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Respiratory protective devices — Methods of test and test equipment —

Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures

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

Partie 12: Détermination du travail respiratoire en fonction du volume respiratoire et détermination des pics de pressions respiratoires

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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

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

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

— *Part 1: Determination of inward leakage*

— *Part 2: Determination of breathing resistance*

— *Part 3: Determination of particle filter penetration*

— *Part 4: Determination of gas filter capacity and migration, desorption and carbon monoxide dynamic testing*

— *Part 5: Breathing machine, metabolic simulator, RPD headforms and torso, tools and verification tools*

— *Part 6: Mechanical resistance/strength of components and connections*

— *Part 7: Practical performance test method*

— *Part 8: Measurement of RPD air flow rates of assisted filtering RPD*

— *Part 9: Determination of carbon dioxide content of the inhaled gas*

— *Part 10: Resistance to ignition, flame, radiant heat and heat*

— *Part 11: Determination of field of vision*

— *Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures*

— *Part 13: RPD using regenerated breathable gas and special application mining escape RPD: Consolidated test for gas concentration, temperature, humidity, work of breathing, breathing resistance, elastance and duration*

— *Part 14: Measurement of sound level*

Introduction

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

The following definitions apply in understanding how to implement an ISO International Standard and other normative ISO deliverables (TS, PAS, IWA):

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” is used to indicate that something is permitted;

— “can” is used to indicate that something is possible, for example, that an organization or individual is able to do something.

3.3.1 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a requirement as an “expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted.”

3.3.2 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a recommendation as an “expression in the content of a document conveying that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred, but not necessarily required, or that (in the negative form) a certain possibility or course of action is deprecated, but not prohibited.”

Respiratory protective devices — Methods of test and test equipment —

Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures

1 Scope

This part of ISO 16900 specifies the test methods for determining the volume-averaged work of breathing and peak respiratory pressures imposed by the respiratory protective device (RPD).

Elastic work, elastic physiological effects, and information on physiological effects of work of breathing (WOB) are specified in ISO 16976-4 and are not included in this test method.

2 Normative references

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

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

ISO 16900-5,[1] *Respiratory protective devices — Methods of test and test equipment — Part 5: Breathing machine, metabolic simulator, RPD headforms and torso, tools and verification tools*

3 Terms and definitions

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

3.1
breathing frequency
number of breaths taken in a minute

Note 1 to entry: Expressed in breaths per minute.

3.2
elastance
E
pressure change resulting from a volume change

Note 1 to entry: Expressed in kPa/l.

3.3
tidal volume
V_T
size of a breath

Note 1 to entry: Expressed in litres.

1) To be published.

3.4
volume-averaged pressure
WOB/V_T
work for a breath divided by its *tidal volume* (3.3)

Note 1 to entry: Expressed in kPa.

Note 2 to entry: The WOB/V_T can be determined separately for an inspiration, for an expiration, or for a whole breath.

4 Prerequisites

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

a) number of specimens;

b) operating parameters specific to RPD;

c) selection and types of support such as RPD headform/torso;

d) any prior conditioning or testing;

e) minute ventilation;

f) temperature(s) at which tests are to be performed.

5 General test requirements

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

Where the assessment of the pass/fail criterion depends on a measurement, an uncertainty of measurement as specified in Annex A shall be reported.

6 Principle

The RPD is fitted to a headform/torso and is operated at the manufacturer's minimum condition, unless specified otherwise by the performance standards.

The breathing machine or metabolic simulator, as applicable, is operated at a combination of tidal volume and breathing frequency, in accordance with the relevant performance standard. The work of breathing is calculated from recorded measurements of volume and pressure. These recordings will also provide peak pressures values.

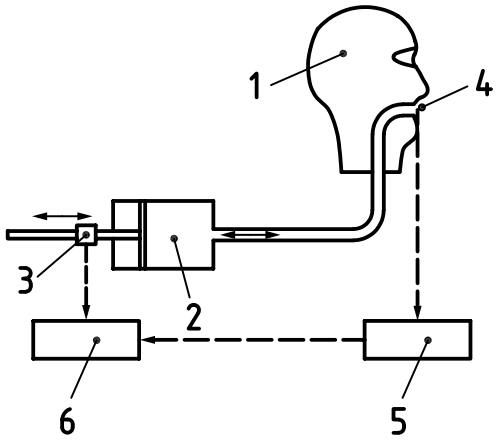
Validation of work of breathing measurements and calculations is performed using the verification orifices as specified in ISO 16900-5.

Validation of the correct functioning of the breathing machine/metabolic simulator is performed using the validation orifices specified in ISO 16900-5. Validation is satisfactory when the WOB calculations give results which are in accordance with the data shown in Table 1.

7 Apparatus

7.1 Breathing machine/metabolic simulator arrangement

A breathing machine or metabolic simulator meeting the specifications of ISO 16900-5 shall be used. An example of a setup is shown in Figure 1.



Key

1 headform or other suitable mechanism to hold RPD under test
2 breathing machine
3 displacement sensor
4 pressure pickup in the airway opening
5 pressure transducer, if separate from 4
6 data acquisition device

NOTE Double-headed arrows and single-headed arrows indicate the motion of the breathing machine piston and the direction of gas flow, respectively.

Figure 1 — Simplified schematic of a setup to measure work of breathing

7.2 RPD headform/RPD torso

Appropriate RPD headform/RPD torso, as specified in ISO 16900-5, shall be used. For RPD with respiratory interface Class E (see the performance standards), it can be necessary, depending on the design, to adjust the test setup to simulate the volume taken up by the arms and legs of the wearer because it can affect the gas flow management of the RPD. It can be necessary to adapt the RPD to allow placement of sensors and probes.

7.3 Pressure measurements

A differential pressure transducer measures the positive and negative pressures relative to ambient pressure generated during breathing. This respiratory pressure shall be measured using a pressure pickup in the RPD headform or mouthpiece attachment as specified in ISO 16900-5. The pressure measurement system shall be able to measure at frequencies up to 50 Hz with less than 3 dB damping.

7.4 Volume measurements

The volume shall be determined from piston displacement which is measured using a displacement sensor mounted on the breathing machine.

7.5 Data acquisition

Pressure and volume signals shall be acquired at a minimum of 100 Hz per channel.

8 Test procedure

8.1 Use the relevant validation orifices as described in ISO 16900-5 to confirm that the measured work of breathing (WOB) from the test system being used is within the tolerances shown in Table 1.

8.2 Fit the respiratory interface or complete RPD, in accordance with the information supplied by the manufacturer, to the appropriate size of RPD headform/torso, and operate the RPD as given by the prerequisites. The respiratory interface should be sealed to the headform where applicable (tight fitting).

8.3 Connect the breathing circuit to the RPD headform/torso.

8.4 If applicable, activate the RPD in accordance with the information supplied by the manufacturer and immediately start the test and operate as specified in Clause 4.

8.5 Collect data at minute ventilations as given by the prerequisites. After stabilization, for any 10 consecutive breaths, perform ensemble averaging of these breaths, calculate the work of breathing and the peak inspiratory and the peak expiratory pressures.

8.6 Remove the RPD from the headform/torso and repeat 8.2 to 8.5 for the required number of test specimens.

8.7 Repeat 8.1.

Table 1 — Volume averaged pressure (WOB/V_T) values for the two verification orifices

Minute ventilation	Breathing frequency	Tidal volume	Orifice A		Orifice B	
		(V_T)	WOB/V_T	Maximum asymmetry[a]	WOB/V_T	Maximum asymmetry[a]
l/min	min^{-1}	l	kPa	%	kPa	%
10 ± 0,3	10,0	1,0	0,06 ± 0,01	8		8
20 ± 0,4	20,0	1,0	0,22 ± 0,02	5		5
35 ± 0,7	23,3	1,5	0,62 ± 0,03	5		5
50 ± 1,0	25,0	2,0	1,22 ± 0,06	5		5
65 ± 1,3	32,5	2,0	2,02 ± 0,10	5	0,62 ± 0,03	5
85 ± 1,7	34,0	2,5	3,39 ± 0,17	5	1,05 ± 0,05	5
105 ± 1,1	42,0	2,5	—	5	1,58 ± 0,08	5
135 ± 1,4	45,0	3,0	—	8	2,60 ± 0,13	8

[a] Asymmetry is calculated as the absolute value of the difference between one and the ratio of peak expiratory pressure and peak inspiratory pressure, expressed in per cent.

NOTE The verification procedure identifies whether or not the breathing machine is capable of delivering acceptable work of breathing results. Where work of breathing results are not within the acceptable limits, it indicates a fault in the breathing machine or metabolic simulator and pipework. Common faults that can cause a deviation of the work of breathing results from the values given in Table 1 include the following:

— a leak in the system;

— too many sharp bends or right angle elbows in the pipework;

— flow restrictions in the pipework;

— incorrect wave form (not sinusoidal);

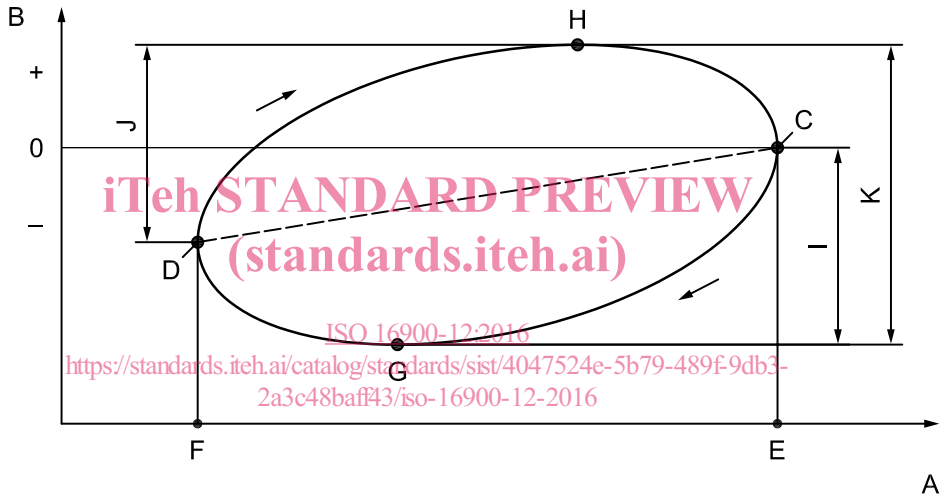
— incorrect calculations.

9 Calculation of work of breathing (WOB)

9.1 General

Work of breathing (WOB) is calculated over the averaged breathing cycles and is calculated from the pressure difference between the airway opening and outside of the RPD and the volume.

A pressure-volume plot is shown in Figure 2. The volume is plotted along axis A and the pressure is plotted along axis B. Points C and D represent the volume at the start and end of inspiration, i.e. points of no flow. The inspiration follows the line CGD and the expiration follows the line DHC. The tidal volume (V_T) is the absolute value of volume difference between points E and F. Annex B provides more detailed information.



Key

A	volume axis	G	lowest pressure during inspiration
B	pressure axis	H	highest pressure during expiration
C	start of inspiration	I	peak inspiratory pressure
D	end of inspiration	J	peak expiratory pressure
E	volume at the start of inspiration	K	peak-to-peak pressure
F	volume at end of inspiration		

NOTE The pressure at point C is shown as zero, but it can be positive, zero, or negative.

Figure 2 — Typical pressure-volume plot for an RPD with flow resistance and elastance

9.2 Calculations

9.2.1 Work of breathing