
**Respiratory protective devices —
Methods of test and test equipment —**

**Part 1:
Determination of inward leakage**

*Appareils de protection respiratoire — Méthodes d'essai et
équipement d'essai —*

Partie 1: Détermination des fuites vers l'intérieur



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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 15, *Respiratory protective devices*.

ISO 16900 consists of the following parts, under the general title *Respiratory protective devices — Methods of test and test equipment*:

- *Part 1: Determination of inward leakage*
- *Part 2: Determination of breathing resistance*
- *Part 3: Determination of particle filter penetration*
- *Part 4: Determination of gas filter capacity and migration, desorption and carbon monoxide dynamic testing*
- *Part 6: Mechanical resistance/strength of components*
- *Part 7: Practical performance test methods*
- *Part 8: Measurement of RPD air flow rates of assisted filtering RPD*
- *Part 9: Determination of carbon dioxide content of inhaled air*
- *Part 10: Resistance to ignition, flame, radiant heat and heat*
- *Part 11: Determination of field of vision*
- *Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures*
- *Part 13: RPD using regenerated breathable gas and special application mining escape RPD: Consolidated test for gas concentration, temperature, humidity, work of breathing, breathing resistance and duration*
- *Part 14: Measurement of sound level*

The following parts are under preparation:

— *Part 5: Breathing machine/metabolic simulator/RPD headforms/torso, tools and transfer standards*

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Introduction

This part of ISO 16900 is intended as a supplement to the respiratory protective devices (RPD) performance standard ISO 17420 (all parts). Test methods are specified for complete devices or parts of devices that are intended to comply with ISO 17420. If deviations from the test method given in this part of ISO 16900 are necessary, these deviations will be specified in ISO 17420.

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Respiratory protective devices — Methods of test and test equipment —

Part 1: Determination of inward leakage

1 Scope

This part of ISO 16900 specifies the test methods for determining inward leakage of respiratory interfaces (RI) and total inward leakage of complete respiratory protective devices (RPD) using specified test agents and incorporating specified body movements, at specified metabolic work rates.

These tests are conducted in laboratories using specific test agents under specified conditions and therefore do not indicate the performance of the device in actual use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16972, *Respiratory protective devices — Terms, definitions, graphical symbols and units of measurement*

ISO 16900-5¹⁾, *Respiratory protective devices — Methods of test and test equipment — Part 5: Breathing machine/metabolic simulator/RPD headforms/torso, tools and transfer standards*

ISO 17420-3, *Respiratory protective devices — Performance requirements — Part 3: Thread connection*

ISO 21748, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*

ISO/TS 16976-2:2010, *Respiratory protective devices — Human factors — Part 2: Anthropometrics*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 16972 and the following apply.

3.1

assisted filtering RPD

filtering RPD in which air is moved through the filter(s) by means of a blower in addition to the breathing of the wearer

3.2

porous device

RPD incorporating materials, excluding filters, that can be penetrated by gases and vapours during an inward leakage test, leading to an increase of the inward leakage

3.3

unassisted filtering RPD

filtering RPD in which air is drawn through the filter(s) solely by the breathing of the wearer

1) To be published.

4 Prerequisites

The performance standard shall indicate the conditions of the test. This includes the following:

- a) minimum number of test specimens;
- b) number of test subjects and selection criteria;
- c) operating conditions of the RPD;
- d) if appropriate, test method (including test agent and sampling methods) to be used;
- e) the exercise regime to be used;
- f) if appropriate, the use of crosswinds during particular test exercises;
- g) any exclusions from the test exercise regimes of [Annex B](#);
- h) any prior conditioning, sequence of preconditioning, and/or testing required;
- i) any optional features of the RPD to be included in the assessment;
- j) characteristics to be assessed subjectively (if appropriate).

5 General test requirements

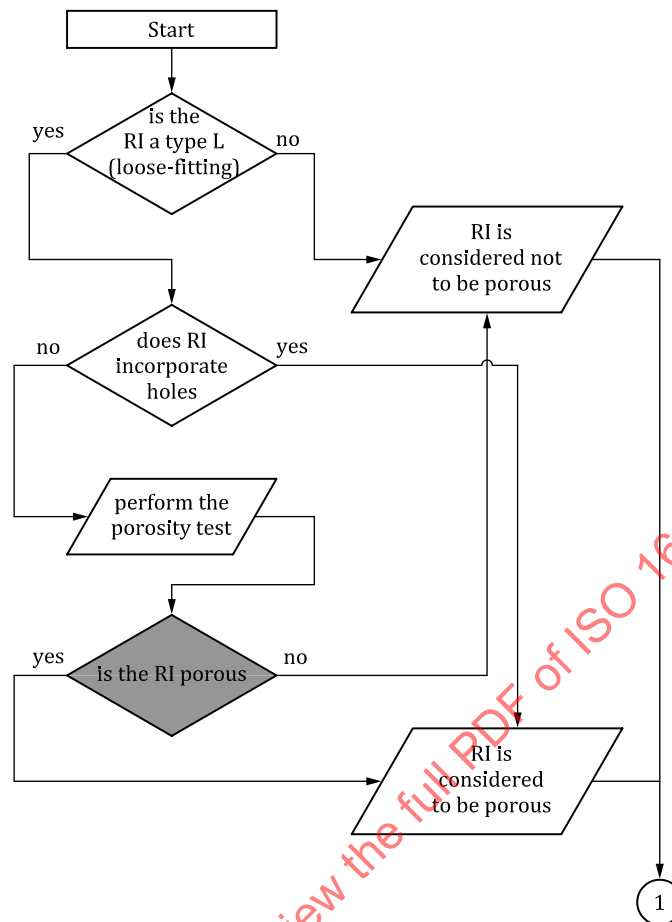
Unless otherwise specified, the values stated in this part of ISO 16900 are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$. Unless otherwise specified, the ambient conditions for testing shall be between $16\text{ }^{\circ}\text{C}$ and $32\text{ }^{\circ}\text{C}$ and $(50 \pm 30)\%$ RH. Any temperature limits specified shall be subject to an accuracy of $\pm 1\text{ }^{\circ}\text{C}$.

6 Principle

A test subject wearing the RPD being tested performs a series of exercises while surrounded by an atmosphere containing a known concentration of a test substance. During these exercises, the concentration of the test substance inside and outside the respiratory interface (RI) is measured and compared.

Three test agents are specified: one solid aerosol, one liquid aerosol, and a gas. The general principle of the test is the same for all substances. The test agent(s) used depend on the type of RPD being tested and are chosen according to [Figure 1](#).

NOTE Where a choice of gas or aerosol is permitted according to [Figure 1](#), the aerosol test methods are preferred since SF_6 is regarded to be a greenhouse gas and its use is deemed undesirable where it could be avoided.



NOTE Excluded are RPD which are obviously open to the atmosphere and which need not be tested using a challenge gas.

Figure 1 — Determination of porosity of RI (Respiratory Interface)

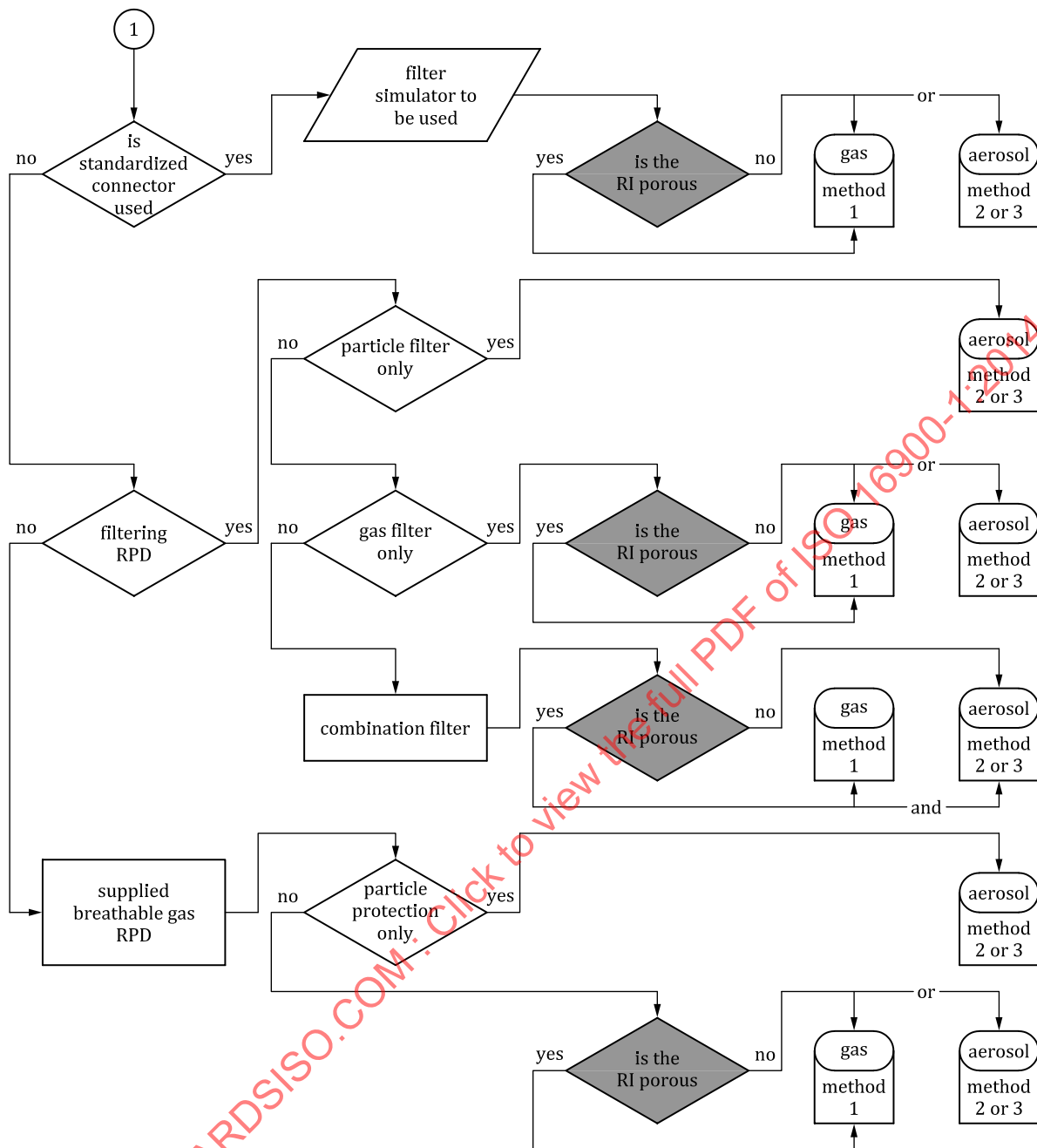


Figure 2 — Determination of test methods for RI (Respiratory Interface)

7 Human test panel

7.1 General

7.1.1 Before performing tests involving human test panels, account should be taken of any national or other regulations concerning, for example the medical history, any know allergies, examination, or supervision of the test subjects.

7.1.2 Test subjects shall be trained by a competent person in wearing the type of RPD being tested.

7.1.2.1 Unless the RPD manufacturer's user instructions specify that the device can be worn by persons with facial hair, then male panel members shall be clean shaven in the area of the face seal.

7.1.2.2 Persons with scars or other facial blemishes in the area of the face seal that might give rise to face seal leakage shall not be selected for the test panel.

7.1.2.3 Persons nominated as test subjects shall follow the manufacturer's donning instructions, which can include a wearer seal check. If the person cannot achieve an adequate seal, following the manufacturer's instructions, the person shall not be used for the inward leakage test.

7.1.2.4 Where a manufacturer specifies a size range for wearers of the device, only subjects who fall within the specified range shall be used for the test.

7.1.2.5 If more than one size of respiratory interface is manufactured, the test subjects shall select the most appropriate size in accordance with the information supplied by the manufacturer.

When using particle counting detection method, the test subject should refrain from smoking for at least 30 min before wearing the RPD.

7.2 Selection of test subjects

The human test panel shall be as defined in ISO/TS 16976-2:2010, 8.3, [principal component analysis (PCA) panel]. Further information is given in [Annex D](#). The selection of the test subject shall be as specified by the RPD manufacturer according to the requirements of ISO 17420.

8 Test agents

Three test agents are specified for the inward leakage tests:

- a) test agent 1 = sulfur hexafluoride gas (SF₆);
- b) test agent 2 = sodium chloride aerosol (NaCl);
- c) test agent 3 = corn oil aerosol.

All three test agents are equally acceptable for determination of inward leakage or total inward leakage, subject to the selection requirements of [Figure 2](#).

If porosity is indicated by the results from the materials porosity test ([Annex C](#)), then it shall be tested using sulfur hexafluoride gas.

9 Apparatus

9.1 Enclosure, large enough to permit each test subject to complete the test exercise regime without restriction. A uniform and continuous flow of the relevant test atmosphere shall be delivered into the test enclosure.

The enclosure design and air flow management system shall permit the test atmosphere concentration within the area occupied by the RPD and wearer during all exercises to be homogeneous and stable (within ±10 %) throughout the duration of any test.

The air velocity through the enclosure measured close (within 30 cm) to the test subject's head, with the test subject standing centrally (on the treadmill where appropriate) and without crosswind conditions, shall be sufficient to maintain the specified concentration but shall not exceed 0,2 m/s.

The enclosure shall be designed so that the test subject is visible from the outside of the enclosure at all times while in the enclosure. A means of providing communication between the test subject(s) and the test supervisor(s) shall be provided.

For RPD to be tested under crosswind conditions, provision shall be made to generate a crosswind of 2 m/s across the enclosure, from the front, rear or side (left or right), in the vicinity of the test subject's head.

NOTE Such provision might need to be adjustable in height to generate the crosswind at the appropriate position for all test subjects.

The design of the enclosure shall be such that the device worn by the subject can be supplied with clean air (free of the test agent), where necessary.

The volume of the test chamber shall be large enough, and the replacement of the test atmosphere shall be such as to prevent dilution of the test atmosphere by clean air emanating from the device under test.

When SF₆ gas is employed as the test atmosphere, the test chamber should preferably permit recirculation of the air/SF₆ volume to minimize exhaust of SF₆ into the ambient atmosphere.

9.2 Treadmill, capable of working up to the speed as required by the exercise regime defined in [Annex B](#), shall be used.

9.3 Test agent generator - General, capable of generating the test agent in the required concentration, and, in case of an aerosol, of the required particle size distribution.

9.4 Detection system - General, either one detector or different detectors for measuring the test enclosure and the respiratory interface sample concentrations.

The detection system including sampling probes and connections shall have a response time of less than 20 s for a response of 10 % to 90 % of the full-scale deflection of the range used. Further details of the detections system required for each specified test agent are given in [11.2](#), [11.3](#), and [11.4](#).

10 RPD preparation

10.1 General

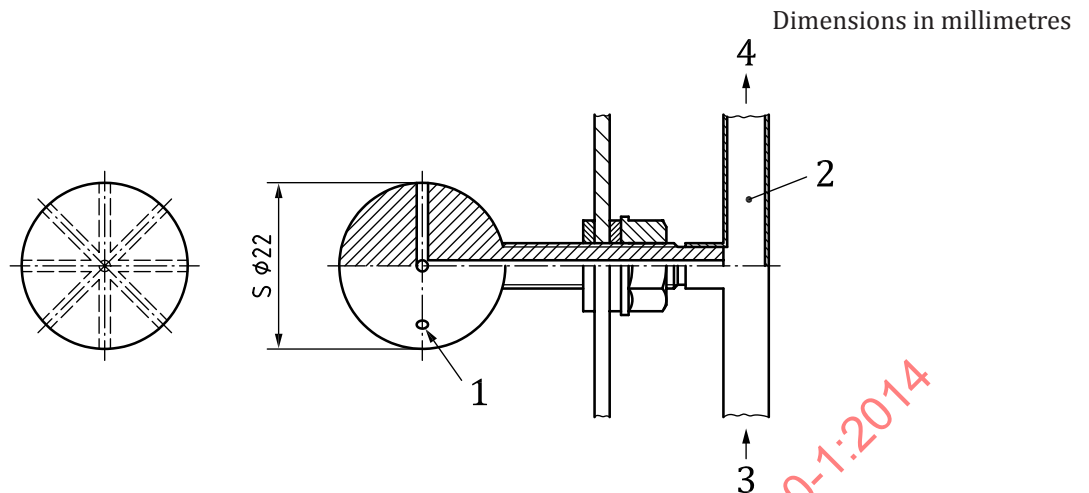
Prior to the inward leakage test, examine the RPD in accordance with the manufacturer's instructions to ensure that it is in good working condition and can be used without hazard to the test subject.

Prepare the RPD to be tested in accordance with their design, the test agent to be used, and whether the inward leakage of a respiratory interface or the total inward leakage of a complete device is to be determined. Further details are given in [10.4](#), [10.5](#), and [10.6](#).

10.2 Sample tubes and probe

In order to sample and analyse the air inside the respiratory interface, use an adapter normally provided by the manufacturer; or where this is not possible, punch a hole in the respiratory interface and insert a probe through which the sample is drawn by a suitable sample pump.

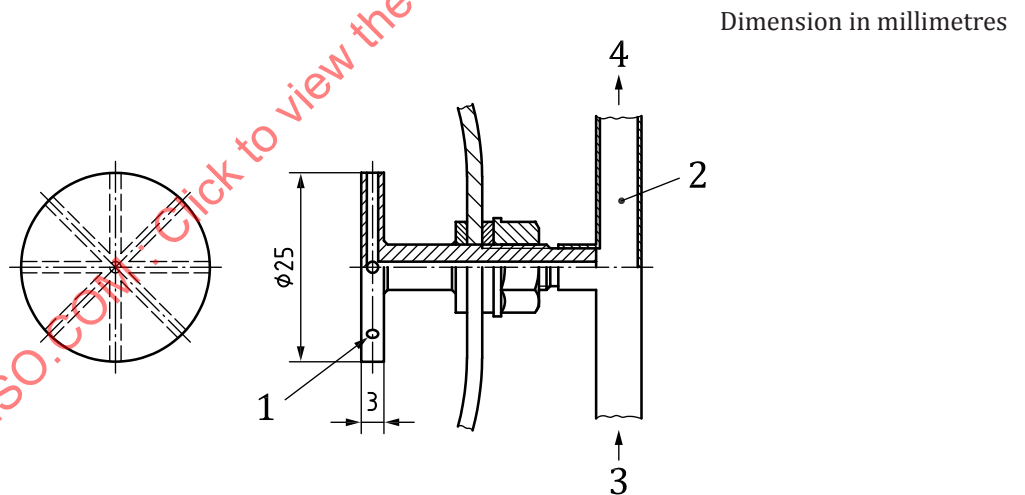
Multiple-hole sampling probe ([Figure 3](#) and [Figure 4](#)) should be used to minimize sampling bias within the respiratory interface. Single-hole probes with chamfered entry ([Figure 5](#)) have been shown to be acceptable. [Figures 6](#) to [9](#) show probe methods of fixation.



Key

- 1 eight holes, diameter 1,5 mm, equally spaced
- 2 suitable flexible tube
- 3 direction of drying air (for sodium chloride only)
- 4 connection to sample pump

Figure 3 — Example of ball probe

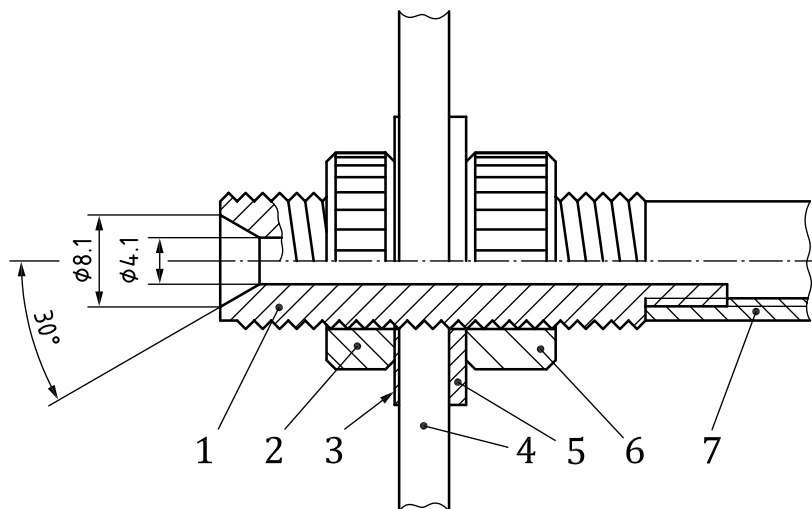


Key

- 1 eight holes, diameter 1,5 mm, equally spaced
- 2 suitable flexible tube
- 3 direction of drying air (for sodium chloride only)
- 4 connection to sample pump

Figure 4 — Example of disc probe

Dimensions in millimetres



Key

- 1 probe tube
- 2 inner nut
- 3 inner washer
- 4 respiratory interface
- 5 outer washer
- 6 outer nut
- 7 sampling tube

Figure 5 — Example of sampling probe (surface fixed)

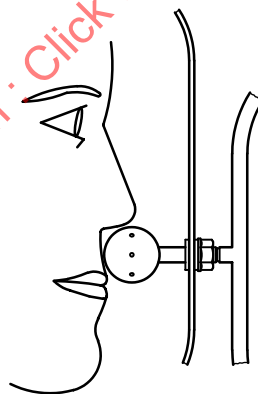


Figure 6 — Example of a ball probe used on device with rigid visor

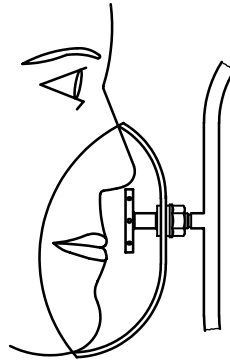
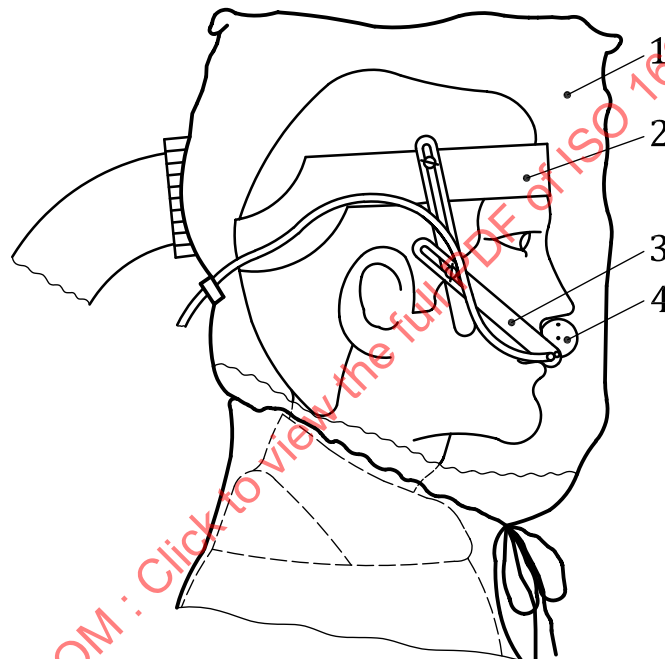


Figure 7 — Example of a disc probe used on filtering device



Key

- 1 hood under test
- 2 headband
- 3 adjustable plastics arm
- 4 ball sample probe

Figure 8 — Typical arrangement for sampling from device with soft plastic hoods

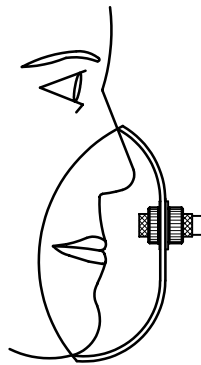


Figure 9 — Example of sampling probe (surface fixed) in filtering device

The probe shall be fitted securely to the respiratory interface, terminating as near as possible to the wearer's face (<10 mm) and approximately midway between the nose and mouth.

Where necessary, for flexible, soft, or lightweight respiratory interfaces, employ a means to support the weight of the probe assembly and associated tubing, e.g. a head harness, to prevent distortion of the respiratory interface. This distortion can alter the face seal causing additional leakage.

A second sampling probe (identical to the first) shall be used to measure the ambient concentration of test agent in the test enclosure. This shall be placed close to the RPD, but away from the effect of any exhalation from the RPD under test. The sampling probes shall be connected to the analysing equipment by means of flexible thin-walled tubing of about 3 mm bore, the length of which shall be kept as short as possible. The two sampling tubes shall be of the same type and length.

Where the performance standard requires that a sample be withdrawn from the ocular region of the respiratory interface, the sampling probe shall be positioned on one side of the test subject at eye level and make up air might be required.

Care shall be taken to ensure that the sample tubes and probe do not disturb the normal fit or shape of the respiratory interface.

10.3 Sample flow rates

Sample flow rates shall be between 0,3 l/min and 2 l/min, depending on the detection system. The sample flow rate shall be kept as low as possible so as not to change the designed performance of the RPD being tested.

It might be necessary to supply a compensating airflow when sampling from an area of the RPD through which, under normal conditions of use, there is no airflow, e.g. when sampling from the ocular region. Position the compensating airflow such that it does not cause sampling bias nor distress the wearer.

When sodium chloride is used to test negative pressure devices, drying air at a flow of about 1 l/min is added to minimize condensation and hence loss of sodium chloride particles in the sampling tube. The sample flow rate from the respiratory interface is equal to the total flow through the sample pump minus the flow rate of dry air. A correction shall be made for the diluting effect of this dry air when leakage calculations are performed (see [11.3.2.2](#) and [11.3.3.2](#)). Dry air is not required if gas or corn oil aerosol is the test agent.

10.4 Filtering RPD preparation

10.4.1 Unassisted filtering RPD with a connector in accordance with ISO 17420-3

Unassisted RPD incorporating a respiratory interface with a connector in accordance with ISO 17420-3 shall be fitted with the filter simulator as specified in ISO 16900-5, instead of a filter.

Breathable air (free of the test agent) shall be supplied (on demand) to the filter simulator via a lightweight hose. It is important that the attachment of the clean air hose to the device does not affect the fit of the device on the test subject. The breathing resistance of the combination of the clean air hose and filter simulator shall be within 10 % of the filter simulator alone when measured at a flow of 110 l/min.

Fitting of the hose shall not replace any seals incorporated in the RPD. If necessary the hose shall be supported.

The test agent(s) to be used shall be chosen in accordance with [Figure 2](#).

10.4.2 Unassisted filtering RPD fitted with particle filters or combination filters

The complete RPD shall be tested for total inward leakage using an aerosol test agent. Fit the RPD with the appropriate filter(s) for the specified RPD class.

10.4.3 Unassisted filtering RPD with gas/vapour or combination filters

The test agent(s) to be used shall be chosen in accordance with [Figure 2](#).

When inward leakage is to be determined using a gas test agent, breathable air (free of the test agent) shall be supplied (on demand) to the filter. For this purpose, lightweight hose(s) and plenum cap(s) shall be attached to the filter element(s) of the test specimen and breathable air (free of the test agent) supplied to it at a flow resistance (including hoses) within ± 10 % (when measured at a flow rate of 110 l/min) compared to that measured for the unmodified RPD.

For gas/vapour filters, when total inward leakage is to be determined using an aerosol test agent, replace the gas filters by particle filters. The replacement particle filters shall have the same mass (± 10 %) and breathing resistance (± 10 %), (when measured at a flow rate of 110 l/min), as their gas/vapour counterparts, based on the mean of the supplied filters.

It is important that the attachment of the surrogate filter(s) does not affect the fit of the device, nor shall its fitting replace any seals incorporated in the device.

10.4.4 Assisted filtering RPD with particle filter(s) or combination filter(s)

The complete RPD shall be tested for total inward leakage using an aerosol test agent. Fit the RPD with the appropriate filter(s) for the specified RPD class.

The RPD shall be tested at the operating conditions as specified in the relevant performance standard. When the performance standard requires that the RPD be operated at the minimum designed operating conditions as specified by the manufacturer, these conditions shall be re-created using appropriate means.

NOTE This might require the use of an external power supply, or the use of a modified device supplied by the manufacturer.

10.4.5 Assisted filtering RPD with gas/vapour or combination filter(s)

The test agent(s) to be used shall be chosen in accordance with [Figure 2](#).

When inward leakage is to be determined using a gas test agent, breathable air (free of the test agent) shall be supplied to the filter. For this purpose, lightweight hose(s) and plenum cap(s) shall be attached to the filter element(s) of the test specimen and breathable air (free of the test agent) supplied to it at a flow resistance (including hoses) within ± 10 % (when measured at a flow rate of 110 l/min) compared to that measured for the unmodified RPD.

For gas/vapour filters, when total inward leakage is to be determined using an aerosol test agent, replace the gas filters by particle filters. The replacement particle filters shall have the same mass (± 10 %) and breathing resistance (± 10 %), (when measured at a flow rate of 110 l/min), as their gas/vapour counterparts, based on the mean of the supplied filters.

It is important that the attachment of the surrogate filter(s) does not affect the fit of the device, nor shall its fitting replace any seals incorporated in the device.

The RPD shall be tested at the operating conditions as specified in the relevant performance standard. When the performance standard requires that the RPD be operated at the minimum designed operating conditions as specified by the manufacturer, these conditions shall be re-created using appropriate means.

NOTE This might require the use of an external power supply, or the use of a modified device supplied by the manufacturer.

10.5 Supplied breathable gas devices

The test agent(s) to be used shall be chosen in accordance with [Figure 2](#).

The RPD shall be tested at the operating conditions as specified in the relevant performance standard. When the performance standard requires that the RPD be operated at the minimum designed operating conditions as specified by the manufacturer, these conditions shall be re-created using appropriate means.

10.6 Supplied breathable gas devices incorporating additional filtration capacity (combined RPD)

Supplied breathable gas devices which incorporate a filtration facility (combined RPD) shall be tested as complete devices in both modes of operation in accordance with the requirements defined in the performance standards. When tested in supplied breathable gas mode, the filters shall be fitted to the RPD and capped. The test agents shall be chosen in accordance with [Figure 2](#).

The devices shall also be tested in the filtration mode using a test aerosol. The device shall be fitted with the appropriate particle filter(s) for the specified RPD class.

The RPD shall be tested at the operating conditions as specified in the relevant performance standard. When the performance standard requires that the RPD be operated at the minimum designed operating conditions as specified by the manufacturer, these conditions shall be re-created using appropriate means.

11 Method(s)

11.1 Test method — General

11.1.1 Train the test subjects on how to correctly select and don the device in accordance with the information supplied by the manufacturer.

11.1.2 The testing officer shall ensure that the device has been correctly donned in accordance with the manufacturer's instructions.

11.1.3 Inform the test subjects that if they wish to adjust the device during the background measurement and acclimatization exercise they can do so. However, no further adjustments are allowed thereafter.

11.1.4 Ensure that the test subjects have no indication of the result as the test proceeds.

11.1.5 Have the subject enter the test enclosure.

11.1.6 Connect up the sampling probe and, if applicable, the clean air supply, the breathing sensor, and compensating air. Operate the device as required in the relevant performance standard.

11.1.7 For NaCl and SF₆, it is necessary to establish a background level within the respiratory interface. Without exposure to the test agent, measure the residual test agent concentration inside the respiratory interface to establish the background level. The test subject shall walk on the treadmill at a speed of 4 km/h until a steady background measurement has been recorded.

11.1.8 Turn on the test atmosphere.

11.1.9 When the test atmosphere has stabilized the test subject shall perform the exercise regime continuously as specified in [Annex B](#).

11.1.10 If required by the relevant performance standard, introduce the 2 m/s crosswind during the appropriate exercise(s).

11.1.11 Record:

- a) enclosure concentration;
- b) the leakage over each exercise period, as defined in [11.2.2](#), [11.3.2.2](#), and [11.3.3.2](#).

11.1.12 When the exercise regime has been completed, the test subject can exit the enclosure. If necessary, turn the test atmosphere off and ensure that the test agent has cleared from the enclosure before removing the test subject.

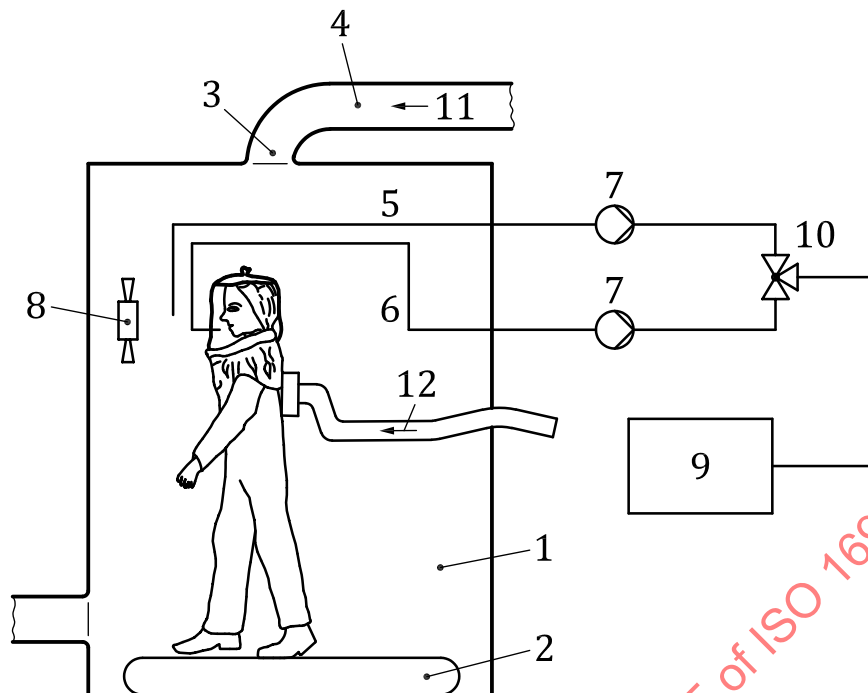
11.1.13 When the RPD is to be reused, the device shall be cleaned, disinfected, and dried ready for use in accordance with the manufacturer's instructions. For RPD that is not designed to be cleaned, a new sample shall be used.

11.2 Test method 1: Sulfur hexafluoride (SF₆)

11.2.1 Test equipment

Typical test arrangements are shown in [Figures 10](#) and [11](#).

This method employs SF₆ as a test agent. The test subject wearing the device under test performs a series of test exercises inside an enclosure containing the SF₆ test atmosphere. Accurate determinations of leakage shall be possible at least within the range from 0,000 5 % to approximately 20 %.



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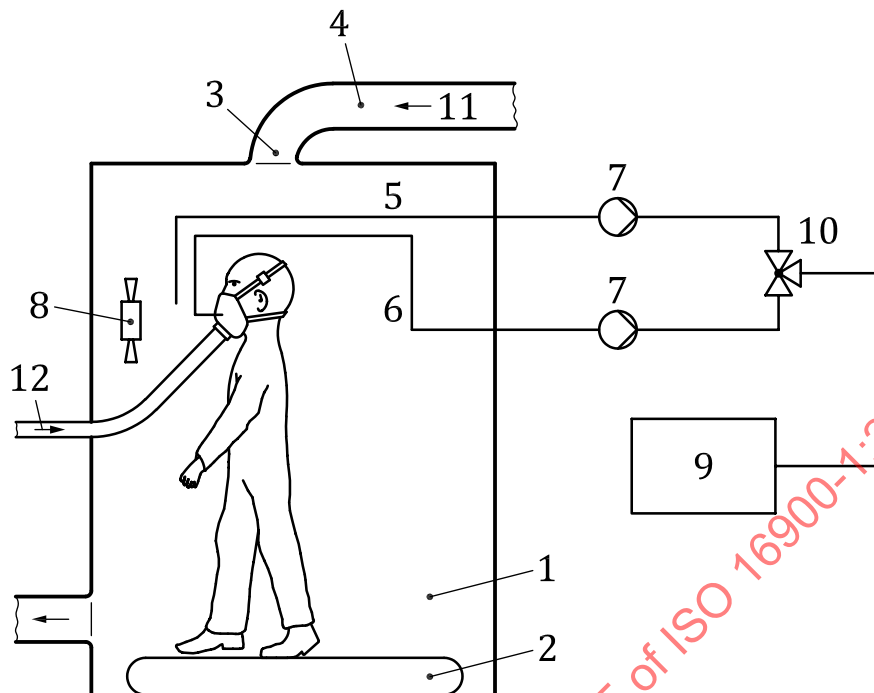
re sample
tory interface sample
pump
ion fan (if required)

9 analyser
10 change-over valve
11 air and SF₆
12 breathable air

10 — Typical test arrangement for determination of inward leakage by the sulfur fluoride method; showing RPD having a respiratory interface type L (loose fitting)

- | | | | |
|---|-------------------------------|----|-------------------------|
| 1 | enclosure | 9 | analyser |
| 2 | treadmill | 10 | change-over valve |
| 3 | baffle | 11 | air and SF ₆ |
| 4 | duct | 12 | breathable air |
| 5 | enclosure sample | | |
| 6 | respiratory interface sample | | |
| 7 | sample pump | | |
| 8 | circulation fan (if required) | | |

Figure 10 — Typical test arrangement for determination of inward leakage by the sulfur hexafluoride method; showing RPD having a respiratory interface type L (loose fitting)

**Key**

- | | |
|---------------------------------|----------------------------|
| 1 enclosure | 9 analyser |
| 2 treadmill | 10 change-over valve |
| 3 baffle | 11 air and SF ₆ |
| 4 duct | 12 breathable air |
| 5 enclosure sample | |
| 6 respiratory interface sample | |
| 7 sample pump | |
| 8 circulation fan (if required) | |

Figure 11 — Typical test arrangement for determination of inward leakage by the sulfur hexafluoride method, showing RPD having a respiratory interface type “T” (tight fitting)

11.2.1.1 Test gas generation

The gaseous test agent is produced by feeding SF₆ from a compressed gas source into the enclosure's air delivery system. A test agent concentration between 0,1 % and 1 % SF₆ by volume is recommended, starting with a low challenge concentration and increasing it when the results of a preliminary test indicate such a low leakage that higher concentrations are required and can be justified.

SF₆ with a 99,99 % or higher purity shall be used.

11.2.1.2 Detection

The detection limit of the detector system shall be at least a factor of 10 lower than the level of SF₆ gas that corresponds to the pass/fail level in the performance standard. The variation of the concentration throughout the effective working volume shall be not more than 10 %. The test atmosphere shall be analysed for SF₆, preferably continuously, by means of a suitable analyser. The SF₆ concentration inside the respiratory interface shall be continuously sampled at a constant sampling rate of between 0,3 l/min and 1,5 l/min; and shall be analysed and recorded, preferably using an integrating recording system. This concentration is a measure of the inward leakage.

A suitable detection system can be either based on electron capture detection (ECD) or infrared (IR) spectroscopy.

NOTE 1 The ECD instrumentation can be affected by changes in oxygen concentration within the respiratory interface during the test, i.e. the change in oxygen concentration between inhalation and exhalation. These changes can cause uncertainties in the measured leakage when measuring concentrations of $< 0,1 \times 10^{-6}$. The measured result is intended to be corrected for this change.

NOTE 2 SF_6 is not removed by filters.

11.2.2 Calculation of leakage

Calculate the leakage, P , from measurements made over the last 80 % of each of the exercise periods.

$$P(\%) = \frac{C_2}{C_1} \cdot 100 \quad (1)$$

where

C_1 is the test agent concentration in the enclosure;

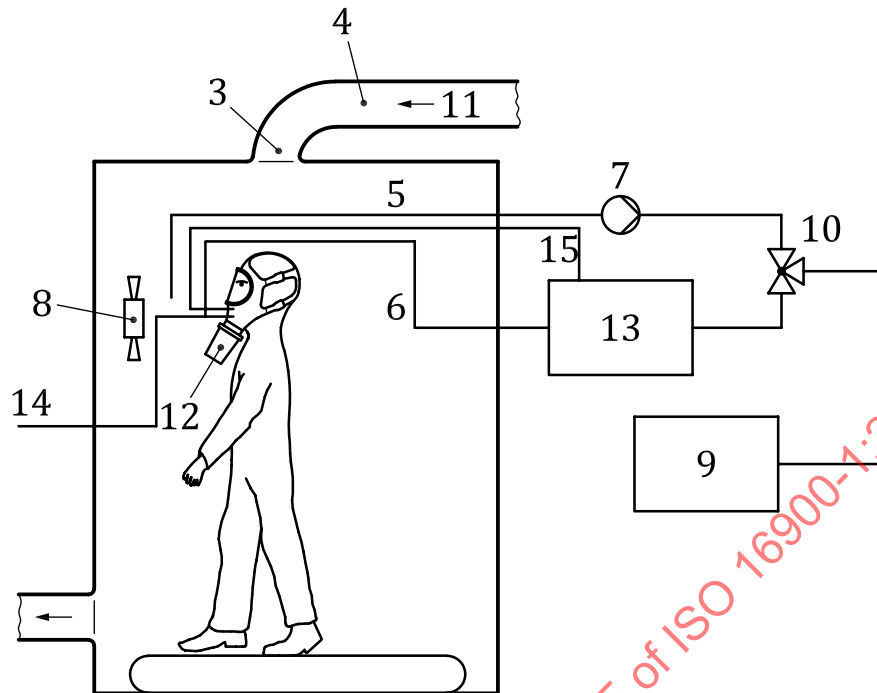
C_2 is the measured mean concentration inside the respiratory interface, corrected for background signal and the effect of oxygen change within the respiratory interface.

11.3 Test method 2: Sodium chloride (NaCl)

11.3.1 Test equipment

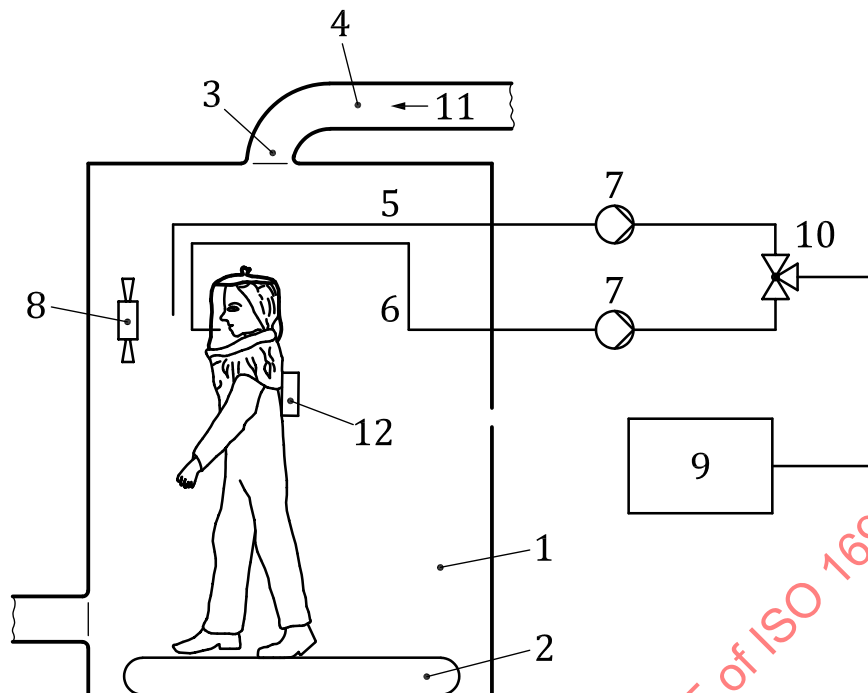
11.3.1.1 General

Typical test arrangements are shown in [Figures 12](#) and [13](#).

**Key**

- | | |
|---------------------------------|--|
| 1 enclosure | 9 photometer |
| 2 treadmill | 10 change-over valve |
| 3 baffle | 11 NaCl aerosol |
| 4 duct | 12 particle filter |
| 5 enclosure sample | 13 pulsed sampling unit |
| 6 respiratory interface sample | 14 dry air flow to sample probe |
| 7 sample pump | 15 differential pressure monitoring line |
| 8 circulation fan (if required) | |

Figure 12 — Typical test arrangement for determination of inward leakage by the sodium chloride method (pulsed sampling method); showing RPD having a respiratory interface type T (tight fitting)

**Key**

- | | |
|---------------------------------|-------------------------|
| 1 enclosure | 9 photometer |
| 2 treadmill | 10 change over valve |
| 3 baffle | 11 air and NaCl aerosol |
| 4 duct | 12 particle filter |
| 5 enclosure sample | |
| 6 respiratory interface sample | |
| 7 sample pump | |
| 8 circulation fan (if required) | |

Figure 13 — Typical test arrangement for determination of inward leakage by the sodium chloride method (continuous sampling); showing RPD having a respiratory interface type L (loose fitting)

This method employs NaCl as the test agent. The test subject wearing the RPD under test performs a series of test exercises inside an enclosure containing the NaCl test agent. Accurate determinations of leakage shall be possible at least within the range from 0,01 % to approximately 20 %.

The mean NaCl concentration within the enclosure shall be $(8 \pm 4) \text{ mg/m}^3$ and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be polydisperse and range between approximately $0,02 \text{ }\mu\text{m}$ to $2 \text{ }\mu\text{m}$ aerodynamic diameter with a mass median aerodynamic diameter of $(0,6 \pm 0,1) \text{ }\mu\text{m}$.

NOTE A cascade impactor has been found suitable for the determination of the particle size distribution within the chamber.

The test agent concentration is monitored, preferably continuously, during the tests using a separate sampling system to avoid contamination of the respiratory interface sampling lines. It is preferable to use a separate detector (e.g. photometer) for this purpose.

If a second detector is not available, sample the test agent concentration using the separate sampling system and the same detector. However, time shall then be required to allow the detector to return to a clean background.

It is important that identical sample rates, flow rates for drying air, and additional photometer air (if required) are used for both respiratory interface and enclosure samples in order to directly apply the formulae shown in [11.3.2.2](#) and [11.3.3.2](#).

11.3.1.2 Test aerosol generation

The NaCl aerosol shall be generated from a solution of reagent grade NaCl in distilled water. An example of an atomiser is shown in [Figure 14](#).

The atomizer shall provide a continuous flow of aerosol into a duct through which a constant flow of air is maintained to deliver the aerosol to the enclosure. The diameter and path length of the duct shall be sufficiently large to allow the water content of the aerosol to evaporate, leaving dry NaCl particles. Any bends should be of large radius to minimize loss of NaCl particles. The air within the enclosure shall have a relative humidity of not greater than 60 %. It might be necessary to heat or dehumidify the air in order to obtain complete drying of the aerosol particles.

11.3.1.3 Detection systems

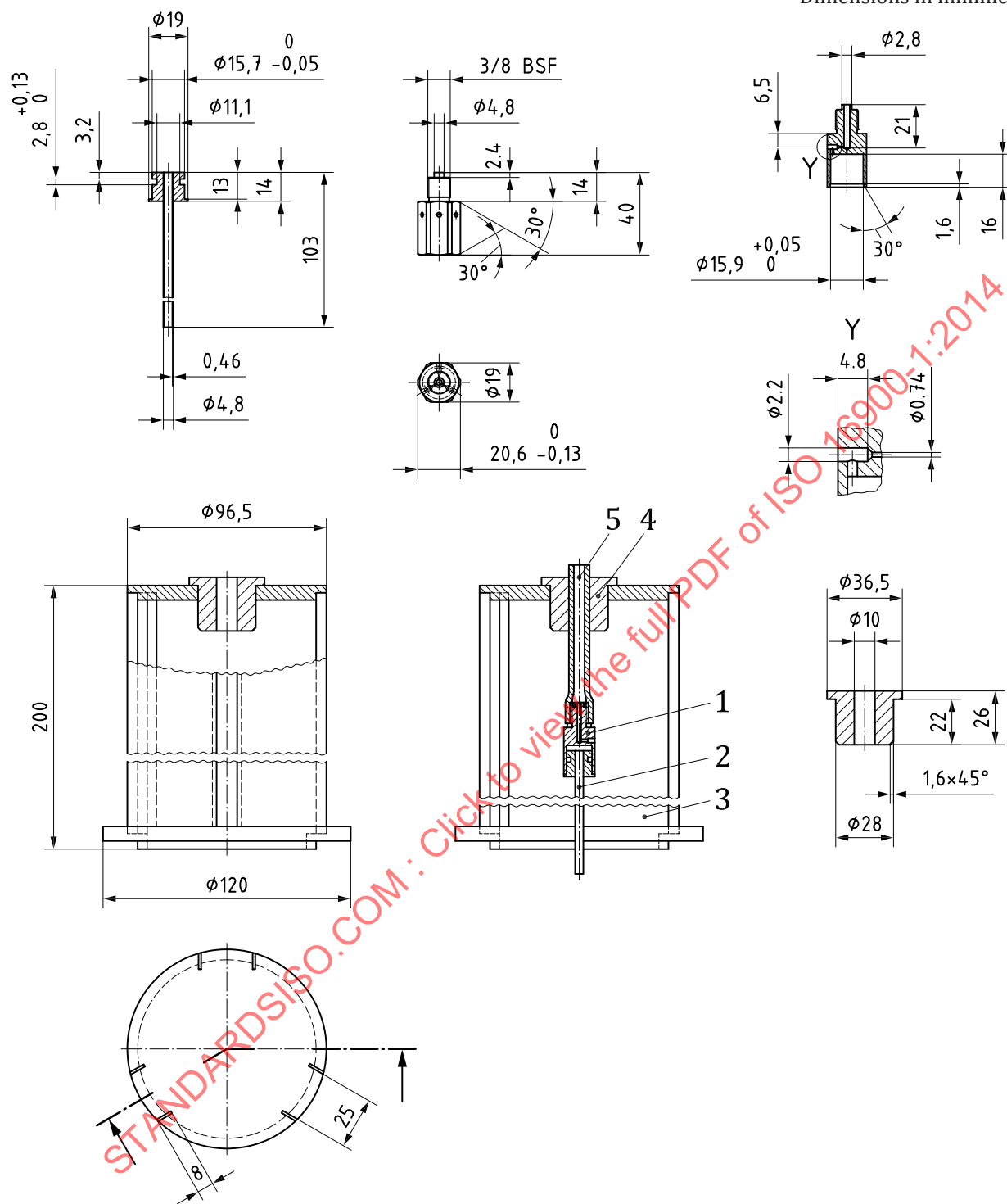
11.3.1.3.1 Flame photometer

A flame photometer is used to measure the concentration of NaCl inside the enclosure and inside the respiratory interface.

The essential performance characteristics for a suitable instrument are set out below.

- a) It shall be a flame photometer specifically designed for the direct analysis of NaCl aerosol.
- b) It shall be capable of measuring concentration(s) of NaCl aerosol between 15 mg/m³ and 10 ng/m³.
- c) The total aerosol sample rate required by the flame photometer shall not be greater than 15 l/min.
- d) The response time of the flame photometer, excluding the sampling system, shall not be greater than 500 ms (to 90 % fsd).
- e) The response to elements other than sodium, particularly carbon, the concentration of which will vary during the breathing cycle, shall be reduced. This can be achieved by ensuring that the band pass width of the interference filter is no greater than 3 nm and that all necessary side-band filters are included.

Dimensions in millimetres



Key

- 1 nozzle
- 2 feet tube (salt solution)
- 3 sleeve
- 4 bush
- 5 air tube (10,0 outer diameter)

Figure 14 — Example of NaCl atomizer assembly

11.3.1.3.2 Condensation particle counter

The CPC analysis method for sodium chloride aerosol shall be restricted to testing inward leakage with supplied breathable gas devices and is not suitable for filtering devices.

A condensation particle counter is employed to measure the concentration of NaCl particles inside the enclosure and inside the respiratory interface.

The essential performance characteristics for a suitable instrument are set out below.

- a) The instrument shall be capable of counting all particles in the range of 0,010 to 1,0 µm diameter.
- b) The condensation particle counter shall have a range of 0 to greater than 10^6 particles/cm³ for the test aerosol.
- c) The total aerosol sample rate required by the detector shall not be greater than 2 l/min.
- d) The response time of the detector, excluding the sampling system, shall not be greater than 500 ms (to 90 % fsd).

Where a condensation particle counter is used, the output from the challenge aerosol generator shall be adjusted so as to maintain a particle concentration of $(2 \pm 0,2) \times 10^5$ particles/cm³ within the test chamber.

11.3.1.3.3 Sample pump

If no pump is incorporated into the detector, an adjustable flow pump is used to withdraw an air sample. The pump shall be such that aerosol losses are minimized within the pump and changes in flow rate caused by changing pressure within the sampling zone are also minimized. Adjust the pump so as to sample at a constant flow of between 0,3 l/min and 2 l/min. Some types of detectors require a flow rate higher than this sampling flow rate. In these cases, dilute the sample with clean air (free of test agent) accordingly in addition to the drying air introduced into the probe at the sample point.

11.3.2 Pulsed sampling — Method 2A

11.3.2.1 General

A system is required which will switch the sample to the detector only during the inhalation phase of the test subject's respiratory cycle. During the exhalation phase, clean air shall be fed to the detector. The source of this clean air is usually laboratory air at ambient temperature, passed through a particle filter of penetration < 0,001 %, shown in [Figure 12](#) as item 9 and 10. The essential elements of such a system are:

- a) an electrically operated valve with a response time of the order of 100 ms (it is recommended that the valve should have the minimum possible dead space compatible with straight-through, unrestricted flow when open);
- b) a breathing sensor that is capable of detecting the change from inhalation to exhalation within 30ms. The breathing sensor, which can be either a pressure sensor or a temperature sensor, is connected to a probe fitted in the respiratory interface near the leakage sample probe;
- c) the sensor shall have an adjustable threshold and be capable of differential signalling when the threshold is crossed in either direction. The sensor shall work reliably when subjected to the accelerations produced by the head movements of the test subjects;
- d) an interfacing system to actuate the valve in response to a signal from the breathing sensor;
- e) a timing device to record the proportion of the total respiratory cycle during which sampling occurred.

[Figure 12](#) shows a schematic diagram of such a sampling system.

11.3.2.2 Calculation of leakage

Calculate the leakage, P , from measurements made over the last 80 % of each of the exercise periods.

The leakage, P , is the ratio of the concentrations with correction terms for the sampling time and the effects of dilution.

$$P(\%) = \left[\frac{C_2}{C_1} \right] \cdot \left[\frac{t_{in} + t_{ex}}{t_{in}} \right] \cdot \left[\frac{S + D}{D} \right] \cdot 100 \quad (2)$$

where

C_1 is the test agent concentration in the enclosure (observing the employed dilution rate for measuring C_2);

C_2 is the measured mean concentration inside the respiratory interface, corrected for background level;

t_{in} is the total duration of inhalation (s);

t_{ex} is the total duration of exhalation (s);

D is the drying air flow rate (l/min);

S is the respiratory interface sample flow rate (l/min).

Measurement of C_2 is preferably made using an integrating recorder.

11.3.3 Continuous sampling — Method 2B

11.3.3.1 General

A sampling system that samples continuously from the cavity of the respiratory interface throughout the respiratory cycle of the test subject. As sodium chloride is retained in the lungs, it is necessary to apply a correction factor in calculating inward leakage.

11.3.3.2 Calculation of leakage

Calculate the leakage P using Formula (3):

$$P(\%) = 1,25 \cdot \left[\frac{C_2}{C_1} \right] \cdot \left[\frac{S + D}{D} \right] \cdot 100 \quad (3)$$

where

C_1 is the test agent concentration in the enclosure (observing the employed dilution rate for measuring C_2);

C_2 is the measured mean concentration inside the respiratory interface, corrected for background level;

D is the drying air flow rate l/min;

S is the sample flow rate in l/min.

1,25 factor to allow for lung retention of sodium chloride (it has been derived on the assumption of an air flow rate of the device of 120 l/min and a wearer's breathing rate of 40 l/min).

11.4 Test method 3: Corn oil aerosol

11.4.1 Test equipment

11.4.1.1 General

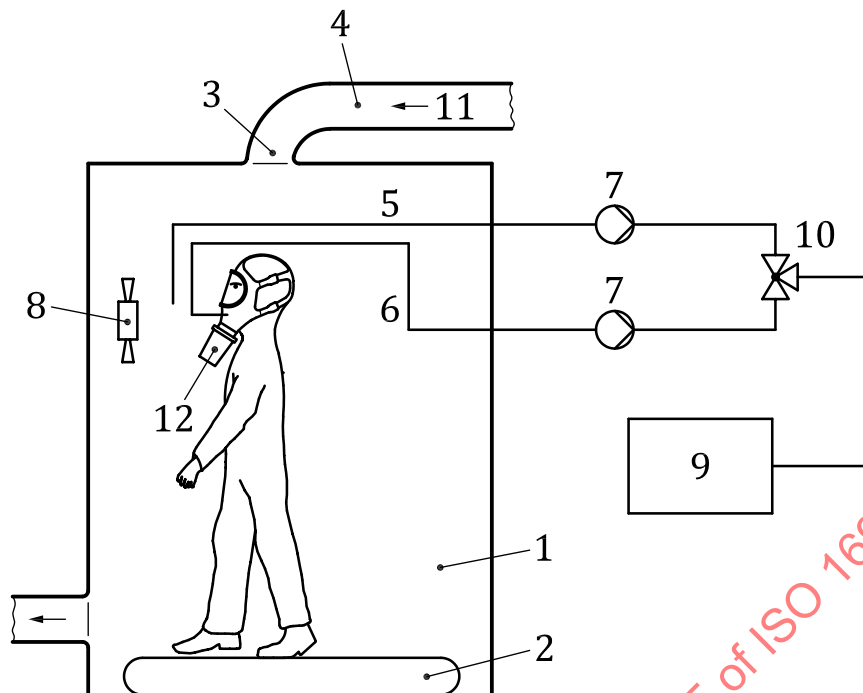
Typical test arrangements are shown in [Figure 15](#).

This method employs corn oil as a test atmosphere. The test subject wearing the RPD under test performs a series of test exercises inside an enclosure containing the corn oil test atmosphere. Accurate determinations of leakage shall be possible at least within the range from 0,01 % to approximately 20 %.

The test agent concentration is monitored, preferably continuously, during the tests using a separate sampling system to avoid contamination of the respiratory interface sampling lines. It is preferable to use a separate detector for this purpose.

The environmental control system shall be capable of maintaining a range of operating conditions from 20 % RH to 80 % RH and from 18 °C to 35 °C. The nominal target test conditions are 16 °C to 28 °C, (50 ± 5) % RH.

An electrostatic classifier is recommended for checking the size distribution of the test aerosol.



Key

- | | |
|---------------------------------|----------------------|
| 1 enclosure | 9 analyser |
| 2 treadmill | 10 change-over valve |
| 3 baffle | 11 corn oil aerosol |
| 4 duct | 12 particle filter |
| 5 enclosure sample | |
| 6 respiratory interface sample | |
| 7 sample pump | |
| 8 circulation fan (if required) | |

Figure 15 — Typical test arrangement for determination of inward leakage by the corn oil method (continuous sampling); showing a RPD with a class cT respiratory interface

11.4.1.2 Test aerosol generation

The test aerosol is generated by atomising the corn oil using compressed air. Corn oil utilized shall comply with Chemical Abstract No. 8001-30-7.

The aerosol generator shall be capable of generating and maintaining 20 mg/m³ to 26 mg/m³ of corn oil test aerosol concentration with a mass median aerodynamic diameter (MMAD) of 0,4 µm to 0,7 µm in the test enclosure and a geometric standard deviation of < 2,0.

The equipment shall be capable of operation without using recycled air.

11.4.1.3 Detection

An aerosol measurement system is used to measure the concentration of the corn oil aerosol inside the enclosure and inside the respiratory interface. Accurate determinations of leakage shall be possible at least within the range from 0,001 % to approximately 20 %. The minimum limit of detection should be < 0,01mg/m³. A suitable aerosol measurement system can be based on rear light scattering laser photometers.

11.4.1.4 Calculation of leakage

Calculate the leakage, P , from measurements made over the last 80 % of each of the exercise periods.

$$P(\%) = \frac{C_2}{C_1} \cdot 100 \quad (4)$$

where

C_1 is the test agent concentration in the enclosure;

C_2 is the measured mean test agent concentration inside the respiratory interface, corrected for background level.

12 Test report

The test report shall include information regarding those parameters specified in [Clause 4](#), together with the following, as a minimum:

- a) information identifying the PCA cell number of the test panel subjects;
- b) the arithmetic mean percentage inward leakage for each exercise for each individual test subject;
- c) the arithmetic mean percentage inward leakage for the whole test exercise regime for each individual test subject;
- d) the 95th percentile percentage inward leakage calculated from the whole data set in c);
- e) identification of the RPD.

For combined and multi-functional RPD test exercise number 11 ([Table B.4](#)) shall be included in the calculation for arithmetic mean.

13 Uncertainty of measurement

An estimate of the uncertainty of measurement associated with this method of test shall be established, as described in ISO 21748. The value of this estimate shall not exceed ± 10 %.

NOTE The use of transfer standards can assist in establishing common uncertainties of measurement between laboratories.

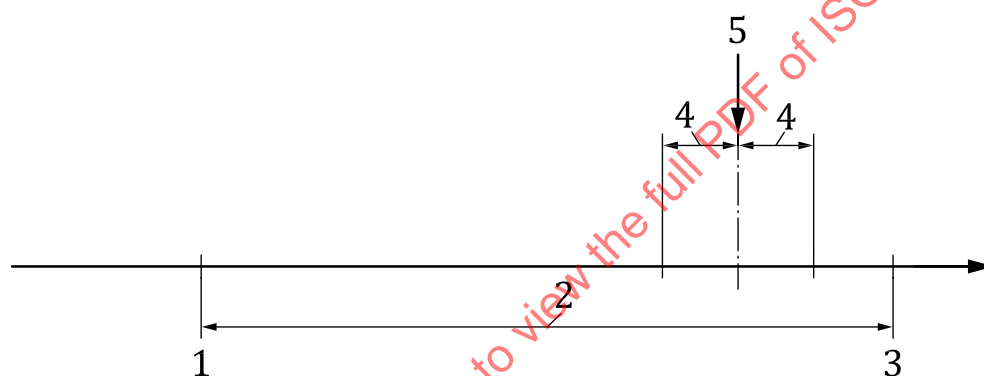
Annex A (normative)

Application of uncertainty of measurement

A.1 Determination of compliance

In order to determine compliance or otherwise of the measurement made in accordance with this test method, when compared to the specification limits given in the protective device standard, the following protocol shall be applied.

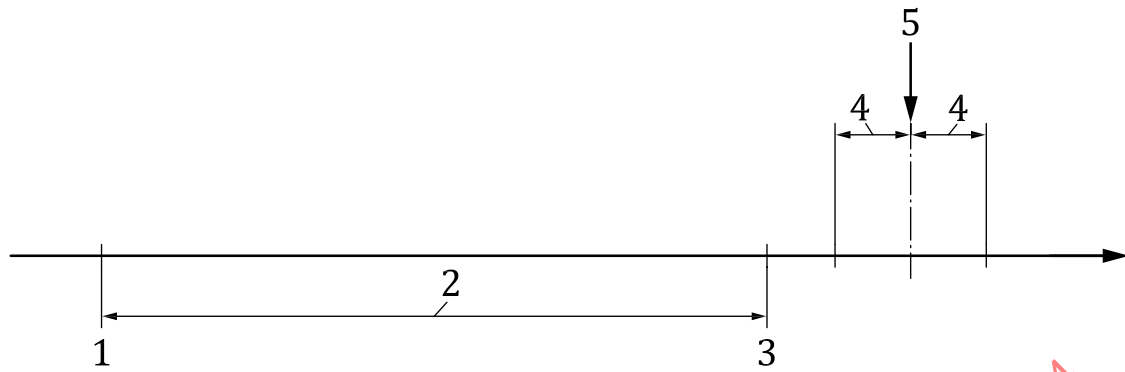
If the test result $\pm$ the uncertainty of measurement, U , falls completely inside or outside the specification zone for the particular test given in the protective device standard, then the result shall be deemed to be a straightforward pass or fail (see [Figures A.1](#) and [A.2](#)).



Key

- 1 lower specification limit
- 2 specification zone
- 3 upper specification limit
- 4 uncertainty of measurement, U
- 5 measured value

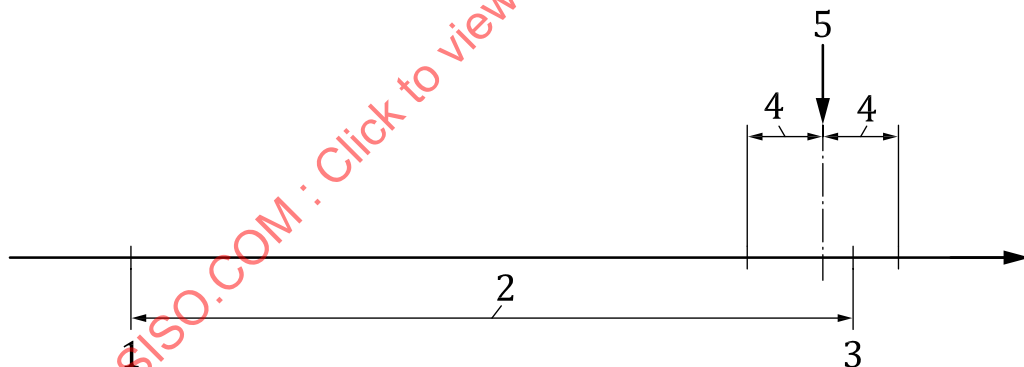
Figure A.1 — Result pass

**Key**

- 1 lower specification limit
- 2 specification zone
- 3 upper specification limit
- 4 uncertainty of measurement, U
- 5 measured value

Figure A.2 — Result fail

If the test result $\pm$ the uncertainty of measurement, U , overlaps a specification limit value (upper or lower) for the particular test given in the protective device standard, then the assessment of pass or fail shall be determined on the basis of safety for the wearer of the device; that is, the result shall be deemed to be a fail (see [Figure A.3](#)).

**Key**

- 1 lower specification limit
- 2 specification zone
- 3 upper specification limit
- 4 uncertainty of measurement, U
- 5 measured value

Figure A.3 — Result fail