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Respiratory protective devices — Performance requirements —

Part 1: General

Appareils de protection respiratoire — Exigences de performances — Partie 1: Généralités

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

To apply the standards properly consider the following:

— ISO 17420-1 specifies the general requirements for supplied breathable gas RPD and filtering RPD and cannot be used as a standard for "certification" alone. Therefore, compliance with the requirements and tests of ISO 17420-2 or ISO 17420-4 is required in addition.

— Should supplied breathable gas RPD and filtering RPD also be used for special applications, take into account the requirements of ISO 17420-5 to ISO 17420-9 addition to the requirements of ISO 17420-1 and ISO 17420-2 or ISO 17420-4.

The structure of the standards is as follows:

ISO 17420-1 specifies the general requirements for RPD.

ISO 17420-2 and ISO 17420-4 gives requirements for filtering RPD or supplied breathable gas RPD and give information if any of the general requirements in Part 1 needs an addition.

EXAMPLE for ISO 17420-4 5.8.1 General

ISO 17420-1:2021, 5.8.1 applies with the following in addition:

ISO 17420-5 to ISO 17420-9 gives requirements for supplied breathable gas RPD or filtering RPD — Special application and some of the requirements will supersede requirements specified in ISO 17420-2 or ISO 17420-4.

EXAMPLE for ISO 17420-6 7.2.1 Contact with hot and cold surfaces generated by the RPD

This clause supersedes ISO 17420-4:2021, 6.7.

For more information see also the introduction in the other parts of the ISO 17420 series.

Respiratory protective devices — Performance requirements —

Part 1: General

1 Scope

This document specifies general requirements for the performance and testing of 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.

The requirements are based on human factors and are for complete respiratory systems.

Requirements for marking and information supplied by the RPD manufacturer are also included.

Additional requirements for special application such as fire services, marine, mining, abrasive blasting, welding and escape as well as RN (Radiological, Nuclear), CBRN (Chemical, Biological, Radiological, Nuclear) and CBRN Escape RPD are addressed in ISO 17420-5 to ISO 17420-9.

This document does not apply to respiratory devices for:

— underwater diving application;

— military application;

— use in aircraft and spacecraft;

— medical life support applications;

— resuscitators.

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

ISO 16900-6, *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 16900-10, *Respiratory protective devices — Methods of test and test equipment — Part 10: Resistance to ignition, flame, radiant heat and heat*

ISO 16900-11, *Respiratory protective devices — Methods of test and test equipment — Part 11: Determination of field of vision*

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

ISO 16975-3, *Respiratory protective devices — Selection, use and maintenance — Part 3: Fit-testing procedures*

ISO 17420-2:2021, *Respiratory protective devices — Performance requirements — Part 2: Requirements for filtering RPD*

ISO 17420-4:2021, *Respiratory protective devices — Performance requirements — Part 4: Requirements for supplied breathable gas RPD*

ISO 18526-1, *Eye and face protection — Test methods — Part 1: Geometrical optical properties*

3 Terms, definitions and abbreviations

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
RPD in 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)

3.2 Abbreviated terms

FMEA	Failure Mode and Effects Analysis
RPD	Respiratory protective devices
RI	Respiratory Interface

4 Classification overview

4.1 General

The detailed classification and examples are described in ISO/TS 16973 and a condensed overview for RPD is given in Table 1.

All filtering RPD are classified based on their performances and their characteristics of the RI.

All supplied breathable gas RPD are classified based on their performance and the characteristic of the RI as well as their breathable gas capacity.

Table 1 — Basic classification of filtering RPD and supplied breathable gas RPD

Classification		Classes (range)
Protection class		PC6 (highest) PC5 PC4 PC3 PC2 PC1 (lowest)
Work rate class		W4 (highest) W3 W2 W1 (lowest)
RI class	Area of coverage (barrier lines)	e (more than head, up to complete body) d (head) c (face) b (mouth and nose) a (mouth only)
	Type	T (tight fitting) L (loose fitting)
Filter performance	Particle filter class	F5 (highest) F4 F3 F2 F1 (lowest)
	Gas filter type and class	Several types based on test gas(es) with up to 4 classes, with class 1 being the lowest (see ISO 17420-2:2021, Table 1)
Supplied breathable gas capacity class		SXXXX (where XXXX equals the amount of breathable gas available for respiration in litres) SY (where Y is the indication for airline devices, including ambient air systems as defined in ISO 16972:2020, 3.11)

5 General requirements for RPD

5.1 General

The requirements in this document shall be fulfilled by all RPD or their components, if applicable.

For reasons of safety, all testing which requires the use of test subjects shall only be carried out after all other tests have been satisfactorily completed.

Allocation of RI size(s) to the appropriate RPD head form(s)/size(s) according to ISO 16900-5 used for testing shall be stated by the manufacturer. The allocated RPD head form sizes shall be used for all testing and their numbers shall be given in the information supplied by the manufacturer using the symbol 3.3.6 in ISO 17420-2:2021, or the symbol 3.3.4 in ISO 17420-4:2021 and an explanation shall be given in the information supplied by the manufacturer. The RI shall be marked by using the symbol 3.3.2 of ISO 17420-2:2021and ISO 17420-4:2021.

The number of test samples is specified in each individual sub-clause. Sample schemes and test schedules are given in ISO 17420-2:2021, Annex C and ISO 17420-4:2021, Annex C respectively.

The number of samples necessary for testing for each requirement depends on the following:

— the requirement itself,

— the required preconditioning(s), if applicable;

— the number of RI sizes, one or more.

EXAMPLE If the requirement includes

— two temperatures (-5 °C and +35 °C),

— three pre-conditionings [vibration and shock (VS), as received (AR), exposure to corrosive atmosphere (CR)],

— RI in three sizes [small (s), medium (m) and large (l)].

see Table 2 for examples of combination for testing.

Table 2 — Example of combinations for testing

Example of combinations	Preconditioning[a]	Test temperature	RI size
1	VS	+35 °C	s
2	VS	-5 °C	m
3	AR	-5 °C	m
4	CR	+35 °C	l

[a] The preconditioning is specified in the other parts of ISO 17420.

The combinations for testing shall be defined by agreement between the involved parties.

Unless otherwise specified in the individual requirement clauses,

— testing shall be performed on test samples without pre-conditioning,

— each sample shall pass the test, and

— testing shall be performed at ambient laboratory conditions between 16 °C and 32 °C and a relative humidity of (50 ± 30) %.

5.2 Field of vision

For special application welding RPD and abrasive blasting RPD see ISO 17420-7[1)].

One non-preconditioned sample of each RI size in its as worn state shall be tested with the appropriate RPD headform(s) as allocated by the manufacturer.

The RPD shall have an average visual field score (VFS) of at least 98. Six out of eight dots of the section between 20° and 30°; 340° and 350°, 150° and 160° and 190° and 200° in the modified VFS scale shall be included in the visual field score.

In addition, at least two of the four critical dots which lie in the section between 20° and 30°; 340° and 350°, 150° and 160° and 190° and 200° shall be included in the field score.

Testing shall be performed in accordance with ISO 16900-11 without corrective eyewear.

1) Under preparation. Stage at the moment of publication: ISO/FDIS 17420-7:2020.

5.3 Resistance to flame – Single burner dynamic

The RPD shall be tested by subjecting all the parts or components exposed to the flame of a single burner dynamic test while the RPD is in it is as worn state. The flame needs to touch only one area of each part/component that is exposed while the RPD is in it is as worn state.

When tested, the materials shall not

— drip at all,

— undergo complete combustion, or

— continue to burn for more than 5 s after removal from the flame.

Deformation/decomposition is allowed.

One sample shall be tested.

The sample does not need to fulfil any other requirement of this standard after this test.

Testing shall be performed in accordance with ISO 16900-10.

5.4 Compatibility with additional equipment

Other PPE and/or accessories, specified by the manufacturer of the RPD for specific use with the RPD shall not degrade the performance of the RPD below the requirements for its class. Any RPD performance requirement whose results can be affected by the addition of such PPE or accessories shall be tested with such PPE or accessory in place according to 5.1 and 5.8 and to the appropriate requirements when tested in accordance with ISO 17420-2, ISO 17420-4, ISO 17420-5[2)], ISO 17420-6[3)], ISO 17420-7, ISO/TS 17420-8[4)] and ISO/TS 17420-9[5)].

Information about such PPE or accessories shall be given in the information supplied by the RPD manufacturer.

Check in accordance with 6.2 and ISO 17420-2:2021, Clause 9 or ISO 17420-4:2021, Clause 9.

5.5 Monitor performance

If the RPD is equipped with a means of monitoring any performance function of the RPD, the monitor function shall be assessed in accordance with the information supplied by the RPD manufacturer.

Test in accordance with ISO 16900-7.

5.6 Warning and checking device(s)

5.6.1 Performance of warning device(s)

Requirements for the performance of warning device(s) are given in ISO 17420-2, ISO 17420-4 and ISO 17420-5.

5.6.2 Performance of checking device(s)

If the RPD is equipped with checking device(s) two samples shall be assessed.

2) Under preparation. Stage at the moment of publication: ISO/DIS 17420-5:2020.

3) Under preparation. Stage at the moment of publication: ISO/FDIS 17420-6:2020.

4) Under preparation. Stage at the moment of publication: ISO/CD TS 17420-8: 2020.

5) Under preparation. Stage at the moment of publication: ISO/CD TS 17420-9: 2020.

Details of the function and operation of the checking device to enable its performance shall be included in the information supplied by the RPD manufacturer. The checking device shall perform in accordance with the information supplied by the RPD manufacturer.

If the RPD is equipped with an integrated checking device the RPD shall be sequentially pre-conditioned in accordance with ISO 17420-2:2021, 6.9, or ISO 17420-4:2021, 6.11.1.1 prior to assessing.

Checking devices that are not integral to the RPD shall not be pre-conditioned.

Check in accordance with 6.2 g) and test in accordance with ISO 16900-7.

5.7 Protection class determination

5.7.1 General

RPD shall be tested for total inward leakage (TIL) after sequential pre-conditioning in accordance with ISO 17420-2:2021, 6.9.2 or ISO 17420-4:2021, 6.11.

The results of a TIL test determines the protection class of the RPD as given in Table 3.

Table 3 — Protection class determination

Class	TIL_{max} %
PC6	0,001
PC5	0,01
PC4	0,1
PC3	1
PC2	5
PC1	20

The test system used in accordance with ISO 16900-1 shall have a detection limit that is at least one-tenth of the expected TIL_{max} of the protection class.

5.7.2 Total inward leakage (TIL)

For tight fitting RIs, the fit of the RPD on each test subject shall be assessed prior to TIL testing in accordance with the information supplied by the RPD manufacturer.

RPD shall be tested for TIL in accordance with ISO 16900-1 and subjects facial dimensions, face width and face length shall be measured and recorded.

Assisted RPD shall be tested at the measured minimum flow rate in accordance with ISO 16900-8.

If the manufacturer requires to perform a fit test procedure in accordance with ISO 16975-3 prior to TIL testing the RPD shall be re-donned prior to the TIL. The required fit factor pass level shall be that of the expected PC class. See ISO 16975-3:2017, Table 2. If the RPD does not fit the test subject after two assessments then this RPD shall not be evaluated with that test subject.

If the RPD is equipped with an adjustable flow control means the operating setting of the RPD shall be adjusted to the minimum flow setting as specified in the information supplied by the RPD manufacturer.

If the RPD is claimed to have two or more different PC classes, testing shall be carried out at the minimum flow settings for each PC class as specified in the information supplied by the manufacturer. Supplied breathable gas RPD equipped with tight fitting respirator interfaces shall be assessed for fit in accordance with the information supplied by the RPD manufacturer. If the RPD does not fit the test subject after two assessments then that RPD shall not be tested with this subject.

Testing shall be performed with fifteen test subjects.

A maximum number of 35 test subjects shall be assessed in order to select the test panel. Since the allocation of the RI size to the appropriate RPD headform(s) is stated by the manufacturer, this information shall be used for the selection of the test panel. If a test panel of 15 cannot be identified after the fit assessment of 35 test subjects, then the RI shall not be tested for TIL and this fact reported in the test report.

RPD equipped with type L-RIs (loose fitting type RI) shall be donned as indicated in the information supplied by RPD manufacturer and tested with cross winds in the test chamber as specified in Table 4.

Table 4 — Cross wind testing — Exercises 6), 7) and 8) of ISO 16900-1:2019, Table B.1

Air flow direction	Exercises	Test subject		
		1 to 5	6 to 10	11 to 15
Front	6)	x		
	7)	x		
	8)	x		
Side	6)		x	
	7)		x	
	8)		x	
Rear	6)			x
	7)			x
	8)			x

At least three RPD shall be used for testing and at least one sample of each size in case of multiple sized RI. Each RI size shall be tested on at least two test subjects.

Accessories specified by the manufacturer shall be tested by agreement between the involved parties with at least two RPD.

The TIL value (or IL value in the case of RI with standardized connector using the filter simulator specified in ISO 16900-5) shall be derived as follows:

Calculate the arithmetic mean of the TIL % for all exercises for each test subject.

Order all fifteen results from smallest to largest. The overall percentage TIL_{MAX} value for the RPD is equivalent to the second largest result.

For example, if the TIL result is 3 %, the selected TIL_{max} value in Table 3 is 5 % so the protection class is PC2.

Test in accordance with ISO 16900-1, using the exercise regime given in ISO 16900-1:2019, Table B.1.

For RIs class aT the determination of the protection class is not possible by design to be performed by TIL test. In this case RI class a shall be classified as PC3 and shall be tested for leaktightness. When tested at the negative pressure of 10 mbar the loss of pressure shall not exceed 1 mbar within one minute.

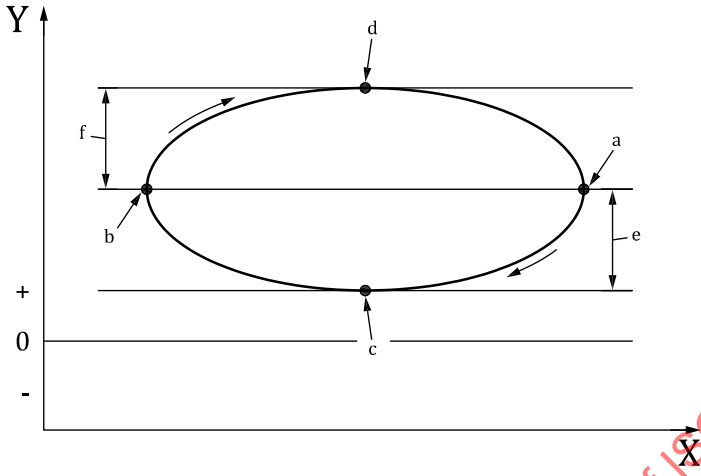
Testing shall be performed in accordance with 6.3. When tested with the breathing machine or metabolic simulator at the relevant setting the pressure inside the RI shall remain positive for RPD intended to be classified as W3 or W4.

The value of point c in Figure 1 shall be positive. Negative spikes shorter than 0,05 s shall not be deemed to be a failure.

For RI with type L, testing shall be performed in accordance with ISO 17420-2:2021, 6.3 or ISO 17420-4:2021, 6.3.

For RI with type bT, testing shall be performed in accordance with ISO 17420-2:2021, 6.3 or ISO 17420-4:2021, 6.3.

For RI with type cT, dT and eT, testing shall be performed in accordance with ISO 17420-2:2021, 6.3 or ISO 17420-4:2021, 6.3, but the sampling point shall be in the ocular zone.



Key

X volume axis
Y pressure axis
a Start of an inhalation.
b Start of an exhalation.
c Lowest pressure during the inhalation.
d Highest pressure during the exhalation.
e Peak inhalation pressure (difference between c and a).
f Peak exhalation pressure (difference between d and b).

Figure 1 — Typical pressure-volume loop for determining work of breathing/peak pressures

5.8 Validation by practical performance

5.8.1 General

The test shall be performed by at least 2 test subjects experienced in wearing RPD.

At least two samples shall be used.

The RPD shall be the appropriate size for the test subject in accordance with the information supplied by the RPD manufacturer.

Two test subjects shall perform the test regime at $\left(35^{0}_{-2}\right)$ °C, and two subjects shall perform the test regime at $\left(-5^{+2}_{0}\right)$ °C in accordance with ISO 16900-7.

Deviations from these conditions will be addressed in ISO 17420-5 and ISO 17420-7.

Each test subject shall read, understand and follow the information supplied by the RPD manufacturer prior to testing.

If the regime of activities cannot be completed due to the performance of the RPD, that shall be deemed a failure.

RI having a standardized connector shall be tested using the filter simulator specified in ISO 16900-5.

5.8.2 Donning/doffing

It shall be demonstrated that the RPD can be donned and doffed in accordance with the information supplied by RPD manufacturer.

If the RPD (excluding the RI) is designed to be removed during use, the wearer shall be able to continue to breathe from the RPD whilst the RPD is moved forward through a square opening of 460 mm.

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

5.8.3 Communication performance - hearing and speech

The RPD, excluding those with RI class a (see Table 1) or RPD for special application class abrasive blasting (AB), shall meet the communication performance requirements when subjected to a communication performance test using the numbers "1" to "20" in random order in accordance with the practical performance test.

Two samples shall be tested as received by two test subjects.

At least 15 numbers out of 20 shall be understood.

Testing shall be performed in accordance with ISO 16900-7:2020, Annex A, activity 8.

5.8.4 Eye irritation caused by the RPD

The RPD shall not cause eye irritation for example due to air flow or release of eye irritating materials, to the extent that the validation of practical performance cannot be completed.

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

5.8.5 Fogging of visor

There shall be no significant impairment of vision by fogging as demonstrated by the wearer's ability to read a sign consisting of black letters 150 mm in height on a white background, in a normally illuminated environment, from a distance of 6 m.

Check in accordance with 6.2 and test in accordance with ISO 16900-7:2020, Annex A, activity 7.

5.8.6 Ergonomic requirements

In order to prevent any undue hazard or discomfort to the wearer, the RPD shall be designed and constructed to take account of the ergonomic factors listed:

— adjustability of RPD and its appropriate attachment to the body;

— irritation caused by RPD;

— anthropometric factors;

— biomechanical factors (mass distribution, restriction and prevention of movements, abrasion or compression of the skin and underlying structures , exacerbation of vibration);

NOTE Regional or national mass restrictions might apply.

— thermal effects; and

— sensory effects (vision, hearing and speech, odour or taste, touch or other skin contact).

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

5.9 Requirements for elements/components

5.9.1 RI

5.9.1.1 RI Class a

RPD using RI class a shall have a means of preventing nasal breathing.

Check in accordance with 6.2.

5.9.1.2 Visual clarity

RPD using RI classes c, d and e, shall meet the minimum optical requirement in Table 5 when tested in accordance with ISO 18526-1.

Corrective eyewear, eyewear segments, magnifiers, custom optically corrected visors and visors in escape RPD are excluded from this requirement.

Table 5 — Minimum optical requirements

Spherical refractive power $(D_1 + D_2)/2$ m^{-1}	**Astigmatic refractive power** $\lvert D_1 - D_2 \rvert$ m^{-1}	**Difference in prismatic refractive power**		
		Horizontal		**Vertical**
		Base out	Base in	
±0,12	0,12	1,00	0,25	0,25
NOTE D_1 and D_2 are the refractive powers in two principal meridiens.				

One sample as received shall be tested.

5.9.1.3 Sight defect correction

The RPD manufacturer shall provide guidance for the use of corrective eyewear with their RPD.

RI class cT can be equipped with facilities for corrective eyewear in accordance with the information supplied by the RPD manufacturer. If applicable, at least one sample shall be tested for each RI size.

Testing shall be performed in accordance with ISO 16900-1 and ISO 16900-7.

5.9.1.4 Strength of visor

Any RI equipped with a visor shall be tested for strength of visor.

One RI shall be equilibrated at $\left(-5^{+2}_{0}\right)$ °C and then tested within 60 s at laboratory temperature in accordance with ISO 16900-6.

The same RI with the same visor shall then be equilibrated at $\left(35^{\ 0}_{-2}\right)$ °C and then tested within 60 s at ambient temperature in accordance with ISO 16900-6.

In both tests the impact point of the steel ball shall be in the central area of the visor at different spots.

After testing the RI shall undergo the inspection to assess any separation of material from the inner surface. Any loose or hanging material shall be regarded as a failure.

Check in accordance with 6.2.

