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

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Safety Appliances Association (JSAA)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 22609 published in 2004 with some modifications of the technical contents.

The portions with dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with explanations is given in Annex JA.

1 Scope

This Standard describes a laboratory test method for face masks that protect against contact with the blood expelled from blood vessels or other body fluids. The test liquid is synthetic blood that simulates blood, etc. This Standard describes a test method for resistance of face masks to penetration by a splash.

The purpose of this Standard is primarily to clarify the test method of materials or certain material constructions used in face masks. This test method does not address the performance of the face masks design, construction, interfaces or other factors which may affect the overall protection (such as filtration efficiency and pressure drop).

This test method does not evaluate the performance of 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 face mask.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 22609 : 2004 *Clothing for protection against infectious agents—Medical face masks—Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)* (MOD)

In addition, symbols, which denote the degree of correspondence in the contents between the relevant International Standard and JIS, are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this Standard. The most recent edition of the standard (including amendment) indicated below shall be applied.

JIS K 8839 2-Propanol (Reagent)

3 Terms and definitions

For the purposes of this Standard, 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 airborne particles

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

3.4 body fluid

any liquid produced by the body

3.5 body-fluid simulant

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

3.6 penetration

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

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

3.7 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

3.8 synthetic blood

mixture of 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 Standard does not simulate the characteristics (colour, coagulation, content of cell matter, etc.) of blood or other body fluids.

4 Principle

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. At that time, whether or not wetting is present shall be observed.

Any evidence of synthetic blood penetration on the rear of the face mask contacting the wearer's face constitutes "wetting". Results are reported as "wetting".

Whether or not face masks are wet are evaluated at three pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa, which correspond to human blood pressures 80 mmHg, 120 mmHg, and 160 mmHg, respectively.

5 Apparatus and materials

5.1 Equipment

Equipment shall be as follows.

5.1.1 Test apparatus, 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 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.

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 (polycarbonate resin). 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 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.

5.2.2 2-Propanol Use the 2-propanol specified in **JIS K 8839** and clean the canula and surfaces contacted by the synthetic blood.

6 Specimens and pretreatment

6.1 Specimens

Use complete face masks as the test specimen.

If in the design of a 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 face mask, seams are claimed to offer the same protection as the base materials, test these areas of the face mask separately.

6.2 Pretreatment

Condition each specimen for at least 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.

7 Procedure

7.1 Preparation and cleaning of test apparatus

Prepare and clean the test apparatus using the following steps.