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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 $\pm$ 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.

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