

Medical Face masks — Specification

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Public review draft

Medical Face masks — Specification

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Foreword

This Kenya Standard has been developed by the Technical Committee on Towels, Medical and Hygienic Textile Products under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

Medical face masks act as an effective means to reduce risk of infectious disease transmission between infected and non-infected persons during health care procedures. One releases smaller or larger amounts of droplets or secretions from the mucous membranes in the mouth and nose. Those droplets quickly disseminate and leave nuclei suspended in the air which can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment. The masks are designed to protect the working environment and the wearer when breathing, speaking, coughing, sneezing etc.

During the preparation of this standard, reference was made to the following documents:

BS EN 14683 Medical face Masks-Requirements and test methods

SANS 1866:2008 Edition 1.1, Medical fac3 face masks.

SANS 5263, Water absorption rate of textile fabrics.

SANS 5637, Determination of tearing strength.

SANS 6163, Water vapor transfer through a textile fabric.

Acknowledgement is hereby made for the assistance derived from these sources.

Medical Face masks — Specification**1 Scope**

This standard specifies construction, design, performance requirements and test methods for medical face masks intended to prevent the transmission of infective agents from one person to another in medical settings and other settings.

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

ISO 11737-1 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products

ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

ISO 10993 series biological evaluation of medical devices (ISO 10993 series)

3 Terms and Definitions

For the purposes of this standard, the following definitions shall apply:

3.1**Medical Face mask**

a medical device covering the mouth, nose and chin and providing a barrier to minimize the direct transmission of infectious agents

3.2**aerosol**

gaseous suspension of solid and/or liquid particles

3.3 bacterial filtration efficiency

efficiency of the medical face mask material(s) as a barrier to bacterial penetration

3.4 biocompatibility

quality of being accepted in a specific living environment without adverse or unwanted side effects

3.5 microbial cleanliness

freedom from population of viable micro-organisms on a product and/or a package in practical use, microbial cleanliness is often referred to as “bioburden”.

3.6 differential pressure

air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity. The differential pressure is an indicator of the “breathability” of the mask.

3.7 filter

material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air

3.8 infective agent

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microorganism that has been shown to cause medical face wound infections or that might cause infection i

3.9 splash resistance

ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure

3.10 surgical procedure

medical face intervention penetrating by skin or mucosa, performed by a surgical team under controlled environmental conditions

3.11 strap

a narrow strip or a flexible material used for securing the mask on to the person wearing the mask.

4 General Requirements

4.1 Classification of medical face mask

Medical face masks specified in this standard are classified into two types (Type I, Type II and Type IIR) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.

4.2 Materials and construction

4.2.1 Construction

The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness

4.2.2 Strap

The mask shall have a tape spun bonded polypropylene or elastic tape sewn to the mask. The tensile strength of the attaching of the tape to the mask shall be at least 20 N when tested in accordance with Annex C. The elastic shall be a synthetic elastomeric material of diameter of 5 mm. The length shall be such that the elastic fits comfortably around the head of the wearer.

4.2.3 Nose piece

The nose piece shall be a flexible strip of aluminum, plastics or similar material of normal width 3 mm which enables the mask to be shaped comfortably around the nose and face.

4.2.4 Reinforcing strip

The reinforcing strip shall be a strip of a synthetic spun bonded material.

4.2.5 Workmanship

The masks shall be free from defects that affect their appearance or may affect their serviceability (or both), and free from marks spots or stains incurred in the making up.

4.3 Design and size

The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

4.3.1 Medical face masks may have additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

4.3.2 The rectangular shaped mask shall be of finished width 170-195 mm and finished depth 90-100 mm. The masks shall be pleated 12-15mm horizontally and the edges ultrasonically sealed with minimum 10mm.

5 Specific requirements

5.1 Bacterial filtration efficiency (BFE)

The BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1 when tested in accordance with Annex A. when a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.

For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE

5.2 Differential pressure (Breathability)

The differential pressure of the medical face mask shall be as specified in Table 1 when tested in accordance with Annex B.

5.3 Splash resistance

The resistance of each of the type of medical face mask to penetration of liquid shall conform to the requirement given in Table 1 when tested in accordance with ISO 22609

5.4 Microbial cleanliness (Bioburden)

The bioburden of the medical mask shall be as specified in Table 1 when tested according to ISO 11737-1: procedure described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in ISO 11737-1 may be applied. The total bioburden per individual mask and based on the mask weight shall be reported which is the total bioburden per gram.

5.5 Biocompatibility

According to the definition and classification in ISO 10993-1, a medical face mask is a surface device with limited contact. The medical mask shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants. The manufacturer shall complete the evaluation of the medical face mask according to ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the ISO 10993 series. The test results shall be available upon request.

Table 1 Performance requirements for Medical face masks

Property	Type I ^a	Type II	Type IIR
bacterial filtration efficiency(BFE) , %, min.	95	98	98
Differential pressure , Pa/cm ² , max	40	40	60
Splash resistance (kPa),min	Not required	Not required	16
Microbial cleanliness(Bioburden) (cfu/g) max	30	30	30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

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6 Packaging

The following packaging requirements shall apply for the medical face masks:

- 6.1** The packaging shall allow for ease of dispensing, whether upright or inverted.
- 6.2** The standard weight of the packaging shall not exceed 30 kg
- 6.3** The pack shall be free of contaminants.

7 Labelling

The following information in English shall be legibly and indelibly marked on the packaging in which the medical face mask is supplied

- a) the manufacturers name and address.
- b) date of manufacture and expiry date.
- c) the country of manufacture.
- d) type of the mask (as indicated in Table 1)
- e) number of units
- f) instructions for use and disposal

Annex A

Method for *in vitro* determination of bacterial filtration efficiency (BFE)**A.1 General**

WARNING — *Staphylococcus aureus* is a pathogen. The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.

A.2 Principle

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol. For test apparatus see Figure A.3.

A.3 Reagents and materials**A.3.1 General**

A.3.2 and A.3.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

A.3.2 Tryptic soy agar**Formula/litre**

Enzymatic digest of casein 15 g

Enzymatic digest of soybean meal 5 g

Sodium chloride 5 g

Agar 15 g

Final pH 7.3 ± 0.2 at 25 °C

A.3.3 Tryptic soy broth**Formula/litre**

Enzymatic digest of casein 17 g

Enzymatic digest of soybean meal 3 g

Sodium chloride 5 g

Dipotassium phosphate 2.5 g

Dextrose 2.5 g

Final pH 7.3 ± 0.2 at 25 °C

A.3.4 Peptone water**Formula/litre**

Peptone 10 g

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Sodium chloride 5 g

Final pH 7.2 ± 0.2 at 25 °C

A.3.5 Culture of *Staphylococcus aureus* ATCC 6538, growing on tryptic soy agar slants

A.4 Test apparatus

A.4.1 Six stage cascade impactor, the arrangement is specified in Table A.1.

A.4.2 Nebulizer, capable of delivering particles with a mean size of $(3,0 \pm 0,3) \mu\text{m}$ when in contact with the cascade impactor.

A.4.3 Aerosol chamber, glass, 600 mm long and 80 mm in external diameter.

A.4.4 Flow meters, capable of measuring a flow rate of 28.3 l/min.

A.4.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa.

A.4.6 Erlenmeyer flasks, 250 ml and 500 ml capacity.

A.4.7 Peristaltic or syringe pump, capable of delivering 0,01 ml/min.

A.4.8 Vacuum pump, capable of maintaining a flow rate of 57 l/min.

A.5 Test specimens

Test specimens shall be cut from complete masks. A complete mask may be used in place of a cut specimen, as long as the extremities are removed, the mask is laid flat and all layers are incorporated (in case of folded masks unfold the mask in order to test a surface as flat as possible). Each specimen shall be minimum 100 mm \times 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask. The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4 %. All specimens tested shall be taken from representative areas to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge. Each test specimen shall be conditioned at $(21 \pm 5) ^\circ\text{C}$ and $(85 \pm 5) \%$ relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing.

A.6 Preparation of bacterial challenge

Staphylococcus aureus (see A.3.5) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of $(37 \pm 2) ^\circ\text{C}$ for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5×10^5 CFU/ml.

The bacterial challenge shall be maintained at $1,7 \times 10^3$ to $3,0 \times 10^3$ CFU per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see A.7.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size (MPS) in the bacterial challenge shall be maintained at $(3,0 \pm 0,3) \mu\text{m}$ (see A.7.9).

Table A.1 — Cascade impactor stage arrangement

Stage number	1	2	3	4	5	6
Size of particle	P1	P2	P3	P4	P5	P6
Viable "particle" plate count	C1	C2	C3	C4	C5	C6

Where

P1 = 7.00 µm
 P2 = 4.70 µm
 P3 = 3.30 µm
 P4 = 2.10 µm
 P5 = 1.10 µm
 P6 = 0.65 µm

$$\text{MPS} = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6}$$

The viable “particles” plate count values used for MPS calculations are the converted “probable hit” counts calculated using the positive hole conversion chart from the cascade impactor manual. The MPS value above is the 50 % effective cut-off diameter calculated for each stage using the equation and information from the cascade compactor manual.

A.7 Procedure

A.7.1 Assemble the test apparatus in accordance with the flow chart shown in Figure A.1 or Figure A.3.

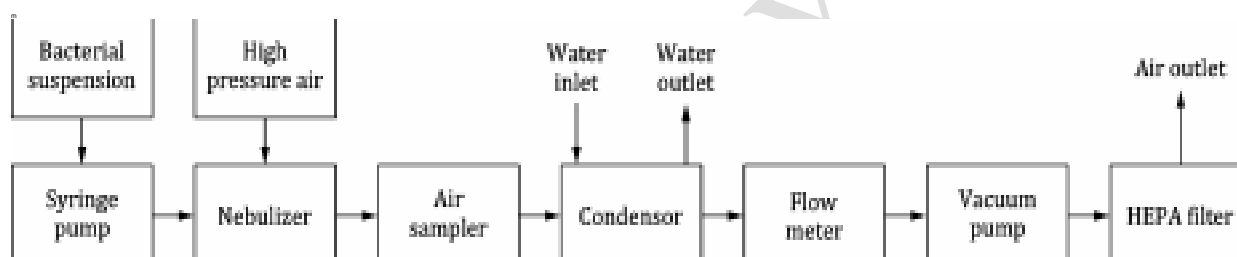


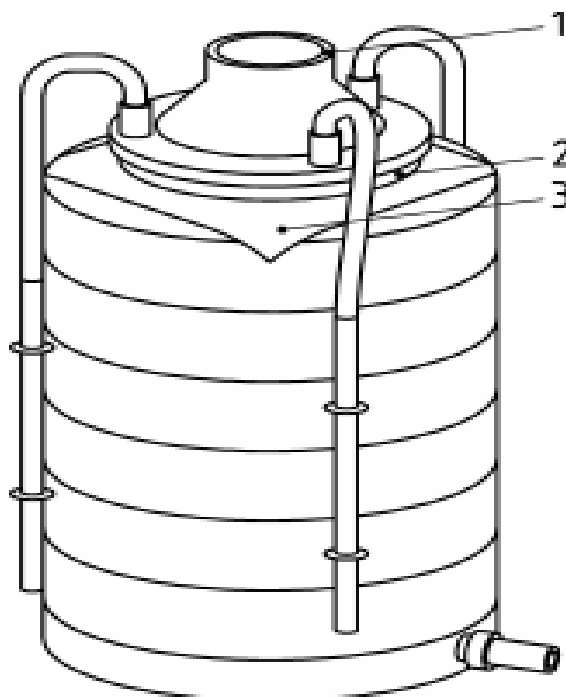
Figure A.1 — Principle of BFE test apparatus

A.7.2 Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

A.7.3 Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28.3 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the cascade impactor one additional minute (total test time is 2 min). Then remove the plates from the cascade impactor. Ensure that each plate is numbered to indicate its position in the cascade impactor.

A.7.4 Place fresh plates in the cascade impactor, clamp the test specimen in place between the first stage of the cascade impactor and the inlet cone (see Figure A.2) and repeat the procedure described in

B.7.3. The test area shall be minimum 49 cm². Alternative means to position the sample may be appropriate, but, if deviated from the procedure, this shall be documented in the test report.



Key

- 1 inlet cone
- 2 o'ring inlet cone
- 3 cloth / mask

Figure A.2 — Placement of test specimen on the cascade impactor

A.7.5 Repeat this procedure for each test specimen.

A.7.6 After the last test specimen has been tested, perform a further positive control run.

A.7.7 Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

A.7.8 Incubate all the plates at $(37 \pm 2) ^\circ\text{C}$ for (20 to 52) h.

A.7.9 For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of CFU collected by the cascade impactor. Use the “positive hole” conversion table¹⁾ in accordance with the instructions of the cascade impactor manufacturer for stages 3 to 6. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size (MPS) of bacterial challenge aerosol using the formula given in B.6.

A.8 Calculation of bacterial filtration efficiency (BFE)

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

Note 1: See the positive hole conversion table found in the cascade impactor manual.

$$B = (C - T) / CX100$$

where

C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

Test report

The following information shall be given in the test report:

- a) dimensions of the test specimens and the size of the area tested;
- b) which side of the test specimen was facing towards the challenge aerosol;
- c) flow rate during testing;
- d) mean of the total plate counts of the two positive controls;
- e) mean plate count of the negative controls;
- f) bacterial filtration efficiency (BFE)

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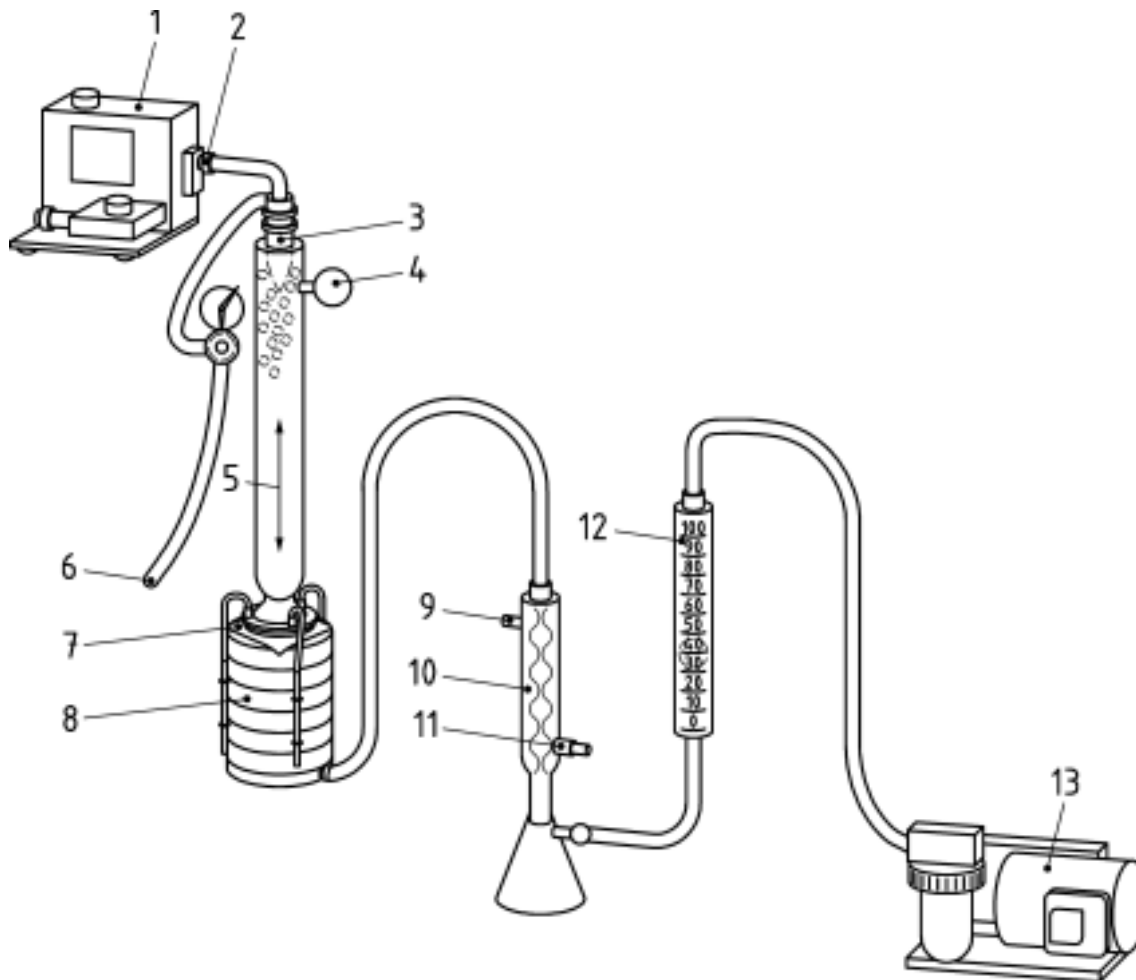


Figure A.3 — Example of real BFE test apparatus

Key

- 1 drive mechanism
- 2 bacterial suspension
- 3 nebulizers
- 4 filter
- 5 aerosol chamber
- 6 high pressure air source
- 7 test material
- 8 cascade impactor
- 9 outlets to sink
- 10 condenser
- 11 cold water inlet
- 12 calibrated flow meter

13 compressors (vacuum pump)

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Annex B

Method for determination of differential pressure (breathability)

B.1 Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure B.1. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.

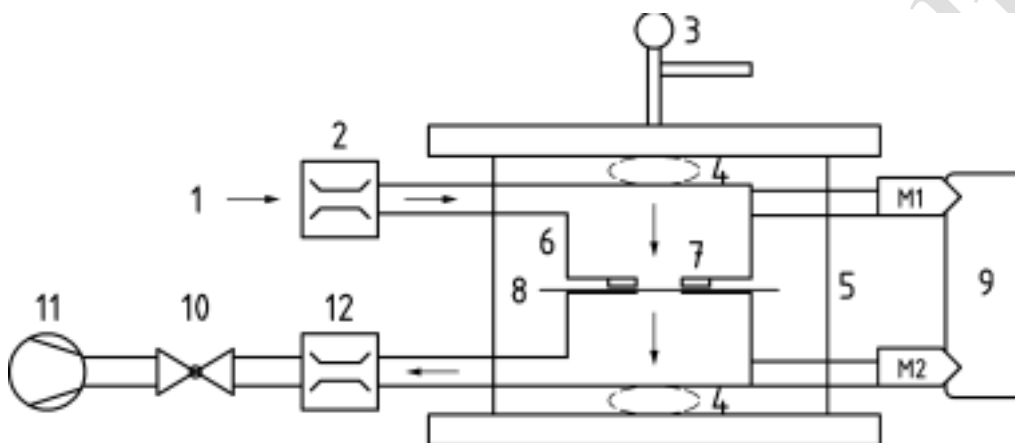


Figure B 1— Test apparatus for measuring differential pressure

Key

- 1 air inlet
- 2 mass flow meter
- 3 lever for mechanical clamping
- 4 systems for final adjustment of the pressure of the sample holder (either at the top or the bottom)
- 5 system ensuring optimal alignment of the 2 parts of the sample holder
- 6 sample holder with a metal sealing mechanism (optional)
- 7 metallic ring (3 mm thick)
- 8 filter material
- 9 differential manometer or M1 and M2 manometers
- 10 valve
- 11 vacuum pump including a pressure buffer tank
- 12 mass flow meter for checking leaks

B.2 Test apparatus

B.2.1 Mass flow meter(s) capable of measuring an airflow of 8 l/min.

B.2.2 Manometer, a differential manometer (water or digital). Individual manometers can also be used. M1 is for the upstream pressure measurement and M2 is for the downstream pressure measurement.

B.2.3 Electric vacuum pump including a pressure buffer tank.

B.2.4 Valve permitting the adjustment of the flow rate.

B.2.5 Sample holder

B.2.5.1 The sample holder shall consist of a mechanical clamping system and alignment of the top and bottom holder.

B.2.5.2 The sample holder shall consist of a mechanism to adjust the clamping pressure. A system with thread of screw can be used either at the bottom or top part of the sample holder.

B.2.5.3 The internal diameter of the top holder and the bottom holder in the contact are with the filter material shall be (25 ± 1) mm.

B.2.5.4 The seal of the top and bottom holder onto the filter material shall consist of a metal-metal contact. A metallic ring of internal diameter of (25 ± 1) mm and ca. 3 mm thick will be fixed to the top holder. The bottom holder will consist of a completely flat metallic surface with an internal diameter of (25 ± 1) mm and a 3 mm area around the open diameter. Materials such as rubber or poly foam do not provide a sufficient seal and may deform into the test area.

B.2.5.5 Validation of the test apparatus shall consist of a leak test. A second flow meter (12) immediately before the valve (10) will allow for evaluation of an air leak within the test apparatus. With the sample holder closed, start the pump and adjust the flow meter to read 8 l/min on the first flow meter (2). If no leaks are present both flow meters should read 8. Another check shall consist of stopping inlet air when both flow meters give 8 l/min. After a few seconds both flow meters should indicate 0 l/min if no leaks.

B.3 Test specimens

Test specimens are complete masks or shall be cut from complete masks. If a complete mask is used, remove extremities and lay the mask flat with all layers incorporated. Each specimen shall be able to provide different circular test areas of 25 mm in diameter. If one specimen cannot provide 5 test areas of 25 mm diameter, the number of test areas retrieved should be representative for the entire mask. For thick and rigid masks, the test method may not be suitable as a proper seal cannot be maintained in the sample holder. The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %. All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the airflow direction from the inside of the mask to the outside of the mask. Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

B.4 Procedure

B.4.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.

B.4.2 The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area $4,9 \text{ cm}^2$) between the top and bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks. Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air. With the specimen in place the flow rate should be 8 l/min as previously set in B.4.1. If the flow rate is not at 8 l/min, a leak may be present. Try to increase the pressure if possible to avoid this problem. In such case the use of a second flow meter during testing is also indicated.

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B.4.3 The differential pressure is read directly if using a differential pressure manometer. If using manometers M1 and M2 read and record each pressure.

B.4.4 The procedure described in steps B.4.1 to B.4.3 is carried out on 5 (or appropriate number) different areas of the mask and the readings averaged.

If the mask comprises different material types in different areas, test an even number of the different areas. For example, the average should consist of 3 readings on the top portion of the mask with material type A and 3 readings on the bottom portion of the mask with material type B.

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B.5 Calculation of differential pressure

For each test specimen calculate the differential pressure $\Delta P/\text{cm}^2$ of each tested area as follows

$$\Delta P = (X_{m1} - X_{m2}) / 4.9$$

where

X_{m1} is the pressure in Pa, measured by manometer M1 – low pressure side of the material;

X_{m2} is the pressure in Pa, measured by manometer M2 – high pressure side of

4.9 is the area (in cm^2) of the test material;

ΔP is the differential pressure per cm^2 of test material expressed in Pa.

NOTE If a differential manometer is used the differential pressure ($X_{m1} - X_{m2}$) is directly obtained.

Annex C

Determination of strap attachment force

C.1 Examine the way the straps are fixed onto the body of the mask note their positions.

C.2 From the body of the mask, at the point at which the strap is fixed, cut out an inline specimen of at least 50mm x 100mm.

C.3 Cut off the strap, leaving out a length of 200mm attached to the test specimen (see Figure C.1).

C.4 The strap attachment strength is tested using a constant-rate-of-extension (CRE) tensile machine as described in ISO13934-1.

C.5 Set the gauge length of the tensile-testing machine to $50 \text{ mm} \pm 1 \text{ mm}$. With a pretension of 1N, mount the test specimen centrally so that the strap center-line passes through the center point of the front edges of the jaws

C.6 Operate the tensile machine at a constant rate of extension of 200 mm per minute, and record the maximum force required to break off the strap from the mask

C.7 Repeat the procedure for at least four other specimens randomly selected.

C.8 Report the Arithmetic mean of the maximum force to the nearest 1N

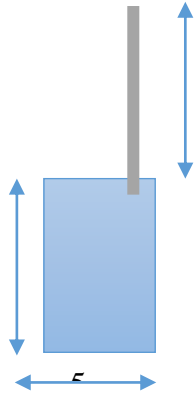


Figure A1 Attachment of the strap to test specimen(mask) after cut off