BS ISO 17420-4:2021

BSI Standards Publication

Respiratory protective devices — Performance requirements

Part 4: Requirements for supplied breathable gas RPD

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National foreword

This British Standard is the UK implementation of ISO 17420-4:2021.

The UK participation in its preparation was entrusted to Technical Committee PH/4, Respiratory protection.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Respiratory protective devices — Performance requirements —

Part 4: Requirements for supplied breathable gas RPD

Appareils de protection respiratoire — Exigences de performances —

Partie 4: Exigences pour les équipements de protection respiratoire alimentés en gaz respirable

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Phone: +41 22 749 01 11
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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).

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).

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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.

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Introduction

This document describes basic requirements for supplied breathable gas 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.

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Respiratory protective devices — Performance requirements —

Part 4: Requirements for supplied breathable gas RPD

1 Scope

This document specifies requirements for the performance and testing of supplied breathable gas 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.

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 10297:2014, *Gas cylinders — Cylinder valves — Specification and type testing*

ISO 10297:2014/Amd 1:2017, *Gas cylinders — Cylinder valves — Specification and type testing — Amendment 1: Pressure drums and tubes*

ISO 12209, *Gas cylinders — Outlet connections for gas cylinder valves for compressed breathable air*

ISO 13341, *Gas cylinders — Fitting of valves to gas cylinders*

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 16900-5, *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 16900-9, *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*

ISO 16900-13, *Respiratory protective devices — Methods of test and test equipment — Part 13: RPD using regenerated breathable gas and special application mining escape RPD: Consolidated test for gas concentration, temperature, humidity, work of breathing, breathing resistance, elastance and duration*

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

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

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

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

EN 144-2, *Respiratory protective devices — Gas cylinder valves — Part 2: Outlet connections*

EN 388:2016, *Protective gloves against mechanical risks*

CGA V-1, *Compressed Gas Cylinder Valve Outlet and Inlet Connections*

JIS B 8246, *Valves for high pressure gas cylinders*

IEC 60068-2-27:2010, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60721-1:2002, *Classification of environmental conditions — Part 1: Environmental parameters and their severities*

IEC 60721-3-2:2018, *Classification of environmental conditions — Part 3-2: Classification of groups of environmental parameters and their severities — Transportation and Handling*

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

Note 1 to entry: All of the various components (e.g. for an SCBA: gas cylinder, respiratory interface, demand valve, harness etc.) have been completely assembled and then connected (RI connected to the demand valve) together in accordance with the information supplied by the manufacturer.

3.1.2
RPD in ready for use state
RPD ready to be donned as described by the manufacturer

Note 1 to entry: In line with the information supplied by the manufacturer for donning the RPD, further actions can be necessary, such as connections of components as part of the donning process.

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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 non separable

3.1.5
replacement part
identical to the one originally supplied with the RPD by the manufacturer, and declared interchangeable by the manufacturer

3.2 Abbreviated terms

BTPS	Body Temperature Pressure Saturated
STPD	Standard Temperature Pressure Dry
FMEA	Failure Mode and Effects Analysis
RI	Respiratory Interface
V_T	Tidal volume
WoB	Work of Breathing

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3.3 Symbols

3.3.1

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

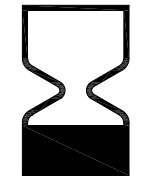
Indication for the RI that it is a part of a RPD system with multiple configurations.

3.3.2

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

Booklet: "See information supplied by the RPD manufacturer"

3.3.3



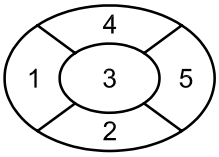
yyyy/mm

Use by date (ISO 7000-2607)

Hourglass: "End of shelf life"

Key: yyyy year, mm month

3.3.4



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 supplied breathable gas RPD is determined by the appropriate combination of the classes:

Example for supplied breathable gas RPD with protection class (PC5), work rate class (W3), RI class (*c*T), supplied breathable gas capacity class (S1800).

Marking for the given example PC5 W3 *c*T S1800

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Multifunctional supplied breathable gas RPD have separate classifications for each function, e.g. one classification as an airline RPD and one classification as an non-airline RPD.

Combined RPD work in both filtering and supplied breathable gas modes and are classified separately for each mode.

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

5 General requirements

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:

If the performance of the RPD is dependent on high pressure it shall be equipped with a pressure monitor, such as a pressure gauge, that continuously monitors that pressure. The accuracy of the pressure monitor shall be within ± 2,5 % of the full scale with the exception of the redundant cylinder valve pressure gauge.

Check in accordance with 7.2 and Clause 9.

5.6 Warning and checking device(s)

5.6.1 Performance of warning device(s)

RPD shall be checked after sequential pre-conditioning in accordance with 6.11.1.1.

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 6.2 for a period of 5 min but with a fixed setting of 35 l/min, see Table 1.

Check in accordance with 7.2 and Clause 9.

Any warning shall be detectable by the wearer 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, k).

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

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Check in accordance with 7.2.

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.

5.6.2 Type Sxxxx RPD

Type Sxxxx RPD using high pressure compressed breathable gas shall have a suitable warning device that operates when the cylinder pressure drops to a predetermined level to warn the wearer.

This warning device shall be activated at a pressure corresponding to at least 200 l of breathable gas per person connected.

The warning shall continue for at least 1 min.

Testing shall be performed in accordance with 6.2 and assessment shall be performed in accordance with 7.2.

5.6.3 Type Sxxxx RPD using generated breathable gas

For RPD using generated breathable gas, a warning shall be activated at, or prior to, the point where any limits in 6.3, 6.5 and 6.6 are no longer met.

5.6.4 Type SY RPD

Type SY RPD using medium or high pressure compressed gas shall be equipped with a warning device to indicate to the wearer when the manufacturer's minimum design conditions are not being achieved.

Testing shall be performed in accordance with 6.2 and assessment shall be performed in accordance with 7.2.

5.6.5 Performance of checking device

ISO 17420-1:2021, 5.6.2, applies.

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.

5.8 Validation by practical performance

5.8.1 General

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

Two RPD as received 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:

— Warning and checking device(s) (5.6);

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— RPD performance (6.2);

— work of breathing/breathing resistance and elastance (6.3);

— determination of capacity of type Sxxxx RPD (6.4);

— CO_2 concentration limits (6.5);

— Temperature and humidity of inhaled breathable gas for generated breathable gas RPD and oxygen enriched breathable gas RPD (6.6), if applicable;

— Contact with skin by hot and cold surface generated by the RPD (6.7), if applicable;

— oxygen content (6.8);

— noise limit (6.9);

— compressed breathable gas cylinder and cylinder valve assemblies (6.13);

— strength of connection (6.14.3).

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.

The following subclause applies in addition:

5.8.7 Restriction and mobility of low pressure hose(s)

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

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

5.9 Requirements for elements/components

ISO 17420-1:2021, 5.9, applies.

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6 Requirements for supplied breathable gas RPD

6.1 Temperature of operation

Integrated RPD or components in their ready for assembly state shall be equilibrated for a minimum of 4 h and tested at $\left(35^{0}_{-2}\right)$ °C and at a relative humidity of (50 ± 25) %. The RPD shall continue to meet the requirements of 6.2.1 a) to e) at the work rate regime for the RPD class.

Integrated RPD or components in their ready for assembly state shall be equilibrated for a minimum of 4 h and tested at $\left(-5^{+2}_{0}\right)$ °C. The RPD shall continue to meet requirements of 6.2.1 a) to e) at the work rate regime for the RPD class.

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

6.2 RPD performance

6.2.1 General

Prior to the test, the number of test samples, in relation to the RPD headform(s) selected and given in Annex C, shall be pre-conditioned.

At least one RPD in its as worn state or components in their ready for assembly state shall be exposed to corrosive atmosphere preconditioning in accordance with 6.11.1.2. This RPD with the components assembled shall be tested at (22 ± 3) °C and (50 ± 25) % relative humidity. At least one RPD or components in their ready for assembly state shall be exposed to temperature, humidity, vibration and shock preconditioning in accordance with 6.11.1.1. This RPD with the components assembled shall be equilibrated and tested at $\left(-5^{+2}_{0}\right)$ °C.

At least one RPD in its as worn state or components in their ready for assembly state shall be exposed to temperature, humidity, vibration and shock preconditioning in accordance with 6.11.1.1. This RPD with the components assembled shall be equilibrated and tested at $\left(35^{0}_{-2}\right)$ °C.

The metabolic simulator or breathing machine shall be operated at ambient conditions at (22 ± 3)°C and (50 ± 25) % relative humidity.

RPD cylinders, if applicable, shall be charged to working pressure before testing.

RPD shall meet the requirements listed in a) to e) when tested in accordance with the steps within the relevant regimes performed.

The RPD shall be tested according to the regime for its work rate class and meet the requirements listed below for each work rate:

— Work of breathing/breathing resistance/elastance, see 6.3;

— CO_2 concentration limits, see 6.5;

— Temperature and humidity of inhaled breathable gas for RPD using generated breathable gas and RPD using oxygen enriched breathable gas, see 6.6;

— Oxygen content of RPD using generated breathable gas, see 6.8.1; and

— Oxygen content of RPD using oxygen enriched breathable gas, see 6.8.2.

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The test termination point for class Sxxxx RPD shall be when any one of the above criteria for the RPD's class is no longer met.

The test termination point for class SY RPD shall be after two complete cycles of the applicable regime.

Regime for RPD class W1:

a) 35 l/min for 10 min;

b) 10 l/min for 5 min;

c) repeat steps a) and b) above until the test termination point or 2 cycles for RPD class SY.

For regime for RPD class W1, the RPD shall have enough capacity to complete step a) at least once. It is not required to complete all of step b) if the test termination point is reached.

Regime for RPD class W2:

a) 35 l/min for 5 min;

b) 65 l/min for 5 min;;

c) 10 l/min for 5 min

d) repeat steps a) to c) above until the test termination point.

For regime for RPD class W2, an RPD shall have enough capacity to complete steps a) and b) at least once. It is not required to complete all of step c) if the test termination point is reached.

Regime for RPD class 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) repeat steps a) to d) above until the test termination point.

For regime for RPD class W3, an RPD shall have enough capacity to complete steps a), b) and c) at least once. It is not required to complete all of step d) if the test termination point is reached.

Regime for RPD class 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) repeat steps a) to e) above until the test termination point.

For regime for RPD class W4, an RPD shall have enough capacity to complete steps a) b), c) and d) at least once. It is not required to complete all of step e) if the test termination point is reached.

The transition period for automatic or manual switching of the test equipment between one flow rate and the next flow rate, including adjustment of all test parameter shall be not more than 30 s whilst the RPD remains in the operational mode.

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During the transition period (occurring between the settings of the different flow rates) stopping of the breathing machine or metabolic simulator for more than 5 s is not allowable for those types of RPD using enriched or generated oxygen.

For all RPD using flow control means the test shall be performed with the operating setting of the RPD adjusted to both the maximum and the minimum flow conditions as specified in the information supplied by the RPD manufacturer.

Examples for allocation are given in Table C.1.

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

6.2.2 Setting for RPD using compressed breathable air or gas mixtures for respiration only

The settings for the breathing machine for each flow rate are given in Table 1.

Table 1 — Setting of breathing machine at flow rates

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

Tidal volumes are expressed at body temperature pressure saturated (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 (1013 hPa) in accordance with Annex D.

An example for normalisation calculation for work of breathing results is given in D.2.

6.2.3 Setting for RPD using regenerated breathable gas or RPD using enriched oxygen

The settings for the metabolic simulator for each flow rate are given in Table 2.

Table 2 — Setting of metabolic simulator and CO_2-concentration of exhaled air at designated flow rates

Flow rate	**Frequency**	**Tidal volume**	**O_2-consumption rate**		**CO_2-injection rate**	
l/min at BTPS	cycles/min	l at BTPS	l/min at STPD	g/min	l/min at STPD	g/min
10 with a tolerance of ±3 %	10,0	1,0	0,31	0,44	0,26	0,51
35 with a tolerance of ±2 %	23,3	1,5	1,09	1,56	0,90	1,78
65 with a tolerance of ±2 %	32,5	2,0	2,03	2,90	1,83	3,62
105 with a tolerance of ±2 %	42,0	2,5	3,28	4,69	3,61	7,14
135 with a tolerance of ±1 %	45,0	3,0	4,22	6,03	4,64	9,17

IMPORTANT — The setting of the metabolic simulator already includes BTPS conditions [body temperature (37 °C) and normalized pressure (1 013 hPa)]. Therefore it is not necessary to normalize to BTPS conditions.

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Binding values for O_2 consumption rate and CO_2 injection rate are given in g/min. The values given in l/min are at STPD and for all other conditions these values have to be calculated.

Performance of the RPD depends on the mass amount of CO_2 and humidity added during the test. Normalization in regard to ambient pressure conditions is therefore not necessary.

6.3 Work of breathing (WoB), breathing resistance and elastance

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 6.2. The measurements shall start after the stabilization of each step.

The work of breathing, breathing resistance (peak pressure), 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.

Table 3 — Limits of work of breathing, breathing resistance (peak pressure) and elastance

Flow rate (dynamic sinusoidal)	**Work of breathing limit measured as** WoB/V_T		**Breathing resistance limit** (peak pressure)		**Elastance limit** measured as $\Delta p^a/V_T$
	Inhalation	**Exhalation**	**Inhalation**	**Exhalation**	
l/min at BTPS	kPa		kPa		kPa/l
10 with a tolerance of ±3 %	0,90	0,90	-1,20	1,20	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 %	1,60	1,60	-2,00	2,00	

[a] Δp is the difference in pressure between the beginning of inhalation and beginning of exhalation

Testing shall be performed in accordance with 6.2, ISO 17420-1 and ISO 16900-12.

6.4 Determination of capacity of type Sxxxx RPD

6.4.1 General

Capacity is designated in litres rounded down to increments of 150 l up to 900 l and increments of 300 l above 900 l.

6.4.2 Type Sxxxx RPD having class T (tight fitting) RIs and using compressed breathable air or gas mixtures for respiration only

The capacity, V_c, of the RPD shall be calculated as the water capacity (volume) of the cylinder multiplied by the working pressure, corrected to BTPS values and divided by the compressibility factor for the breathable air or gas mixtures down to 2,0 MPa in accordance with Formula (1).

$$V_c = \frac{(p-2{,}0)\times V_w \times f_{BTPS}}{Z \times p_{atm}} \quad (1)$$

where

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p is the working pressure, in MPa;

p_{atm} is the atmospheric pressure in MPa = 0,1013 Mpa;

V_w is the water capacity of the cylinder, in litres;

f_{BTPS} is the constant correction factor to convert V at 15 °C to V at BTPS = 37 °C, which is 1,076;

Z is the compressibility factor at 15 °C for the air or gas mixtures at working pressure, p.

Compressibility factor for air is given in Table 4 and the compressibility factor for gas mixtures shall be determined and rounded to two decimals.

Table 4 — Compressibility factor for air at 15 °C

Working pressure p MPa	Compressibility factor Z
10	0,98
15	1,00
20	1,02
25	1,05
30	1,10
40	1,20

EXAMPLE Cylinder with working pressure 300 bar and a water capacity of 6,0 l

p = 30 MPa

V_w = 6,0 l

Z = 1,10

p_{atm}= 0,1013 MPa

$V_c = (p - 2{,}0) \times V_w \times f_{BTPS}/(Z \times p_{atm})$

$= (30 - 2{,}0) \times 6{,}0 \times 1{,}076/(1{,}1 \times 0{,}1013) = 1\,622$ l

V_c = 1 622 l, rounded to 1 500 l

6.4.3 Type Sxxxx RPD having class L (loose fitting) RIs using compressed breathable gas

Two RPD in ready for use state or components in their ready for assembly state preconditioned in accordance with 6.11.1.1 shall be tested.

The RPD cylinder shall be charged to its working pressure before testing.

The determination of the capacity shall be performed at a setting as given in Table 5.

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Table 5 — Settings of breathing machine

Work rate class	Flow rate[a] (dynamic sinusoidal) l/min with a tolerance of ±2 % at BPTS	Tidal volume l at BTPS	Frequency cycles/min
W1	30	1,5	20
W2	40	2,0	20
W3	50	2,0	25
W4	65	2,0	32,5

[a] The flow rates are derived as the rounded average of the flow rates over the time from the regimes given in 6.2.

RPD shall be evaluated as listed below when tested according to Table 5 at ambient temperature and pressure. Results need to be corrected in relation to ambient pressure conditions in accordance to Formula 2.

Capacity for RPD is the usable breathable gas volume down to 2,0 MPa. Time shall be measured from the start at working pressure down to a cylinder pressure of 2,0 MPa.

$$V_{c,BTPS} = t \times q_{wx} \times \frac{p_{amb}}{p_{norm}} \tag{2}$$

where

t is the time from the start at working pressure down to a cylinder pressure of 2,0 MPa, in min

q_{wx} is the flow rate of the work rate class, in l/min

p_{amb} is the ambient atmospheric pressure during the test, in hPa

p_{norm} is the atmospheric pressure at normalized conditions in hPa = 1013 hPa

EXAMPLE Termination point down to 2 MPa after 17 min, work rate class W2 (flow rate 40 l/min), ambient pressure is 990 hPa.

$V_{c,BTPS}$ = 17 min × 40 l/min × (990 hPa/1 013 hPa)

$V_{c,BTPS}$ = 664 l

Resulting capacity class is S 600

6.4.4 Type Sxxxx RPD - using generated breathable gas or using enriched oxygen

Two RPD in ready for use state or components in their ready for assembly state which have been preconditioned in accordance with 6.11.1.1 shall be evaluated.

One RPD in ready for use state or components in their ready for assembly state shall be evaluated after testing at $\left(35^{0}_{-2}\right)$ °C and one at $\left(-5^{+2}_{0}\right)$ °C in accordance with Table 6, or if outside these temperatures, at temperatures specified by the information supplied by the RPD manufacturer. RPD shall be equilibrated at each specified test temperature and tested at (22 ± 3) °C and (50 ± 25) % relative humidity, according to the designated work rate by the manufacturer. The determination of the capacity shall be performed at a setting as given in Table 6.

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Table 6 — Settings of metabolic simulator

Flow rate (dynamic sinusoidal) l/min with a tolerance of ±2 % at BTPS	Frequency cycles/min	Tidal volume l at BTPS	O_2 - consumption rate		CO_2 - injection rate	
			l/min at STPD	g/min	l/min at STPD	g/min
30	20,0	1,5	0,94	1,34	0,77	1,52
40	20,0	2,0	1,25	1,79	1,06	2,09
50	25,0	2,0	1,56	2,23	1,41	2,79
65	32,5	2,0	2,03	2,90	1,83	3,62

[a] The flow rates are derived as the rounded average of the flow rates over the time from the regimes given in 6.2.

Capacity is the usable breathable gas supplied by the RPD until the performance limits in 6.3, 6.5, 6.6 and 6.8 are no longer met. The test shall be terminated when the warning device is activated.

The capacity shall be determined by the result.

Capacity is designated in l rounded down to increments of 150 l up to 900 l and increments of 300 l above 900 l.

EXAMPLE Termination point of CO_2 limit after 38 min, work rate class W3 (flow rate 50 l/min).

38 min × 50 l/min = 1 900 l

Capacity is rounded down to 1 800 l in accordance with 6.4.1 which results in a capacity class S 1 800

6.5 CO_2 concentration limits

One RPD, as received, for each size RI shall be tested on the RPD headform based on the size as designated by the manufacturer.

The setting of the metabolic simulator shall follow the values given in Table 7.

Table 7 — 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 carbon dioxide content of the inhaled breathable gas shall not exceed an average volume fraction of CO_2 concentration according to Table 7. During the testing of the RPD the CO_2 concentration of the inhaled breathable gas shall not exceed a volume fraction of 3,0 % at any time.

A peak of CO_2 concentration resulting from the switch of the testing equipment from one work rate level to the next shall not be considered as a failure and shall not be assessed during the CO_2 measurement.

Testing shall be performed in accordance with ISO 16900-9 and ISO 16900-13 using the relevant regimes outlined in 6.2.

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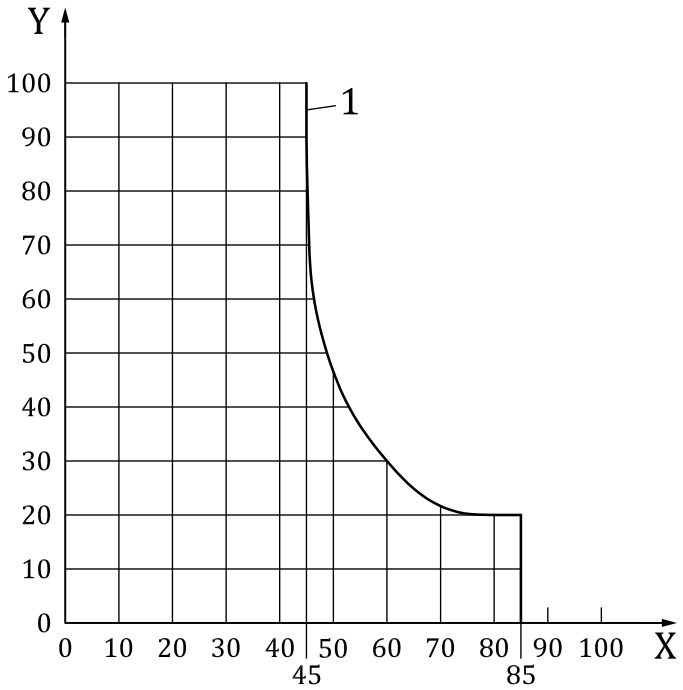
6.6 Temperature and humidity of inhaled breathable gas for regenerated breathable gas RPD and oxygen enriched breathable gas RPD

When tested in accordance with 6.2, the temperature and humidity limits shall be on or below the curve given in Figure 1, item 1.

In addition, the inhalation temperature shall be ≥–30 °C.



Key

X temperature in °C

Y relative humidity in %

1 temperature limit for inhaled air

Figure 1 — Allowable inhalation temperature at relative humidity levels

6.7 Contact with skin by hot and cold surface generated by the RPD

Hot or cold surfaces generated by the RPD which may come into constant contact to the wearer's skin during use shall not exceed 43 °C or fall below 0 °C.

A warning concerning the potential for hot or cold surface temperatures shall be given in instructions for use, if applicable. See Clause 9.

During laboratory testing at (22 ± 3) °C and (50 ± 25) % relative humidity in accordance with 6.2, in its as-worn-state, the maximum and minimum surface temperature of each part which are likely to come into constant contact with the wearer during use, shall be measured.

NOTE Breathing gas temperature limits are excluded from the given surface temperature limits.

Testing shall be performed during 6.2.

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6.8 Oxygen content

6.8.1 Oxygen content of RPD using regenerated breathable gas

The oxygen concentration shall be no less than 20,9 % when tested in accordance with ISO 16900-13 and ISO 16900-5 using the relevant regimes given in 6.2. The oxygen concentration at start up may be lower than 20,9 % but shall be greater than 17 % for the initial 2 min. After one additional minute the concentration shall be at least 20,9 %.

Number of samples and pre-conditioning are specified given in Annex C.

6.8.2 Oxygen content of RPD using oxygen enriched breathable gas

The oxygen concentration shall be no less than 20,9 % when tested in accordance with ISO 16900-13 and ISO 16900-5 using the relevant regimes given in 6.2. The oxygen concentration at start up may be lower than 20,9 % but shall be greater than 17 % for the initial 2 min. After one additional minute the concentration shall be at least 20,9 %.

Number of samples and pre-conditioning are specified in Annex C.

6.9 Noise limit

This requirement is limited to RI covering the ears which are dL, dT, eL and eT.

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

The noise generated by the RPD, when operating at the manufacturers maximum flow conditions and with the breathing machine adjusted according to Table 5 or with the metabolic simulator adjusted according to Table 6 for the work rate class of the RPD, and without any warning device being activated, 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. This measurement may be taken during the test in accordance with 6.2 at (22 ± 3)°C and (50 ± 25) % relative humidity.

Requirements on the performance of warning devices are given in ISO 17420-1:2021, 5.6.

Testing shall be performed in accordance with ISO 16900-14.

6.10 Assement 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

— abrasion resistance,

— pressure increase beyond the design limits,

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

— cleaning, disinfection and decontamination procedures and cycles, and

— dusty environment,

on the function of the RPD.

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

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

6.11 Pre-conditioning (Sequential/Non-sequential)

6.11.1 General

The pre-conditioning shall follow the pre-conditioning test sequence as given in Figure 2.

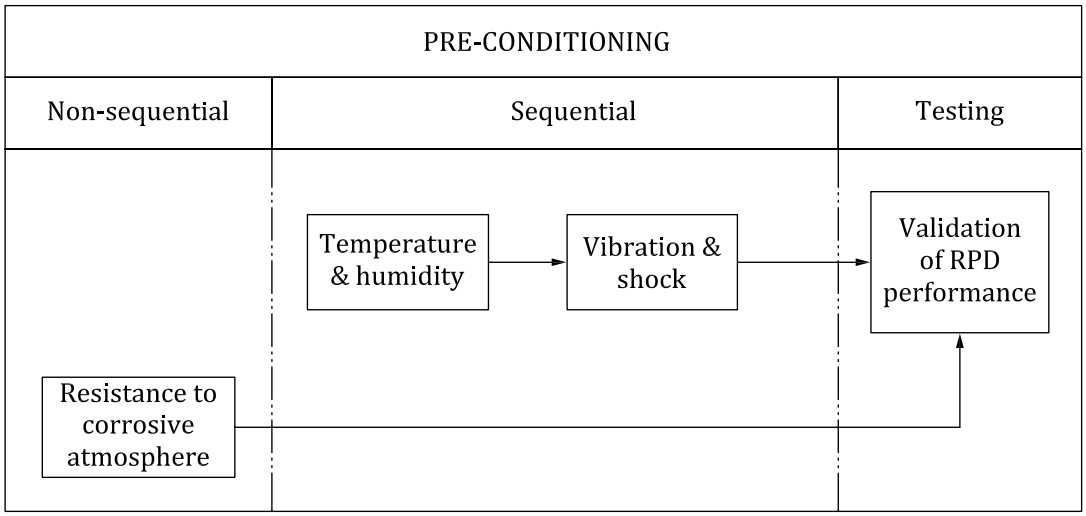

Figure 2 — Pre-conditioning test sequence

6.11.1.1 Sequential pre-conditioning

6.11.1.1.1 General

The RPD in as worn state and components in their ready for assembly state shall be pre-conditioned in the following sequence:

— exposure to temperature and humidity according 6.11.1.1.2,

— exposure to vibration according to 6.11.1.1.3.1 and shock according to 6.11.1.1.3.2.

6.11.1.1.2 Exposure to temperature and humidity

The RPD in its ready for use state and components in their ready for assembly state shall be pre-conditioned according to the following thermal cycle, without interruption:

— ambient temperature and humidity;

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

— (–15 ± 3) °C for (24 ± 1) h;

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

— ambient temperature between 16 °C and 32 °C and (50 ± 30) % relative humidity 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.

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