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Respiratory protective devices — Performance requirements —

Part 2: Requirements for filtering RPD

Appareils de protection respiratoire — Exigences de performances — Partie 2: Dispositifs de filtration

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Foreword

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety - Personal protective equipment*, Subcommittee SC 15, *Respiratory protective devices*.

A list of all parts in the ISO 17420 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document describes basic requirements for filtering respiratory protective devices (RPD) and its elements and components.

Requirements for RPD used in environments for special applications are given in the relevant parts of the ISO 17420 series.

Some test methods are described. For other test methods references are given to the ISO 16900 series "Methods of test and test equipment" or other test methods not developed by ISO/TC 94/SC 15.

Annex A gives information about reliability.

Annex B features an example of a FMEA (Failure Mode and Effects Analysis).

Annex C gives the test schedules including any pre-conditioning and number of samples.

Annex D provides information for normalisation of test results.

The sequence of testing follows the principle to minimize the necessary number of samples by carrying out destructive tests at the end. It also includes for safety reason that tests with test subjects are only carried out after the test samples have shown their safe performance in other tests.

Respiratory protective devices — Performance requirements —

Part 2: Requirements for filtering RPD

1 Scope

This document specifies requirements for the performance and testing of filtering respiratory protective devices (RPD) in accordance with their classification and for use in the workplace to protect the wearer from hazardous atmospheres and/or environments.

Requirements for RPD elements and components are also specified in this document.

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 9227, *Corrosion tests in artificial atmospheres — Salt spray tests*

ISO 16900-1:2019, *Respiratory protective devices — Methods of test and test equipment — Part 1: Determination of inward leakage*

ISO 16900-2, *Respiratory protective devices — Methods of test and test equipment — Part 2: Determination of breathing resistance*

ISO 16900-3, *Respiratory protective devices — Methods of test and test equipment — Part 3: Determination of particle filter penetration*

ISO 16900-4:2011, *Respiratory protective devices — Methods of test and test equipment — Part 4: Determination of gas filter capacity and migration, desorption and carbon monoxide dynamic testing*

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

ISO 16900-6:—[1)], *Respiratory protective devices — Methods of test and test equipment — Part 6: Mechanical resistance/strength of components and connections*

ISO 16900-7:2020, *Respiratory protective devices — Methods of test and test equipment — Part 7: Practical performance test methods*

ISO 16900-8, *Respiratory protective devices — Methods of test and test equipment — Part 8: Measurement of RPD air flow rates of assisted filtering RPD*

ISO 16900-9, *Respiratory protective devices — Methods of test and test equipment — Part 9: Determination of carbon dioxide content of the inhaled gas*

ISO 16900-12, *Respiratory protective devices — Methods of test and test equipment — Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures*

1) Under preparation, Stage at the time of publication ISO/DIS 16900-6:2020.

ISO 16900-14:2020, *Respiratory protective devices — Methods of test and test equipment — Part 14: Measurement of sound level*

ISO 16972, *Respiratory protective devices — Vocabulary and graphical symbols*

ISO/TS 16973, *Respiratory protective devices -- Classification for respiratory protective device (RPD), excluding RPD for underwater application*

ISO 17420-1:2021, *Respiratory protective devices — Performance requirements — Part 1: General*

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

IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity standard for industrial environments*

3 Terms, definitions, abbreviations and symbols

3.1 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
non pre-conditioned state
without pre-conditioning but possibly modified to carry out tests or already used in non-destructive tests

Note 1 to entry: This includes e.g. cleaning and disinfection.

3.1.2
as worn state
RPD where all components are connected and assembled in the way that it is intended to be used and worn (e.g. worn by the wearer, adapted to a RPD headform or RPD headform and torso or suitable holder)

Note 1 to entry: All of the various components [e.g. for an assisted filtering device: blower unit, battery, respiratory interface (RI), filters, etc.] have been completely assembled and then connected (RI connected to the hose of the blower unit) together in accordance with the information supplied by the manufacturer.

3.1.3
ready for assembly state
RPD or components with seals, plugs or other environmental protective means, still in place ready to be assembled and/or donned

Note 1 to entry: RPD or components can remain sealed and plugged until donning if so stated in the information supplied by the manufacturer.

3.1.4
integrated RPD
RPD designed so that components in the breathable gas supply chain are nonseparable

3.1.5
measured maximum flow rate
volumetric flow rate of an assisted filtering RPD, determined in a laboratory test, when the RPD is in the condition which results in the highest air flow rate, where this condition takes into account the influences of temperatures, settings of RPD, pre-conditionings, use of accessories and any other related factors

[SOURCE: ISO 16900-8:2015, 3.6]

3.1.6
migration
diffusion of the gas or vapour molecules within the sorbent after the filter is partially loaded

3.1.7
standardized connector
device that allows an optional connection between a filter and a respiratory interface

Note 1 to entry: Filter connector meeting the requirements of ISO 17420-3.

3.1.8
replacement part
identical to the one originally supplied with the RPD by the manufacturer, and declared interchangeable by the manufacturer

3.1.9
normalised condition
test condition adjusted to 1013 hPa and body temperature (37 °C or 310 K) saturated with water vapour, which is 63 hPa, used for the normalization of test results

Note 1 to entry: Further information is given in Annex D.

3.2 Abbreviated terms

FMEA	Failure Mode and Effects Analysis
V_T	Tidal volume
WoB	Work of Breathing
BTPS	body temperature pressure saturated

3.3 Symbols

3.3.1

Product information; information point (ISO 7000-2760).

Indication for the RI that it is a part of a RPD system with multiple configurations.

3.3.2

Operator's manual; operating instructions (ISO 7000-1641).

Booklet: "See information supplied by the RPD manufacturer"

3.3.3

Do not re-use (ISO 7000-1051).

Crossed out 2: “For single shift use only”

3.3.4

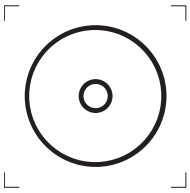
yyyy/mm

Use by date (ISO 7000-2607)

Hourglass: "End of shelf life"

Key: yyyy year, mm month

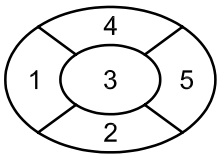
3.3.5



Roller; cylinder (ISO 7000-0566)

Target: "Standardized connector"

3.3.6



RPD headform number allocation for size designation

4 Classification overview

ISO 17420-1:2021, 4.1 applies with the following addition:

The classification of a filtering RPD is determined by the appropriate combination of the following classes: (protection class) (work rate class) (RI class) (particle filterclass and/or gas filter type and class).

Additionally filtering RPD may be classified for one or more special applications, as given in ISO 17420-5 to ISO 17420-9.

Table 1 — Gas filter type and class

Type	Class(es)	Type description
OV	1, 2, 3 or 4	Organic vapours
OG	1	Organic gases (low boiling, i.e. below 65 °C)
AC	1, 2, 3 or 4	Acidic compounds
BC	1, 2, 3 or 4	Basic compounds
NO_x	1, 2 or 3	Nitrogen oxides
HG	1, 2 or 3	Mercury (Hg)
OZ	1	Ozone (O_3)
HCN	1, 2, 3 or 4	Hydrogen Cyanide (HCN)
AH	1	Arsine (AsH_3)

Table 1 *(continued)*

Type	Class(es)	Type description
HF	1, 2 or 3	Hydrogen fluoride (HF)
CD	1	Chlorine dioxide (ClO_2)
ETO	1, 2 or 3	Ethylene oxide ($(CH_2)_2O$)
FM	1, 2 or 3	Formaldehyde (CH_2O)
MB	1, 2 or 3	Methyl bromide (CH_3Br)
CO	Three classes based on time (20 min, 60 min or 180 min)	Carbon monoxide (CO)
PH	1 or 2	Phosphine (PH_3)

The designation of a filtering RPD is determined by an appropriate combination of the classes given in ISO 17420-1:2021, Table 1 and Table 1 of this document.

Example for a basic RPD with protection class (PC3), work rate class (W2), RI class (bT), particle filter class (F3) and gas filter type and class (OV2).

Marking for the given example PC3 W2 bT F3 OV2

Multi-functional filtering RPD have separate classifications for each function, i.e. one classification for the unassisted mode and one classification for the assisted mode.

5 General requirements for RPD

5.1 General

ISO 17420-1:2021, 5.1, applies.

5.2 Field of vision

ISO 17420-1:2021, 5.2, applies.

5.3 Resistance to flame – Single burner dynamic

ISO 17420-1:2021, 5.3, applies.

5.4 Compatibility with additional equipment

ISO 17420-1:2021, 5.4, applies.

5.5 Monitor performance

ISO 17420-1:2021, 5.5, applies with the following addition:

The monitor system shall not interfere with the operation of the RPD.

5.6 Warning device(s), checking device(s) and control means

5.6.1 Performance of warning device(s), if applicable

RPD shall be checked after sequential pre-conditioning in accordance with 6.9.2.

RPD powered by an energy source shall be equipped with a low energy warning device to warn the wearer at least 5 min prior to the performance of the RPD falling below the manufacturer's minimum design conditions. From the activation of the warning the RPD shall be tested in accordance with 6.3.2 for a period of 5 min but with a fixed setting of 35 l/min, see Table 2.

Check in accordance with 7.2 and Clause 9.

For assisted filtering RPD a warning device shall warn the wearer when the performance of the RPD is outside of the manufacturer's design conditions.

Testing shall be performed in accordance with 6.3.2 and, if applicable, in accordance with ISO 16900-8.

During use, warning devices shall not switch off automatically and shall not be capable of being switched off by the wearer while the cause of the warning remains other than to correct the warning condition.

Check in accordance with 7.2.

Any warning shall be detectable without any intervention by the wearer. Any warning shall be detectable by the wearer within 15 s.

Testing shall be performed in accordance with ISO 16900-7:2020, Annex B, activity k).

Any warnings which require different reactions by the wearer shall be distinguishable from one another.

Check in accordance with 7.2.

5.6.2 Performance of checking device

ISO 17420-1:2021, 5.6.2, applies.

5.6.3 Control means (if applicable)

Manual control means installed on a RPD shall be clearly identifiable and, if more than one, distinguishable from one another by the wearer during use.

If there is a control means for setting different PC classes it shall not be possible to change the PC class during use without indication to the wearer.

Adjustable control means shall be tested in accordance with 6.3.

Testing shall be performed in accordance with ISO 16900-7.

5.7 Protection class determination

5.7.1 General

ISO 17420-1:2021, 5.7.1, applies.

5.7.2 Total inward leakage (TIL)

ISO 17420-1:2021, 5.7.2, applies.

The following applies in addition to ISO 17420-1:2021, 5.7.

5.7.3 Total inward leakage requirement for RPD not using a standardized connector

RPD, except those with RIs class aT, shall be tested for total inward leakage in accordance with ISO 17420-1:2021, 5.7.2.

NOTE 1 For RI using standardized connector see 6.11.3.3.

NOTE 2 For RI class a see ISO 17420-1:2021, 5.7.2.

5.8 Validation by practical performance

5.8.1 General

ISO 17420-1:2021, 5.8.1, and the following applies:

Two RPD sequentially pre-conditioned in accordance with 6.9.2 shall undergo practical performance tests.

Prior to the practical performance testing the RPD performance shall have passed the tests according to at least the following clauses:

— 6.3 [work of breathing, breathing resistance (peak pressure) and elastance];

— 6.4 (CO_2 concentration);

— ISO 17420-1:2021, 5.9.1 (RI);

— 6.5 (noise limit for assisted RPD),

— 6.7 (connections);

— 5.6 [warning and checking device(s)].

5.8.2 Donning/doffing

ISO 17420-1:2021, 5.8.2 applies.

5.8.3 Communication performance - hearing and speech

ISO 17420-1:2021, 5.8.3 applies.

5.8.4 Eye irritation caused by the RPD

ISO 17420-1:2021, 5.8.4 applies.

5.8.5 Fogging of visor

ISO 17420-1:2021, 5.8.5 applies.

5.8.6 Ergonomic requirements

ISO 17420-1:2021, 5.8.6 applies.

5.9 Requirements for elements/components

ISO 17420-1:2021, 5.9 applies.

6 Requirements for filtering RPD

6.1 Determination of air flow rate of assisted RPD

For assisted RPD the air flow rate shall be determined at conditions which result in the minimum flow rate and the maximum flow rate of the RPD.

Depending on the design of the RPD these air flow rates can be influenced by

— possible flow settings of the RPD,

— service life,

— the charging status of the battery,

— different filter types,

— alarm settings,

— the temperature of the RPD, including the temperature range for use,

— use of accessories,

— hose length, and

— other factors, if applicable.

— Testing shall be performed in accordance with ISO 16900-8.

6.2 Determination of the effect of temperature on flow rates for assisted RPD

To determine the influence of temperature the RPD shall be tested for flow after each of the following:

a) equilibrated for a minimum of 4 h at $\begin{pmatrix} 35 \begin{smallmatrix} 0 \\ -2 \end{smallmatrix} \end{pmatrix}$ °C and at a relative humidity of (50 ± 20) %

b) and equilibrated for a minimum of 4 h at $\begin{pmatrix} -5 \begin{smallmatrix} +2 \\ 0 \end{smallmatrix} \end{pmatrix}$ °C.

Testing shall be started within 3 min after each equilibration at ambient laboratory conditions.

Taking into account the influencing parameters as listed in 6.1 the measured minimum and the measured maximum flow rate shall be determined in accordance with ISO 16900-8.

6.3 Work of breathing, breathing resistance (peak pressure) and elastance

6.3.1 Work of breathing, breathing resistance (peak pressure) and elastance for unassisted RPD

For filters with standardized connectors see 6.11.2.1.

For RI with standardized connectors see 6.11.3.2.

The RPD shall be tested with one of each size of the RI.

The RPD headform number(s) allocated to the RI used for the tests is/are specified by the manufacturer.

Integrated RPD or components in ready for assembly state shall be exposed to the sequential preconditioning in accordance with 6.9.2.

In addition to the sequential pre-conditioning in accordance with 6.9.2 one integrated RPD in its ready to worn state containing electronics or component(s) in its ready for assembly state containing electronics shall be exposed to the non-sequential preconditioning in accordance with 6.9.3.2. RPD shall meet the requirements set forth in Table 3 for work of breathing/breathing resistance, when tested in accordance with the settings for the breathing machine for each work rate as given in Table 2.

The temperature of operation of unassisted RPD is covered by the pre-conditioning according to 6.9.2.2 because for those types of RPD testing at the extremes gives no further information.

The work of breathing, breathing resistance (peak pressure), and elastance shall be calculated from the average pressure volume loop based on 10 consecutive breathing cycles and shall not exceed the limits given in Table 3.

The settings for the breathing machine for each work rate are given in Table 2.

Table 2 — Setting of breathing machine at work rates for assisted and unassisted RPD

Work rate	Flow rate (dynamic sinusoidal) l/min at BTPS	Frequency cycles/min	Tidal volume l at BTPS
Resting	10 with a tolerance of ±3 %	10,0	1,0
W1	35 with a tolerance of ±2 %	23,3	1,5
W2	65 with a tolerance of ±2 %	32,5	2,0
W3	105 with a tolerance of ±2 %	42,0	2,5
W4	135 with a tolerance of ±1 %	45,0	3,0

Testing shall be performed in accordance with ISO 16900-5 and ISO 16900-12.

Tidal volumes are expressed at BTPS. In order to be able to compare the performance of different RPD the results achieved at any laboratory conditions shall be normalized to body temperature (37 °C) and normalized pressure (1 013 hPa) in accordance with Annex D.

An example for normalisation calculation for work of breathing results is given in D.2.1.

6.3.2 Work of breathing, breathing resistance (peak pressure) and elastance for assisted RPD

Integrated RPD or components in ready for assembly state shall be pre-conditioned in accordance with 6.9.2.

In addition to the sequential pre-conditioning in accordance with 6.9.2 one integrated RPD or component(s) in ready for assembly state shall be pre-conditioned in accordance with 6.9.3.2 (salt spray) as applicable, prior to validation testing.

RPD shall be set to the minimum and maximum measured flow rates determined in accordance with 6.2.

RPD shall be tested in accordance with the test regime for its work rate class as stated by the manufacturer and meet the requirements for work of breathing, breathing resistance and elastance for each flow rate as given in Table 3.

RPD work of breathing and breathing resistance (peak pressures) shall be measured in each step of the performance regime for the designated work rate class, given in Table 3. The measurements shall start after the stabilization of each step in the test regimes W1 to W4.

The transition period between one work rate and the next work rate shall be no more than one minute, which includes the stabilization, whilst the RPD remains in operational mode.

The work of breathing, breathing resistance and elastance shall be computed from the average pressure volume loop based on ten consecutive breaths and shall not exceed the limits given in Table 3.

Test regime to achieve W1:

a) 35 l/min for 5 min;

b) 10 l/min for 5 min;

c) 35 l/min for 5 min.

Test regime to achieve W2:

a) 35 l/min for 5 min;

b) 65 l/min for 5 min;

c) 10 l/min for 5 min;

d) 35 l/min for 5 min.

Test regime to achieve W3:

a) 35 l/min for 4 min;

b) 65 l/min for 3 min;

c) 105 l/min for 3 min;

d) 10 l/min for 5 min;

e) 35 l/min for 5 min.

Test regime to achieve W4:

a) 35 l/min for 2 min;

b) 105 l/min for 3 min;

c) 65 l/min for 2 min;

d) 135 l/min for 3 min;

e) 10 l/min for 5 min;

f) 35 l/min for 5 min.

The test termination point shall be after one complete cycle of the applicable test regime. Each test regime shall be performed with the operation of the RPD adjusted to both the maximum and the minimum measured flow rates as determined by ISO 16900-8.

Table 3 — Limits of work of breathing, breathing resistance (peak pressure) and elastance for assisted and unassisted RPD

Flow rate (dynamic sinusoidal) l/min at BTPS	**Work of breathing limit measured as** WoB/V_T		**Breathing resistance limit** (peak pressures)		**Elastance limit measured as** $\Delta p/V_T$
	inhalation	**exhalation**	**inhalation**	**exhalation**	
	kPa		kPa		kPa/l
10 with a tolerance of ± 3 %[a]	0,9	0,9	-1,2	1,2	1,0
35 with a tolerance of ± 2%					
65 with a tolerance of ± 2%					
105 with a tolerance of ± 2%					
135 with a tolerance of ± 1%	1,6	1,6	-2,0	2,0	
Δp is the difference in pressure between the beginning of inhalation and beginning of exhalation.					
NOTE Flow rates and tidal volumes are expressed at BTPS (body temperature, ambient pressure, saturated gas).					

RPD work of breathing and breathing resistance (peak pressures) shall be measured in each step of the regime for the designated work rate class above. The measurements shall begin after the stabilization of each step.

The transition period between one work rate and the next work rate shall be no more than one minute, which includes the stabilization, whilst the RPD remains in operational mode.

During the transition between different flow rates, stopping of the breathing machine is allowable as long as the 1 min time period is not exceeded.

The settings for the breathing machine for each work rate are given in Table 2.

Testing shall be performed in accordance with ISO 17420-1 and ISO 16900-12.

6.4 CO_2 concentration limits

6.4.1 CO_2 concentration limits for assisted RPD

One RPD in non pre-conditioned state, for each size RI shall be tested on the RPD headform based on the size as designated by the manufacturer.

RPD shall meet the requirements when tested at ambient temperature when adjusted to the measured minimum flow as tested in ISO 16900-8.

The carbon dioxide content of the inhalation air shall not exceed an average volume fraction as given in Table 4 tested at its work rate class and at resting to determine the average.

Table 4 — Maximum average volume fraction of CO_2 concentration in the inhalation air in relation to flow rate

Flow rate (dynamic sinusoidal) l/min at BTPS	**CO_2 concentration** %
10 with a tolerance of ±3%	2,50
35 with a tolerance of ±2%	2,00
65 with a tolerance of ±2%	
105 with a tolerance of ±2%	1,40
135 with a tolerance of ±1%	

After stabilization, the measurement of at least 10 cycles shall be taken to determine the average. Within at least 10 cycles the average value of CO_2 at the end of each exhalation cycle shall contain (5,3 ± 0,1) % CO_2.

The setting of the breathing machine is as given in Table 2.

Testing shall be performed in accordance with ISO 16900-9.

6.4.2 CO_2 concentration limits of unassisted RPD

One RPD in non pre-conditioned state, for each RI size shall be tested on the RPD headform based on the size as designated by the manufacturer.

The carbon dioxide content of the inhalation air shall not exceed an average volume fraction as given in Table 4 with the setting of the breathing machine as given in Table 2. After stabilization, the measurement of at least 10 cycles shall be taken to determine the average.

Within at least 10 cycles the average value of CO_2 at the end of each exhalation cycle shall contain (5,3 ± 0,1) % CO_2.

Testing shall be performed in accordance with ISO 16900-9.

6.4.3 CO_2 concentration limits for RI with standardized connector

One RI with standardized connector in non pre-conditioned state, for each size shall be tested on the RPD headform based on the size as designated by the manufacturer.

The carbon dioxide content of the inhalation air shall not exceed an average volume fraction as given in Table 4 for the flow rates of 10 l/min, 35 l/min and 65 l/min with the setting of the breathing machine as given in Table 2. After stabilization, the measurement of at least 10 cycles shall be taken to determine the average.

Within at least 10 cycles the average value of CO_2 at the end of each exhalation cycle shall contain (5,3 ± 0,1) % CO_2.

Testing shall be performed in accordance with ISO 16900-9.

6.5 Noise limit for assisted RPD

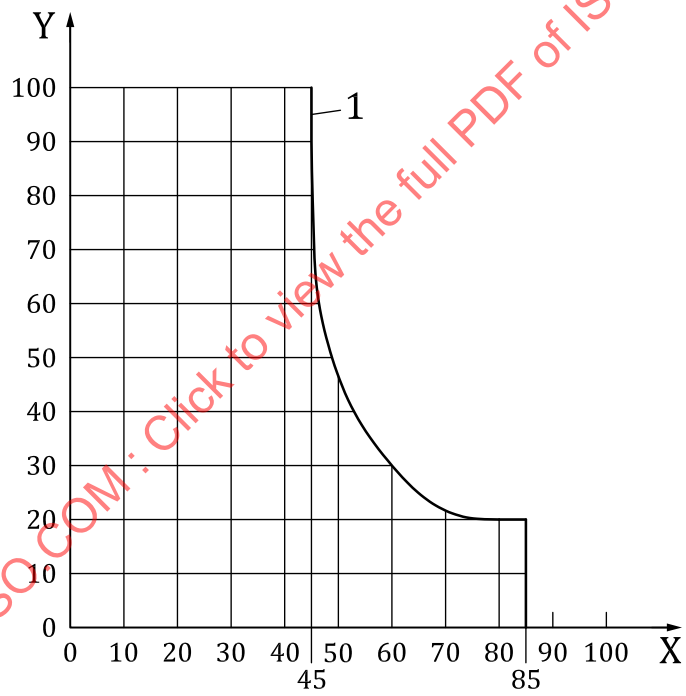
Only one RI size in non pre-conditioned state shall be tested.

RI Type d and e, when operated at the manufacturer's maximum flow conditions on a breathing machine set according to Table 2 for its work rate, and without activated warning device, the noise of the RPD shall be less than or equal to 80 dB(A) at both ears on the RPD headform. The measurement shall start 5 min after the activation of the RPD for a period of 5 min.

Testing shall be performed in accordance with ISO 16900-14:2020, method A.

6.6 Temperature and humidity of inhaled air for RPD which protect against CO

When tested in accordance with 6.10.1.3.2, Table 9, with the test gas concentration of 3 000 ml/m^3 CO, the temperature and relative humidity of the air supplied by the filtering RPD to the wearer shall not exceed the limits given in Figure 1, item 1, measured at the filter outlet. Preconditioning is required for filters only.



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X temperature in °C

Y relative humidity in %

1 temperature limit for inhaled air

Figure 1 — Temperature and humidity curve for inhaled air

Testing shall be performed in accordance with ISO 16900-4.

6.7 Connections

6.7.1 General

If more than one connection is present on an RPD incorrect combinations shall be prevented by design. If for certain RPD systems such design solutions are not possible (for example for multiple-filter

configuration), this shall be covered by information on the correct selection of combinations contained in the information supplied by the RPD manufacturer.

Check in accordance with 7.2.

6.7.2 Strength of connections – Connections to RI

RPD in non pre-conditioned state shall be tested.

Connections to a RI shall withstand the axial force perpendicular to the plane of affixation as defined in Table 5 and 6 and identified in Figure 2 and Figure 3. During the test it is acceptable that the direction of the force shift from the plane of affixation. The force shall be applied for $\begin{pmatrix} +2 \\ 10 \\ 0 \end{pmatrix}$ s when the RI is mounted on a headform, in accordance with the information supplied by the RPD manufacturer for proper donning by a wearer. The force shall be applied progressively avoiding an initial shock or jerking motion to the connection.

No further fixation means of the RI to the headform is allowed.

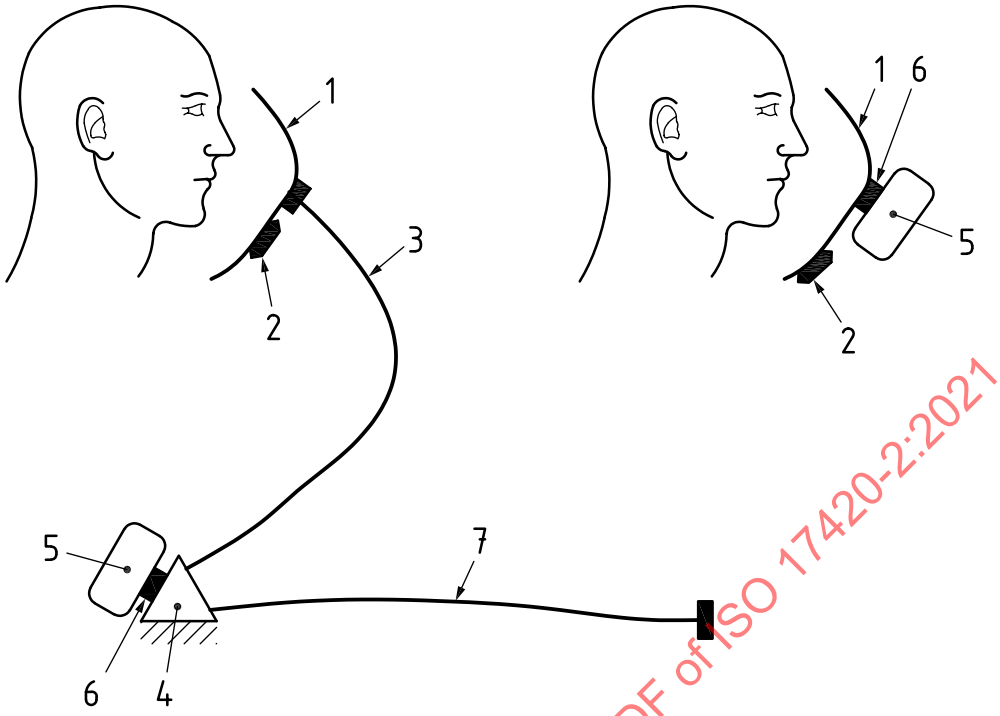
The RI is allowed to slip off the headform provided that the RI can be readily re-donned.

The F_{2a} and F_3 requirements apply to filters, exhalation valves and/or accessories attached to the RI only which have the potential of being snagged. These are identified by using the exposed surface identification probe defined in ISO 16900-5. The procedure for using the probe is given in ISO 16900-6.

As a result of the applied force, no connection or other component, including the components that attach the RI to the wearer, shall separate, break or permanently deform to such an extent that a further donning in accordance with the information supplied by the RPD manufacturer is no longer possible.

A separation or break of a component that does not affect the respiratory function of the RPD shall not be deemed a failure (e.g. heads-up display on the outside of the visor).

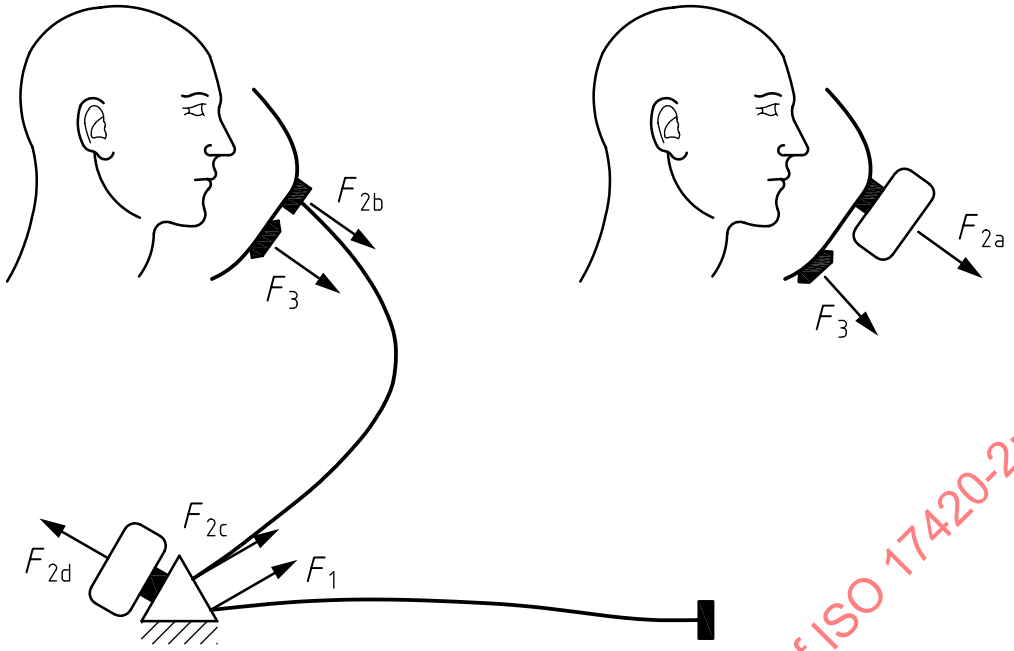
Testing shall be performed in accordance with ISO 16900-6 and checked in accordance with 7.2.



key

1 RI
2 accessory/exhalation valve
3 breathing hose
4 fixation to wearer
5 filter
6 filter connection
7 low pressure hose

Figure 2 — Typical arrangements of RPD for pull force test



key

F_1 pull force direction for connection between manifold and supply hose
F_{2a} pull force direction for connection between RI and filter
F_{2b} pull force direction for connection between RI and breathing hose
F_{2c} pull force direction for connection between manifold and breathing hose
F_{2d} pull force direction for connection between manifold and filter
F_3 pull force direction for connection between RI and accessories

Figure 3 — Pull force arrangement

Table 5 — Pull forces on RPD classes without standardized connector

Pull Force Area/Direction (Vectors)	F_1	F_{2a}	F_{2b}, F_{2c}, F_{2d}	F_3
	N			
PC 4 and greater	(1 000 ± 50)	(50 ± 2,5)	(250 ± 10)	(50 ± 2,5)
PC 3	(500 ± 25)	(25 ± 1)	(100 ± 5)	(10 ± 0,5)
PC 1 and PC 2	(500 ± 25)	(25 ± 1)	(50± 5)	(10 ± 0,5)

Table 6 — Pull forces on RPD class PC 2, PC 3 and PC 4 with standardized connector

Pull Force Area/Direction (Vectors)	F_1	F_{2a}	F_{2b}, F_{2c}, F_{2d}	F_3
	N			
PC 2, PC 3 and PC 4	NA	(100 ± 5)	(250 ± 10)	(50 ± 2,5)

6.7.3 Low pressure connections other than to the RI

RPD in non pre-conditioned state shall be tested.

Any low pressure connection of RPD other than those directly to the RI, such as filter(s) or hoses connected to a RPD, shall withstand a progressively applied axial force in accordance with Table 5 and 6 and identified in Figure 2 and Figure 4 for 10 s without separating, breaking or permanently deforming

to the extent a leak path is created. The force shall be applied progressively avoiding an initial shock or jerking motion to the connection.

After being exposed to the applied force, the hose connection shall be pressurized to (2 ± 0,2) kPa and submerged in water for 1 min unless separating, breaking or permanently deforming is observed on the hose connection. The connector shall not leak at a rate of more than one bubble per second.

For this test the components or sub-assemblies, such as filter housing or hose connector, may be used instead of a complete RPD.

One of each connection shall be tested.

Testing shall be performed in accordance with ISO 16900-6.

Check in accordance with 7.2, followed by testing in accordance with 7.3.

6.8 Assessment of reliability

Since many types of failure are possible, FMEA (failure mode and effects analysis) is a recommended way to examine failure situations and suggest safety design and procedures.

Manufacturers shall state, by providing a written declaration, that the reliability of the RPD or component was adequately considered in the design.

Special attention shall be given to the effects of

— temperature and humidity of inhaled air during use for filtering RPD which protects against contaminants other than CO,

— abrasion resistance,

— chemical resistance of materials,

— dusty environment,

— compatibility of materials with the wearer's body, and

— cleaning, disinfection and decontamination procedures and cycles on the function of the RPD.

In Annex A some aspects that should be considered by manufacturers to ensure reliability are indicated.

NOTE FMEA is a suitable tool to comply with this requirement.

6.9 Pre-conditioning (Sequential/Non-sequential)

6.9.1 General

The pre-conditioning shall follow the pre-conditioning test sequence as given Figure 4.

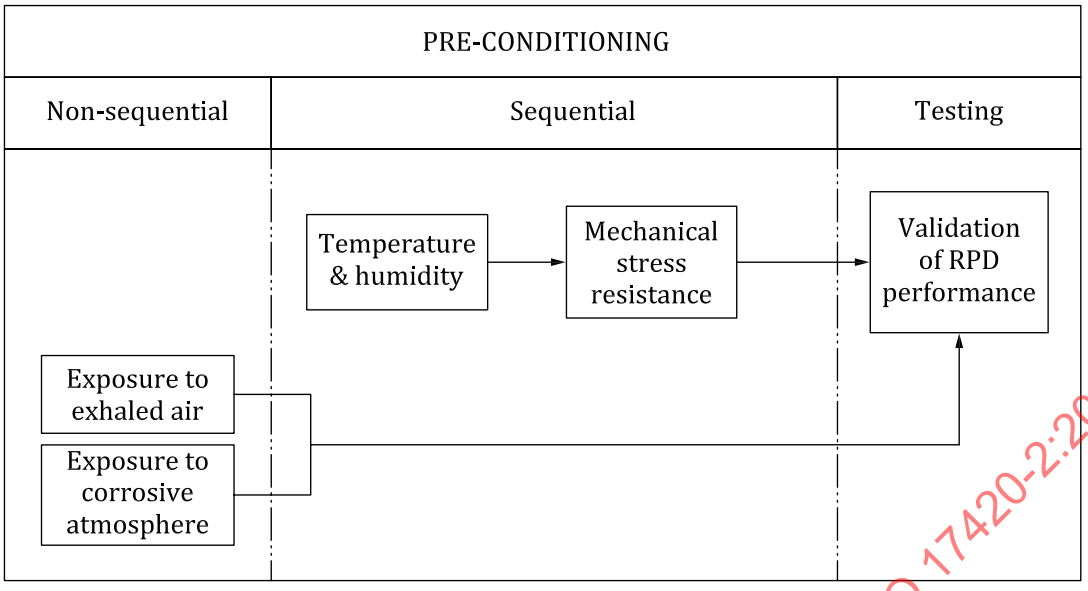


Figure 4 — Pre-conditioning test sequence

6.9.2 Sequential pre-conditioning

6.9.2.1 General

Integrated RPD and components shall be pre-conditioned in the following sequence:

— exposure to temperature and humidity conditioning, see 6.9.2.2;

— exposure to mechanical stress resistance, see 6.9.2.3.

6.9.2.2 Exposure to temperature and humidity

Integrated RPD and components shall be pre-conditioned in accordance with the following thermal cycle, without interruption:

— ambient temperature and humidity;

— (40 ± 3) °C and <20 % RH for (24 ± 1) h;

— (−10 ± 3) °C for (24 ± 1) h;

— (40 ± 3) °C and (90 ± 5) % RH for (24 ± 1) h; and

— ambient temperature between 16 °C and 32 °C and (50 ± 30) % RH until temperature is equilibrated.

In order to ensure that there is no temperature shock during the conditioning of the samples, the temperature gradient shall be less than 2 °C/min between phases at different temperatures, and between the beginning and the end of a thermal cycle.

The number of samples is given in the relevant requirement clauses.

6.9.2.3 Mechanical stress resistance

Integrated RPD, replaceable filter(s) and components containing electronics and/or electro-mechanics in their ready for assembly state shall be positioned in accordance with ISO 16900-6:—, 6.8, in the steel case in such a way that the samples do not touch each other during the test and allows horizontal movement and free vertical movement.

Other PPE and accessory components containing electronics are excluded.

Integrated RPD and components in ready for assembly state shall be subjected to mechanical pre-conditioning in three different orientations (x, y, z) with 650 rotations each.

In the case of replaceable filter(s), they shall be positioned in the steel case in such a way, that the axis of air flow through the filter is horizontal and such that the filters do not touch each other during the test, allowing horizontal movement and free vertical movement for a total of 1 950 rotations.

The exposure shall be conducted at the rate of (100 ± 5) r/min.

After the exposure any loose materials that have been released from the filter shall be removed from the filter prior to the performance testing.

Testing shall be performed in accordance with ISO 16900-6:—, 6.8.

6.9.3 Non-sequential pre-conditioning

6.9.3.1 Exposure to exhaled air

RPD whose air management allows the wearer's exhaled air to pass through the filter shall be tested for filter efficiency and/or gas capacity as appropriate within 30 min after the following pre-conditioning.

A test setup consisting of a RPD headform of appropriate size, complying with ISO 16900-5, connected to a breathing machine complying with ISO 16900-5 with the additional function to warm and humidify exhaled air shall be used. Temperatures and humidity shall comply with ISO 16900-5:2016, 4.4 c) and d).

The ambient laboratory condition for intake of air shall comply with (22 ± 3) °C and (50 ± 25) % RH.

The appropriate work rate for the RPD class shall be used.

In order to prevent excess water spilling out of the mouth and contaminating the filter the head shall be tilted back so that the water runs away from the mouth and is collected in a trap.

The test setup shall be allowed to stabilise and the RPD shall be mounted on the RPD headform and exposed for $\left(180\ ^{+20}_{0}\right)$ min.

Numbers of samples to be exposed are given in Table 14.

6.9.3.2 Exposure to corrosive atmosphere

Integrated RPD and components in ready for assembly state containing electronics shall be subjected to the salt spray test specified in ISO 9227 (neutral salt spray test NSS) for an exposure time of (24 ±1) h.

The RPD shall be tested with the open connection(s) blocked and with the RI mounted on an appropriate form in the as worn state to prevent the salt spray from getting on its inside.

Check in accordance with 7.2 and record any observation.

6.10 Requirements for elements/components

6.10.1 Filters

6.10.1.1 General

If RPDs are equipped with non-separable filters all filter requirements shall be met when using the integrated RPD for testing.

When testing one filter of a multiple filter RPD the appropriate filter performance requirements of this standard shall be met with the defined proportioned air flow.

When testing separately, the air flow specified for a test shall be divided by the number of filters through which the air flow is proportioned.

NOTE If, however, it is possible that one filter of a multiple filter device can be used alone in the configuration of a different RPD then the full air flow can be used for testing.

If the filters' resistances meet Formula (1) then the filter may be tested as a single filter with a proportioned flow applicable to the work rate class. Two complete sets of multiple filters shall be tested

$$\frac{|\Delta fr_{max}|}{fr_{mean}} \leq 0,2 \quad (1)$$

where

Δfr_{max} is the maximum resistance difference of all filters tested

fr_{mean} is the mean flow resistance,

If the filters' breathing resistances do not meet that equation, the filters shall be tested in the configuration the filters are intended to be assembled as in the complete RPD at the full flow rate.

6.10.1.2 Particle filter

6.10.1.2.1 General

Prior to the filter efficiency test, particle and combination filters shall be pre-conditioned in ready for assembly state in accordance with 6.9.2.

6.10.1.2.2 Particle filter efficiency and particle filter classes

Particle and combination filters for unassisted and assisted RPD shall meet one of the following particle filter classes listed in Table 7 when tested in accordance with 6.10.1.2.3, 6.10.1.2.4 or 6.10.1.2.5 as applicable.

Table 7 — Particle and combination filter classes

Filter class	Efficiency %	Penetration %
F5	≥99,99	≤0,01
F4	≥99,90	≤0,1
F3	≥99,00	≤1,0
F2	≥95,00	≤5,0
F1	≥80,00	≤20,0

6.10.1.2.3 Particle filter efficiency of unassisted filtering RPD

Filters shall be tested in accordance with ISO 16900-3 for their designated efficiencies against $\begin{pmatrix} 150 \begin{smallmatrix} +5 \\ 0 \end{smallmatrix} \end{pmatrix}$ mg exposure to both NaCl and paraffin oil using an untested filter for each test.

For filters classified as W1, testing shall be conducted at a continuous test air flow rate of 85 l/min with a tolerance of ±2%.

For filters classified as W2, testing shall be conducted at a continuous test air flow rate of 135 l/min with a tolerance of ±2%.

For filters classified as W3, testing shall be conducted at a continuous test air flow rate of 205 l/min with a tolerance of ±2%.

For filters classified as W4 testing shall be conducted at a continuous test air flow rate of 255 l/min with a tolerance of ±2%.

After the stabilization period of 3 min, at no point during the exposure test shall the efficiency fall below its designated class.

Filters other than those designated "for single shift use only" after the exposure to $\left(150\,^{+5}_{0}\right)$ mg of Paraffin oil shall then be re-sealed and stored for (24 ± 1) h in ambient conditions. Storage shall start as soon as paraffin oil exposure is completed.

Following storage the sample shall be retested for efficiency using paraffin oil (ISO 16900-3). The measurement of efficiency shall be performed in accordance with 6.10.1.2.5. The filter efficiency shall be equal or greater than that for the designated class.

Filters designated as single shift use only shall be marked using the symbol given in 3.3.3.

6.10.1.2.4 Particle filter efficiency of assisted filtering RPD

Filters shall be tested in accordance with ISO 16900-3 for their designated efficiencies during an exposure test. The exposure is defined as the product of concentration and time ($C \times t$). The $C \times t$ shall be 2 400 (with a tolerance of ± 10%) mg × min/m^3 for both NaCl and paraffin oil. The test flow rate (q_{test}) for the exposure test shall be calculated as given in Formula (2).

$$q_{test} = (q_{max} - q_{min}) \cdot 0{,}75 + q_{min} \tag{2}$$

where

q_{max} is the averaged maximum interactive flow rate

q_{min} is the averaged minimum interactive flow rate

Interactive flow rates of the RPD are determined in accordance with ISO 16900-8 by setting the breathing machine to the designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

After the stabilization period of 3 min, at no point during the exposure test shall the efficiency fall below its designated class.

An untested filter shall be used for each test.

Filters other than those designated "for single shift use only" shall then be re-sealed and stored for (24 ± 1) h in ambient conditions after exposure to paraffin oil. Storage shall start as soon as exposure to paraffin oil is completed.

Following storage the sample shall be retested using paraffin oil challenge (ISO 16900-3). The measurement of efficiency shall be performed in accordance with 6.10.1.2.5. The filter efficiency shall be equal or greater than that for the designated class.

Filters designated as single shift use only shall be marked using the symbol given in 3.3.3.

6.10.1.2.5 Short term test for particle efficiency

The measurement of efficiency shall be taken as the average over a time period of (30 ± 3) s beginning 3 min after the start of the test.

The measured filter efficiency shall fulfil the requirement for the filter's designated class.

Testing shall be performed in accordance with ISO 16900-3.

Number of samples is given in Table 14.

6.10.1.3 Gas filter

6.10.1.3.1 General

After pre-conditioning specified in 6.9 filters shall meet the requirements for their type and class for capacity (6.10.1.3.2, Table 8 and Table 9), resistance to migration (6.10.1.3.3), if applicable, and performance at specified work rates (6.10.1.3.4). Gas filter types having more than one test gas shall meet the capacity requirements for each test gas. New samples shall be used for each test gas.

Gas filter of the type OG shall be for single shift use only and shall be marked using the symbol given in 3.3.3.

The gas capacity test parameter given in the Table 8 and Table 9 refer to laboratory testing using specified test agents under specified conditions which do not indicate the performance of the device in actual use at the workplace.

Air flow rates given in Tables 8, 9 and 10 to 12 are deemed to be volumetric flow rates and shall be corrected to 1 013 hPa.

The test flow is proportioned by minimum number of filters used on device.

6.10.1.3.2 Gas filter capacity testing

Gas filter capacity shall be tested according to their type and class using the test parameters given in Table 8.

For CO filters used in RPD the gas capacity test shall be performed using the test parameters given in Table 9.

Table 8 — Gas filter capacity classes and test parameters

Type/ class	Test gas concentration		Flow rate (constant)	Temperature	Relative humidity	Breakthrough concentration	Minimum breakthrough time
	ml/m³	mg/m³	l/min with a tolerance of ±2%	°C	%	ml/m³	min
Type OV	Organic vapour[a] (Cyclohexane)						

[a] Organic compound having a boiling point >65 °C at atmospheric pressure.

[b] Since high concentration of cyclohexane has potential risk to exceed the lower explosion limit the test concentration of class 4 has been reduced to 6 000 ml/m³ and the breakthrough time has been expanded accordingly.

[c] Organic compound having a boiling point ≤65 °C at atmospheric pressure.

[d] Any or all of NO, NO_2 and N_2O_4 can be present in effluent air. The total concentration of ($NO + NO_2 + N_2O_4$) shall not exceed 5ml/m³. There is no distinction in measurement for the different effluents necessary.

[e] This concentration of Hg is the saturated vapour pressure at the test temperature.

[f] Both concentrations shall be tested.

[g] Both HCN and $(CN)_2$ may be present in effluent air. The total concentration of HCN and $(CN)_2$ shall not exceed 5ml/m³.

[h] For assisted filtering RPD, the test flow rate shall be the average interactive flow rate of the RPD as determined in accordance with ISO 16900-8 by setting the breathing machine to the highest designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

Table 8 *(continued)*

Type/ class	Test gas concentration		Flow rate (constant)	Temperature	Relative humidity	Breakthrough concentration	Minimum breakthrough time
	ml/m³	mg/m³	l/min with a tolerance of ±2%	°C	%	ml/m³	min
class 1	300	1 042	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	10	60
class 2	1 000	3 474					60
class 3	3 000	10 422					60
class 4	6 000	20 845					90[b]
Type OG	Organic gas and vapour low boiling[c] (Dimethylether)						
class 1	300	285	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	10	60
	Isobutane						
	3 000	2 853	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	10	40
Type AC	Acidic gases SO_2/Cl_2/H_2S						
class 1 SO_2	300	801	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	5	20
class 1 Cl_2	300	878					
class 1 H_2S	300	422					
class 2 SO_2	1 000	2 669					
class 2 Cl_2	1 000	2 927					
class 2 H_2S	1 000	1 407					
class 3 SO_2	3 000	8 007					
class 3 Cl_2	3 000	8 787					
class 3 H_2S	3 000	4 220					
class 4 SO_2	9 000	24 022					
class 4 Cl_2	9 000	26 344					
class 4 H_2S	9 000	12 661					
Type BC	Basic gases (NH_3)						

[a] Organic compound having a boiling point >65 °C at atmospheric pressure.

[b] Since high concentration of cyclohexane has potential risk to exceed the lower explosion limit the test concentration of class 4 has been reduced to 6 000 ml/m³ and the breakthrough time has been expanded accordingly.

[c] Organic compound having a boiling point ≤65 °C at atmospheric pressure.

[d] Any or all of NO, NO_2 and N_2O_4 can be present in effluent air. The total concentration of (NO + NO_2 + N_2O_4) shall not exceed 5ml/m³. There is no distinction in measurement for the different effluents necessary.

[e] This concentration of Hg is the saturated vapour pressure at the test temperature.

[f] Both concentrations shall be tested.

[g] Both HCN and $(CN)_2$ may be present in effluent air. The total concentration of HCN and $(CN)_2$ shall not exceed 5ml/m³.

[h] For assisted filtering RPD, the test flow rate shall be the average interactive flow rate of the RPD as determined in accordance with ISO 16900-8 by setting the breathing machine to the highest designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

Table 8 *(continued)*

Type/ class	Test gas concentration		Flow rate (constant)	Temperature	Relative humidity	Breakthrough concentration	Minimum breakthrough time
	ml/m³	mg/m³	l/min with a tolerance of ±2%	°C	%	ml/m³	min
class 1	300	211	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	10	40
class 2	1 000	703					
class 3	3 000	2 109					
class 4	9 000	6 327					
Type NO_x	Nitrogen monoxide (NO) and Nitrogen dioxide (NO_2)						
class 1 NO	300	37	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	5[d]	20
class 1 NO_2	300	57					
class 2 NO	1 000	124					
class 2 NO_2	1 000	190					
class 3 NO	3 000	372					
class 3 NO_2	3 000	570					
Type HG	Mercury (Hg)						
class 1	1,9[e]	13,2	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	0,012	240
class 2							480
class 3							6 000
Type OZ	Ozone						
class 1[f]	1	2	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	0,1	480
	50	99					30
Type HCN	Hydrogen Cyanide (HCN)						
class 1	300	335	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	5[g]	25
class 2	1 000	1 116					
class 3	3 000	3 347					
class 4	9 000	10 042					
Type AH	Arsine (AsH_3)						
class 1	1	3,2	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	0,01	170
Type HF	Hydrogen Fluoride (HF)						

[a] Organic compound having a boiling point >65 °C at atmospheric pressure.

[b] Since high concentration of cyclohexane has potential risk to exceed the lower explosion limit the test concentration of class 4 has been reduced to 6 000 ml/m³ and the breakthrough time has been expanded accordingly.

[c] Organic compound having a boiling point ≤65 °C at atmospheric pressure.

[d] Any or all of NO, NO_2 and N_2O_4 can be present in effluent air. The total concentration of ($NO + NO_2 + N_2O_4$) shall not exceed 5ml/m³. There is no distinction in measurement for the different effluents necessary.

[e] This concentration of Hg is the saturated vapour pressure at the test temperature.

[f] Both concentrations shall be tested.

[g] Both HCN and $(CN)_2$ may be present in effluent air. The total concentration of HCN and $(CN)_2$ shall not exceed 5ml/m³.

[h] For assisted filtering RPD, the test flow rate shall be the average interactive flow rate of the RPD as determined in accordance with ISO 16900-8 by setting the breathing machine to the highest designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

Table 8 *(continued)*

Type/ class	Test gas concentration		Flow rate (constant)	Temperature	Relative humidity	Breakthrough concentration	Minimum breakthrough time
	ml/m³	mg/m³	l/min with a tolerance of ±2%	°C	%	ml/m³	min
class 1	70	58	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	3	90
class 2							480
class 3							1 500
Type CD	Chlorine dioxide (ClO_2)						
class 1	500	1 392	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	0,1	30
Type ETO	Ethylene Oxide ($(CH_2)_2O$)						
class 1	100	182	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	1	20
class 2	300	546					
class 3	1 000	18 184					
Type FM	Formaldehyde (CH_2O)						
class 1	100	124	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	1	20
class 2	100	124					120
class 3	500	620					240
Type MB	Methylbromide (CH3Br)						
class 1	300	1 176	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	1	30
class 2	1 000	3 919					
class 3	3 000	11 757					
Type PH	Phosphine (PH_3)						
class 1	300	421	30[h]	(22 ± 1)	(25 ± 3) and (70 ± 3)	0,3	25
class 2	300	421					75

[a] Organic compound having a boiling point >65 °C at atmospheric pressure.

[b] Since high concentration of cyclohexane has potential risk to exceed the lower explosion limit the test concentration of class 4 has been reduced to 6 000 ml/m³ and the breakthrough time has been expanded accordingly.

[c] Organic compound having a boiling point ≤65 °C at atmospheric pressure.

[d] Any or all of NO, NO_2 and N_2O_4 can be present in effluent air. The total concentration of ($NO + NO_2 + N_2O_4$) shall not exceed 5ml/m³. There is no distinction in measurement for the different effluents necessary.

[e] This concentration of Hg is the saturated vapour pressure at the test temperature.

[f] Both concentrations shall be tested.

[g] Both HCN and $(CN)_2$ may be present in effluent air. The total concentration of HCN and $(CN)_2$ shall not exceed 5ml/m³.

[h] For assisted filtering RPD, the test flow rate shall be the average interactive flow rate of the RPD as determined in accordance with ISO 16900-8 by setting the breathing machine to the highest designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

Table 9 — Gas filter type CO classes and test parameters

Type/ class	Test gas concentration		Flow rate (dynamic)[a]	Flow rate (constant)	Temperature	Relative humidity	Breakthrough concentration	Breakthrough dose	Minimum breakthrough time
	ml/m³	mg/m³	l/min with a tolerance of ± 2%		°C	%	ml/m³	ml	min
Type CO	Carbon Monoxide (CO)								
class 20	300	347	35	—	(25 ± 1)	(95 ± 3)	200[b]	140	20
	300	347	—	30[e]	(5 ± 1)	NA			20
	3 000	3 469	35	—	(25 ± 1)	(95 ± 3)		200[c]	20
class 60	300	347	35	—	(25 ± 1)	(95 ± 3)			60
	300	347	—	30[e]	(5 ± 1)	NA			20[d]
	3 000	3 469	35	—	(25 ± 1)	(95 ± 3)			60
class 180	300	347	35	—	(25 ± 1)	(95 ± 3)			180
	300	347	—	30[e]	(5 ± 1)	NA			20[d]
	3 000	3 469	35	—	(25 ± 1)	(95 ± 3)			180

NA Not applicable (the absolute humidity at this temperature is very low and therefore neglectable)

[a] Tested as complete filtering RPD even if standardized connector filters are used. Only one RI size shall be tested. RI shall be leaktight on the headform.

[b] Average time weighted over any 5 min interval (moving average).

[c] The dose shall be calculated by using the normalized real measurement data.

[d] After this time, the test at low temperatures can be terminated because the essential performance is verified.

[e] For assisted filtering RPD, the test flow rate shall be the average interactive flow rate of the RPD as determined in accordance with ISO 16900-8 by setting the breathing machine to the highest designated work rate. If the RPD has the option for wearer to select multiple flow settings this will be determined at the highest flow setting.

6.10.1.3.3 Gas filter resistance to migration

Gas filter of type ETO, MB, FM, CO, and NO_x can be sensitive to migration and shall be for single shift use only and shall be marked using the symbol given in 3.3.3, unless they meet the requirements of resistance to migration. Filters being tested for migration shall be exposed to the same conditions and breakthrough times as specified in 6.10.1.3.2 , but for half of the required minimum breakthrough time and then, after storage, test gas shall be passed through the filter for 40% of the required minimum breakthrough time and breakthrough shall not occur prior to that calculated time.

Testing shall be performed in accordance with ISO 16900-4:2011, Migration Test B.

Number of test samples in ready for assembly state is specified in Table 16 or Table 14.

6.10.1.3.4 Gas filter other than type CO performance at specified work rates

The gas filter performance at specified work rates verifies that the filter achieves a minimum performance level at the work rate class of the RPD.

Multiple Type filters and combination filters shall be tested at the same work rate for each gas filter Type and/or efficiency clas

Filters shall meet the minimum breakthrough times given in Table 10 for their specific test gas(es) at the given breakthrough concentration for its type and class under the test parameters provided in 6.10.1.3.2 and Table 8 with the exception of the tolerance of the relative humidity to be extended to ± 5 % If the test gas concentration in Table 8 is above 1 000 ml/m³, the test shall be conducted at 1 000 ml/m³.

Table 10 — Minimum breakthrough times at test flow rates for work rate classes

Work rate class	Unassisted RPD Filter Flow rate (constant) l/min	Assisted RPD Filter Flow rate (constant) l/min	Minimum breakthrough times min
W1	110 with a tolerance of ±2%	Measured maximum flow rate	3
W2	180 with a tolerance of ±2%		3
W3	270 with a tolerance of ±2%		6
W4	340 with a tolerance of ±2%		12

Measured maximum flow rate is determined in accordance with ISO 16900-8 by setting the breathing machine to the designated work rate class as given in Table 2.

Prior to this test, gas and combination filters shall be pre-conditioned in accordance with 6.9.2.

As an alternative to a test conducted at flow rates greater than 110 l/min the breakthrough time may be calculated from measured breakthrough times at lower flow rates in accordance with method described in ISO 16900-4:2011, Annex B. This method only applies to filter types OV, OG, AC and BC.

6.10.1.3.5 Gas filter type CO at specified workrates

The gas filter capacity test in 6.10.1.3.2 includes the validation test for workrate class W1.

For CO filters used in unassisted RPD the validation test shall be performed for the workrate class 2, 3 and 4.

— W2 using the test parameters given in Table 11,

— W3 using the test parameters given in Table 12,

— W4 using the test parameters given in Table 13.

For assisted RPD the CO filters shall be tested at the measured maximum flow rate which substitutes the dynamic flow rate given in Tables 11 to 13.

The number of test samples shall be as specified in Annex C.

Testing shall be performed in accordance with ISO 16900-4.

Table 11 — Gas filter validation of type CO classes and test parameters for work rates class W2

Type/ class	Test gas concentration			Flow rate (dynamic)[a]	Temperature	Relative humidity	Breakthrough		Minimum breakthrough time
							concentration	dose	
	ml/m³	mg/m³		l/min with a tolerance of ± 2%	°C	%	ml/m³	ml	min
Type CO	Carbon Monoxide (CO)								
class 20	300	347		65	(25 ± 1)	(90 ± 5)	200[b]	40	3
class 20	3 000	3 469						200	3
class 60	300	347						40	3
class 60	3 000	3 469						200	3
Class 180	300	347						40	3
Class 180	3 000	3 469						200	3

[a] Testing as complete filtering RPD.

[b] Average over the 3 min testing time.

Table 12 — Gas filter validation of type CO classes and test parameters for work rates class W3

Type / class	Test gas concentration			Flow rate (dynamic)[a]	Temperature	Relative humidity	Breakthrough		Minimum breakthrough time
							concentration	dose	
	ml/m³	mg/m³		l/min with a tolerance of ± 2%	°C	%	ml/m³	ml	min
Type CO	Carbon Monoxide (CO)								
class 20	300	347		105	(25 ± 1)	(90 ± 5)	200[b]	60	3
class 20	3 000	3 469						200	3
class 60	300	347						60	3
class 60	3 000	3 469						200	3
class 180	300	347						60	3
class 180	3 000	3 469						200	3

[a] Testing as complete filtering RPD.

[b] Average over the 3 min testing time.

Table 13 — Gas filter validation of type CO classes and test parameters for work rates class W4

Type/ class	Test gas concentration			Flow rate (dynamic)[a]	Temperature	Relative humidity	Breakthrough		Minimum breakthrough time
							concentration	dose	
	ml/m³	mg/m³		l/min with a tolerance of ± 1%	°C	%	ml/m³	ml	min
Type CO	Carbon monoxide (CO)								

[a] Testing as complete filtering RPD.

[b] Average over the 3 min testing time.

Table 13 *(continued)*

Type/ class	Test gas concentration			Flow rate (dynamic)[a]	Temperature	Relative humidity	Breakthrough		Minimum breakthrough time
							concentration	dose	
	ml/m³	mg/m³		l/min with a tolerance of ± 1%	°C	%	ml/m³	ml	min
class 20	300	347		135	(25 ± 1)	(90 ± 5)	200[b]	80	3
class 20	3 000	3 469						200	3
class 60	300	347						80	3
class 60	3 000	3 469						200	3
class 180	300	347						80	3
class 180	3 000	3 469						200	3

[a] Testing as complete filtering RPD.

[b] Average over the 3 min testing time.

6.10.1.4 Combination filters

The particle filter of combination filters shall be on the inlet side of the filter as used.

Combination filters shall meet the requirements of particle filters (6.10.1.2) and gas filters (6.10.1.3).

6.10.1.5 Test schedule for particle filters, gas filters or combination filters

The numbers of filters to be pre-conditioned and tested are given in Table 14.

Table 14 — Test schedule for particle filters, gas filters or combination filters

Particle filter or combination filter for each test aerosol			
Sample No	Preconditioning Seq [a]	Preconditioning Exh[b]	Test
1	X	—	6.10.1.2.3 or 6.10.1.2.4
2	X	—	
3	X	—	6.10.1.2.3 or 6.10.1.2.4 followed by 6.10.1.2.5
4	—	(X)[c]	6.10.1.2.3 or 6.10.1.2.4
5	—	(X)[c]	
6	—	(X)[c]	6.10.1.2.3 or 6.10.1.2.4 followed by 6.10.1.2.5

Gas filter or combination filter for each test gas and concentration				
Sample No	Preconditioning Seq[a]	Preconditioning Exh[b]	Test	Relative humidity
1	X	—	6.10.1.3.2	(25 ± 3) %
2	X	—		70 ± 3) %
3	—	(X)[c]		(25 ± 3) % or (70 ± 3) %[d]

[a] Sequential preconditioning (6.9.2) for testing in ready for assembly state

[b] Preconditioning by exposure to exhaled air (6.9.3.1)

[c] If applicable

[d] Based on the result of 6.10.1.3.2 the relative humidity leading to a shorter breakthrough time has to be used

Table 14 *(continued)*

Particle filter or combination filter for each test aerosol				
Sample No	Preconditioning		Test	
	Seq [a]	Exh[b]		
4	X	—	6.10.1.3.4	(25 ± 3) %
5	—	(X)[c]		(70 ± 3) %
6	(X)[c]	—	6.10.1.3.3	(25 ± 3) %
7	—	(X)[c]		(70 ± 3) %

[a] Sequential preconditioning (6.9.2) for testing in ready for assembly state

[b] Preconditioning by exposure to exhaled air (6.9.3.1)

[c] If applicable

[d] Based on the result of 6.10.1.3.2 the relative humidity leading to a shorter breakthrough time has to be used

6.10.2 Flexibility and resistance to deformation of hoses

6.10.2.1 Resistance to deformation of the breathing hose for RPD without a flow warning device

For identification of the breathing hose see Figure 3, Item 3.

For assisted filtering RPD, a breathable gas supply chain shall be the source of air flow used in the test. The flow rate used in the test shall be the measured minimum flow rate of the assisted filtering RPD. The flow resulting from the compression load shall not be reduced by more than 50%.

When testing unassisted filtering RPD with a breathing hose at a constant flow rate of (110 ± 5) l/min with a compression load of (50 ± 2,5) N applied to the hose the resulting flow rate shall not be reduced by more than 50 %. Hose and compression plates shall be equilibrated to $\left(35\ ^{0}_{-2}\right)$ °C and tested at a temperature of (22 ± 3)°C and (50 ± 25)% RH with testing commencing within 1 min.

One sample in non pre-conditioned state shall be tested in accordance with ISO 16900-6:—, 6.2.

6.10.2.2 Resistance to deformation of low pressure hose

For identification of the low pressure hose see Figure 3, Item 7.

When tested at a constant flow rate of (110 ± 5) l/min with a compression load of (1 000 ± 50) N applied to the hose the resulting flow rate shall not be reduced by more than 50%. Hose and compression plates shall be equilibrated at $\left(35\ ^{0}_{-2}\right)$ °C and tested at a temperature of (22 ± 3) °C and (50 ± 25)% RH with testing commencing within one minute.

One sample in non pre-conditioned state shall be tested in accordance with ISO 16900-6:—, 6.2.

6.10.2.3 Flexibility of hose(s)

Hose(s) (if fitted) shall not unduly restrict the wearer's mobility when the RPD is used in accordance with the information supplied by RPD manufacturer.

Testing shall be performed in accordance with 5.8 and ISO 16900-7.

6.11 Requirements for RPD with standardized connector

6.11.1 General

Standardized connector on the RPD shall meet the requirements of ISO 17420-3.

RPD using standardized connector shall have the male thread connector on the filter and the female thread connector on the RI.

Any RPD having a standardized connector shall meet all requirements of 6.1 through 6.10 and ISO 17420-1 unless otherwise specified.

Filters with standardized connectors shall be work rate classes W1 or W2.

The work rate class of the complete RPD with standardized connector is determined by the work rate class of the filter.

For assisted filtering RPD a standardized connector is allowed on the RI class 'bT' or 'cT'. All requirements for assisted filtering RPD shall be fulfilled. Filters with standardized connector shall not be allowed in assisted filtering RPD.

The RI shall fulfil the relevant requirements when using a standardized connector. The breathing resistance of the breathable gas supply chain without RI shall not exceed 800 Pa when tested with 180 l/min constant flow.

Multi-functional filtering RPD in the unassisted mode shall be equal to or less than W2.

Electronics used in RI and filters shall have an independent functionality.

6.11.2 Filters with standardized connector

6.11.2.1 Resistance of filters with standardized connectors

This requirement supersedes 6.3.1.

The resistance of filters shall be determined on two filters after sequential pre-conditioning in accordance with 6.9.2.

The resistance shall be measured with any filter accessory in place.

Test shall be performed at a constant flow rate of 110 l/min for filters of work rate class W1 and 180 l/min for filters of work rate class W2.

The maximum resistance of filters shall not exceed the values in Table 15 regardless of type, capacity class or efficiency class.

NOTE To improve the comfort to the wearer for particle and gas filters the values for W1 in Table 15 are lower than the physiological limits.

Table 15 — Resistance of filters

Filter	Maximum resistance for W1 filters tested at 110 l/min at BTPS with a tolerance of ± 2% Pa	Maximum resistance for W2 filters tested at 180 l/min at BTPS with a tolerance of ± 2% Pa
Particle	400	800
Gas	800	
Combination	1 000	
Resistance values given in this table and Table 17 in combination shall not exceed the acceptable value of 1 200 Pa for the RPD.		

Air flows are expressed at BTPS. When the measurement is performed at a temperature other than 37 °C and a pressure other than 1 013hPa, the result shall be normalised to BTPS using a linear approach.

An example for normalisation calculation for resistance of filters results is given in D.2.2.

6.11.2.2 Mass and size of filters with standardized connector

The mass of a filter (including any holder and accessories) with a standardized connector shall not exceed 500 g.

The maximum size of a filter which uses a standardized connector shall be such that the filter (including any holder and accessories) shall pass through a $\begin{pmatrix} 120 \, ^{+0,3}_{0} \end{pmatrix}$ mm square opening in the orientations shown in Figure 5. The centre line of the standardized connector shall be no more than 60 mm from any edge, see Figure 6, Item 1.

One filter with seals and plugs removed shall be checked in accordance with 7.2.

Dimensions in millimetres

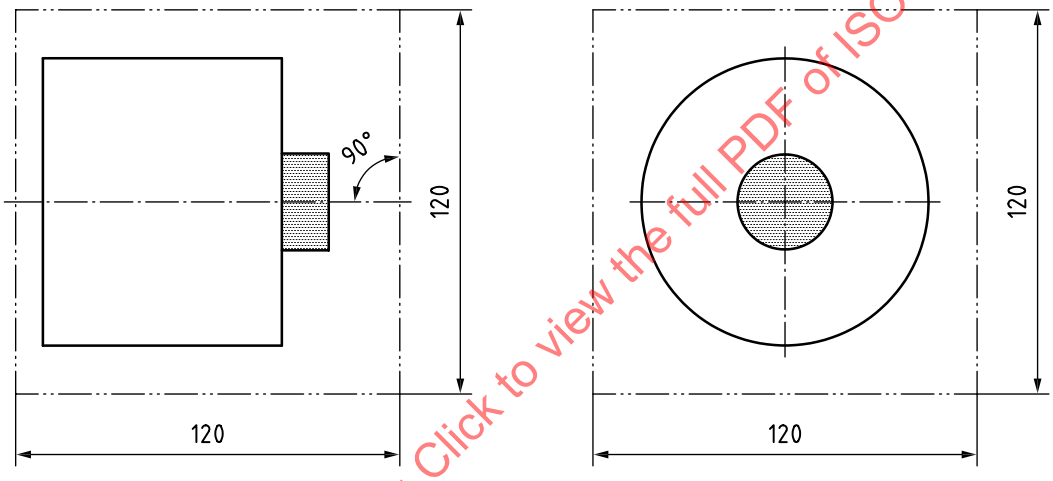
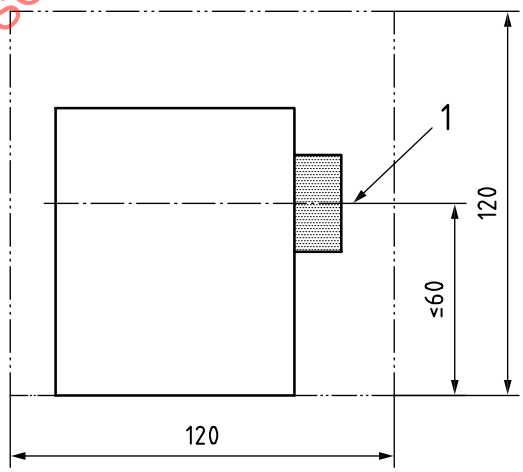


Figure 5 — Schematic drawing of filter gauge for dimensions and orientation

Dimensions in millimetres



Key

1 filter connector centre line

Figure 6 — Schematic drawing of filter gauge for distance from filter connector centre line to filter edge

6.11.2.3 Particle filters with standardized connector

Particle filters used in filters with a standardized connector are limited to the following classes: F2, F3, F4 and F5.

6.11.2.4 Test schedule for particle filters, gas filters or combination filters with standardized connector

The numbers of filters to be pre-conditioned and tested are given in Table 16.

Table 16 — Test schedule for particle filters, gas filters or combination filters with standardized connector

Filter with standardized connector (particle, gas or combination filters)				
Sample No	Preconditioning		Test	Relative humidity[c] %
	AR[a]	Seq[b]		
1	X	—	6.11.2.1	(25 ± 3) or (70 ± 3)
2	—	X	6.11.2.1	(25 ± 3)
3	—	X	6.11.2.1	(70 ± 3)

[a] Tested as received.

[b] Tested after sequential preconditioning (6.9.2).

[c] For gas filters or combination filters except type CO.

Additional samples for requirements specified in 6.10.1.5 are given in Table 15.

6.11.3 RI with standardized connector

6.11.3.1 General

Only one standardized connector shall be operational at any time.

If the RI has a standardized connector and one or more additional filter connector(s), a means of making the additional connector(s) inoperable must be provided. All necessary information about the safe configuration of those systems shall be provided in the information supplied by the manufacturer.

RIs with standardized connectors shall be either class ‘bT’ or ‘cT’.

RI with standardized connector shall be equipped with a means to avoid the exhaled air passing through the filter.

Check in accordance with 7.2.

6.11.3.2 Breathing resistance of RI with standardized connector

This requirement supersedes 6.3.1.

After sequential pre-conditioning two RI shall be tested for breathing resistance and meet the requirements in Table 17, at both a constant flow of 110 l/min with a tolerance of ±2 % and a constant flow of 180 l/min with a tolerance of ±2 %, when equipped with a filter simulator in accordance with ISO 16900-5.

To determine the inhalation resistance of the RI the resistance of the filter simulator shall be subtracted from the measured value.

Table 17 — Breathing resistance for RI with standardized connector

	Breathing resistance constant flow at 110 l/min with a tolerance of ±2 % Pa	Breathing resistance constant flow at 180 l/min with a tolerance of ±2 % Pa
Inhalation resistance	200	400
Exhalation resistance	NA	400
Resistance values given in this table and Table 15 in combination shall not exceed the acceptable value of 1 200 Pa for the RPD.		

Testing shall be performed in accordance with ISO 16900-2.

6.11.3.3 Inward leakage requirement for RI using a standardized connector

After sequential pre-conditioning RI using standardized connector shall meet the requirements for inward leakage given in Table 18 when tested in accordance with 5.7.2.

For this test the filter simulator according to ISO 16900-5 shall be used.

Table 18 — Inward leakage requirements for RIs with standardized connector

RI class	IL_{MAX} %
cT	0,05
bT	1

6.11.4 Protection class determination for RPD using standardized connector

RPD using standardized connector shall be classified by protection class as specified in Table 19.

Table 19 — Determination of protection class for RPD with standardized connector and combination filters

RI class	Filter class			
	F5 Combination filter	F4 Combination filter	F3 Combination filter	F2 Combination filter
cT	PC4	PC3	PC3	PC2
bT	PC3	PC3	PC2	PC2

For RPD with standardized connector and gas filter only, cT will be allocated to PC4 and bT will be allocated to PC3.

6.11.5 RPD using standardized connector and low pressure hoses

If a breathing hose or adaptor is included in the RI as shown in Table 20, it shall be permanently affixed or shall be connected by a non-standardized connector. The breathing hose shall be provided with a fixation means to the body of the wearer.

Only configurations 1, 3, 3a, 3b and 5 of Table 20 shall be used and shall fulfil all requirements related to RI with standardized connector, see 6.11.3.

Table 20 — Acceptable and non-acceptable configurations

Configuration	RI (bT or cT)	Breathing hose (adaptor)	Filter	Acceptable configuration (yes or no)
1	◎	NONE	◎	YES
2	◎	◎ ---------- ◎	◎	NO
3	● ---------- ◎		◎	YES
3a	∆	∆ ---------- ◎	◎	YES
3b	∆	Adaptor: ∆ ● ◎	◎	YES
4	◎	◎ ---------- ●		NO
5	◎	◎ ---------- ∆	∆	YES

Key:
◎ standardised connector
∆ non-standardised (dedicated) connector
● fixed connection
--- hose

6.12 Multi-functional RPD

A multi-functional RPD shall meet all of the requirements relevant to its classes in all modes of operation. The operation of changing from unassisted to assisted filtering mode, or vice versa shall not result in a decrease in PC class below that of the lower PC class of the multi-functional RPD.

This shall be tested by adding an extra exercise for 2 min at the end of the TIL test regime using the filtering mode with the lower PC class. This exercise shall be performed while standing still.

At the beginning of these 2 min the multi-functional RPD shall be set from one filtering mode to the other and after 1 min back, if compatible with the design.

The arithmetic mean percentage inward leakage of the extra exercise for the entire panel shall fulfil the TIL requirements for the RPD function which has the lower PC class.

Testing shall be performed using the exercise regime in accordance with ISO 16900-1:2019, Table B.2 and B.4

The RPD shall be designed in such a way that the mode of operation can be identified by the wearer during use.

After sequential pre-conditioning, testing shall be performed in accordance with ISO 16900-7.

6.13 Requirements for optional features

6.13.1 General

RPD with optional features shall meet all applicable performance requirements of ISO 17420-1 and this document

6.13.2 Extreme low temperature requirements

Where the manufacturer`s chosen temperature is below −5 °C, the following performance requirements shall be met.

Filters designated to operate at the manufacturer’s chosen temperature shall be stored for a minimum of 4 h for equilibration at that temperature and then tested in accordance with 6.10.1.3.4 at the

temperatures given in Tables 8, 9, 11, 12 and 13. Testing shall start within 5 min after completion of equilibration.

RPD designated to operate in the chosen temperature shall meet the following performance requirements:

— breathing resistance/work of breathing/elastance;

— mechanical strength of visor (see ISO 17420-1:2021, 5.9.1.4).

Testing shall be performed in accordance with 6.3.1 or 6.3.2 as applicable.

For assisted RPD, the RPD in ready for assembly state, except the RI, is equilibrated at the chosen cold temperature. The RPD is assembled in the chosen cold temperature, but no colder than -15 °C, and the practical performance test commenced within two minutes thereafter at that temperature or -15 °C whichever is warmer.

Testing in accordance with ISO 16900-7:2020, Annex B j) and Annex A, Activity 1 to 8.

6.13.3 Extreme high temperature requirements

Where the RPD manufacturer has chosen a temperature above 35 °C, the requirements of 6.3.1 or 6.3.2, as applicable, shall be met when the RPD is operated at that temperature.

Testing shall be performed in accordance with 6.3.1 or 6.3.2.

In addition, the following performance requirements shall also be met at that temperature:

— resistance of deformation of breathing hose;

— mechanical strength of visor.

Testing shall be performed in accordance with 6.10.2 and ISO 17420-1:2021, 5.9.1.4.

Filters designated to operate in the manufacturer's chosen temperature shall be stored for a minimum of 4 h for equilibration at that temperature and then tested in accordance with 6.10.1.3.4. Testing shall start within 5 min after completion of equilibration.

6.13.4 Contact with hot surface

When exposed parts and components of the RPD are in contact with a hot surface there shall be no deterioration that affects the function.

Exposed parts and components are those that can be touched in as worn state by the exposed surface identification probe specified in ISO 16900-5.

Test in accordance with 7.4 and check in accordance with 7.2.

6.13.5 Hydration

If the RPD is fitted with a facility for drinking, the hydration facility shall

— be able to be used by the wearer without assistance, without the use of tools, and without removing the RPD.

— be capable of supplying a drinking rate of at least 100 ml/min.

— incorporate means that ensure the wearer cannot inadvertently create a leak when the system is disconnected from the liquid container.

Testing shall be performed in accordance with ISO 16900-7.

— allow intake of liquid while in a contaminated area. The protection of the device shall be assessed during the total inward leakage test while connecting, disconnecting, drinking and with the drinking device in its stowed position.

Testing shall be performed using the exercise regime in accordance with ISO 16900-1:2019, Tables B.1, B.2 or B.3.

6.13.6 Performance of RPD using prefilters

The RPD, or its components, shall be tested for the following applicable requirements with the prefilter(s), including any holder(s), in place.

— Breathing resistance/work of breathing/elastance (see 6.3).

— Resistance to flame – Single burner dynamic (see 5.3).

— Size and mass of filter, if standardized connector is used (see 6.11.2.2).

— Validation of practical performance (see 5.8).

— Field of vision (see 5.2).

6.13.7 Use of RPD in potentially explosive atmospheres

If the information supplied by the manufacturer states that the RPD can be used in potentially explosive atmospheres, the RPD shall comply with the IEC Ex Certified Equipment Program or other equivalent national programs.

6.13.8 Electromagnetic compatibility of RPD

If the information supplied by the manufacturer states that the RPD is electromagnetically compatible (EMC), the RPD shall comply with the IEC 61000-6-2 EMC Publications or other equivalent national programs.

7 Testing

7.1 General

This clause contains testing which is not included in the ISO 16900 series.

7.2 Inspection

The inspection shall be made prior to laboratory or practical performance tests or as specified in this document.

This may entail a certain amount of assembly, dismantling or adjustment of the RPD.

Inspection shall include a report of the findings of the following, as applicable.

a) Visible damages, deformation, corrosion.

b) The operation of switches, connections, control means, etc., including use of gloves (if required).

c) The need for special tools.

d) If connections can be disconnected inadvertently.

e) If means for sealing, such as O-rings or gaskets, will be retained in position, unless deliberately removed for maintenance.

f) If incorrect combinations are prevented by design solutions.

g) Warning devices, monitoring devices, checking devices and indicators, whether or not signals intended to give different information can be distinguished from one or the other. This may require certain adjustments on the RPD, e.g. replacing a battery with a controllable power supply, relieving pressure, etc.

h) The presence of flow rate.

i) The compatibility with additional equipment.

j) The marking.

k) The information supplied by the manufacturer.

l) Availability of documentation, e.g. safety data sheets or declarations relevant to the materials used, declaration of reliability conducted or the declaration that relevant parts of the FMEA have been conducted.

7.3 Testing of leak tightness using positive pressure

The components shall be immersed in water to a depth of between 0,2 m and 0,3 m. After 1 min the bubble rate shall be measured for 1 min and recorded.

7.4 Contact with hot surface

Exposed parts and components are placed in contact with a horizontal orientated laboratory hot plate suitable to test the exposed parts and components at (130 ± 15) °C for 15 s.

8 Marking

8.1 General

As a minimum, the manufacturer shall provide marking on the RPD conforming to this clause.

Contact information of the manufacturer shall be included on the package. This can be done by a weblink which directly leads to address and telephone number of the manufacturer.

All markings shall be readable, permanent and clearly visible.

NOTE Permanent marking is marking that cannot be removed without evidence of its removal.

Where applicable, marking may be added in order to comply with national or local regulations.

8.2 Marking of RPD without separable components

The RPD shall include at least the following marking:

a) manufacturer name, logo or identifying mark;

a) RPD model number, name or any other type identifying mark;

b) reference to this standard and year of publication;

c) RPD classification in the following sequence:

1) protection class

2) work rate class

3) RI type and class

4) particle filter class, if applicable

5) gas filter class, if applicable

d) means of traceability, e.g. serial number, batch number, lot number;

NOTE Format can be chosen by the manufacturer.

e) instructions to read the information supplied by the RPD manufacturer, by using the graphical symbol given in 3.3.2;

f) RPD for single-shift use only shall be marked by using the graphical symbol given in 3.3.3;

g) shelf life indication, e.g. end of shelf life, by using the graphical symbol given in 3.3.4;

h) size designation, if applicable.

8.3 Marking of RPD replacement parts

RPD replacement parts which are designated by the manufacturer as replaceable shall be marked with

a) the manufacturer name, logo or identifying mark, and

b) part number or type identifying mark.

If marking on replacement parts is not feasible, the labelling shall be on the smallest commercially available package.

8.4 Marking of RPD components as part of a system

8.4.1 RI

The RI shall be marked with at least the following information:

a) RI class and type;

b) when the RI is part of a RPD system with multiple configurations this shall be indicated by also using the graphical symbol given in 3.3.1;

EXAMPLE ① bT

c) size, if applicable;

d) reference to this standard and year of publication;

e) means of traceability, e.g. serial number, batch number, lot number;

NOTE Format can be chosen by the manufacturer.

f) instructions to read the information supplied by the RPD manufacturer, by using the graphical symbol given in 3.3.2;

g) designation of compliance with other standards (e.g. eye protection) on the RI, if applicable;

h) RIs with standardized connector in accordance with ISO 17420-3 shall be marked with the graphical symbol 3.3.5 ;

8.4.2 Marking of particle, gas/vapour or combination filters

The filter shall be marked with the following information

a) filter type and class,

The sequence of the marking is as follows: particle filter type and class,blank space, gas filter type(s) and class(es) and work rate indicated by lower case 'w' in accordance with ISO/TS 16973. If there are more than one gas filter type and class, a single space shall be used for separation.

EXAMPLE F3 OG1 AC2 w2

b) colour code in accordance with Table 21,

Table 21 — Equivalent color code for filter marking

Filter types	Color	UCL (Universal Colour Language)	CMYK (Cyan, Magenta, Yellow, blacK)	RGB (Red, Green, Blue)	HSL (Hue, Saturation Lightness)	Munsell	Pantone	RAL
Gas filters	Blue	#007197	100, 25, 0, 41	0, 113, 151	139, 255, 76	2.5PB4/10	7690 C	5007
Particle filters	White	#ffffff	0,0,0,0	255, 255, 255	0,0,100	N9.5/	white	9010

Colors shall be visible at a distance of one metre.

Each of the applicable colors shall be readily discernible.

c) reference to this standard and year of publication,

d) shelf life indication, e.g. end of shelf life, by using the graphical symbol given in 3.3.4,

e) means of traceability, e.g. serial number, batch number, lot number,

NOTE Format can be chosen by the manufacturer.

f) Filters for single-shift use only shall be marked by using the graphical symbol given in 3.3.3,

g) filter(s) fulfilling the requirements of this document and ISO 17420-3 shall be marked with the symbol for standardized connector in accordance with 3.3.5, blank space, particle filter type and class, blank space and if applicable, followed by gas filter type(s) and class(es), blank space and work rate class indicated by lower case 'w' in accordance with ISO/TS 16973. If there are more than one gas filter type and class, a single space shall be used for separation between the each type and class,

EXAMPLE ◎ 2 OV1 BC2 w2

h) instruction to read the information supplied by the RPD manufacturer, by using the graphical symbol given in 3.3.2.

8.4.3 Other separable components

All components, if separable, e.g. blower units, batteries and charging systems, shall be marked or labelled with the following information:

a) means of traceability, e.g. serial number, batch number, lot number;

NOTE Format can be chosen by the manufacturer.

b) instructions to read the information supplied by the RPD manufacturer, by using the graphical symbol given in 3.3.2;

c) if applicable, shelf life information using the graphical symbol according to 3.3.4; and;

d) if applicable, graphical symbols for disposal.

9 Information supplied by the RPD manufacturer

9.1 General

The information supplied by the RPD manufacturer shall be available in a readable format accompanied with the RPD or the smallest commercially available package. If the RPD is reusable, instructions shall be given that the information is to be retained for the life of the RPD. In certain cases, national regulations may require certain information to be on the shipping container.

Information supplied by the RPD manufacturer shall be at least in the official language(s) of the country of destination, or nationally recognized language(s), as accepted.

9.2 RPD

9.2.1 Minimum information

Information supplied by the RPD manufacturer shall provide minimum information, necessary for trained and qualified personnel on:

a) a warning that the RPD is unsuitable for use in oxygen deficient atmosphere;

b) application and limitations of the RPD and warnings and cautions associated with its use;

c) RPD model number, name or any other type identifying mark;

d) RPD classification;

e) assembly and operational instructions (description of pre-use checks and the mounting and orientation of RPD components and parts);

f) meaning of graphical symbols on the RPD;

g) storage conditions prior to use;

h) assessment of fit (e.g. size selection, recommendations for fit testing);

i) pre-use checks (e.g. wearer seal checks, adequate airflow, checking devices);

j) compatibility with other personal protective equipment (PPE);

k) correct donning and doffing;

l) shelf life, which may include a shelf life indicator attached to the packaging, RPD, component or expiry date;

m) reusability of the RPD;

n) service life of the RPD;

o) contact information of the manufacturer or supplier;

p) disposal;

q) information about the use in potentially explosive atmosphere;

r) warning about actions to be taken in case of a failure of the RPD during use (e.g .failure of blower unit of a RPD with loose fitting RI);

s) information on single shift use only, if applicable.

9.2.2 Additional information

In addition, information supplied by the RPD manufacturer shall provide information, necessary for trained and qualified personnel, if applicable, on:

a) warning devices or checking devices, such as alarms, signals, etc., related to the use of the product;

b) storage conditions between each use;

c) post-use checks for damage during use and checks during use;

d) RPD maintenance, repair and inspection;

e) use of correct components and replacement parts of the RPD;

f) cleaning, disinfection and decontamination;

g) information about the use and limitations of optional features;

h) information about the use and limitations of a hydration facility (e.g. on connection and disconnection of the drinking reservoir, cleaning and disinfection of the drinking device and warning that when the device is being connected in contaminated environment, traces of contaminant could be drawn inside the RI);

9.3 RPD components and replacement parts

9.3.1 Particle, gas/vapour or combination filters

9.3.1.1 Minimum information

The information supplied by the RPD manufacturer shall provide minimum information, necessary for trained and qualified personnel on:

a) a warning that the RPD is unsuitable for use in oxygen deficient atmosphere;

b) application and limitations of the filter, and warnings and cautions associated with its use;

c) explanation of filter type, class and colour code and its relation to the RPD classification;

d) assembly and operational instructions (description of pre-use checks and the mounting and orientation of the filters in the RPD for which they are designed to be used);

e) meaning of graphical symbols;

f) storage conditions prior to use;

g) explanation of the shelf life indication;

h) how to estimate or determine service life of the filter(s);

i) disposal;

j) contact information of the manufacturer or supplier;

k) information on single shift use only, if applicable.

9.3.1.2 Additional information

In addition, information supplied by the RPD manufacturer shall provide information, necessary for trained and qualified personnel, if applicable, on:

a) indicators related to the use of the filter and RPD;

b) use of correct components and replacement parts of the filter;

c) storage conditions between each use;

9.3.2 RI

9.3.2.1 Minimum information

The information supplied by the RPD manufacturer shall provide minimum information, necessary for trained and qualified personnel on:

a) application and limitations of the RI and warnings and cautions associated with its use;

b) explanation of RI class and its relation to the RPD classification;

c) assembly and operational instructions (description of pre-use checks and the mounting and orientation of RPD components and parts);

d) meaning of graphical symbols;

e) storage conditions prior to use

f) shelf life information on the RI and its replacement parts;

g) correct donning and doffing;

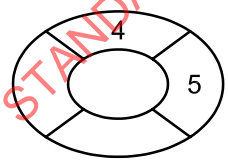
h) assessment of fit (e.g. size selection, recommendations for fit testing);

i) disposal;

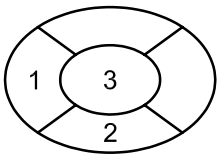
j) contact information of the manufacturer or supplier;

k) indication of the RPD headform(s) number used for testing using the symbol given in 3.3.6.

EXAMPLE 1 RI size where the RPD headform numbers 4 and 5 according to ISO 16900-5 are used for testing.



EXAMPLE 2 RI size where the RPD headform numbers 1, 2 and 3 according to ISO 16900-5 are used for testing.



9.3.2.2 Additional information

In addition, information supplied by the RPD manufacturer shall provide information, necessary for trained and qualified personnel, if applicable, on:

a) use of correct components and replacement parts of the RPD;

b) warning devices, such as alarms, signals, etc., related to the use of the RI;

c) storage conditions between each use;

d) cleaning, disinfection and decontamination;

e) service life of the RI, which may include components of the RI;

f) user maintenance, repair and inspection;

g) in case that RI contains substances which are known to be potentially sensitizing or allergenic, the manufacturer shall display each individual relevant substance in the information supplied by the RPD manufacturer to give a warning to all potentially concerned wearers.

9.3.3 Other components or replacement parts

The information supplied by the RPD manufacturer for blower units, battery and charging systems, regulators, or other parts, shall give reference to the information supplied by the RPD manufacturer of the RPD, to which the component or replacement part belongs to.

Annex A
(informative)

Reliability

A.1 General

In this annex some aspects that involve reliability are indicated. They are examples of the most common issues that can affect reliability of RPD, but many others can exist

The preferred way to accomplish the task of ensuring reliability is to perform a FMEA.

A typical FMEA procedure is given in Annex B.

However, manufacturers can follow other procedures to comply with 6.8.

A.2 Temperature and humidity of inhaled air for filtering RPD which protects against contaminants other than CO

The temperature of the air supplied by the RPD to the wearer should be on or below the curve given in Figure 1, Item 1 as assessed at expected use concentration.

A.3 Abrasion resistance

The RPD should be sufficiently robust to withstand the abrasion that it is likely to receive in service with respect to its intended application.

A.4 Exposure to dust

The RPD should be sufficiently robust to withstand the effects of dusty environment that it is likely to receive in service with respect to its intended application.

A.5 Chemical resistance of materials

The RPD should be resistant against those chemicals/substances for which it is likely to be used.

A.6 Compatibility of materials with the wearer's body

RPD component materials, or agents used for cleaning, disinfection or anti-fogging, which may come into direct contact with the wearer's skin or that can be released into the inhaled breathable gas should not be known to be likely to cause irritation or any other adverse effects to health under the use conditions.

A.7 Cleaning, disinfection and/or decontamination procedures and cycles

If the manufacturer claims that the RPD can be cleaned, disinfected and/or decontaminated, the RPD should be sufficiently robust to withstand these procedures that it is likely to receive during its

service life, and this shall be included in the information supplied by the RPD manufacturer. At least the following aspects should be considered:

— which parts need to be cleaned, disinfected, decontaminated and dried;

— necessary disassembly and reassembly;

— agents for cleaning, disinfection and decontamination;

— procedures for cleaning, disinfection, decontamination and drying (time, concentration, temperature, etc.)

— number of cycles of cleaning, disinfection, decontamination and drying during the expected service life.

Annex B
(informative)

Example of failure modes and effect analysis (FMEA)

B.1 General

The FMEA is an important tool for the prediction of the reliability of the product that conforms to intended standards and consistently performs to its design specifications. The manufacturer has the greatest knowledge and experience of the product to perform a FMEA. Respiratory Protective Device (RPD) manufacturers may follow any FMEA process, however, at a minimum the FMEA process shall include the following: the probability that the occurrence of a potential failure cause will occur; the severity of the potential failure effect; the ability to detect the occurrence of the potential failure cause or failure, and specific instructions including cautions, limitations, and restrictions of use to assure product reliability.

In preparing this guidance the authors referred to The International Engineering Society for Advancing Mobility, Land-Sea-Air and Space SAE J1739, NASA procedures NHB 5300.4 and CR 5230.9, and examples of FMEA from RPD manufacturers. The following information is provided for general guidance to RPD manufacturers in performing an FMEA. The following guidelines and examples are provided for illustrative purposes only. There are many FMEA templates available in reliability literature that could be referenced. The scale used in the following examples was simply 1 to 10 to illustrate the process. However, any scale could be used that serves the purpose of identifying and differentiating the levels associated with the likelihood, potential severity, and the ability to detect the failure.

B.2 Procedure guidelines

Develop a process flow diagram to indicate system functional interdependencies.

Write an intended use statement, which defines how the product is expected to perform as well as its intended life expectancy. Intended use also aids in establishing what is actually considered a failure.

A technical team (FMEA Team) with solid knowledge of the technology, regulations, processes and use, should be formed to assure an objective and more thorough evaluation of the product.

The team should assure that all applicable technical and regulatory requirements are considered.

In completing the FMEA matrix (see Table B.1) place the part number, ID or reference number in the 1st row. List the part name in the 2nd row. The 3rd row is for a brief description of the part function. Many times the failures are the opposite of the function.

The team should use brainstorming techniques to develop a comprehensive list of potential failures for the product. Potential failure modes are in the 4th row of the FMEA process matrix. Potential failure modes which are less likely to occur or those that will not create a problem for the end-user if they do occur will get a lower priority for corrective action.

For each potential failure mode, list the effects that the failure may have on the system functionality and list those in the 5th row of the matrix next to the failure mode.

Next, for all of the potential failure modes of a product, list all of the potential causes of the failure. For each Potential Failure Mode, there may be several potential causes of the failure. List them all in 6th row.

Determine if there are current measures, controls or means of preventing/detecting failures causes which are in place or will be in place at the time of introduction to ensure the quality of the product and to avoid the failure effects-list them in 7th row.

For each of the failure modes three specific ratings will be assessed by the team and listed in sequential rows labeled Occurrence (OCC), Severity (SEV), and Detection (DET) (row 8, 9, 10).

Assign an “OCC” number to indicate the probability that the failure cause will occur and result in the failure mode in consideration of the planned/implemented preventive actions. (See Table B.2)

Assign a “SEV” number to indicate -the severity of the effect that the listed potential failure might have on the end-user. (See Table B.3)

Assign a “DET” number to indicate the likelihood of detection or prevention of the listed potential cause of failure or of detecting or preventing the failure mode before it causes the effect. Take into account the planned/implemented detection measure. (See Table B.4)

Assign an Index Number which is the product of the numbers assigned for "OCC", "SEV", and "DET". The Index Number is commonly called the Risk Priority Number (RPN) and is used to help prioritize the risks. List this index in a row following the OCC, SEV, and DET ratings. Some FMEA forms also use a Criticality ranking which is the product of OCC and SEV.

The RPN will be used to help to determine which potential failures are the most important to eliminate (row 11). At this point, you have completed the "assessment" cycle of the FMEA. You will have identified the potential product failures, the effects of those failures to the system functionality, and the most likely causes of the failures.

Next, determine what actions can be taken to prevent the failures from occurring in the first place.

Develop "Recommended Actions" or the plan of action(s) that will be taken to prevent the potential failure from occurring. You may have a Recommended Action for each cause of a potential failure. Recommended Actions are documented in the row following the RPN.

It should then be documented as to what actions were actually undertaken, and re-calculate the ratings and the RPN’s. To result in an acceptable RPN it can require more than one iteration.

Table B.1 — Typical FMEA process matrix

Part No.	1234	1357	5678
Part name	Connection	Exhalation valve disk	Sealing of RI
Function of part	Connecting RI with RPD	Manage air within RI	Seal face to RI protection
EXAMPLES of Potential Failure Mode	Connector falls off RI	Leakage of disk	Leakage in sealing
Effect of Failure	User has no respiratory protection	Contaminated air enters RI	Contaminated air enters RI
Root Cause of Failure	Connector not installed on RI correctly	Disc too thin, wall thickness outside tolerance	Wrong donning
Measures Controls Detection	Information supplied by the manufacturer	Measurement of wall thickness	Fit check prior to use
OCC	1	1	2
SEV	9	7	5
DET	1	9	1
RPN Index	9	63	10
Recommended Action	No action required, as information supplied by the manufacturer covers correction action	Corrective action: tool correction and wall thickness will be checked first lots prior to assembly	Review and make necessary corrective action to implement necessity of Fit check into information supplied by the manufacturer

B.3 Definitions and explanations

Potential Failure Mode: The manner in which the product does not perform as it was intended to perform, or which causes the product to fail before its intended life expectancy. Applying FMEA to RPDs during product design and development minimizes the potential for failures which are likely to reduce the protection provided to the user.

Potential effects of failure: The effects on the system functionality that could be seen if the listed failure mode occurs.

Potential causes of failure: Probable cause(s) of the failure mode.

Controls: Things that are in place to ensure the quality of the product.

OCC: An acronym for occurrence or event likelihood; the probability that a particular cause of a potential failure mode might occur and result in the failure mode.

For illustrative purposes, the following examples use a scale of 1 to10 (other indexes could have been selected).

SEV: An acronym for severity. This is an indication of how severe the problem would be to the end-user if the potential failure mode occurred. Scored on a scale of 1 to10.

DET: An acronym for likelihood of detection. This is an indication of how detectable or preventable the failure mode cause would be or of detecting or preventing the failure mode before it causes the effect. The object is to detect any potential product failures before it leaves the manufacturing plant.

Table B.2 — Occurrence OCC

Ranking	Probability of Occurrence
10	>1 in 2
9	1 in 3
8	1 in 8

Table B.2 *(continued)*

Ranking	Probability of Occurrence
7	1 in 20
6	1 in 80
5	1 in 400
4	1 in 2 000
3	1 in 15 000
2	1 in 150 000
1	1 in 1 500 000

Table B.3 — Severity SEV

Ranking	Severity of Failure
10	Hazardous to health or safety - without warning
9	Hazardous to health or safety - with warning
8,7	Premature wear-out, reduced service
6,5,4	Uncomfortable, difficult to operate, some performance degradation
3,2	Slight annoyance, minor performance degradation
1	Cosmetic

Table B.4 — Detection DET

Ranking	Description
10	Cannot detect, latent durability failure
9	Subtle, very remote chance of detection
8	Remote chance of detection
7	Very low chance of detection
6	Low chance of detection
5	Moderate chance of detection
4	Moderately high chance of detection
3	High chance of detection
2	Very high chance of detection
1	Almost certain chance of detection

Index: The index (RPN) is a ranking number which is used to prioritize the team's preventative actions. It is derived by taking the product of the OCC, SEV and DET numbers. The higher the index number, the higher the priority is in taking preventative action (to prevent a potential failure mode from occurring). For example, a potential failure mode which has a high probability of occurring, a high level of severity (if it occurs), and a low detection, will score higher and require earlier attention than a failure mode which is less likely to occur, not as severe (if it does occur), and is easy to detect. Some FMEA teams look at the severity and occurrence numbers to calculate a criticality index (I_c = SEV × OCC). The severity of a failure typically will not change; therefore actions should be taken to mitigate the probability of occurrence and detection.

Recommended action: This is the preventative action for each potential failure mode which is recommended by the FMEA team.

Action taken: This is a summary of the preventative action implemented by the team to prevent the potential failure mode. These may be design changes, or system redundancies that inform the user of a reduction in RPD performance.

Annex C
(normative)

Test schedules

C.1 General

This annex consists of three main subclauses: C.2, C.3 and C.4.

Requirements which shall be assessed only by inspection (7.2) are not included in the test schedule.

Test schedules for special application RPD are not included as this information is given in the specific standards of the ISO 17420 series. Some special application requirements supersede the requirements given in this document and in those cases the test schedules have to be adapted accordingly.

Requirements for optional features (6.13) are not included in the test schedule.

C.2 Test schedules for tests using RPD headforms - allocation of RI sizes to headforms, number of samples and preconditioning

C.2.1 RI sizes

The number of RPD samples needed for the tests is depending on the number of RI sizes and the number of RPD headforms used. The following test schedule tables cover up to five RI sizes to be tested on any possible number of headforms, i.e. between one and five. If more RI sizes shall be tested the test schedule tables have to be extended accordingly.

C.2.2 RPD headforms

C.2.2.1 General

Five RPD headforms are defined in ISO 16900-5, designated by numbers 1 to 5. The allocation of RI sizes to the headforms shall be stated by the manufacturer.

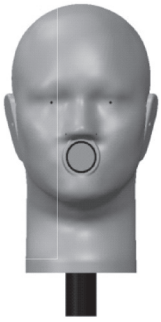
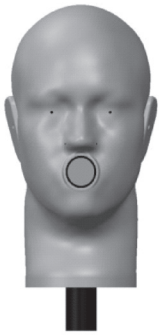
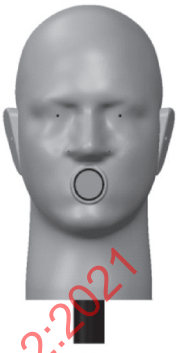
EXAMPLES

One RI size (stated by the manufacturer “large”) is allocated to RPD headform 5 of ISO 16900-5,

a second RI size (stated by the manufacturer “medium”) is allocated to RPD headform 2 and 3 of ISO 16900-5,

a third RI size (stated by the manufacturer “small”) is allocated to RPD headform 1 of ISO 16900-5,

i.e. three RI sizes (“large”, “medium”, “small”) are allocated to four different RPD headforms (5, 2, 3 and 1).

RI Size	RPD Headforms according to ISO 16900-5				
	 1	 2	 3	 4	 5
Small 	X				
Medium 		X	X		
Large 					X

Key

1 small
2 short/wide
3 medium
4 long/narrow
5 large

Figure C.1 — Example for allocation of RI sizes to RPD headforms

In Figure C.1 the RPD headform 4 is not included because this RPD is not intended to cover the whole population but only the population represented by the headforms 1, 2, 3 and 5.

NOTE 1 It is possible to allocate a RI size to more than one RPD headform.

It is possible to allocate a RPD headform to more than one RI size. In this case the test schedule needs to be extended accordingly.

The combination given in Table C.1, three RI sizes tested on four RPD headforms, is an example based on Table C.14. In this table RI sizes are designated by generic terms α, β, γ and δ. RPD headforms are designated by generic letters A, B, C and D. This was done to keep the number of tables as small as possible. Depending on the allocation, the RPD headforms 1 to 5 according to ISO 16900-5 shall be correlated to the headform designations A to D, accordingly. The RI sizes α, β, γ and δ shall be correlated to the RI size designation stated by the manufacturer.

Table C.1 shows the example for a table filled out with the information supplied by the manufacturer.

Table C.1 — Completed Table C.14 based on the example given in Figure C.1

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform			
			A	B	C	D
			Corresponding headform according to ISO 16900-5			
			2[a]	3[a]	5[a]	1[a]
$\alpha(1)$	medium[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)		
$\alpha(2)$	medium[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)		
$\alpha(3)$	medium[b]	Corrosive atmosphere (see 6.9.3.2) [c]		Work of breathing at -5 °C (see 6.3) [c]		
$\beta(1)$	large[b]	as received			Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	
$\beta(2)$	large[b]	Sequential preconditioning (see 6.9.2)			Work of breathing at -5 °C (see 6.3)	
$\beta(3)$	large[b]	Corrosive atmosphere (see 6.9.3.2) [c]	Covered by RPD headform B			
$\gamma(1)$	small[b]	as received				Field of vision (see5.2) CO_2 concentration limits (see 6.4)
$\gamma(2)$	small[b]	Sequential preconditioning (see 6.9.2.)				Work of breathing at 35 °C (see 6.3)
$\gamma(3)$	small[b]	Corrosive atmosphere (see 6.9.3.2)[c]	Covered by RPD headformB			
$\alpha(1)$ or $\beta(1)$ or $\gamma(1)$	medium[b] or large[b] or small[b]	as received	Noise limit for assisted RPD (see 6.5)[d] Strength of connections (see 6.7.2)			

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD or RPD with electronics.

[d] Applies only to assisted RPD.

C.2.2.2 How to read the Table C.1

In the first column the generic RI size(s) and sample numbers is (are) listed. In the second column the RI size(s) are filled in according to the manufacturer's designation (small, medium and large). In the third column the required preconditioning for each RI size is listed.

For each sample number the required tests are listed in each cell of this line indicating which headform shall be used.

All tests within one cell may be carried out with the same sample, unless, depending on the design of the RPD, the devices are not reusable after tests. In those cases, for each test a new sample is needed. The test for strength of connection 6.7.2 shall be regarded as destructible in any case and samples shall not be reused for other tests. In the case of reusable RPD some maintenance can be necessary prior to the next test, e.g. charging batteries.

C.2.2.3 Test schedules tables

The test schedules for all possible combinations of up to five RI sizes allocated to one to five RPD headforms are given in Table C.2 to Table C.18.

Table C.2 — Test schedule for tests using one RI size, tested on one RPD headform

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform A Corresponding head-form according to ISO 16900-5 ___[a]
α(1)	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4) Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)
α(2)	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C Work of breathing at 35 °C (see 6.3)
α(3)	_____[b]	Exposure to corrosive atmos-phere (see 6.9.3.2)[d]	Work of breathing at 35 °C (see 6.3)[d]

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.3 — Test schedule for tests using one RI size, tested on two RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform	
			A	B
			Corresponding headform according to ISO 16900-5	
			___[a]	___[a]
α(1)	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	
			Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)	
α(2)	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)
α(3)	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]	Work of breathing at 35 °C (see 6.3) [d]	Covered by RPD headform A

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.4 — Test schedule for tests using one RI size, tested on three RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform		
			A	B	C
			Corresponding headform according to ISO 16900-5		
			___[a]	___[a]	___[a]
α(1)	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)		
			Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)		
α(2)	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)		Work of breathing at 35 °C (see 6.3)
α(3)	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]	Work of breathing at 35 °C (see 6.3) [d]	Covered by RPD headform A	

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.5 — Test schedule for tests using one RI size, tested on four RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Pre-conditioning	RPD headform			
			A	B	C	D
			Corresponding headform according to ISO 16900-5			
			___[a]	___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)			
			Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)			
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)		Work of breathing at -5 °C (see 6.3)
$\alpha(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]	Work of breathing at 35 °C (see 6.3) [d]	Covered by RPD headform A		

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.6 — Test schedule for tests using one RI size, tested on five RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Pre-conditioning	RPD headform				
			A	B	C	D	E
			Corresponding headform according to ISO 16900-5				
			___[a]	___[a]	___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)				
			Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)				
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)	Work of breathing at -5 °C (see 6.3)

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.6 *(continued)*

RI size (sample number)	Manufacturers designation for RI size(s)	Pre-conditioning	RPD headform				
			A	B	C	D	E
			Corresponding headform according to ISO 16900-5				
			___[a]	___[a]	___[a]	___[a]	___[a]
α(3)	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]	Work of breathing at 35 °C (see 6.3) [d]	Covered by RPD headform A			

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.7 — Test schedule for tests using two RI sizes, tested on two RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform	
			A	B
			Corresponding headform according to ISO 16900-5	
			___[a]	___[a]
α(1)	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	
α(2)	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	
α(3)	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]	Work of breathing at 35 °C (see 6.3)[c]	
β(1)	_____[b]	as received		Field of vision (see 5.2) CO_2 concentration limits (see 6.4)
β(2)	_____[b]	Sequential preconditioning (see 6.9.2)		Work of breathing at 35 °C (see 6.3)
β(3)	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]	Covered by RPD headform A	
α(1) or β(1)	_____[b]	as received	Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)	

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.8 — Test schedule for tests using two RI sizes, tested on three RPD headforms

RI size (sample number)	Manufacturers designation for RI size(s)	Pre-conditioning	RPD headform		
			A	B	C
			Corresponding headform according to ISO 16900-5		
			___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)		
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)	
$\alpha(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]		Work of breathing at -5 °C (see 6.3)[d]	
$\beta(1)$	_____[b]	as received			Field of vision (see 5.2) CO_2 concentration limits (see 6.4)
$\beta(2)$	_____[b]	Sequential preconditioning (see 6.9.2)			Work of breathing at 35 °C (see 6.3)
$\beta(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]	Covered by RPD headform B		
$\alpha(1)$ or $\beta(1)$	_____[b]	as received	Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)		

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.9 — Test schedule for tests using two RI sizes, tested on four RPD headforms (Scheme 1)

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform			
			A	B	C	D
			Corresponding headform according to ISO 16900-5			
			___[a]	___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)			
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)	Work of breathing at -5 °C (see 6.3)	
$\alpha(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]		Work of breathing at -5 °C (see 6.3) [d]		
$\beta(1)$	_____[b]	as received				Field of vision (see 5.2) CO_2 concentration limits (see 6.4)
$\beta(2)$	_____[b]	Sequential preconditioning (see 6.9.2)				Work of breathing at 35 °C (see 6.3)
$\beta(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2) [d]	Covered by RPD headform B			
$\alpha(1)$ or $\beta(1)$	_____[b]	as received	Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)			

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.10 — Test schedule for tests using two RI sizes, tested on four RPD headforms (Scheme 2)

RI size (sample number)	Manufacturers designation for RI size(s)	Preconditioning	RPD headform			
			A	B	C	D
			Corresponding headform according to ISO 16900-5			
			___[a]	___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)			
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)		
$\alpha(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]		Work of breathing at -5 °C (see 6.3)[d]		
$\beta(1)$	_____[b]	as received			Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	
$\beta(2)$	_____[b]	Sequential preconditioning (see 6.9.2)			Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)
$\beta(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]	Covered by RPD headform B			
$\alpha(1)$ or $\beta(1)$	_____[b]	as received	Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)			

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.

Table C.11 — Test schedule for tests using two RI sizes, tested on five RPD headforms (Scheme 1)

RI size (sample number)	Manufacturers designation for RI size(s)	Pre-conditioning	RPD headform				
			A	B	C	D	E
			Corresponding headform according to ISO 16900-5				
			___[a]	___[a]	___[a]	___[a]	___[a]
$\alpha(1)$	_____[b]	as received	Field of vision (see 5.2) CO_2 concentration limits (see 6.4)				
$\alpha(2)$	_____[b]	Sequential preconditioning (see 6.9.2)	Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)	Work of breathing at -5 °C (see 6.3)		
$\alpha(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]		Work of breathing at -5 °C (see 6.3)[d]			
$\beta(1)$	_____[b]	as received				Field of vision (see 5.2) CO_2 concentration limits (see 6.4)	
$\beta(2)$	_____[b]	Sequential preconditioning (see 6.9.2)				Work of breathing at -5 °C (see 6.3)	Work of breathing at 35 °C (see 6.3)
$\beta(3)$	_____[b]	Exposure to corrosive atmosphere (see 6.9.3.2)[d]	Covered by RPD headform B				
$\alpha(1)$ or $\beta(1)$	_____[b]	as received	Noise limit for assisted RPD (see 6.5)[c] Strength of connections (see 6.7.2)				

[a] Allocation of RPD headform number stated by the manufacturer.

[b] Allocation of RI size designation stated by the manufacturer.

[c] Applies only to assisted RPD.

[d] Applies only to RPD with electronics or assisted RPD.