ kPa.

6.4 Stopwatch, or electronic timer.

6.5 Balance, with a precision of at least 0,01 g.

6.6 Vessel, or graduated cylinder or vessel, with a precision of 1 ml.

6.7 Thickness gauge, suitable for measuring thickness to the nearest 0,02 mm.

7 Test specimens

7.1 Selection

7.1.1 Select specimens from single material samples or individual protective clothing items, consisting of either a single layer or a composite of multiple layers that is representative of an actual protective clothing construction with all layers arranged in proper order.

If in the design of an item of protective clothing, different materials or thicknesses of material are specified at different locations, select specimens from each location.

If in the design of an item of protective clothing, seams are claimed to offer the same protection as the base materials, test additional specimens containing such seams.

Cut each material specimen into squares with a minimum dimension of 70 mm. A 75 mm square is preferred.

Test three specimens taken at random from each material, composite, area (in the case of heterogeneous design), or other condition.

If this procedure is used for quality control or to support broad product claims concerning the blood-resistant properties of materials used in protective clothing, proper statistical design and analysis of larger data sets than those specified in this test method should be performed. Examples of acceptable sampling plans are found in references such as ISO 2859-1[9].

7.1.2 It is possible that protective clothing materials incorporating an impervious layer between two fabric layers are sensitive to false positive failures by wicking at the edges. Seal the edges of the test specimens to

prevent “wicking” modes of failure. Seal test specimens with an adhesive, parafilm, paraffin wax, or adhesive-backed foam prior to testing. Seal only the edges of the test specimens, leaving the centre 57 mm area (57 mm square) open for testing. Do not allow sealants to intrude, block, or occlude the structure of the test specimen in the test area. Choose sealants and sealing methods that are compatible with the protective clothing materials.

7.2 Preparation

Condition each test specimen for a minimum of 24 h by exposure to a temperature of (21 ± 5) °C and a relative humidity of (60 ± 10) %.

If warranted, use other preconditioning options, such as sterilization, to assess possible degradation mechanisms of protective clothing.

8 Procedure

8.1 Preliminary measures

8.1.1 Measure the thickness of each specimen to the nearest 0,02 mm in accordance with ISO 5084.

8.1.2 Determine the mass of each specimen and calculate the mass per unit area to the nearest 10 g/m^2 in accordance with ISO 3801.

8.1.3 Place a small droplet (10 µl) of the synthetic blood on the normal inside surface of an extra piece of the material to be tested. The droplet shall remain easily visible to ensure that a droplet that penetrates the material will be seen.

NOTE In order to enhance droplet visibility, alternative methods can be used, such as talcum powder or an oblique light source.

8.2 Test apparatus setup

8.2.1 With the cell placed horizontally on the lab bench, insert the specimen in the penetration cell with the normal outside surface of the fabric toward the cell reservoir which will be filled with synthetic blood.

Use a retaining screen in the normal inside surface of the sample to support extensible or elastomeric materials.

8.2.2 Assemble the components of the cell as follows:

a) place gaskets between the penetration cell and the test specimen, the specimen and the retaining screen (if used), and the retaining screen and the flange cover as shown in Figure 1;

b) close the penetration cell by putting on the flange cover and transparent cover.

Polytetrafluoroethylene (PTFE) gasket material is recommended for use between the cell body and the test specimen to help prevent leakage.

NOTE Clear plastic film is an acceptable substitute for the transparent cover.

8.2.3 Torque the bolts in the test cell to 13,6 N·m each.

8.2.4 Mount the penetration cell in the test apparatus in a vertical position as shown in Figure 2 (drain valve down) but do not connect the air line to the cell.

8.2.5 Close the drain valve.

8.3 Test procedure

8.3.1 Select an appropriate procedure from Table 1.

Table 1 — Time and pressure protocols

Procedure	Pressure and time sequence	Remarks
A	0 kPa for 5 min, followed by 14 kPa for 1 min, followed by 0 kPa for 4 min. A retaining screen is not used to support the sample.	Used for selecting critical zone materials and components to limit exposure in situations involving presence of a large amount of blood or body fluids, a direct liquid contact, pressing and leaning.
B	0 kPa for 5 min, followed by 14 kPa for 1 min, followed by 0 kPa for 4 min. A retaining screen is used to support the sample.	Procedure B involves the use of a retaining screen to support extensible or elastomeric materials. When distortion of the test material is suspected of causing failure with Procedure A, Procedure B may be used.
C	0 kPa for 5 min, followed by 1,75 kPa for 5 min, followed by 3,5 kPa for 5 min, followed by 7 kPa for 5 min, followed by 14 kPa for 5 min, followed by 20 kPa for 5 min. A retaining screen is not used to support the sample.	Used for selecting critical zone materials and components to limit exposure in situations involving presence of blood or body fluids and different possible levels of contact pressure. A selection as to which level of protection is required should be made, based on a task analysis and on the degree of exposure anticipated.
D	0 kPa for 5 min, followed by 1,75 kPa for 5 min, followed by 3,5 kPa for 5 min, followed by 7 kPa for 5 min, followed by 14 kPa for 5 min, followed by 20 kPa for 5 min. A retaining screen is used to support the sample.	Procedure D involves the use of a retaining screen to support extensible or elastomeric materials. When distortion of the test material is suspected of causing failure with Procedure C, Procedure D may be used.
When using Procedure C or D, the visual endpoint can be used to determine the appropriate time and pressure sequence to be used in ISO 16604. The highest pressure with no visible penetration in ISO 16603 should be used for ISO 16604.		

8.3.2 Carefully fill the chamber of the penetration cell through the top port with approximately 60 ml of synthetic blood (a syringe or funnel is useful). If liquid penetrates through the test specimen at anytime during the test, terminate the test.

8.3.3 Connect the air line to the penetration cell.

8.3.4 Set the pressure regulator to a pressure of 0 kPa and close the cell vent valve.

8.3.5 Expose the test liquid to the pressure(s) and for the time(s) called for in the desired procedure from Table 1, changing the pressure at the rate of no more than $(3,5 \pm 0,5)$ kPa/s. Hold the pressure constant at each specified level for the specified time.

8.3.6 Observe the viewing surface of the specimen at the end of each specified pressure and time interval for the appearance of synthetic blood or other evidence of wetness.

If this occurs, terminate the test. If elected, record the time and pressure of failure.

If there is no visible penetration, continue on to the next step of the time and pressure protocol.

If no liquid or characteristic discoloration appears for the duration of the test, then the specimen passes the test.

8.3.7 At the conclusion of the test, turn off the pressure and open the cell valve to the vent position.

8.3.8 Test the remaining specimens.

8.4 Final cleanup of test apparatus

At the end of the test period, open the drain valve and drain the penetration test cell of the synthetic blood. Flush the test cell with an appropriate wash liquid to remove any traces of the synthetic blood. Remove the specimen and gasket from the cell. Clean any external parts of the test cell which may have been touched by synthetic blood.

9 Test report

The test report shall include the following information:

a) a reference to this International Standard (ISO 16603:2004);

b) the manufacturer's identity and the identification of the material tested (supplier, lot number and date of receipt);

c) a description of the sampling method used, e.g. if the material was taken from roll goods or garments;

d) the characteristics of the material:

   1) the composition of the material types of fibres and coatings, presence of seams or other conditions, etc.,

   2) the position on the garment of each specimen shall be indicated if the specimens were taken from garments,

   3) whether the material was subjected to sterilization and, if so, the sterilization procedure;

e) the thickness of each material specimen and the average thickness of the material tested (in millimetres);

f) the mass per unit area of each material specimen and the average mass per unit area of the material tested (in grams per square metre);

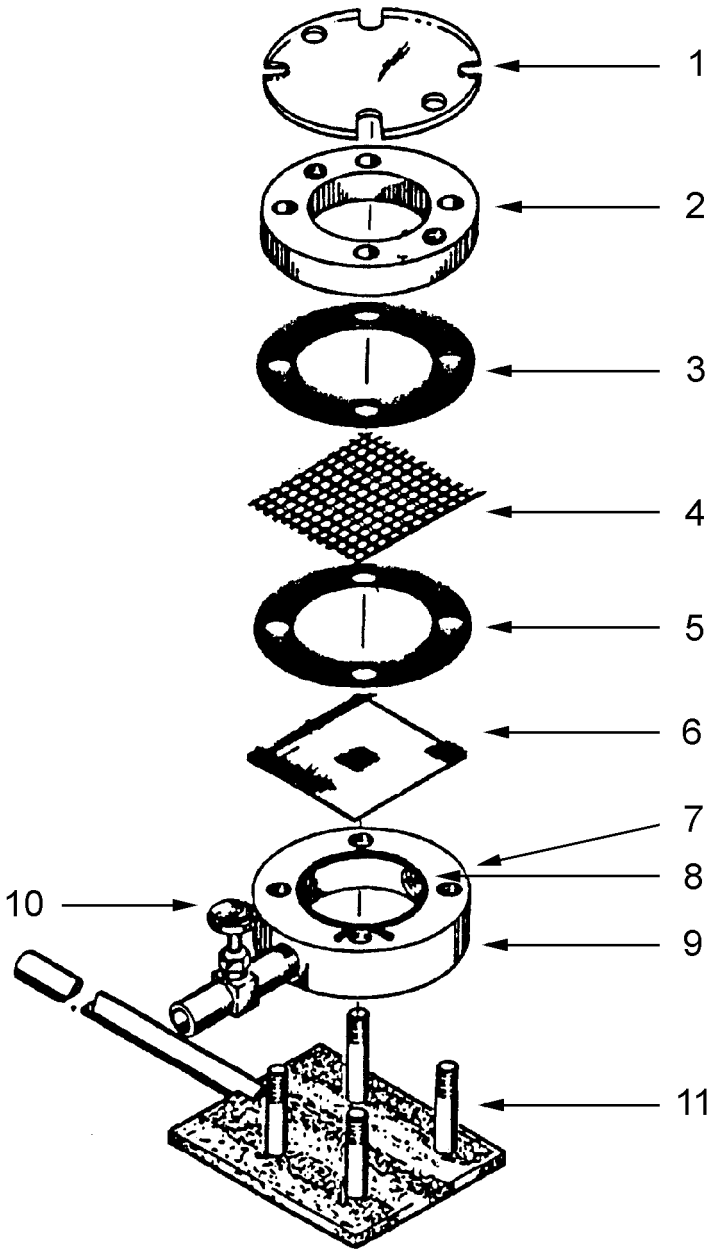
g) a description of any technique used to enhance visual detection of synthetic blood penetration;

h) the procedure selected (from Table 1);

i) the type and specification of the retaining screen, if used;

j) the “pass” or “fail” result for each specimen at each time and pressure interval;

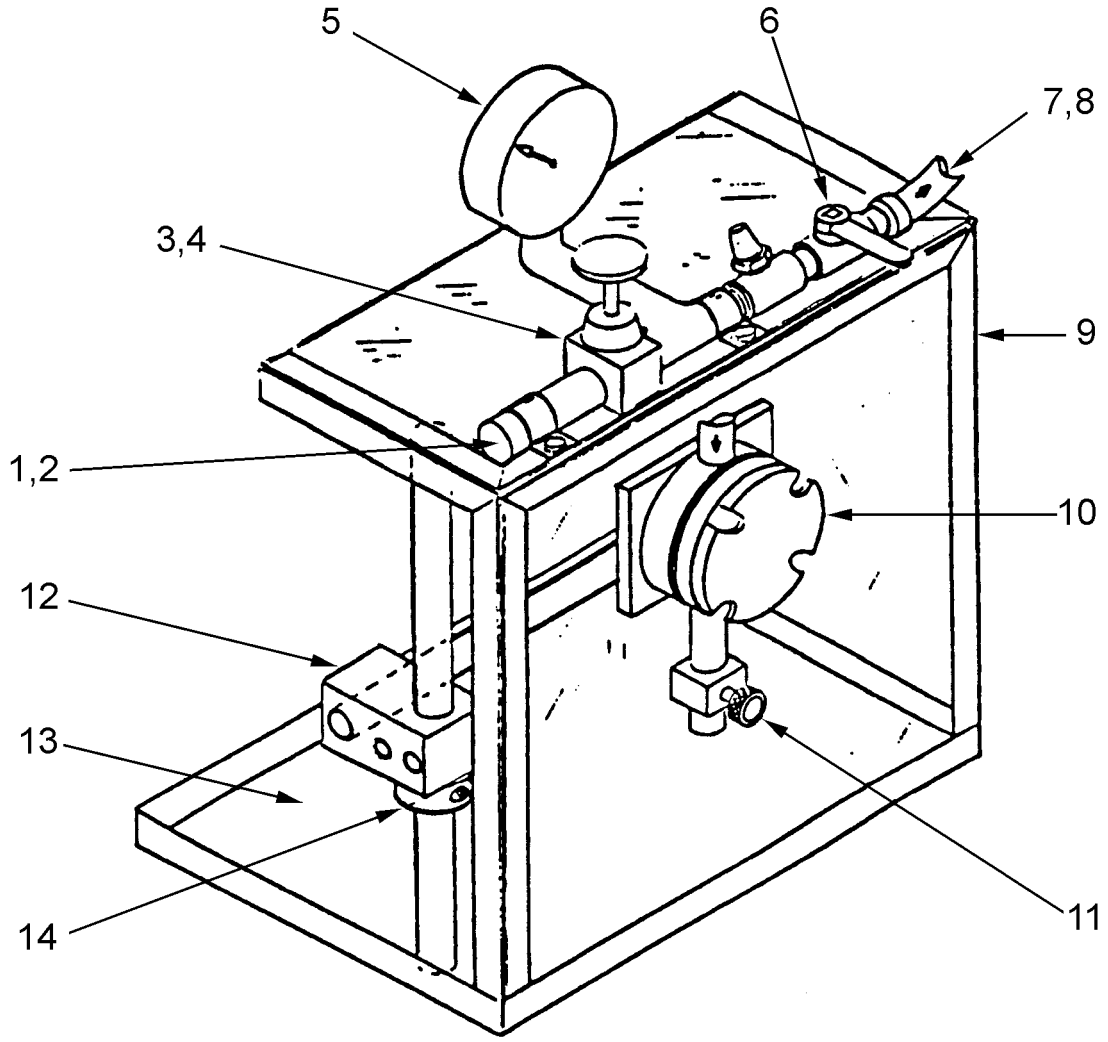
k) the time of failure for each specimen (if elected to report).



Key

1	transparent cover	7	top port
2	flange cover	8	expanded PTFE gasket material
3	gasket (specimen exposure Procedures B and D)	9	cell body
4	retaining screen (specimen exposure Procedures B and D)	10	drain valve
5	gasket	11	cell support
6	test sample		

Figure 1 — Penetration test cell with retaining screen (exploded view)



Key

1 compressed air or nitrogen
2 air line connector
3 air pressure regulator
4 adjustable relief valve
5 pressure gauge
6 cell vent valve
7 female coupling
8 rubber air hose with male coupling to connect to 7 and a female coupling to connect to 10
9 safety enclosure
10 penetration test cell
11 drain valve
12 swivel clamp
13 spill pan
14 two-piece shaft collar

Figure 2 — Test apparatus (three-dimensional side view)

Annex A
(informative)

Synthetic blood formula

A.1 Ingredients

The following ingredients should be used to prepare 1 l of synthetic blood:

— carboxymethyl cellulose (CMC) [e.g. CMC-Sigma 9004-32-4[1)] medium viscosity]	2 g
— polyethylene glycol sorbitan monolaurate {e.g. Tween 20 [Fluka 9377[1)]]}	0,04 g
— sodium chloride (analytical grade)	2,4 g
— amaranth dye [e.g. Sigma 915-67-3[1)]]	1 g
— potassium dihydrogen phosphate (KH_2PO_4)	1,2 g
— disodium hydrogen phosphate (Na_2HPO_4)	4,3 g
— distilled or deionized water	up to 1 l

NOTE 2-Methyl-4-isothiazolin-3-one hydrochloride **(**MIT) (0,5 g/l) can be added to increase the storage lifetime of the solution.

A.2 Preparation

Dissolve the CMC in half the amount of water and mix 60 min on a magnetic stirring plate.

Weigh the Tween 20 in a small beaker, add water and mix. Add the Tween 20 solution to the CMC solution, rinse the beaker several times with water and add this to the solution.

Dissolve the sodium chloride in the solution. Dissolve the KH_2PO_4 and Na_2HPO_4 in the solution.

Add MIT (if used) and the amaranth dye.

Dilute the solution with water up to 1 000 g.

Adjust the pH of the synthetic blood to ($7,3 \pm 0,1$) using phosphate buffer solution.

Measure the surface tension of the synthetic blood in accordance with ISO 304.

1) Sigma 9004-32-4, Tween 20 (Fluka 9377) and Sigma 915-67-3 are examples of suitable products 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 B
(informative)

Sources of apparatus

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

A suitable penetration test apparatus is available from Wilson Road Machine Shop, 1170 Wilson Road, Rising Sun, MD 21911, USA.

An alternative air pressure controller is the FX hydrostatic head tester which must be operated in the programme mode for this test. This apparatus is available from Texttest AG, Dubendorfstrasse 4, CH-9051 Zurich Switzerland (Phone ++41-1-321-2141) or Schmid Corporation, 140-B Venture Boulevard, Spartanburg, SC 29301 USA (Phone ++1-864-595-0087).

A suitable PTFE gasket material is available from W.L. Gore & Associates, Inc., Industrial Sealant Group, Elkton, MD 21921, USA.

Bibliography

[1] TELFORD, G.L. and QUEBBEMAN, E.J. Assessing the risk of blood exposure in the operating room. *American Journal of Infection Control*, **21** (6), December 1993, pp. 351-356

[2] *Geigy Scientific Tables, Volume 1: Units of measurement, body fluids, composition of blood, hematology, somatometric data*. (Lentner, C. ed.) Medical Education Division, Ciba-Geigy Corporation, West Caldwell, NJ, 1984

[3] MCCULLOUGH, E.A. and SCHOENBERGER, L.K. Liquid barrier properties of nine surgical gown fabrics. *INDA Journal of Nonwovens Research*, **3** (3), 1991, pp. 14-20

[4] SMITH, J.W. and NICHOLS, R.L. Barrier efficiency of surgical gowns. *Archives of Surgery*, **126**, June 1991, pp. 756-762

[5] ALTMAN, K.W. *et. al*. Transmural surgical gown pressure measurements in the operating theater. *American Journal of Infection Control*, **19**, 1991, pp. 147-155

[6] LYTLE, C.D. BAKER, K.H. Ability of a viral penetration test (ASTM F1671-95) to detect small holes. *Journal of Testing and Evaluation (JTEVA)*, **27** (3), May 1999, pp. 231-233

[7] ASTM F1670-98, *Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood*

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

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

[10] ISO 16604, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage*

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