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**Anaesthetic vaporizers — Agent-specific filling systems**

*Évaporateurs d'anesthésie — Systèmes de remplissage spécifiques à l'agent*



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## Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://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](http://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 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 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This fourth edition cancels and replaces the third edition (ISO 5360:2012), of which it constitutes a minor revision with the following changes:

- [Figure 5](#) has been technically revised;
- minor editorial modifications have been incorporated into the text.

# Anaesthetic vaporizers — Agent-specific filling systems

## 1 Scope

This International Standard specifies requirements, including dimensions, for agent-specific filling systems for agent-specific anaesthetic vaporizers.

This International Standard does not specify construction materials.

NOTE 1 For recommendations on materials, see [Annex A](#).

Because of the unique properties of desflurane, dimensions for this agent have not been specified in this International Standard.

NOTE 2 Designs of connection systems, which only permit engagement of the agent-specific bottle adaptor to the bottle when the bottle collar is in place, are encouraged.

## 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 1101, *Geometrical Product Specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 3.1

#### **agent-specific**

having both a prescribed configuration and prescribed dimensions, which are specific for a prescribed liquid anaesthetic agent

### 3.2

#### **agent-specific filling system**

functional system of *agent-specific* (3.1) coded connections between an anaesthetic bottle and an *agent-specific* (3.1) anaesthetic vaporizer (3.3), consisting of, for example, a threaded *bottle neck* (3.7) with collar, *bottle connector* (3.6), *male adaptor* (3.9), and *filler receptacle* (3.8)

Note 1 to entry: Different types of agent-specific filling systems are shown in [Annex B](#).

### 3.3

#### **anaesthetic vaporizer**

device designed to facilitate the change of an anaesthetic agent from a liquid to a vapour

### 3.4

#### **bottle adaptor**

assembly that is intended to connect a bottle for liquid anaesthetic agent to an *agent-specific* (3.1) anaesthetic vaporizer (3.3)

### 3.5

#### **bottle collar**

*agent-specific* (3.1) component on the neck of a bottle causing it to be *agent-specific* (3.1)

**3.6  
bottle connector**

*agent-specific (3.1) component that fits the thread on the bottle neck (3.7) and mates with the agent-specific (3.1) bottle collar (3.5)*

**3.7  
bottle neck**

*external threaded part of the bottle and the adjacent contour over which an agent-specific (3.1) collar is fitted*

**3.8  
filler receptacle**

*receptacle for a bottle or a bottle adaptor (3.4) on an agent-specific (3.1) anaesthetic vaporizer (3.3)*

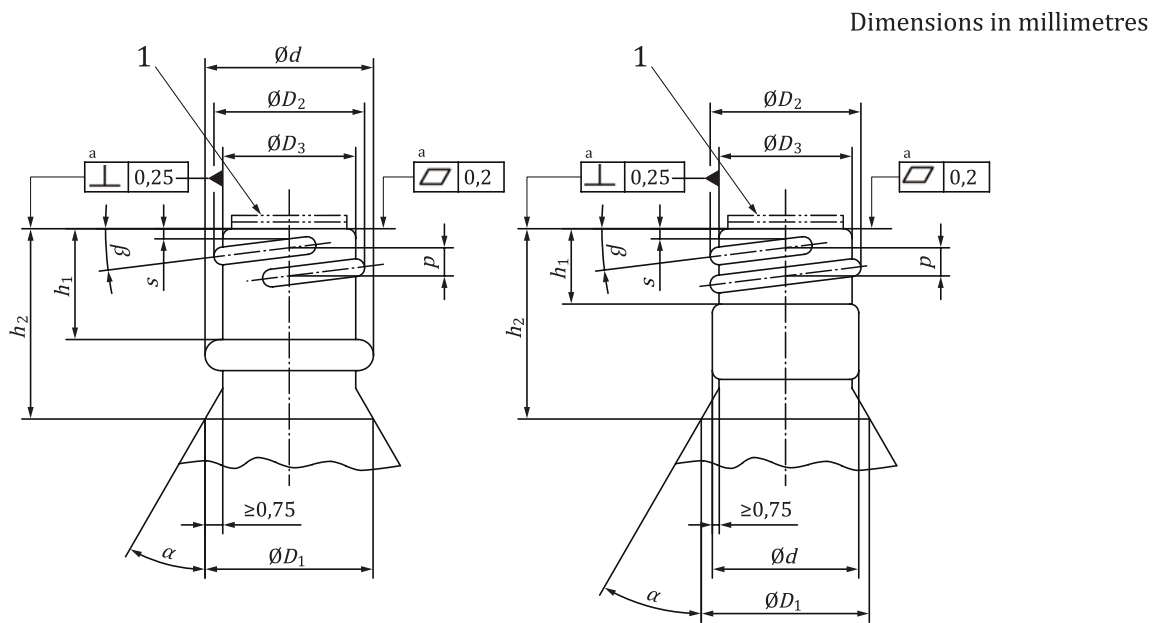
**3.9  
male adaptor**

*part of a bottle adaptor (3.4) that mates with a filler receptacle (3.8) on an agent-specific (3.1) vaporizer*

**4 Bottle**

Each bottle shall have the following:

- a) name of the anaesthetic agent with which it is intended to be used marked on it;
- b) either a bottle collar complying with [Clause 5](#) and a threaded neck complying with [Figure 1](#) and [Table 1](#), or a permanently attached bottle adaptor complying with [6.2](#).



**Key**

- 1 optional pouring lip (dimension not specified)
- a Flatness and perpendicularity tolerances in accordance with ISO 1101.

NOTE The dimensions shown form part of this International Standard. Other features are for illustrative purposes only. See [Table 1](#).

**Figure 1 — Two examples of threaded necks of bottles for anaesthetic agents**

**Table 1 — Dimensions of threaded necks of bottles for anaesthetic agents**

Bottle type	Anaesthetic agent	$h_1$ $\pm 0,3$ mm	$h_2^a$ min. mm	$s$ $\pm 0,45$ mm	$\beta$	$\alpha$ min. at $\varnothing D_1$	$p$ mm	Thread turns min.	$D_1^a$ nom. mm	$D_2^b$ $\pm 0,3$ mm	$D_3^b$ $\pm 0,3$ mm	$d$ max. mm
1	Isoflurane Enflurane	9,75	23	1,2	2° 35'	30°	3,2	1	28	23,6	21,5	28
2	Halothane	6,8	18,7	1,2	2° 15'	30°	2,54	1,25	24	21,45	19,7	28
3	Halothane (USA)	15	26,3	1	2° 50'	30°	3,2	1,75	24	21,7	19,5	28
4	Spare	9,05	20	1,15	3° 30'	30°	3,2	1,25	20	17,65	15,5	28
5	Spare	9,05	20	1,15	3° 7'	30°	3,2	1,25	22	19,65	17,5	28
6	Methoxy- flurane	9,8	20	1,15	2° 57'	30°	4,25	1,25	30	27,3	24,9	32
7	Spare	9,85	20	1,15	2° 31'	30°	4,25	1,25	34	31,8	29,4	32
8	Sevoflurane	8,9	23,9	1,3	2° 56'	30°	3,63	1,25	23,9	23,5	21,5	28

NOTE See [Figure 1](#).

<sup>a</sup> Recommended values.

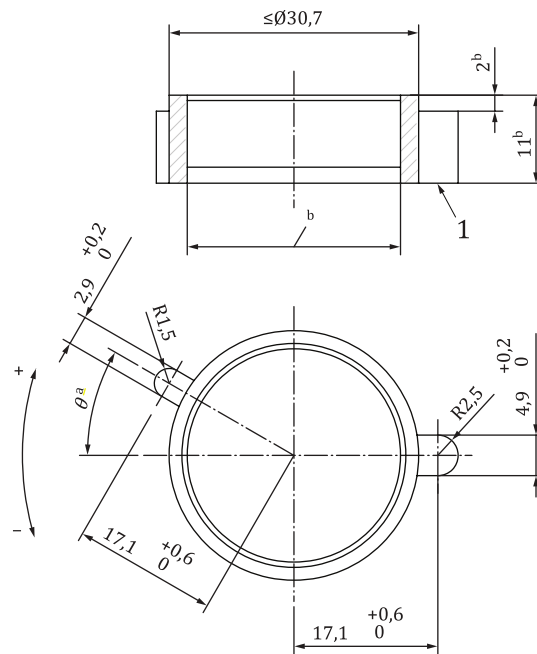
<sup>b</sup> Summation of the tolerances of measures  $D_2$  and  $D_3$  shall be avoided. A maximum tolerance of  $\pm 0,3$  mm for  $(D_2 - D_3)$  should be required to avoid problems with the fitting of any bottle connector.

## 5 Bottle collar

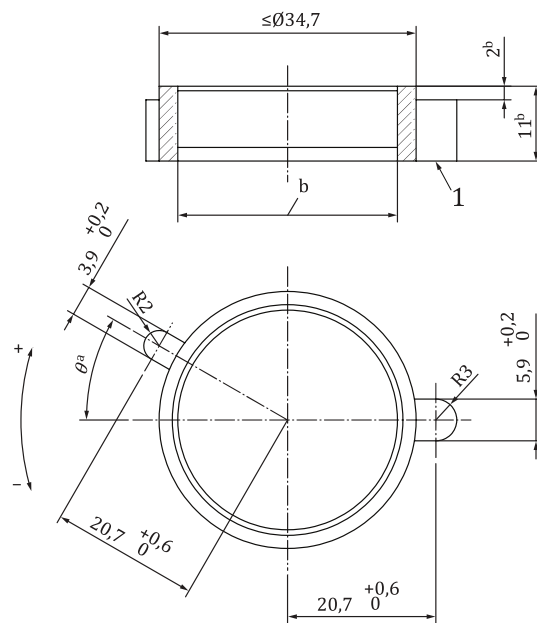
**5.1** Bottle collars shall comply with the configuration and dimensions shown in [Figure 2](#) and angle,  $\theta$ , specified in [Table 2](#) for the anaesthetic agent with which it is intended to be used.

**5.2** The position of the bottle collar relative to the screw thread of the bottle shall be as shown in [Figure 3](#).

**5.3** The bottle collar shall be attached to the bottle and shall be rotatable by hand.



a) Bottle collar for small bottles, i.e. types 1 to 5 and 8



b) Bottle collar for large bottles, i.e. types 6 and 7

**Key**

- 1 face A
- a See [Table 2](#).
- b May vary to suit bottle.

**Figure 2 — Configuration of agent-specific bottle collars**

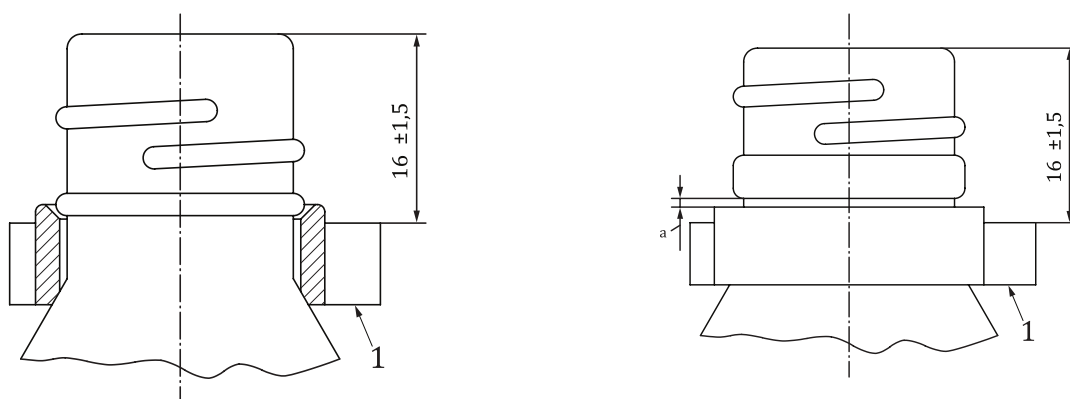


**Table 2 — Dimensions and colours of agent-specific bottle collars and connectors**

Anaesthetic agent	$\theta^a$ $\pm 0^\circ 30'$	Specified colour <sup>b</sup>	Example of colour samples					
			Federal Standard 595 colour <sup>[5]</sup>	BS 5252 colour <sup>[3]</sup>	Pantone colour <sup>[2]</sup>	SS 01 91 02 colour <sup>[9]</sup>	Munsell colour <sup>[6]</sup> <sup>c</sup>	DIN 6164-2 colour <sup>[4]</sup>
Halothane	-20°	Red	11 105	04 E 56	200 C	NCS S 1080 R	5R4/14	8:7:2
Enflurane	+20°	Orange	22 510	06 E 55	151 C	NCS S 0585-Y50R	2,5YR 6/16	5:5:1
Methoxy-flurane	0°	Green	14 187	14 E 53	334 C	NCS S 2060-B90G	10G 5/10	21:6:3
Desflurane	N.S. <sup>d</sup>	Blue	N/A <sup>e</sup>	18 E 53	3 015 C	NCS S 3060 B	10B 4/10	18:4:3
Not for agent identification		White	37 875	18 B 15	5 455 C	NCS S 0502-B	10B 9/1	N:0:0.5
Not for agent identification		Black	15 042	00 E 53	Process black C	NCS S 9000-N	N 0,5	N:0:9
Sevoflurane	+50°	Yellow	N/A <sup>e</sup>	10 E 53	108 C	NCS S 0570-Y	6,25Y 8,5/12	2:6:1
Isoflurane	-40°	Purple	N/A <sup>e</sup>	24 E 53	254 C	NCS S 3055-R50B	7,5P4/12	11:4:4
Spare		Grey	16 251	00 A 09	Cool grey 9 C	NCS S 5502 B	5PB 5/1	N:0:4

a The sign “+” means clockwise rotation and sign “-” means counter-clockwise rotation, when viewed from the top.  
 b If a colour is used on a vaporizer, bottle, or package label to facilitate correct identification, it is important that only the colour for the appropriate anaesthetic agent be used.  
 c Munsell colour is the original. Other colour systems show the nearest available colour sample.  
 d N.S. means not specified.  
 e N/A means not available.

Dimensions in millimetres



**a) Position without clearance between collar and transfer ring      b) Position with clearance between collar and transfer ring**

**Key**

- 1 face A (see [Figure 2](#))
- a Clearance to suit bottle.

**Figure 3 — Alternative positions of agent-specific bottle collar**

## 6 Bottle adaptor

**6.1** If the bottle adaptor is not permanently attached to the bottle or the vaporizer (see [Annex B](#)), it shall include an agent-specific bottle connector complying with the configuration and dimensions specified in [Figure 6](#) for the anaesthetic agent with which it is intended to be used. The bottle connector shall be designed so that the coding slots in the bottle connector engage with the bottle collar before a tight connection is obtained.

If an agent-specific male adaptor is used, it shall comply with the dimensions specified in [Figure 4](#) or [Figure 5](#) for the anaesthetic agent with which it is intended to be used.

**6.2** If the bottle adaptor is permanently attached to the bottle and an agent-specific male adaptor is used, the agent-specific male adaptor shall comply with the dimensions specified in [Figure 4](#) or [Figure 5](#) for the anaesthetic agent with which it is intended to be used.

**6.3** If the bottle adaptor is a permanent part of the vaporizer, it shall include an agent-specific bottle connector complying with the configuration and dimensions specified in [Figure 6](#) for the anaesthetic agent with which it is intended to be used. The bottle connector shall be designed so that the coding slots in the bottle connector engage with the bottle collar before a tight connection is obtained.

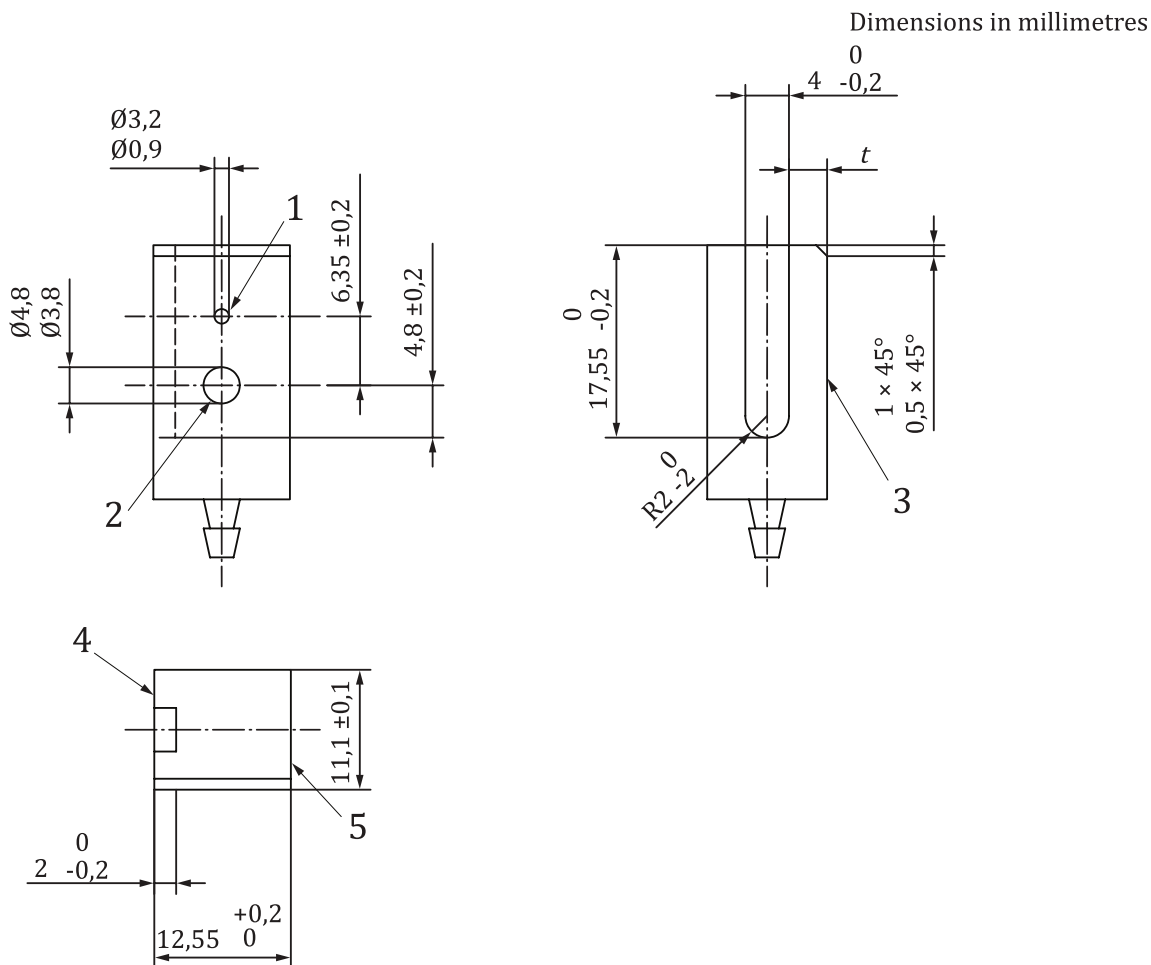
**6.4** Bottle adaptor threads shall be designed so that they

- a) ensure an engagement of at least 0,75 thread turns on a threaded neck [see [Clause 4 b](#)]) of an anaesthetic bottle, and
- b) withstand, without visible damage, a tightening torque of  $(3 \pm 0,3)$  N·m, when fitted to an appropriate bottle.

NOTE The intention of these requirements is to render the bottle adaptor unlikely to be accidentally displaced from the bottle during filling.

**6.5** If the bottle adaptor is permanently attached to the bottle (see [Annex B](#)) and an agent-specific male adaptor complying with the configuration shown in [Figure 4](#) or [Figure 5](#) is used, means shall be provided for sealing the liquid and air/vapour passages on the adaptor when it is not inserted into the filler receptacle.

**6.6** The bottle adaptor shall not break when dropped from a height of 1 m on to a hard surface.



**Key**

- |   |                 |   |        |
|---|-----------------|---|--------|
| 1 | air/vapour port | 4 | face A |
| 2 | liquid port     | 5 | face B |
| 3 | sealing face    |   |        |

NOTE 1 See also [Table 3](#).

NOTE 2 Port identification applies to filling procedure only.

**Figure 4 — Configuration and dimensions of agent-specific male adaptors for use with enflurane, methoxyflurane, and halothane**

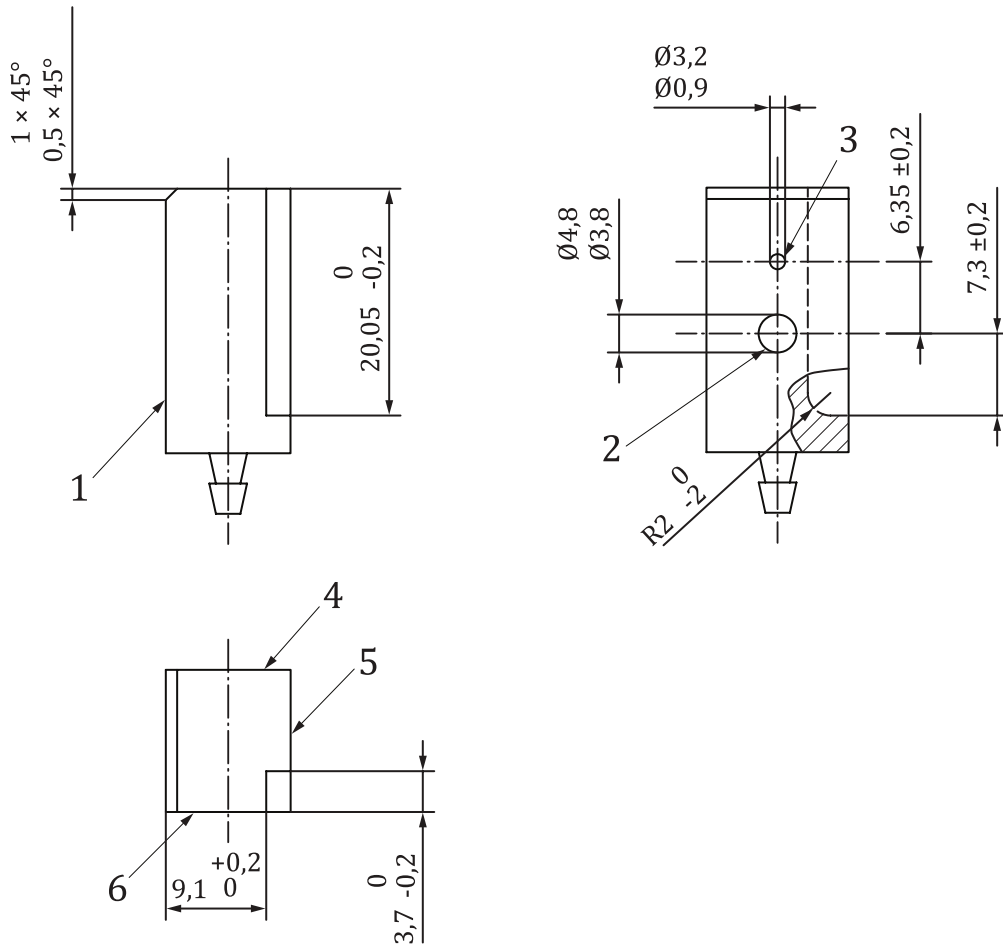
**Table 3 — Details of male adaptors for use with enflurane, methoxyflurane and halothane**

Anaesthetic agent	$t$ $+0,1$ $0$ mm	Slot in face
Enflurane	3,5	A
Methoxyflurane	7,5	B
Halothane	3,5	B
Spare	5,5	B
Spare	5,5	A

**Table 3 (continued)**

Anaesthetic agent	$t$ $+0,1$ $0$ mm	Slot in face
Spare	1,5	A
Spare	1,5	B

Dimensions in millimetres



**Key**

- |   |                 |   |        |
|---|-----------------|---|--------|
| 1 | sealing face    | 4 | face A |
| 2 | liquid port     | 5 | face C |
| 3 | air/vapour port | 6 | face B |

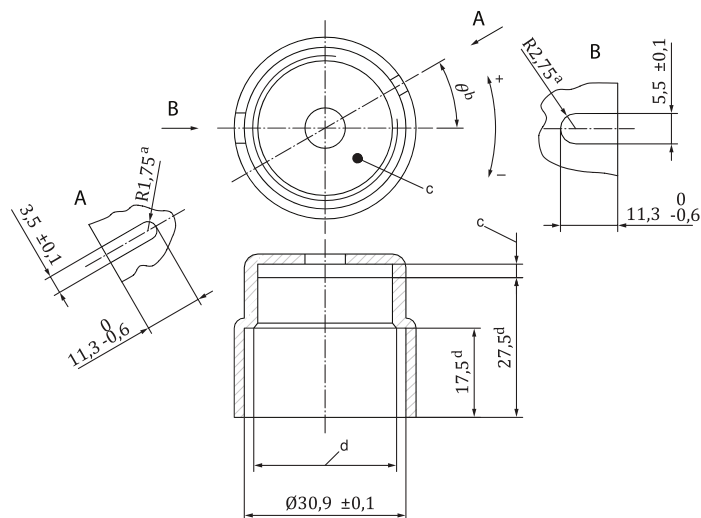
NOTE See [Table 4](#) and [Figure 4](#).

**Figure 5 — Configuration and dimensions of agent-specific male adaptors for use with isoflurane and sevoflurane**

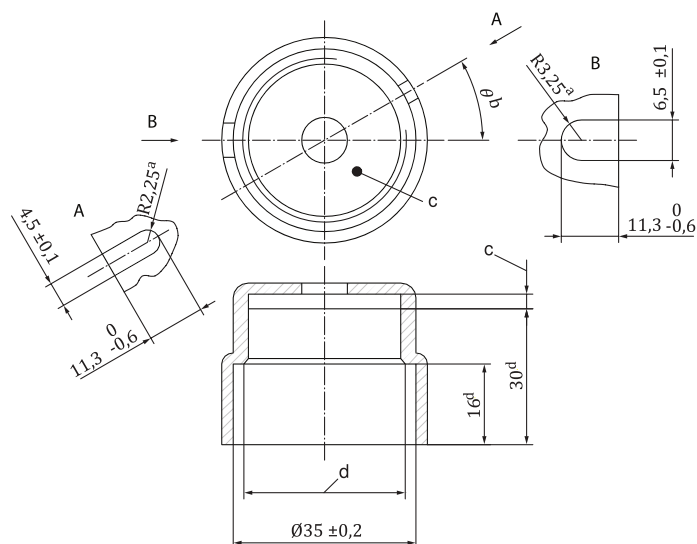
Table 4 — Details of male adaptors for use with isoflurane and sevoflurane

Anaesthetic agent	Slot position
Isoflurane	Faces A and C
Sevoflurane	Faces B and C

Dimensions in millimetres



a) Connector for small bottles i.e. types 1 to 5 and 8



b) Connector for large bottles i.e. types 6 and 7

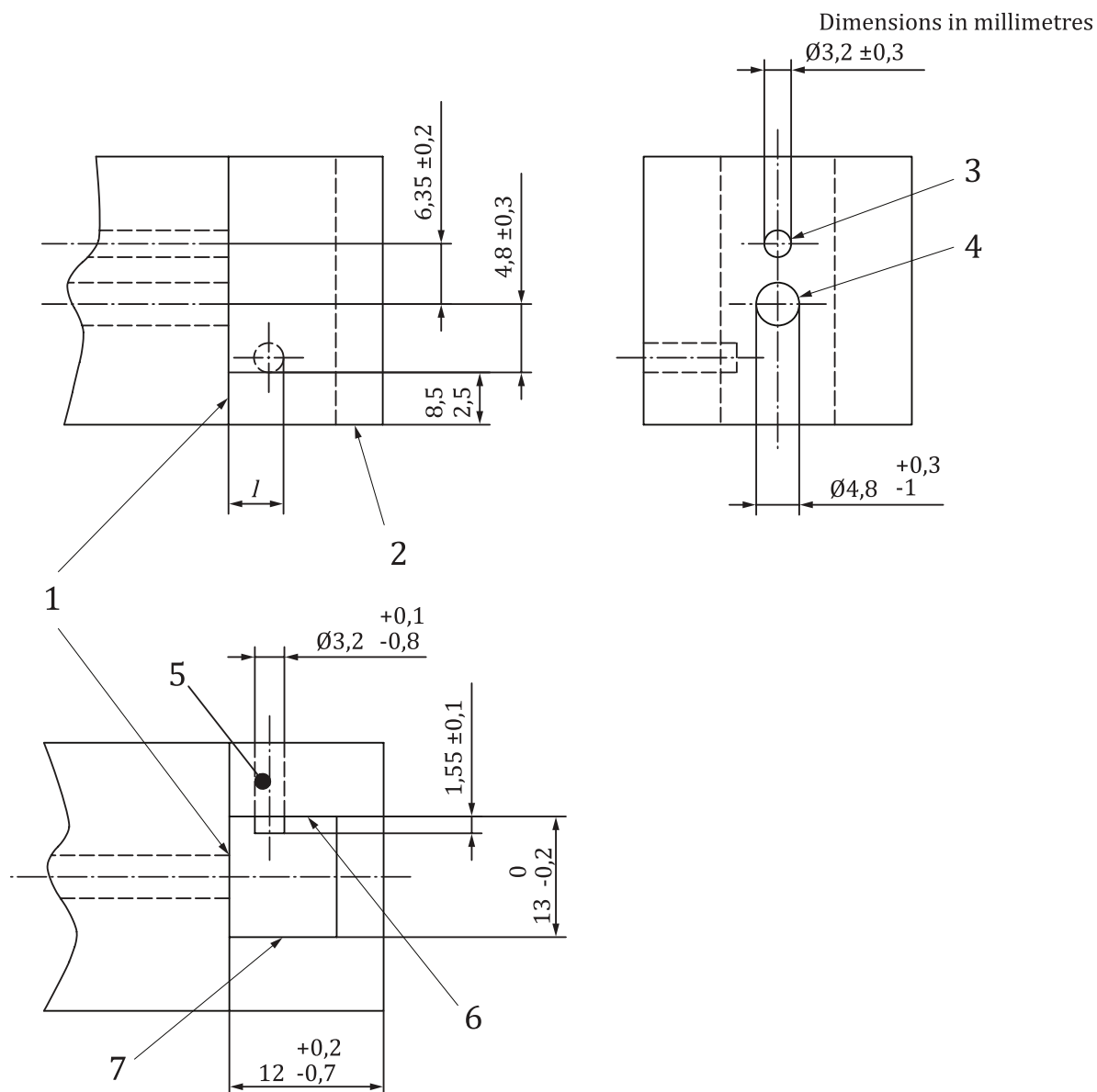
- a Square corners optional.
- b See [Table 2](#).
- c Space (dimension not specified) for sealing component.
- d May vary to suit bottle.

Figure 6 — Configuration and dimensions of agent-specific bottle connectors

## 7 Filler receptacle

7.1 The filler receptacle of the vaporizer shall

- a) comply with the configuration and dimensions shown in [Figure 7](#) or [Figure 8](#) for the anaesthetic agent with which it is intended to be used, and the design shall only permit the insertion of the agent-specific male adaptor complying with [6.1](#) or [6.2](#) into the front face of the filler receptacle as illustrated in [Figure 7](#) or [Figure 8](#), or
- b) comply with the configuration and dimensions of the bottle connector shown in [Figure 6](#) and angle,  $\theta$ , specified in [Table 2](#) for the anaesthetic agent with which it is intended to be used.

**Key**

- 1 sealing face, space (dimension not specified) for sealing component
- 2 front face
- 3 air/vapour port
- 4 liquid port
- 5 pin
- 6 face A
- 7 face B
- l* dimension according to Table 5

NOTE 1 See also [Table 5](#).

NOTE 2 Port identification applies to filling procedure only.

**Figure 7 — Configuration and dimensions of agent-specific filler receptacles for use with enflurane, methoxyflurane and halothane**

**Table 5 — Details of filler receptacles for use with enflurane, methoxyflurane and halothane**

<b>Anaesthetic agent</b>	<b><i>l</i> +0,15 -0,10 mm</b>	<b>Pin in face</b>
Enflurane	7,1	A
Methoxyflurane	11,1	B
Halothane	7,1	B
Spare	9,1	B
Spare	9,1	A
Spare	5,1	A
Spare	5,1	B

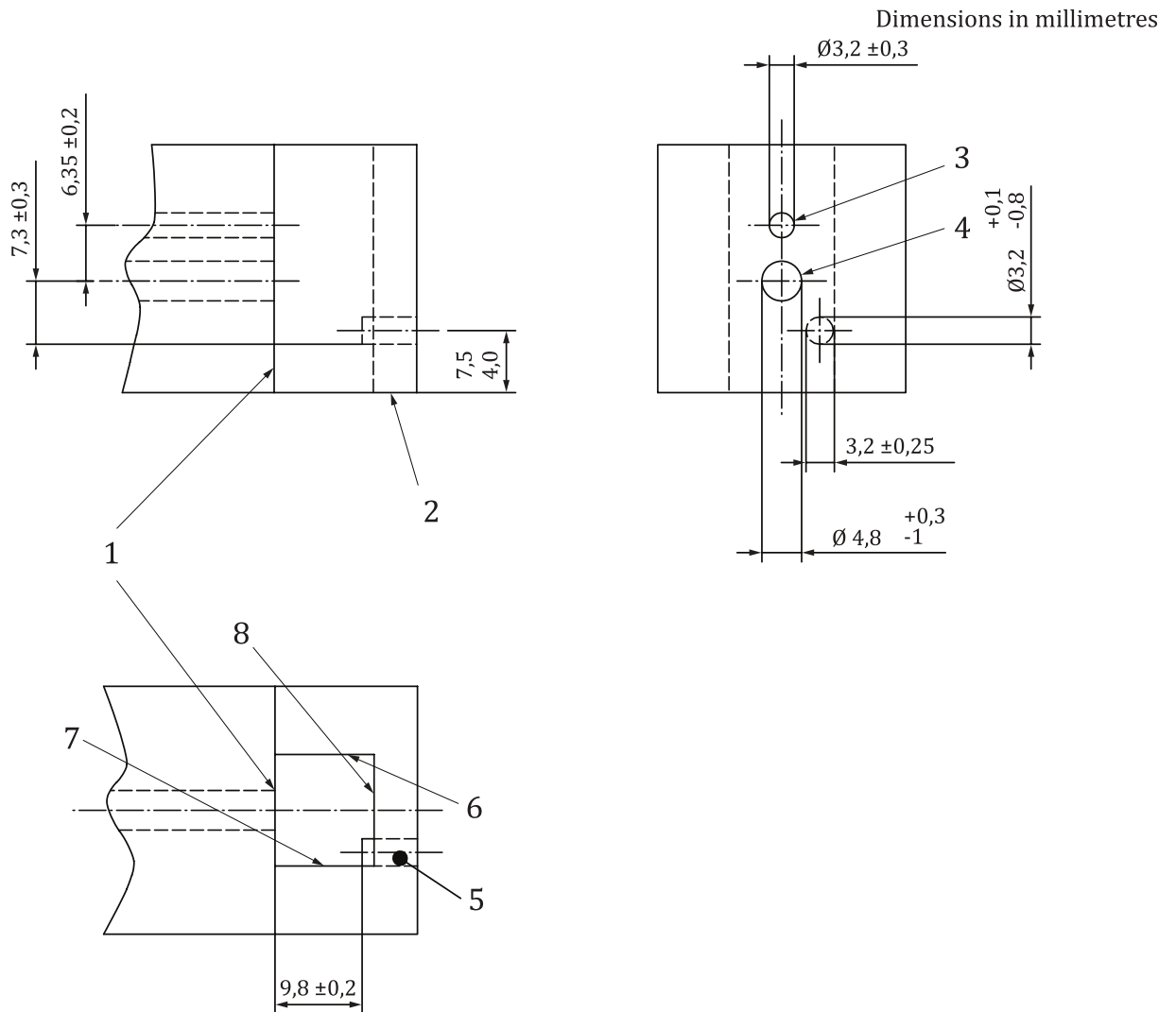
**7.2** If the filler receptacle is of the type specified in 7.1 a), means for tightening the male adaptor against the receptacle seal(s) when the adaptor is inserted into the filler receptacle shall be provided.

**7.3** The filler receptacle shall be provided with a means of sealing the liquid and air/vapour passages in the receptacle while the bottle adaptor is not inserted.

## **8 Filling rate**

When tested according to the manufacturer's instructions, the mean filling rate shall exceed 2 ml/s.





**Key**

- 1 sealing face, space (dimension not specified) for sealing component
- 2 front face
- 3 air/vapour port
- 4 liquid port
- 5 pin
- 6 face A
- 7 face B
- 8 face C

NOTE 1 See [Table 6](#).

NOTE 2 See [Figure 7](#) for all other details.

**Figure 8 — Configuration and dimensions of agent-specific filler receptacles for use with isoflurane and sevoflurane**

**Table 6 — Details of filler receptacles for use with isoflurane and sevoflurane**

Anaesthetic agent	Pin inserted in face C and adjacent to
Isoflurane	Face A
Sevoflurane	Face B

## 9 Leakage

When measured in accordance with [Annex C](#), the mean leakage of liquid or vaporized anaesthetic agent into the atmosphere shall not exceed 0,5 ml.

It is recognized that during disconnection of the male adaptor from the vaporizer and the bottle adaptor from the bottle, small amounts of anaesthetic agent escape to the environment. This should be noted in the user instruction manual.

Means should be provided to ensure that as little anaesthetic agent as possible escapes from the male adaptor to the environment when the adaptor is affixed to the bottle during storage.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic, or toxic to reproduction.

## 10 Overfilling protection

When filled in accordance with the manufacturer's instructions, it shall not be possible to overfill the vaporizer such that

- a) its performance is affected, and
- b) fluid level is no longer visible.

## 11 Colour coding

The bottle collar and the bottle connector shall incorporate colour coding using the colour specified by name in [Table 2](#) for the anaesthetic agent intended.

If the filler receptacle is colour-coded, the colour shall comply with the colour specified by name in [Table 2](#).

## 12 Usability

The manufacturer shall address, in a usability engineering process, the risk resulting from poor usability (see IEC 62366-1).

Check compliance by inspection of the usability engineering file.

## 13 Clinical evaluation

A clinical evaluation shall be performed and documented in the risk management file.

Check compliance by inspection of the risk management file.

## 14 Information provided by the manufacturer

### 14.1 Marking

Agent-specific filling systems or bottle collars or bottle adaptors supplied individually shall be marked with the following:

- a) manufacturer's name and/or trademark and where the manufacturer does not have an address within the locale, the name and address of an authorized representative within the locale;
- b) batch code or the serial number;
- c) name of the anaesthetic agent with which it is intended to be used.

The use of the generic names of anaesthetic agents according to [Table 2](#) is recommended.

### 14.2 Labelling

**14.2.1** Agent-specific filling systems or components supplied individually shall provide the following information on the device itself, on the unit pack, or on a leaflet accompanying the device:

- a) name and address of the manufacturer/supplier and where the manufacturer does not have an address within the locale, the name and address of an authorized representative within the locale;
- b) information necessary to identify the device or the contents of the package;
- c) anaesthetic agent with which the device shall be used;
- d) if appropriate, an indication of the time limit for using the device safely, expressed as year/month;
- e) indication if the device is for single use only;

NOTE Manufacturer's attention is drawn to consistent use of indication for single-use devices.

- f) any relevant particular storage and/or handling instructions.

If phthalates are incorporated in parts of the device coming directly or indirectly into contact with the patient, the device shall be labelled accordingly (see EN 15986).

**14.2.2** The bottle adaptor shall have a leaflet enclosed with the device giving the following warning: "Caution: agent-specific filling cannot be assured when bottles without collars are used".

### 14.3 Instructions for use

Instructions for use of agent-specific filling systems or components thereof shall be provided by the vaporizer manufacturer or supplier and shall include the following:

- a) details referred to in [14.2.1](#) with the exception of those in items c) and d);
- b) warning given in [14.2.2](#);
- c) information necessary to ensure that the agent-specific filling system is in safe and correct working order;
- d) details on the nature and frequency of maintenance operations to ensure safe and correct operation at all times;
- e) statement indicating compliance of the agent-specific filling system with this International Standard;

- f) indication of the residual risks, if phthalates are incorporated in parts of the device coming directly or indirectly into contact with the patient and if such device is used for the treatment of children or the treatment of pregnant or nursing women;
- g) for single-use devices upon request, a disclosure of the risks associated with reusing;
- h) date of issue or the latest revision of the instructions for use.

## **Annex A**

### **(informative)**

### **Recommendations on materials**

Materials used for the parts of filling systems which come into contact with liquid anaesthetic agent should be selected with regard to the following:

- a) toxicity;
- b) compatibility with anaesthetic agents;
- c) minimization of health risks due to substances leached from the materials.

## Annex B (informative)

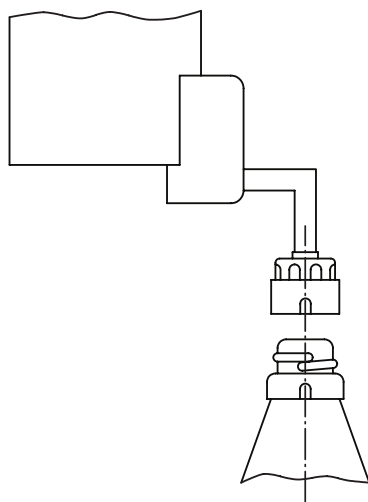
### Types of agent-specific filling systems

Different types of agent-specific filling systems are shown in [Figure B.1](#).



**a) Threaded bottle neck with collar and separate bottle adaptor with bottle connector and male adaptor and filler receptacle**

**b) Male adaptor permanently attached to bottle and filler receptacle**



**c) Bottle connector permanently attached to vaporizer and threaded bottle neck with collar**

**Figure B.1 — Different types of agent-specific filling systems**

## Annex C (normative)

### Determination of total leakage into atmosphere of anaesthetic agent during filling

#### C.1 Preparation of test samples

Carry out the tests and all preparatory steps at  $(20 \pm 3)$  °C. Test the appropriate agent-specific vaporizer, bottle adaptor, and bottle of liquid anaesthetic agent specified in the operating instruction(s). Carry out 20 complete filling and emptying procedures following the filling and emptying procedures given in the operating instructions.

#### C.2 Procedure

**C.2.1** Prepare the vaporizer in accordance with the operating instructions.

**C.2.2** Fill the vaporizer to the maximum liquid level, allow it to stand for 1 h and then drain the vaporizer to the minimum liquid level.

**C.2.3** Fit the adaptor to a full anaesthetic bottle. Allow all components, including the vaporizer, to stand for 1 h prior to testing.

**C.2.4** Weigh the vaporizer and the full anaesthetic bottle with the adaptor affixed, using a balance of accuracy better than  $\pm 0,25$  g and a repeatability of better than  $\pm 0,1$  g.

**C.2.5** Fill the vaporizer in accordance with the operating instructions, from the minimum liquid level, until one of the following conditions is reached:

- a) maximum liquid level is reached;
- b) agent ceases to flow, if this is intended by the design of the vaporizer and the agent-specific filling system.

**C.2.6** Remove the bottle and the adaptor from the vaporizer. Do not remove the adaptor from the bottle.

**C.2.7** After  $(2 \pm 1)$  min, weigh the vaporizer and the bottle with the bottle adaptor attached.

**C.2.8** Empty the vaporizer to the minimum liquid level and refill the anaesthetic bottle.

**C.2.9** Repeat [C.2.2](#) to [C.2.8](#) four times.

#### C.3 Calculation of results

Calculate the total leakage, in millilitres, of liquid anaesthetic agent from the difference in the masses measured in [C.2.4](#) and [C.2.7](#) and the appropriate density of the liquid. Calculate the mean result of the five tests.

#### **C.4 Test report**

The test report shall contain at least the identity of the equipment tested and the mean leakage, expressed in millilitres.



## Bibliography

- [1] IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*
- [2] EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*
- [3] BS 5252, *Framework for colour co-ordination for building purposes*
- [4] DIN 6164-2, *DIN colour chart — Specification of colour samples*
- [5] USA FEDERAL STANDARD 595, *Colors*, 1994<sup>1)</sup>
- [6] *Munsell Book of Color*<sup>2)</sup>
- [7] *Pantone Colours*<sup>3)</sup>
- [8] SS 01 91 00, *Colour notation system*
- [9] SS 01 91 02, *NCS atlas (NCS colour atlas)*
- [10] SS 01 91 04, *NCS-colour samples — Observation and measurement conditions and tolerance*

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1) Available from DoD Document Automation and Production Service, Building 4/D, 700 Robins Avenue, Philadelphia, Pennsylvania 19111-5094 USA. “Colors” 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.

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, Maryland 21218 USA. “Munsell Book of Color” 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.

3) Available from Pantone UK Inc. 8 Strade Street, Hythe, Kent, CT21 6BD, United Kingdom or regional offices ([www.pantone.com](http://www.pantone.com)). “Pantone Colours” 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.

