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

Part 5:

**Breathing machine, metabolic
simulator, RPD headforms and torso,
tools and verification tools**

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

*Partie 5: Machine respiratoire, simulateur métabolique, têtes factices
et torses des APR, outils et outils de vérification*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Description of test equipment	2
4.1 RPD head forms	2
4.1.1 General	2
4.1.2 RPD head form CAD files	3
4.1.3 Surface finish and materials of construction	4
4.1.4 Trachea tube assembly and interface connections	5
4.2 RPD torso	10
4.3 Breathing machine	13
4.4 Metabolic simulator	14
4.5 Performance requirements of breathing machines and metabolic simulators	14
4.5.1 General	14
4.5.2 Minute ventilation	14
4.5.3 Ventilation setting switching	15
4.5.4 Output characteristics	15
4.6 RPD verification tools	15
4.6.1 General	15
4.6.2 Verification orifices	15
4.6.3 Verification orifice adapter	16
4.6.4 Verification procedure for work of breathing	18
4.6.5 RPD carbon dioxide verification tube and verification tube adapter	19
4.7 RPD tools	21
4.7.1 Filter simulator	21
4.7.2 F_x force probe	28
4.7.3 Exposed surface identification probe	29
Annex A (informative) Dynamic procedure for leak testing of breathing machines and metabolic simulators	31
Bibliography	34

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 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.

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 head forms and torso, tools and verification tools*
- *Part 6: Mechanical resistance/strength of components and connections*
- *Part 7: Practical performance test methods*
- *Part 8: Measurement of RPD air flow rates of assisted filtering RPD*
- *Part 9: Determination of carbon dioxide content of 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*

Respiratory protective devices — Methods of test and test equipment —

Part 5:

Breathing machine, metabolic simulator, RPD headforms and torso, tools and verification tools

1 Scope

This part of ISO 16900 specifies the characteristics of breathing machines, metabolic simulators, RPD head forms/torso, RPD tools and RPD verification tools that are common to RPD test laboratories. Standardization of these items is essential for the standardization of the test methods.

Standardization of the RPD verification tools is essential for demonstrating the delivery of comparable results in different test laboratories.

Descriptions on the use of the RPD tools for the different tests are specified in the relevant parts of ISO 16900.

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 16900-9:2015, *Respiratory protective devices — Methods of test and test equipment — Part 9: Determination of carbon dioxide content of the inhaled gas*

ISO 16900-12:2016, *Respiratory protective devices — Methods of test and test equipment — Part 12: Determination of volume-averaged work of breathing and peak respiratory pressures*

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

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

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

3 Terms and definitions

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

3.1

RPD head form

laboratory test head simulating human heads used in testing RPD

3.2

RPD torso

generic body form used in combination with an RPD head form used in testing RPD

3.3

trachea tube assembly

tube that simulates the human trachea, containing ports for the measurement of pressure, carbon dioxide content and temperature of breathed breathable gas, and interface connections permitting seating to the RPD head form, RPD torso or alternative (benchtop) fixture

3.4

RPD head form assembly

RPD head form with trachea tube assembly included

3.5

breathing machine assembly

breathing machine plus all connecting tubes, control valves and other necessary hardware leading to the trachea tube assembly

3.6

metabolic simulator assembly

metabolic simulator plus all connecting tubes, control valves and other necessary hardware leading to the trachea tube assembly

3.7

RPD verification tool

test device that simulates specific performance characteristic(s) of a respiratory protective device

Note 1 to entry: The theoretical results from the test device are known and are compared with the actual results obtained in a given test laboratory when the test device is used with the appropriate test system in that laboratory.

3.8

RPD tool

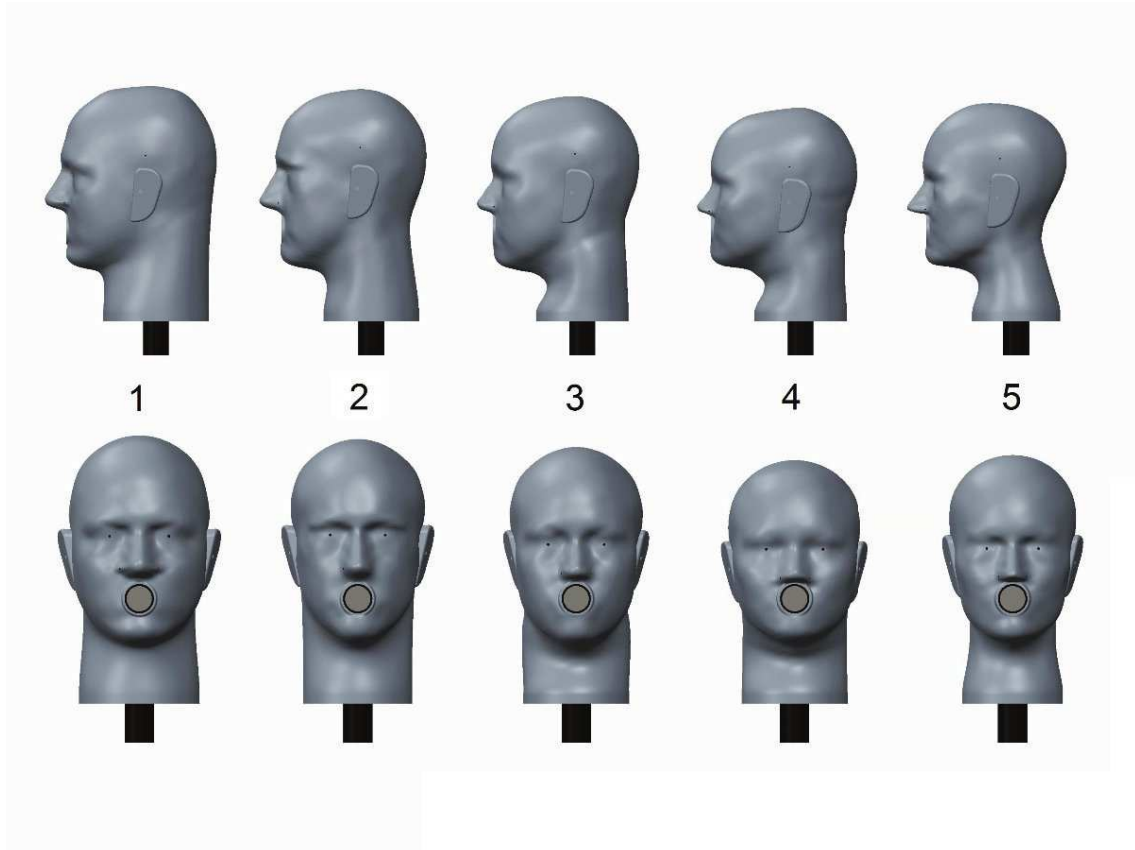
device that assists with the testing of RPD

4 Description of test equipment

4.1 RPD head forms

4.1.1 General

The five RPD head forms used for laboratory testing are based on the anthropometric measurements and averaged head dimensions specified in ISO/TS 16976-2. Neck lengths are elongated and diameters are sized in accordance with anthropometric data to permit the sealing of RPD interfaces with neck dams. All RPD head forms contain the same sized trachea tube assembly so that the connection between the neck and an RPD torso or alternative fixture is identical for all sizes. For the purpose of acoustic measurements, the ears are flat and the position of the microphones is marked. For the purposes of field of vision measurements, the positions of the pupils are marked to permit the fixing of light sources. The RPD head forms are illustrated in [Figure 1](#).



Key

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

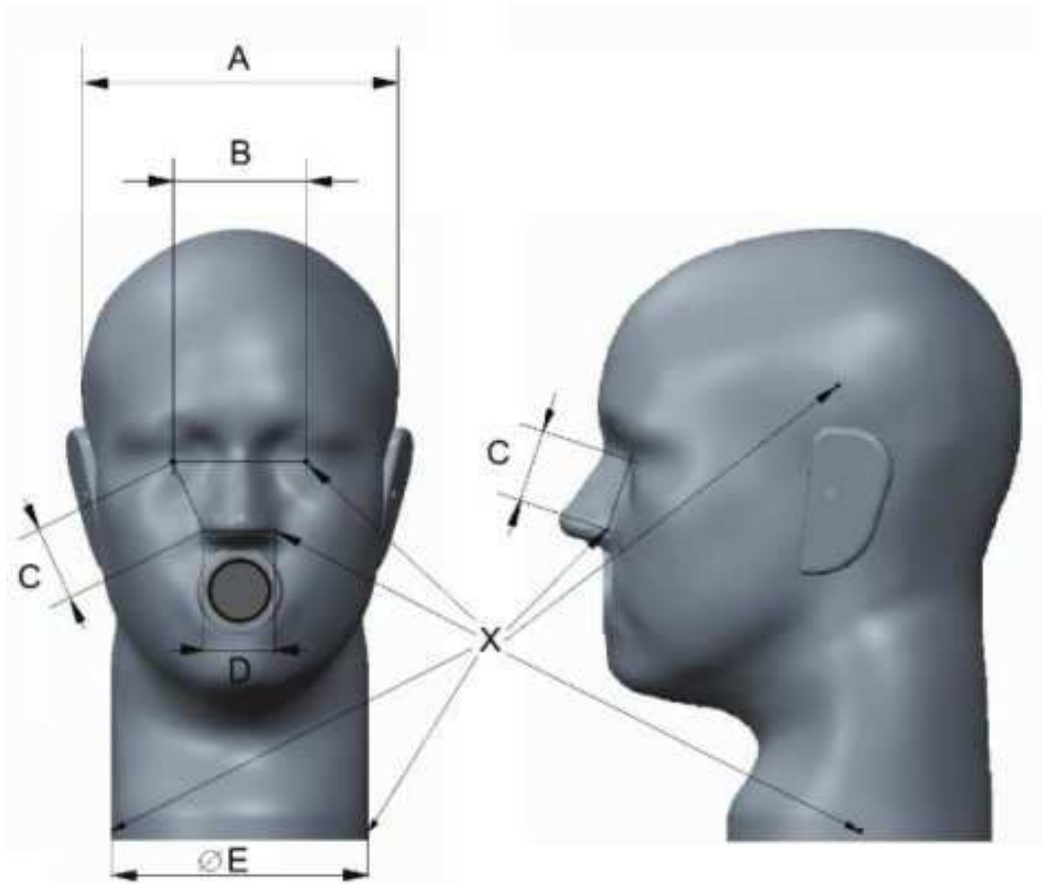
Figure 1 — RPD head forms front and side view

4.1.2 RPD head form CAD files

The RPD head forms are defined by the three-dimensional computer-aided design (CAD) files derived from the dimensions specified in ISO/TS 16976-2. CAD files of the RPD head forms are available from the source given in Reference [3] and these will permit the production of RPD head forms of the correct dimensions. The CAD files represent the final surface geometry of the RPD head forms 1 to 5.

Each manufactured RPD head form shall be marked on the top or the back of the head with the head form number consistent with key in [Figure 1](#).

The conformance of the manufactured RPD head forms to the CAD file can be determined by reference to the table of reference dimensions marked by small indents, contained in the CAD files, see [Figure 2](#), key X. The reference indents are located at the left and right side of the RPD head forms, the left and right side of the nose and the centre of the pupils. The deviation of the manufactured RPD head form from the source CAD file data shall be no more than ± 1 mm in any of the referenced dimension.



Head form (see Figure 1)	A ^a	B	C ^a	D	E
All dimensions are subject to a tolerance of ±1.					
1	161	68	40	42	138
2	153	63	43	35	125
3	152	64	37	36	121
4	152	65	39	39	121
5	144	59	36	32	115

^a These dimensions are for verification of head size only and are not the same as the anthropometric dimensions given in ISO 16976-2.

Key

- A maximum head width
- B interpupilliary distance
- C eye to nose diagonal
- D nose breadth
- E neck diameter in cylindrical section
- X examples of reference indent

Figure 2 — Positions of the reference dimensions used to verify the RPD head form sizes

4.1.3 Surface finish and materials of construction

The general materials of construction of the RPD head form are not specified, but are related to the test method in which the RPD head form is used. The surface finish of the RPD head forms shall be smooth and can be hard or soft. A soft surface finish shall have a hardness between 10 Shore A and 30 Shore.

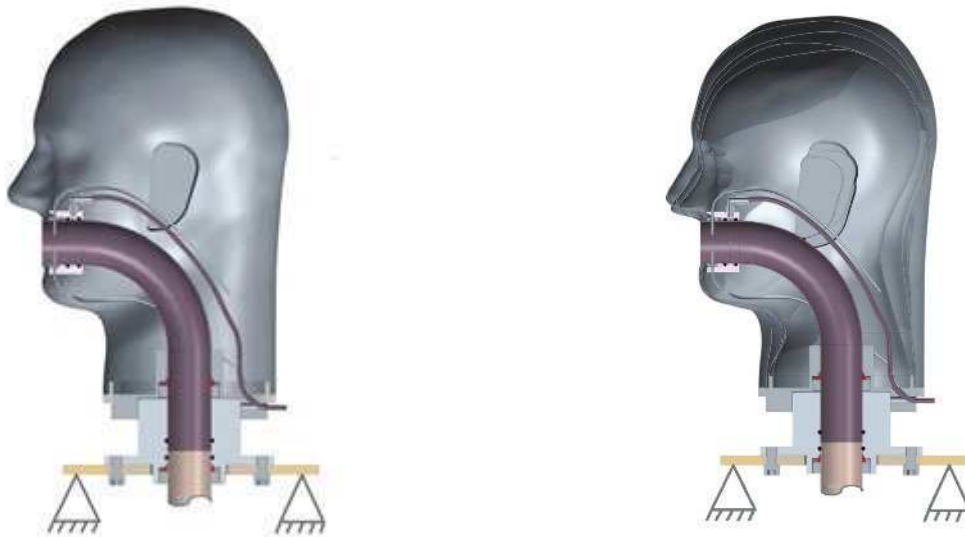
The hardness of a hard surface finish RPD head form is determined by the material of construction. Irrespective of the surface finish of the RPD head form, the dimensions defined by the CAD file (see Reference [3] and [Figures 2](#)) shall be met.

The materials of construction for the RPD head form for the flame and thermal exposure tests shall be metal, ceramic or other heat-tolerant material and the surface finish shall be smooth.

4.1.4 Trachea tube assembly and interface connections

The same trachea tube assembly is used in all five RPD head forms. The trachea tube component shall be manufactured from stainless steel. The trachea tube assembly may be designed so that it can be inserted into hollow RPD head forms via the neck opening or be manufactured such that all components of the trachea tube assembly are permanently fixed. The connection between the mouth opening and the trachea tube assembly shall be sealed. The connection between the RPD head form and RPD torso or alternative fixture is achieved using a mechanical socket (see [Figures 3](#) to [5](#)).

The volume of the trachea tube assembly and connecting tubes within the RPD head form and RPD torso or alternative fixture up to the position of the control valves shall be (500 ± 150) ml. [Figure 3](#) a) shows the trachea tube assembly inside the RPD head form 1 positioned on an alternative fixture. [Figure 3](#) b) shows an overlay of all RPD head forms on an alternative fixture. [Figure 4](#) shows an overlay of all RPD head form sizes mounted on the RPD torso to demonstrate how the trachea tube assembly is positioned inside the RPD head forms.



a) RPD head form 1 with inserted trachea tube and control valve connection positioned on alternative fixture b) Overlay of all RPD head forms 1 to 5 positioned on alternative fixture

Figure 3 — Trachea tube assembly inside RPD head form(s) positioned on an alternative fixture

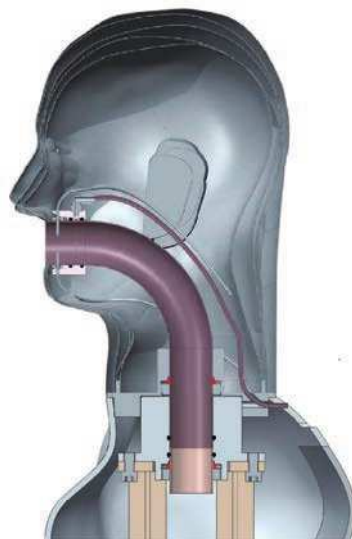


Figure 4 — Overlay of RPD head forms 1 to 5 positioned on RPD torso illustrating single size of trachea tube assembly in RPD head forms

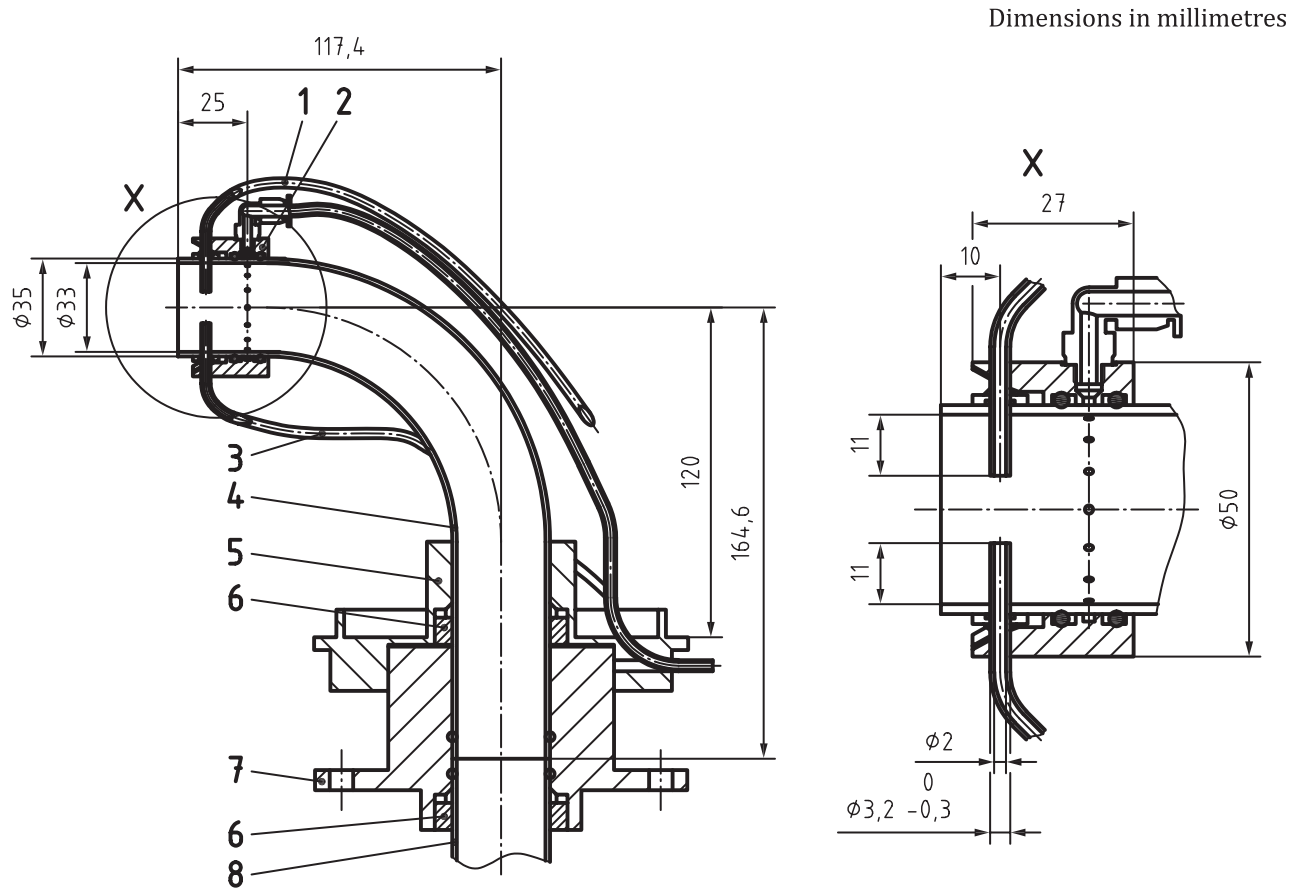
The dimensions of the trachea tube assembly, interface and interface socket for RPD torso or alternative fixture are given in [Figure 5](#).

The dimensions of the stainless steel trachea tube showing the drilled holes for the pressure pickup ring (pitot ring) are given in [Figure 6](#). It is deliberate that there are no holes drilled vertically top and bottom. The holes are eliminated to prevent the possibility of liquid entering the pickup ring assembly.

The dimensions of the pressure pickup ring sampling port assembly are shown in [Figure 7](#).

The dimensions of the sample tubes, either for temperature measurement by insertion of a temperature sensor or for CO₂ sampling, are shown in [Figure 8](#).

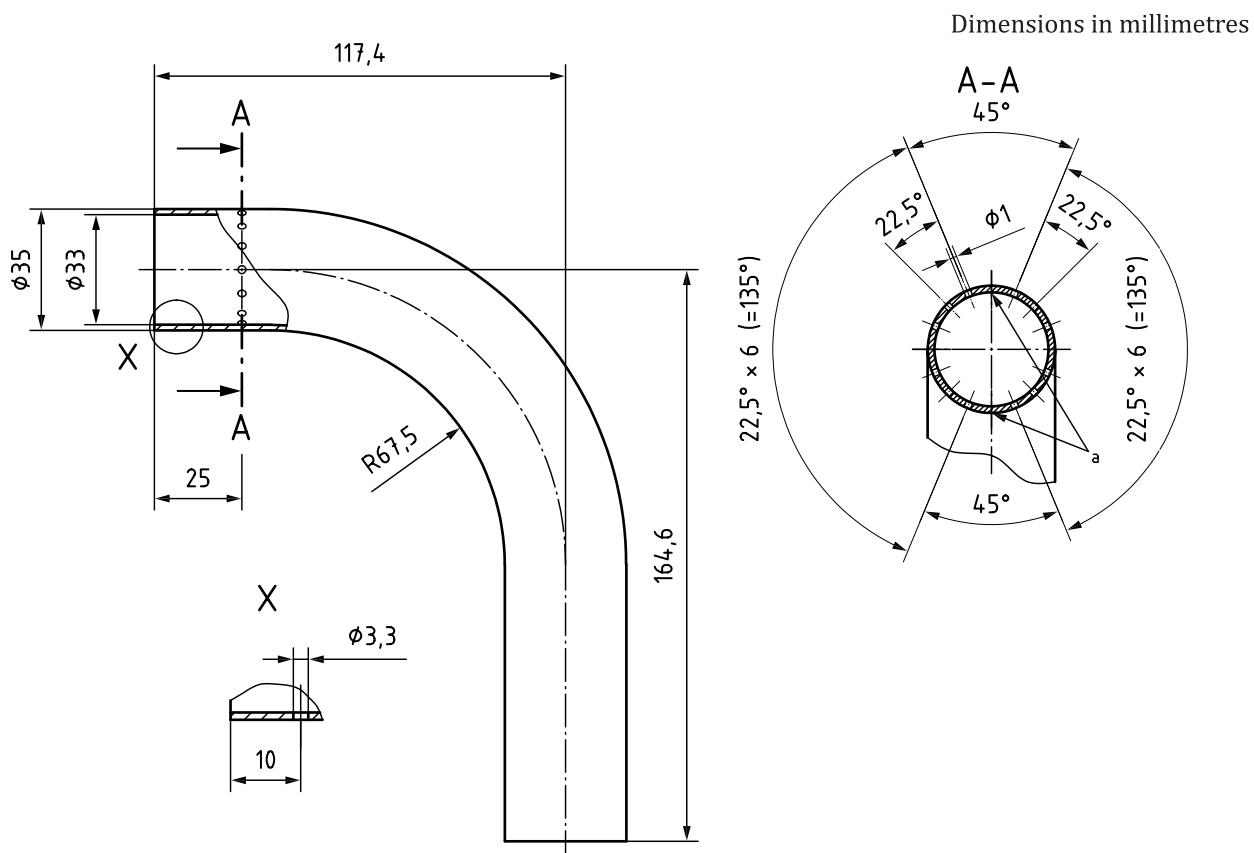
NOTE It is intended that when using breath-by-breath CO₂ analysis technique (ISO 16900-9, Method 3), a narrow bore capillary tube is inserted into the CO₂ sample tube (item C in [Figure 5](#)) to ensure rapid transfer of the breathed air sample to the fast response CO₂ analyser.

**Key**

- 1 temperature measuring port
- 2 pressure sampling port (pitot ring positioned over 14 holes, with a diameter of 1 mm each, equally distributed over tube cross section, excluding vertically top and bottom)
- 3 CO₂ sampling tube
- 4 trachea tube
- 5 RPD head form fixture
- 6 interface screw thread
- 7 RPD head form interface to RPD torso or alternative fixture
- 8 connection to control valves

NOTE Tolerances in accordance with ISO 2768-m.

Figure 5 — Dimensions of the trachea tube assembly, interface and interface socket



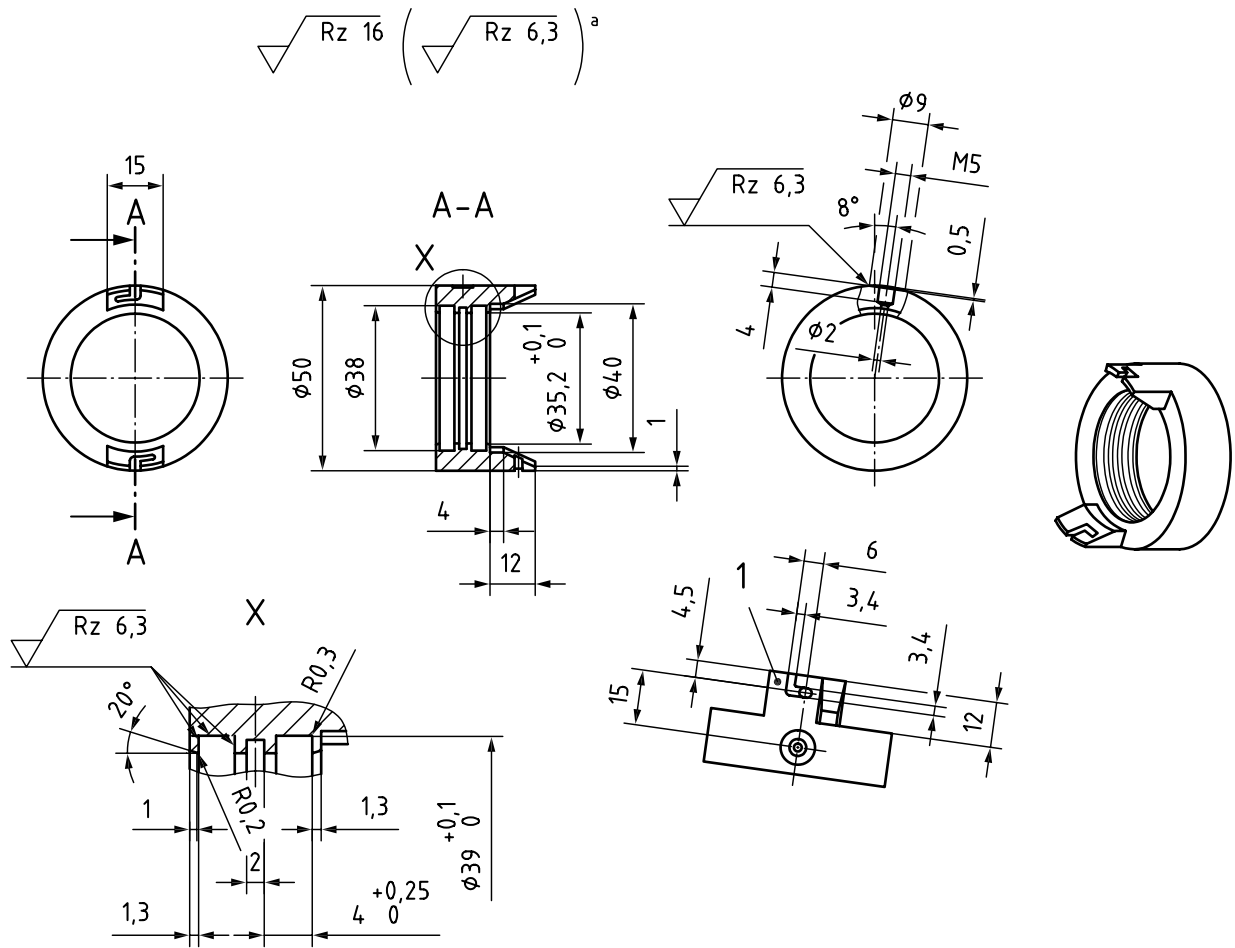
Key

^a Attention: No holes at this position.

NOTE Tolerances in accordance with ISO 2768-m.

Figure 6 — Dimensions of trachea tube assembly: Details of trachea tube

Dimensions in millimetres



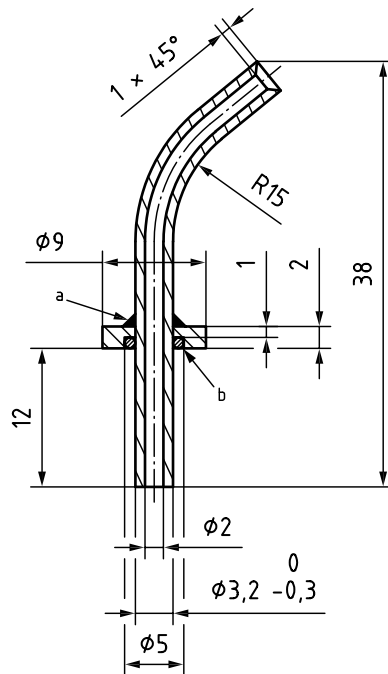
Key

- 1 bayonet socket
- a According to ISO 1302.

NOTE Tolerances in accordance with ISO 2768-m.

Figure 7 — Dimensions of trachea tube assembly: Details of pressure pickup ring (pitot ring)

Dimensions in millimetres



Key

- a Welded.
- b O-ring.

NOTE Tolerances in accordance with ISO 2768-m.

Figure 8 — Dimensions of trachea tube assembly: Details of sampling tubes

4.2 RPD torso

The RPD torso is a holder for the RPD and a support for the appropriate RPD head form. It is used to mount an RPD which cannot be mounted on an RPD head form alone. The overall RPD torso design is not specified, but it shall contain the specified interface socket assembly for the RPD head forms. The socket shall be positioned in the RPD torso such that the centre of the trachea tube assembly at the mouth area of the RPD head form is vertically in line with the front of the breast. The centre of the trachea tube assembly shall be at a fixed height of (165 ± 3) mm from the breastbone position. The breastbone position is located at the RPD torso breast area (50 ± 3) mm behind the front of breast ([Figure 9](#)).

Dimensions in millimetres

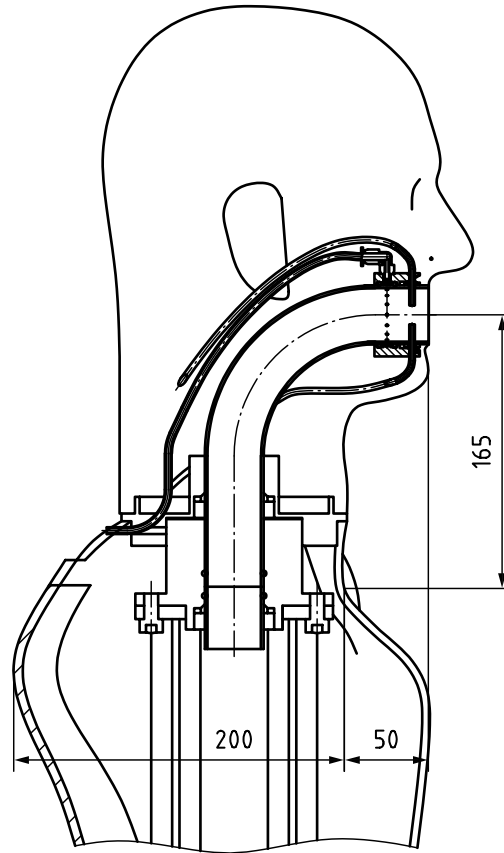


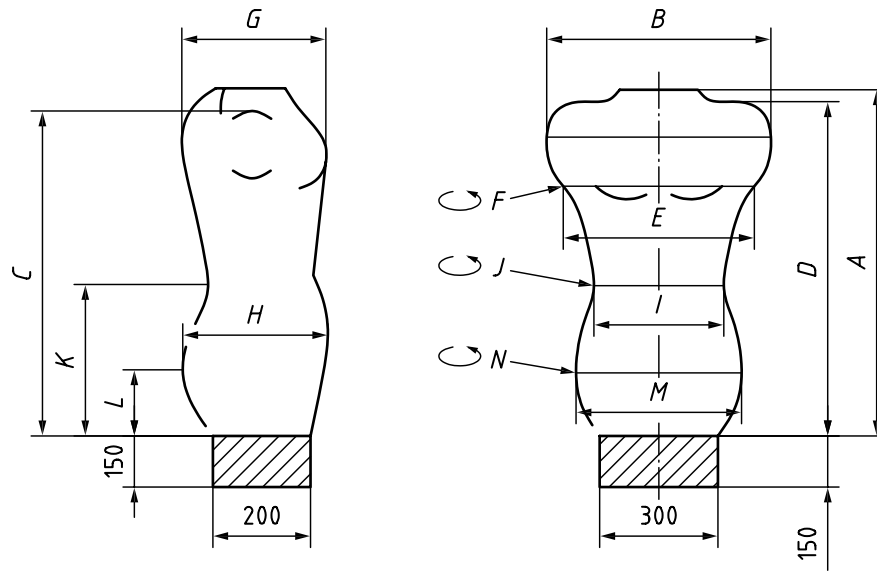
Figure 9 — RPD head form position in relation to the RPD torso (breastbone point)

The RPD torsos shall have the following attributes:

- space to mount hoses and valves internally;
- access to breathing hoses and valves;
- a closed surface, not an open wireform construction;
- horizontal shoulders large enough to hold harnesses without slipping;
- a base section (shaded area in [Figure 10](#)) to allow 150 mm room between the floor/table and the bottom of the RPD torso.

[Figure 10](#) shows a suitable RPD torso, taken from ISO 16976-2. The typical reference dimensions are derived from averaging anthropometric dimensions of male and female populations (see Reference [\[4\]](#)).

[Figure 11](#) shows an RPD head form 1 positioned on a typical RPD torso with front, cross-sectional and rear views.



Key reference	ADULTDATA Handbook reference	Dimension ^a All dimensions are subject to a tolerance of ±3.
A	(51)	611 ^b
B	(55)	437
C	(59)	587
D	(61)	606
E	(64)	306
F	(66)	919
G	(68)	250
H	(73)	267
I	(74)	262
J	(75)	804
K	(82)	237
L	(83)	161
M	(84)	324
N	(87)	1 058

^a Dimensions are derived from Reference [4].

^b Dimension modified to correlate with RPD head form neck geometry.

Key

- A height of prominent neck vertebra (sitting)
- B shoulder breadth (deltoid)
- C shoulder (acromion) height (sitting)
- D mid-shoulder height (sitting)
- E chest breadth, at level of nipples
- F chest circumference, at level of nipples
- G chest depth, at level of nipples
- H lower abdominal depth
- I waist breadth
- J waist circumference - natural indentation
- K height of maximum lumbar curvature, sitting
- L sacral height (sitting)
- M hip breadth
- N mid hip circumference

Figure 10 — Typical RPD torso

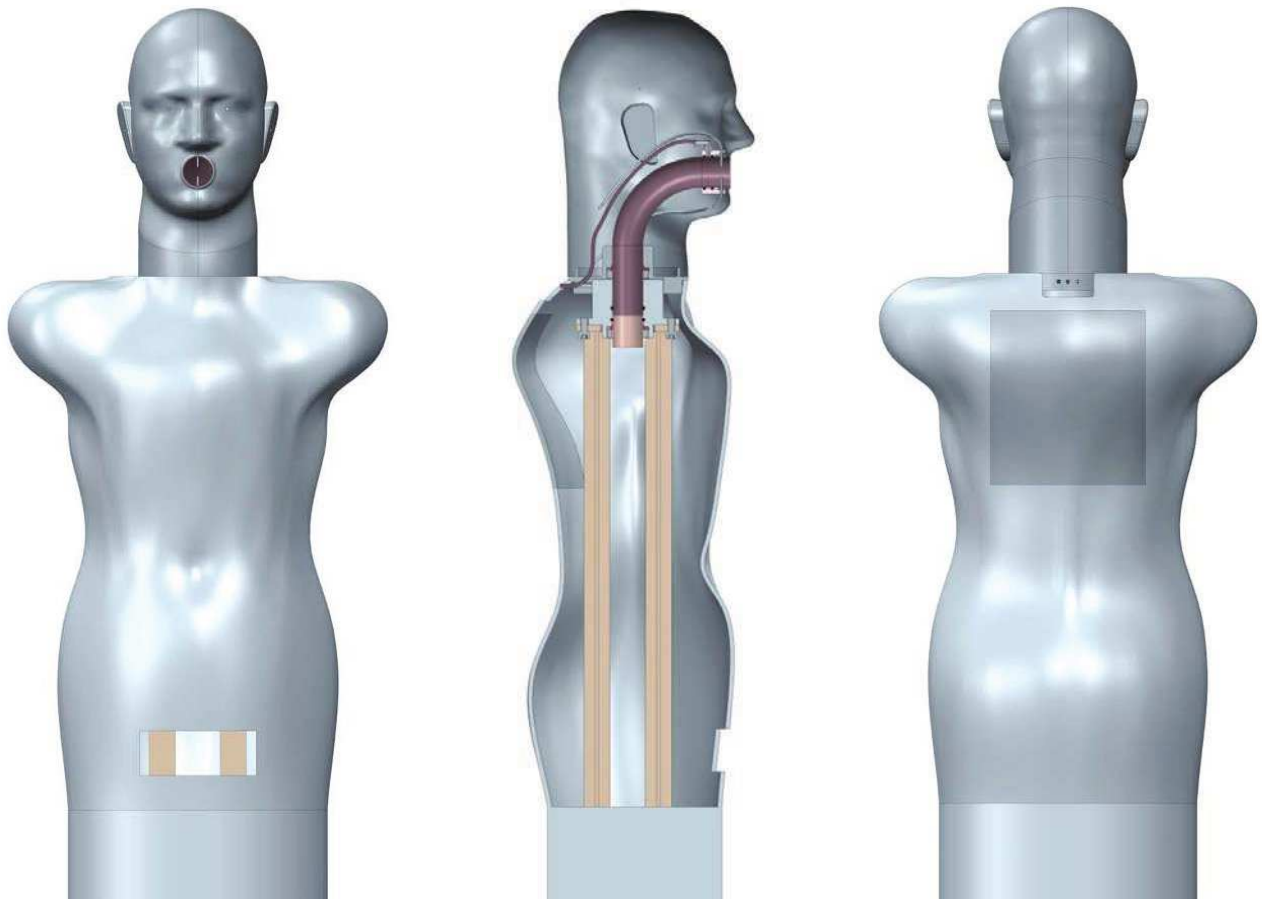


Figure 11 — RPD head form 1 positioned on typical RPD torso: Front, cross-sectional and rear views

4.3 Breathing machine

The simple laboratory breathing machine simulates the human inhalation and exhalation function using untreated laboratory air and a sinusoidal breathing pattern.

The breathing machine and associated components that make up the breathing machine assembly shall have the following specific attributes.

- a) Pipework and connecting tube diameter: The design of test system pipe work and routing valves are critical, particularly with regard to accurate measurement at high ventilation rates. Avoidance of sharp 90° elbows is recommended. Connecting tubes shall have an internal diameter sufficiently large such that the highest air flow is not restricted.

NOTE It has been found that tubes with diameter of 25 mm or larger are sufficient to meet this attribute.

- b) Constrictions within the breathing circuit: The maximum constriction within the breathing circuit, including valves, shall have a cross-sectional area sufficiently large such that the highest air flow is not restricted.

NOTE It has been found that a cross-sectional area equivalent to a tube of 20 mm diameter is sufficient to meet this attribute.

- c) Externally triggered valve response time: Externally triggered valves, if used in the breathing circuit, shall have a response time of not more than 5 ms from triggering to fully open/closed.

- d) Total volume of connecting tube: The effective tubing volume between the output of the breathing machine to the mouth of the RPD head form shall be not more than 4 l.
- e) Leak tightness: The breathing machine assembly and trachea tube assembly shall be leak tight such that the decay in vacuum or overpressure is not more than 0,1 kPa in 1 min from 2,0 kPa overpressure or vacuum.

NOTE The leak tightness can additionally be checked by a dynamic method, see [Annex A](#).

- f) Operating temperature: All components of the breathing machine assembly and associated test apparatus, such as controllers, pressure transducers or computerised waveform control mechanisms, shall operate satisfactorily over the expected temperature range of the tests to be conducted.

4.4 Metabolic simulator

The metabolic simulator is a breathing machine using a sinusoidal breathing pattern but with additional features to condition the exhaled gas to simulate human metabolic functions. Oxygen is removed and carbon dioxide and humidity are added to the exhaled gas. The exhaled gas temperature and humidity are set to a given level simulating human physiology.

The metabolic simulator and associated components that make up the metabolic simulator assembly shall have the specific attributes given in [4.3](#) a) to e) together with the following.

- a) Addition of carbon dioxide to exhaled air circuit: The metabolic simulator shall be capable of adding sufficient carbon dioxide to the exhaled air to cover all operating ranges specified in the performance standards.
- b) Oxygen consumption: The metabolic simulator shall be capable of simulating the consumption of oxygen between 0,3 l/min and 4,3 l/min oxygen over the full operating range.
- c) Temperature: The metabolic simulator shall be capable of delivering exhaled gas at a temperature of (37 ± 2) °C at the entry to the control valve that carries exhaled gas to the trachea tube.
- d) Humidity: The metabolic simulator shall be capable of delivering exhaled gas with humidity levels of 95 % to 100 %, without exhaling liquid condensate, measured at the entry to the control valve leading to the RPD head form.

4.5 Performance requirements of breathing machines and metabolic simulators

4.5.1 General

Breathing machines and metabolic simulators shall meet the following performance requirements.

4.5.2 Minute ventilation

The breathing machine or metabolic simulator shall be capable of delivering the minute ventilation settings given in [Table 1](#), using a sinusoidal waveform.

Table 1 — Breathing machine/metabolic simulator minute ventilation settings

Minute ventilation settings l/min (BTPS)	Tidal volume l (BTPS)	Breathing frequency Breathing cycles/min
(10 ± 0,3)	1	10
(20 ± 0,4)	1,0	20
(30 ± 0,6)	1,5	20
(35 ± 0,7)	1,5	23,3
(40 ± 0,8)	2	20
(50 ± 1,0)	2	25
(65 ± 1,3)	2	32,5
(85 ± 1,7)	2,5	34
(105 ± 1,1)	2,5	42
(135 ± 1,4)	3	45

4.5.3 Ventilation setting switching

The breathing machine or metabolic simulator shall be capable of switching from one ventilation setting to another in less than 60 s. It is permissible to stop the device once during the switching process from one setting to another.

4.5.4 Output characteristics

The breathing machine or metabolic simulator shall display output characteristics which are within the specified values of the work of breathing diagram in ISO 16900-12:2016, Table 1, when the appropriate RPD verification tool is attached to the RPD head form assembly or trachea tube assembly. A pressure-volume diagram is generated by plotting pressure versus the change in volume during a breathing cycle. The area of the diagram is proportional to the work of breathing (WOB); see ISO 16900-12.

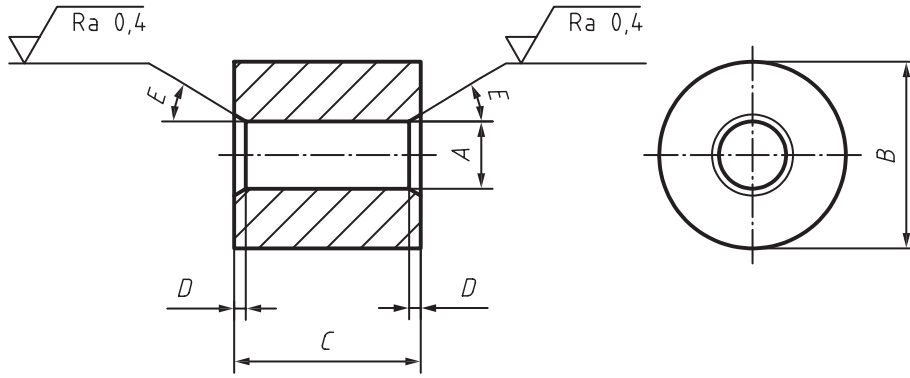
4.6 RPD verification tools

4.6.1 General

The RPD verification tools shall be used to demonstrate, through verification tests, that the performance of the laboratory test equipment/procedure is within the specified limits, as defined by the relevant test method standards.

4.6.2 Verification orifices

The output performance of breathing machine and metabolic simulator assemblies, when connected to a trachea tube assembly, shall be verified using standardized verification orifices to generate pressure-volume diagrams (see ISO 16900-12). The dimensions and construction of the two standardized orifices, orifice A and orifice B, are shown in [Figure 12](#). The verification orifices shall be made from stainless steel. The surfaces of the bore and the chamfer at the openings shall each have roughness average of 0,4 µm, i.e. be polished.



Dimension	Orifice A	Orifice B
A	$(9,53 \pm 0,03)$ mm	$(12,8^{+0,05}_0)$ mm
B		$(25,4 \pm 0,2)$ mm
C		$(25,4 \pm 0,2)$ mm
D	$(1,5 \pm 0,1)$ mm	$(2,0 \pm 0,1)$ mm
E		$(30 \pm 1)^\circ$

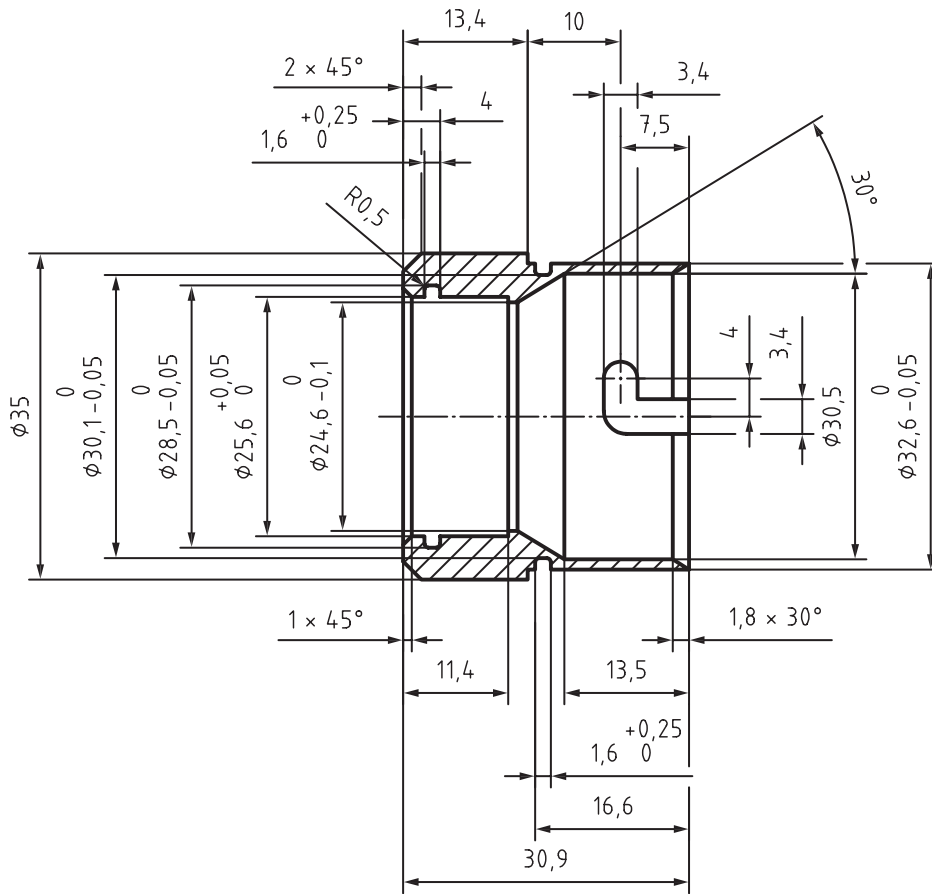
Figure 12 — Dimension markers for the verification orifices

4.6.3 Verification orifice adapter

The verification orifice adapter shown in [Figures 13](#) and [14](#) shall be used to attach, in a pre-set position, the verification orifices specified in [Figure 12](#) to the RPD head form assembly or trachea tube assembly in order to conduct the work of breathing verification tests specified in [4.6.4](#).

[Figure 13](#) shows the geometry and dimensions of the verification orifice adapter that is used to connect the orifices to the RPD head form assembly or trachea tube assembly. [Figure 14](#) shows an example of the RPD head form assembly with the verification orifice inserted into the verification orifice adapter.

Dimensions in millimetres



a) Production drawing

b) 3D view showing O-rings

O-ring sizes: 0251-16
0291-16

NOTE Tolerances in accordance with ISO 2768-m.

Figure 13 — Verification orifice adapter

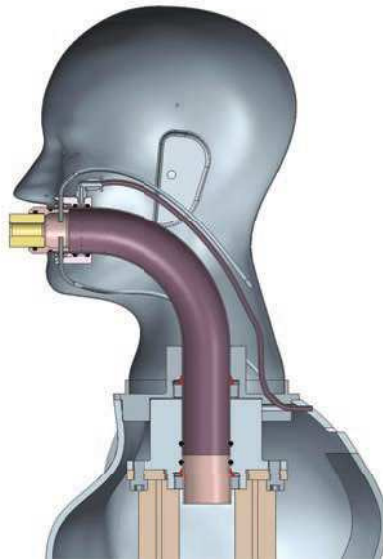


Figure 14 — Example of RPD head form 5 assembly and verification orifice inserted into the verification orifice adapter and positioned in trachea tube assembly opening

4.6.4 Verification procedure for work of breathing

The procedure for verifying the output characteristics of a breathing machine or metabolic simulator is as follows.

- Connect the breathing machine or metabolic simulator assembly to the trachea assembly.

NOTE Generally, the trachea assembly will be fitted inside an RPD head form, but the verification procedure can be conducted using the trachea assembly on its own without an RPD head form.
- Select the appropriate size of verification orifice for the range of the minute volumes under test (see ISO 16900-12:2016, Table 1) and insert the verification orifice into the verification orifice adapter, ensuring it is located on the positioning ridge in the adapter. Note that the higher minute volume settings will require the use of the larger verification orifice and vice versa.
- Insert the verification orifice adapter into the trachea tube assembly and firmly secure the bayonet connectors to the sampling port tubes.
- Start the breathing machine/metabolic simulator and conduct the work of breathing procedure given in ISO 16900-12 for the range of minute volume settings appropriate to the size of verification orifice selected.
- Calculate the work of breathing for each minute volume setting. The breathing machine/metabolic simulator assembly output is acceptable if the calculated work of breathing values are within the tolerance range for each setting given in ISO 16900-12:2016, Table 1.

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 results given in ISO 16900-12:2016, 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;

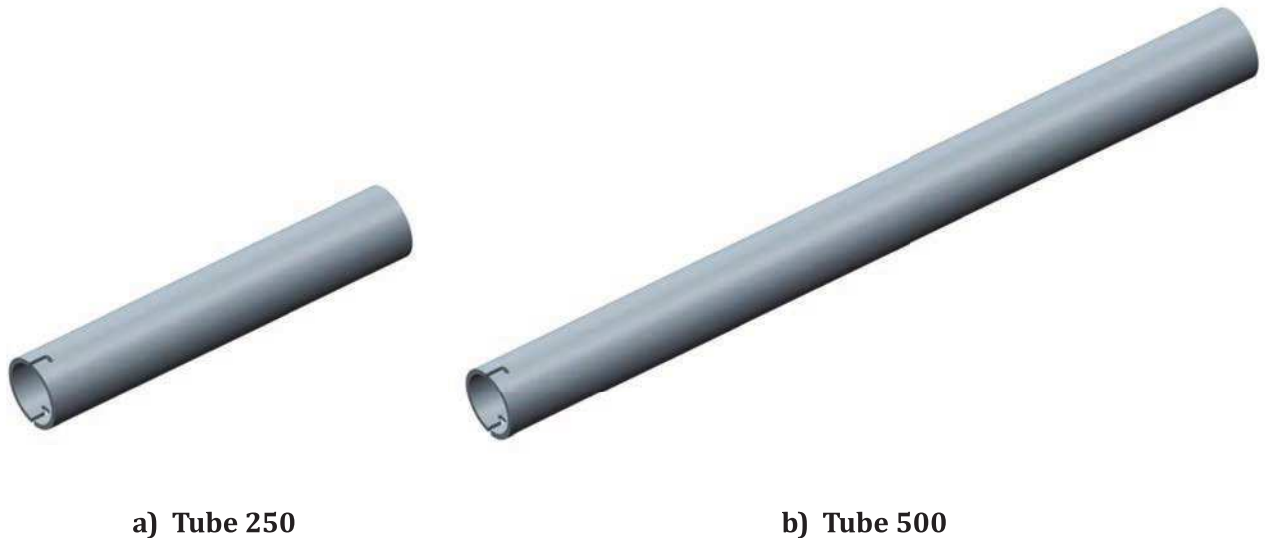
- incorrect waveform (not sinusoidal);
- incorrect calculations.

4.6.5 RPD carbon dioxide verification tube and verification tube adapter

The output characteristics of test systems for measuring the average carbon dioxide content of inhaled air (see ISO 16900-9) can be verified using the carbon dioxide verification tubes and carbon dioxide verification tube adapter. The verification procedure follows that described in ISO 16900-9:2015, Annex B.

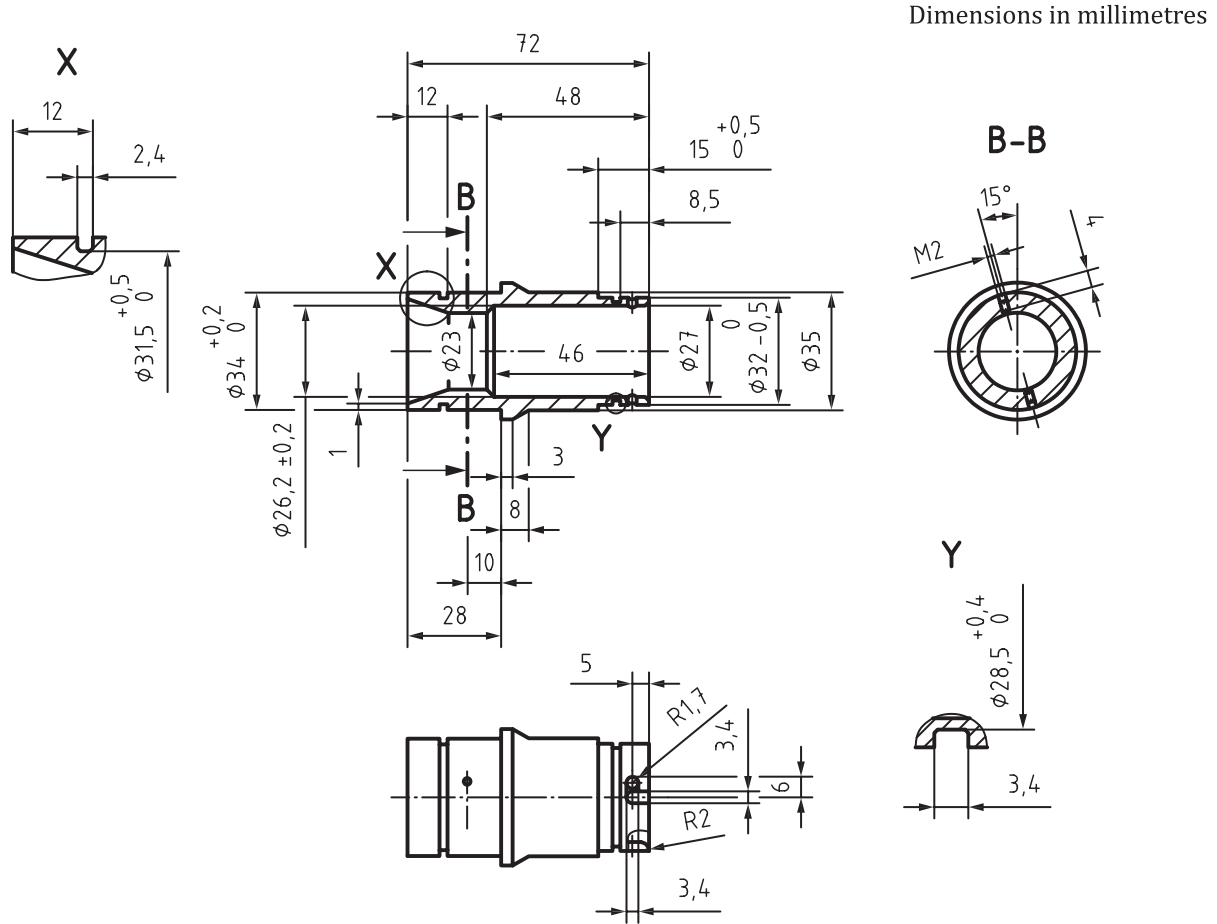
The carbon dioxide verification tubes [Figure 15 a) and b)] are attached to the carbon dioxide verification tube adapter (Figure 16), which connects to the trachea tube assembly using the bayonet connectors (Figure 17).

The two verification volumes are (250 ± 50) ml and (500 ± 50) ml. The accuracy of the verification procedure depends on knowing precisely the actual volume of the verification tube plus verification tube adapter (Figure 16) used for the test. Water displacement has been shown to be a suitable method for the precise determination of this volume.



NOTE Internal diameter is 35 mm. Length depends on volume calculation.

Figure 15 — RPD carbon dioxide verification tubes



NOTE Tolerances in accordance with ISO 2768-m.

Figure 16 — RPD carbon dioxide verification tube adapter — Production drawing

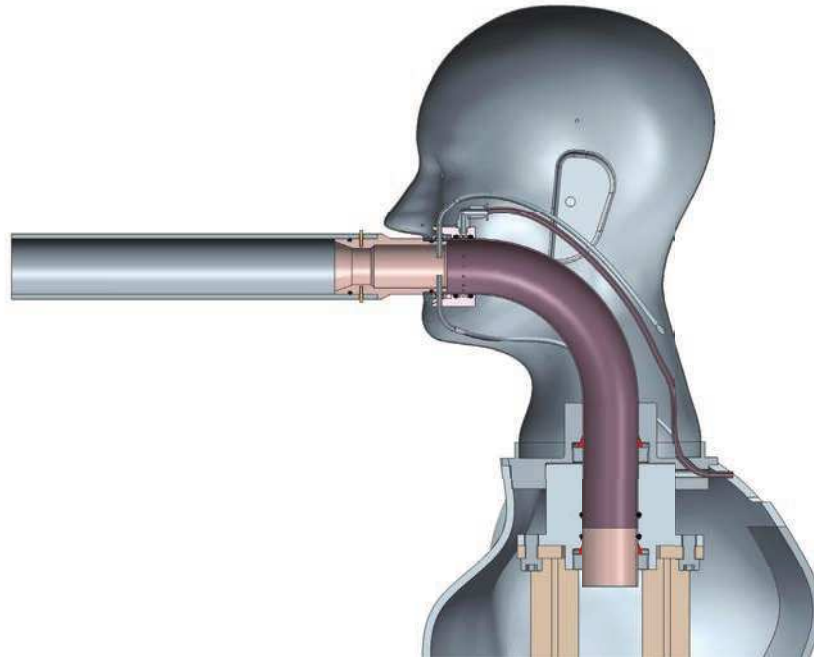


Figure 17 — Example of RPD head form 5 assembly with carbon dioxide verification tube inserted into the verification tube adapter and positioned in trachea tube opening

4.7 RPD tools

4.7.1 Filter simulator

The filter simulator is used for testing requirements given in the performance standards where the respiratory interface (RI) contains a standardized connector. The specific tests used are described in the relevant parts of ISO 16900.

The filter simulator shall have the following attributes:

- overall length: 120^{+3}_0 mm including thread, excluding inlet connection;
- diameter: 120^{+3}_0 mm;
- position of centre of gravity: (45 ± 5) mm from end of thread opening;
- thread form: ISO 17420-3;
- weight: (500 ± 5) g;
- airflow resistance: $(1\,000 \pm 20)$ Pa at (110 ± 3) l/min;
- inlet connection: capable of accepting lightweight fresh air hose;
- maintenance: easy to clean;
- leak tightness: shall be leak tight such that the decay in vacuum or overpressure is not more than 0,1 kPa in 1 min from 2,0 kPa overpressure or vacuum;
- materials of construction: resistant to corrosion.

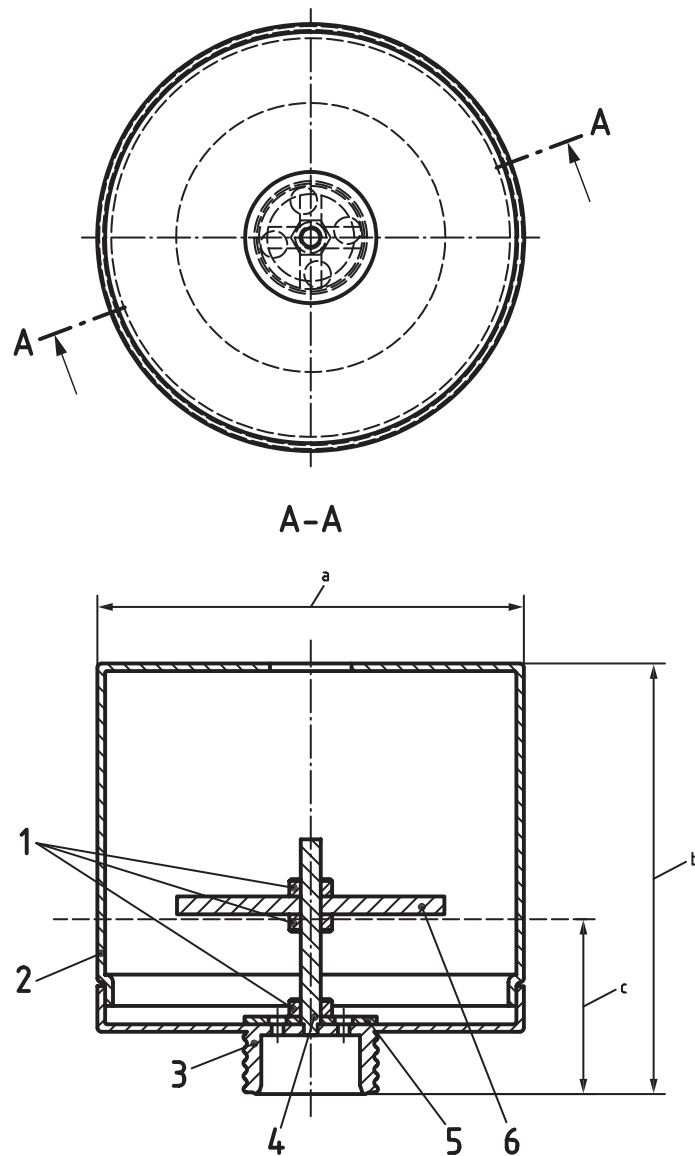
A schematic representation of the filter simulator is shown in [Figure 18](#). The exploded view of the filter simulator assembly is shown in [Figure 19](#). Production drawings of the individual parts are as follows:

- body with thread ([Figure 20](#));
- centre weight ([Figure 21](#));
- pressure drop adjustment plate ([Figure 22](#));
- threaded rod ([Figure 23](#)).

The centre weight can be adjusted in height on the threaded rod to allow the centre of gravity of the filter simulator to be at 45 mm from the thread opening (see [Figure 18 c](#)).

The pressure drop adjustment plate ([Figures 18, 19 and 22](#)) allows adjustment of the pressure drop to achieve the specified airflow resistance. The plate is turned to increase or reduce the cross-section area of the outlet to adjust airflow resistance.

Dimensions in millimetres

**Key**

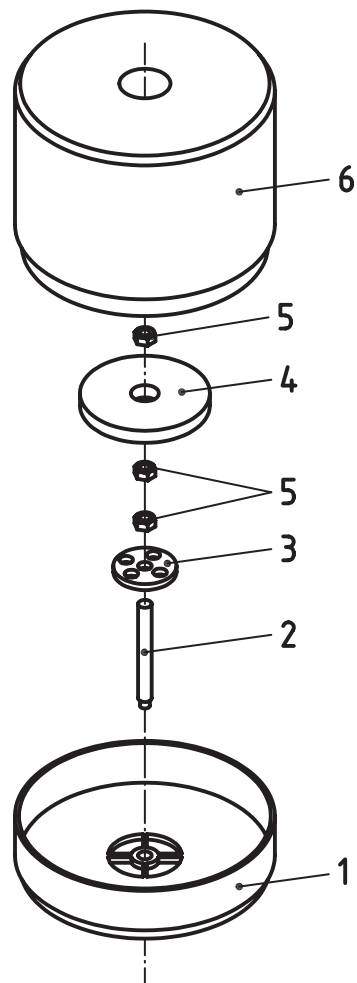
- 1 hex nut M5 to lock centre weight and flow restrictor
- 2 lid is interference fit to body for retention
- 3 body with outlet thread according to ISO 17420-3
- 4 threaded rod press fit to body
- 5 pressure drop adjustment plate
- 6 centre weight for positioning centre of gravity

a Diameter ($120^{+0,3}_0$) mm.

b Overall length including thread ($120^{+0,3}_0$) mm.

c Centre of gravity (45 ± 5) mm.

Figure 18 — Schematic representation of the filter simulator

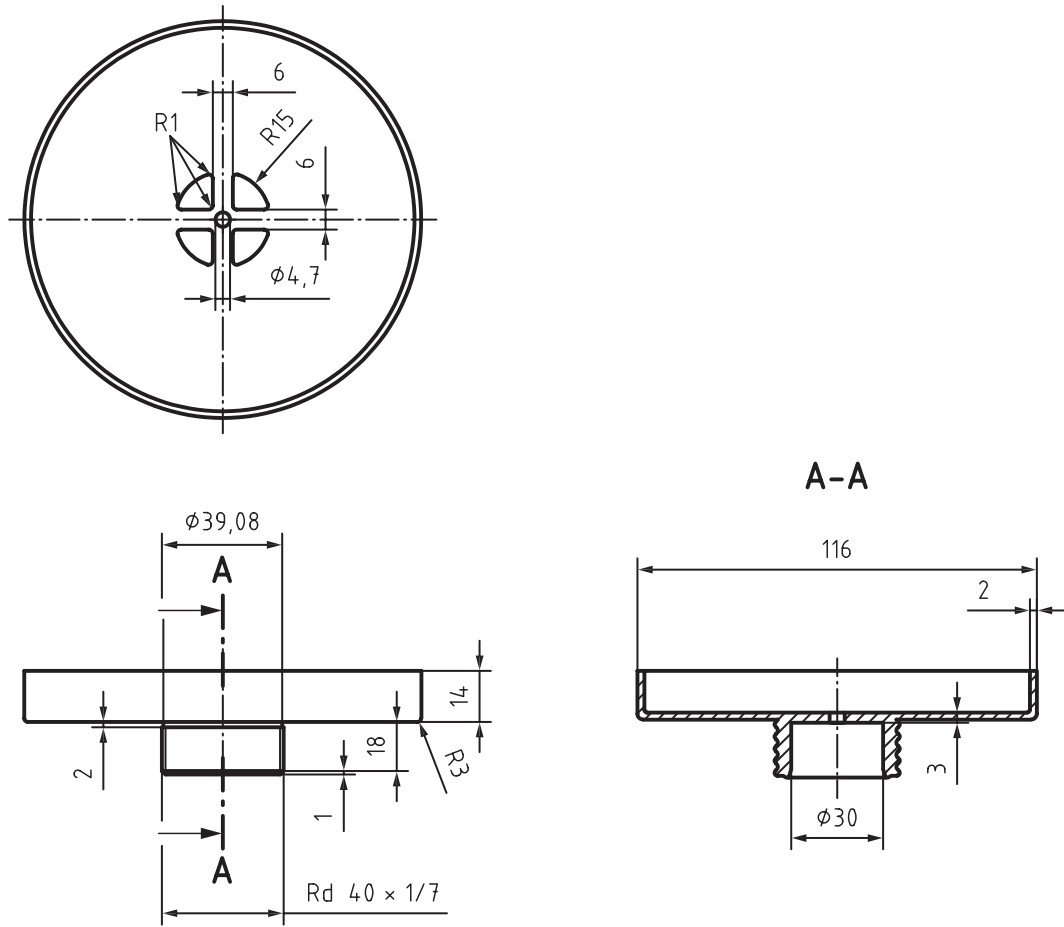


Key

- 1 body with thread in accordance with ISO 17420-3
- 2 threaded rod
- 3 pressure drop adjustment plate
- 4 centre weight for positioning centre of gravity
- 5 hex nut M5
- 6 lid

Figure 19 — Exploded view of the filter simulator assembly

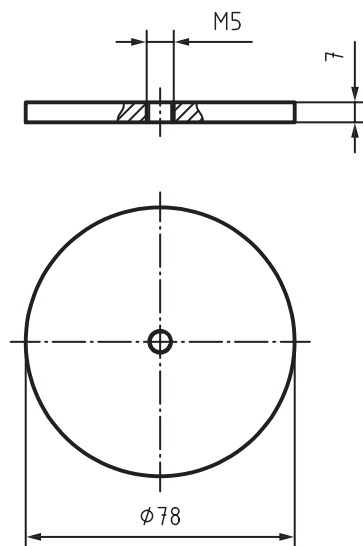
Dimensions in millimetres



NOTE Tolerances in accordance with ISO 2768-m.

Figure 20 — Filter simulator production drawing — Body with outlet thread

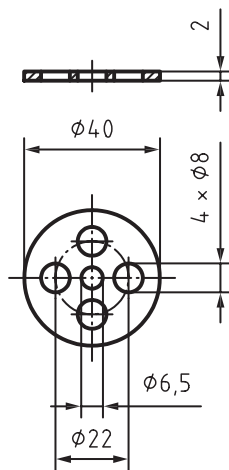
Dimensions in millimetres



NOTE Tolerances in accordance with ISO 2768-m.

Figure 21 — Filter simulator production drawing — Centre weight

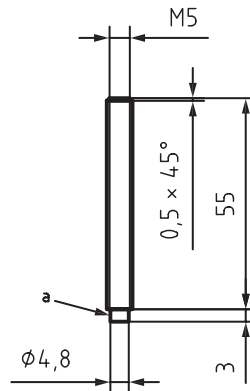
Dimensions in millimetres



NOTE Tolerances in accordance with ISO 2768-m.

Figure 22 — Filter simulator production drawing — Pressure drop adjustment plate

Dimensions in millimetres

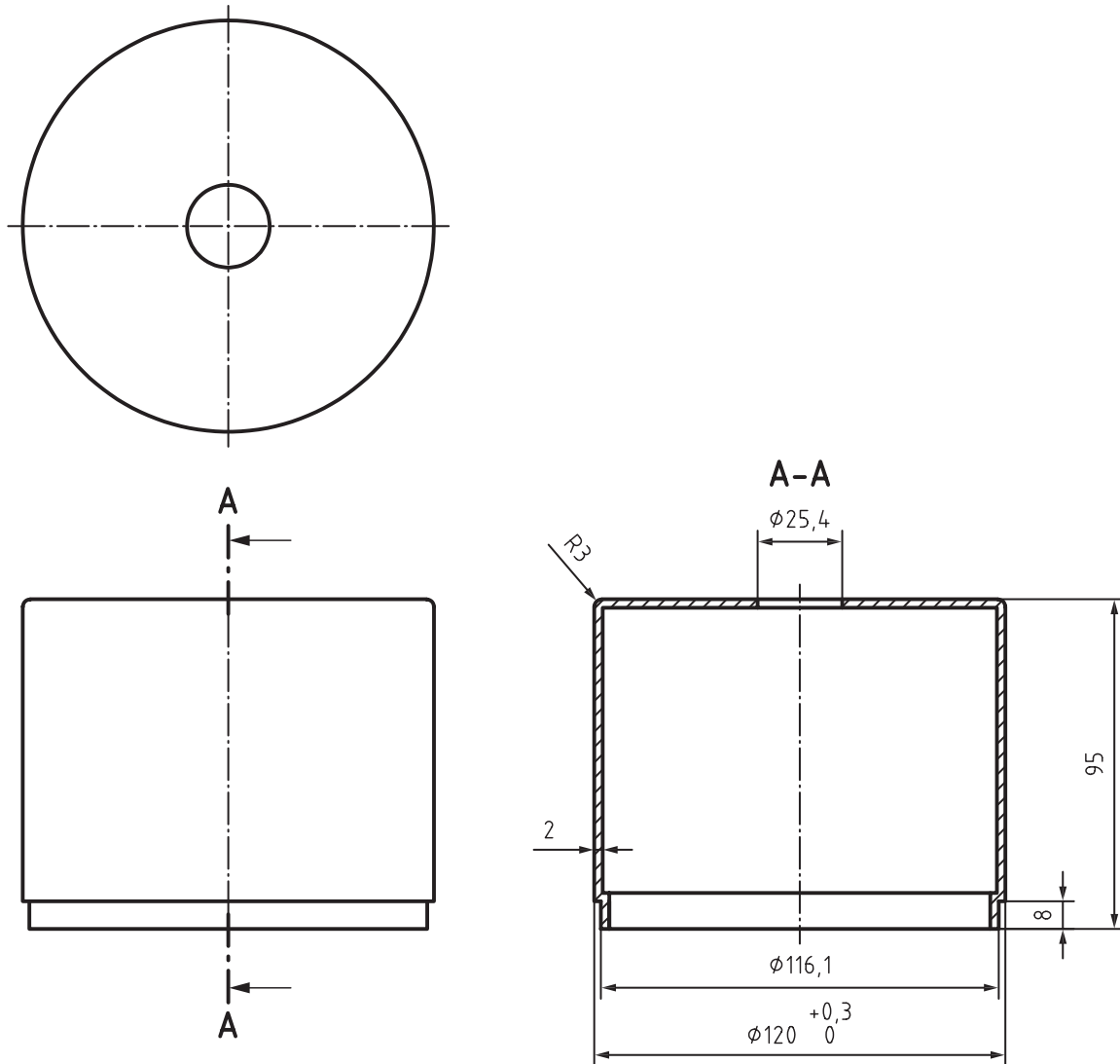
**Key**

a Machined end for press fit into body.

NOTE Tolerances in accordance with ISO 2768-m.

Figure 23 — Filter simulator production drawing — Threaded rod

Dimensions in millimetres



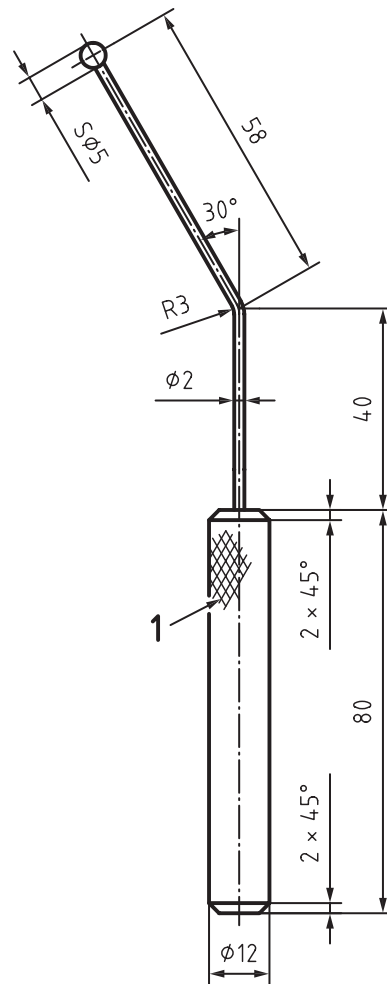
NOTE Tolerances in accordance with ISO 2768-m.

Figure 24 — Filter simulator production drawing — Lid

4.7.2 F_x force probe

The F_x force probe as shown in [Figure 25](#) is used, as described in ISO 16900-6, to assess whether a given part or component of an RI of an RPD needs to be subjected to a mechanical strength test. This probe is not to be used to stress the RPD by loading any force on it.

Dimensions in millimetres

**Key**

1 surface, corrugated at the discretion of the manufacturer

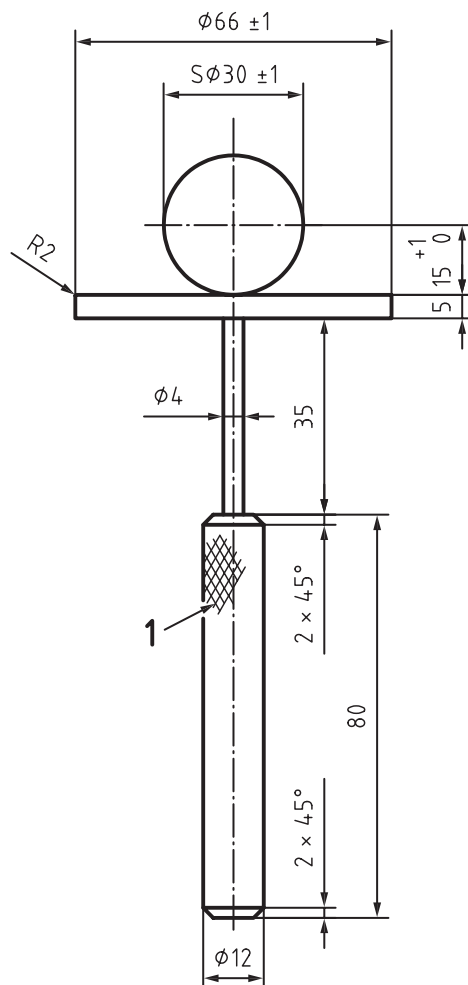
NOTE Tolerances in accordance with ISO 2768-m.

Figure 25 — F_x force probe

4.7.3 Exposed surface identification probe

The exposed surface identification probe as shown in [Figure 26](#) is used, as described in ISO 16900-6, to assess whether a part of an RPD is considered to be exposed and is therefore subject to the avoidance of frictional sparks requirements of the performance standards.

Dimensions in millimetres



Key

1 surface, corrugated at the discretion of the manufacturer

NOTE Tolerances in accordance with ISO 2768-m.

Figure 26 — Exposed surface identification probe

Annex A

(informative)

Dynamic procedure for leak testing of breathing machines and metabolic simulators

A.1 General

Leak detection procedures conducted without cycling the breathing machine or metabolic simulator do not provide a complete analysis of the system as it is used for equipment evaluation. The following dynamic procedure evaluates a breathing machine or metabolic simulator assembly as a complete unit.

A.2 Background

The need exists to verify the integrity of any breathing machine or metabolic simulator assembly. Depending on the design, the mechanism used to seal the device will degrade with age and use. This procedure will evaluate total system leakage. Subsequent testing may be required to eliminate any other possible source for a loss of pressure prior to assessing the remainder of the leakage to the piston or diaphragm seal.

Breathing machines and metabolic simulators in general circulate against a relatively low pressure, typically less than 2 kPa to 3 kPa. This amount of pressure is above the limit well tolerated by human physiology and should be at the limit of what a typical RPD under test could be expected to perform.

A.3 Equipment and configuration

A volume measuring device is required to detect loss of the contained gas while allowing for cyclic simulated respiration. In the example, the same unit is used to apply pressure to the system and record a change in system volume.

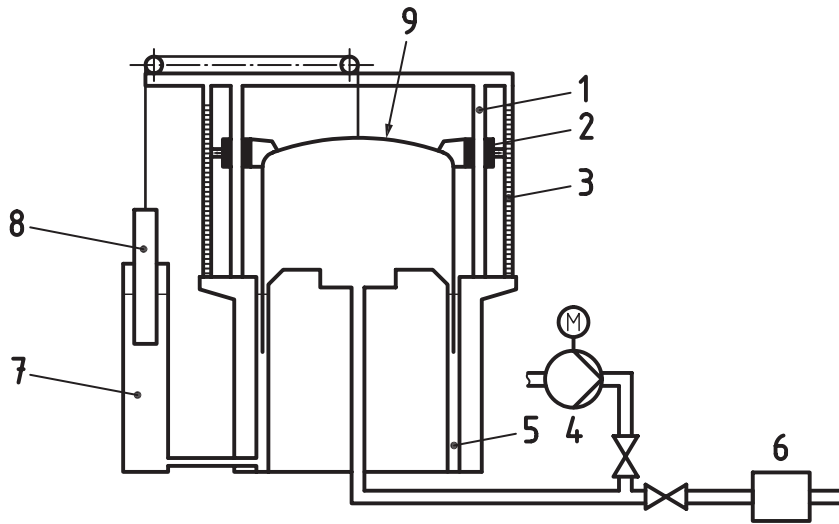
The starting and ending position of the breathing machine's or metabolic simulator's motion needs to be defined. This "home position" is established as the beginning and end point for the dynamic breathing test. A method of counting a given number of cycles (at least 100) is required. Stepper motor drives accomplish this with an accurate pulse count feedback. A touch switch in analog systems is acceptable, if an adequate braking system for the motor is employed. Top-dead-centre on rotary-cam type machines is adequately definable as well.

The breathing machine or metabolic simulator is sealed to the measuring device. There should be an adequate volume of air held within the measuring device to accommodate the start of respiration irrespective of the starting position within the breathing cycle. The system is then pressurized by adding weight to the bell or removing weight from the counter weight system. Continuous monitoring of breathing loop pressure through the use of the pressure sampling port in the trachea tube assembly will ensure consistent testing for wear and leakage.

A.4 Example

The following method employs a chain compensated Bell Prover¹⁾ (see [Figure A.1](#)). This volume measuring device is balanced and compensates for buoyancy of water by weight of the chain as it passes over the pulley. The Bell Prover, in its normal configuration, exhibits minimal weight/pressure on the gas collected.

Water vapour compensation is not included in these calculations. The effect is minimal in a thermally balanced system. Equal and stable temperature conditions are required for the machinery, water bath and breathing media.



Key

- | | | | |
|---|---------------------------|---|-------------------|
| 1 | guiding shaft | 6 | device under test |
| 2 | longitudinal ball bearing | 7 | reservoir |
| 3 | volume scale | 8 | counter weight |
| 4 | air blower | 9 | bell |
| 5 | sealing liquid | | |

Figure A.1 — Typical chain compensated gasometer

A.5 Procedure

The procedure for assessing leakage is as follows (see Reference [3] for further information).

- Drain a portion of the liquid contained in the reservoir to avoid overflow when the bell (see [Figure A.1](#), key 9) is pressurized.
- Apply pressure gradually to attain $(2,5 \pm 0,5)$ kPa using the air blower (see [Figure A.1](#), key 4) or equivalent mechanism.
- Position the breathing machine or metabolic simulator at the “home position”.

1) Bell Prover, a 120-litre chain compensated gasometer manufactured by Warren E. Collins, Inc., is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product. Equivalent products may be used if they can be shown to lead to the same results.

- Record the start value on the volume scale (see [Figure A.1](#), key 3).
- Start the required number of breathing cycles (at least 100).

A slow cycle rate should be used so as to minimize inertia effects on the Bell Prover's water reservoir. Ten cycles per minute has been proven to be sensitive enough to monitor piston seal degradation. Use of a mechanical or digital stroke counter is recommended. The tidal volume selected for the evaluation should be one of the standard ventilation rate settings.

- Stop the breathing machine/metabolic simulator at the required number of complete cycles.
- Record the end value on the volume scale.

The leak volume is the difference between the end volume and the start volume. The percentage leak can be calculated by dividing the leaked volume by the total volume breathed. For example, if the leaked volume was 0,3 l after breathing 100 breaths with a tidal volume of 3 l, the leak would $0,3 / (3 \times 100) = 0,1 \%$.

A.6 Acceptable leakage limit

A loss of less than 0,5 % of the total volume moved demonstrates an acceptable integrity of the breathing machine.

Bibliography

- [1] ISO 1302, *Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation*
- [2] ISO 16900-6, *Respiratory protective devices — Methods of test and test equipment — Part 6: Mechanical resistance/strength of components and connections*
- [3] CAD file for the RPD head forms, available at ISO Livelink
- [4] PEEBLES L., & NORRIS B. *ADULTDATA: the Handbook of Adult Anthropometric and Strength Measurement*. Institute for Occupational Ergonomics, Department of Manufacturing Engineering and Operation Management, University of Nottingham, Nottingham, UK, 1998
- [5] NIST Special Publication 250-49: Calibration Services for Gas Flow Meters Piston Prover and Bell Prover Gas Flow Facilities August 1998

