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Anaesthetic vaporizers — Agent-specific filling systems

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

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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

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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 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

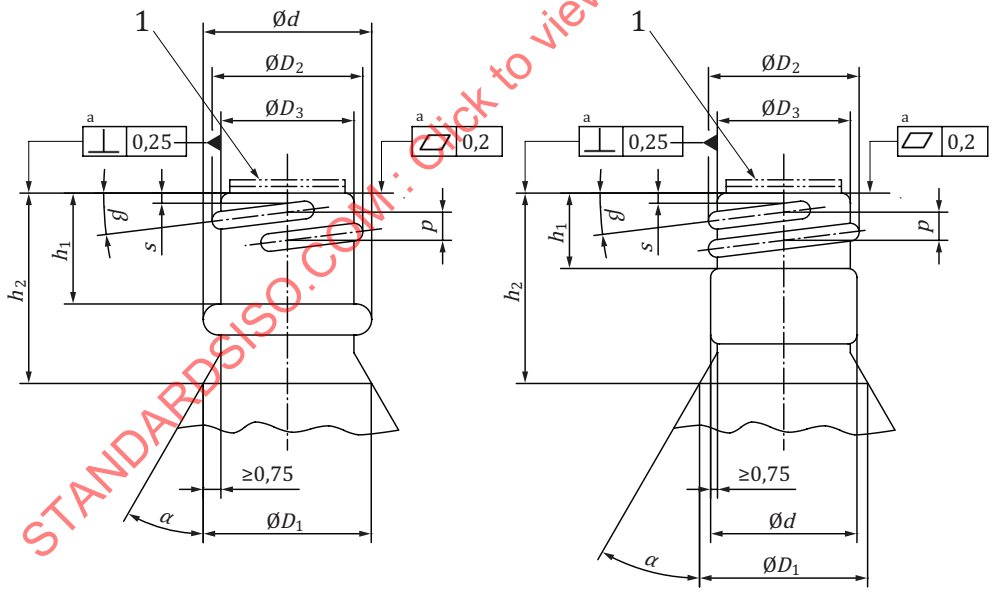
4 Bottle

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.

Dimensions in millimetres



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 ±0,3 mm	h_2[a] min. mm	s ±0,45 mm	β	α min. at $\emptyset D_1$	p mm	Thread turns min.	D_1[a] nom. mm	D_2[b] ±0,3 mm	D_3[b] ±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	29,9	23,5	21,5	28

NOTE See Figure 1.

[a] Recommended values.

[b] Summation of the tolerances of measures D_2 and D_3 shall be avoided. A maximum tolerance of ±0,3 mm for $(D_2 - D_3)$ should be required to avoid problems with the fitting of any bottle connector.

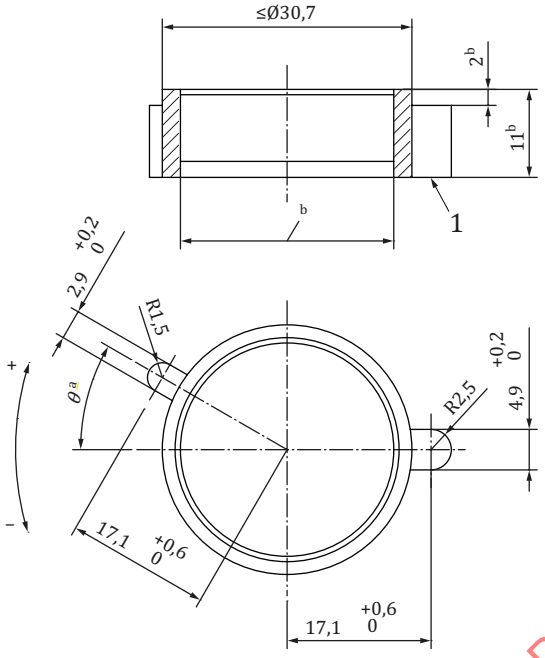
5 Bottle collar

5.1 Bottle collars shall comply with the configuration and dimensions shown in Figure 2 and angle, θ, specified in Table 2 for the anaesthetic agent with which it is intended to be used.

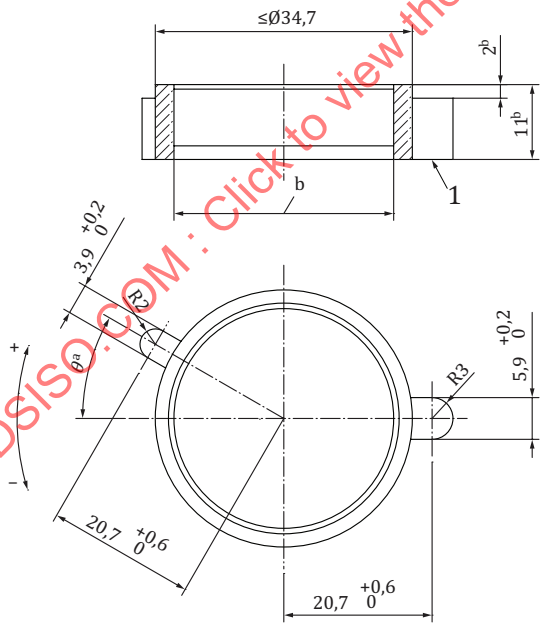
5.2 The position of the bottle collar relative to the screw thread of the bottle shall be as shown in Figure 3.

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

Dimensions in millimetres



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	θ[a] ±0° 30′	Specified colour[b]	Example of colour samples					
			Federal Standard 595 colour[5]	BS 5252 colour[3]	Pantone colour[7]	SS 01 91 02 colour[9]	Munsell colour[6][c]	DIN 6164-2 colour[4]
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.[d]	Blue	N/A[e]	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[e]	10 E 53	108 C	NCS S 0570-Y	6,25Y 8,5/12	2:6:1
Isoflurane	−40°	Purple	N/A[e]	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.

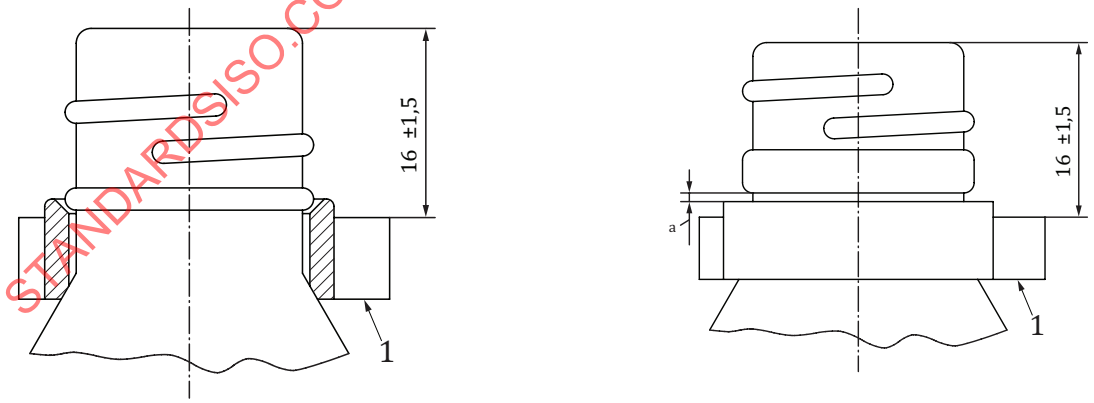
[b] If a colour is used on a vaporizer, bottle, or package label to facilitate correct identification, it is important that only the colour for the appropriate anaesthetic agent be used.

[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

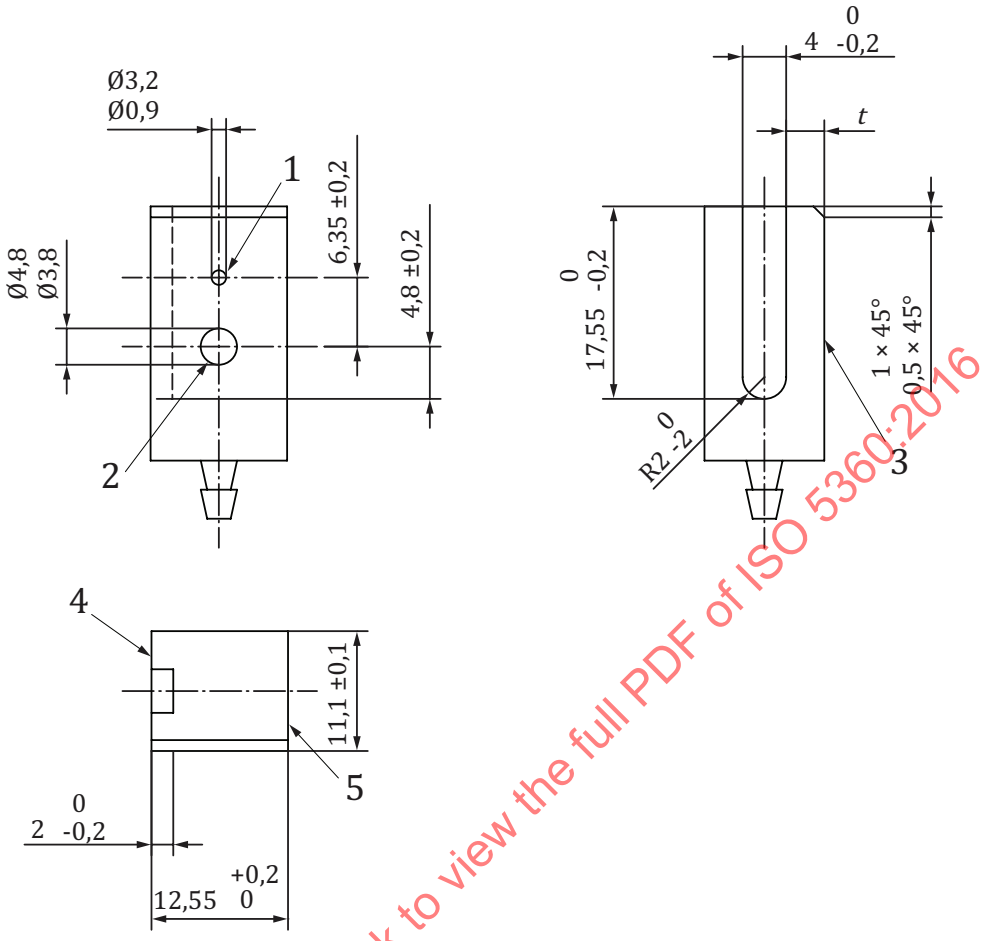
b) withstand, without visible damage, a tightening torque of (3 ± 0,3) N·m, when fitted to an appropriate bottle.

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.

Dimensions in millimetres



Key

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

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

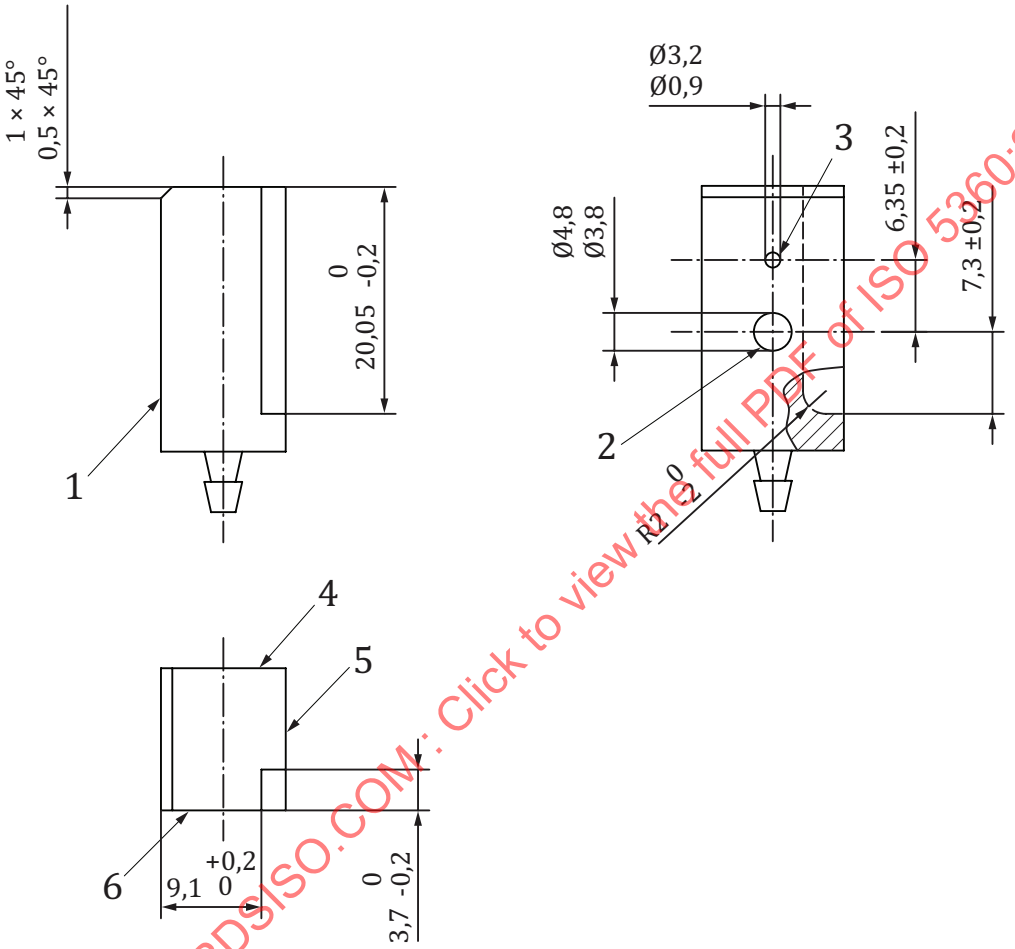
Table 3 — Details of male adaptors for use with enflurane, methoxyflurane and halothane

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

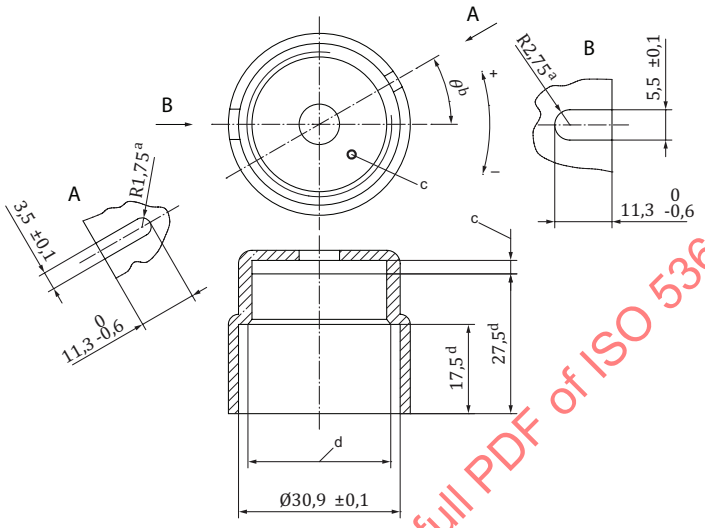
NOTE See Table 4 and Figure 4.

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

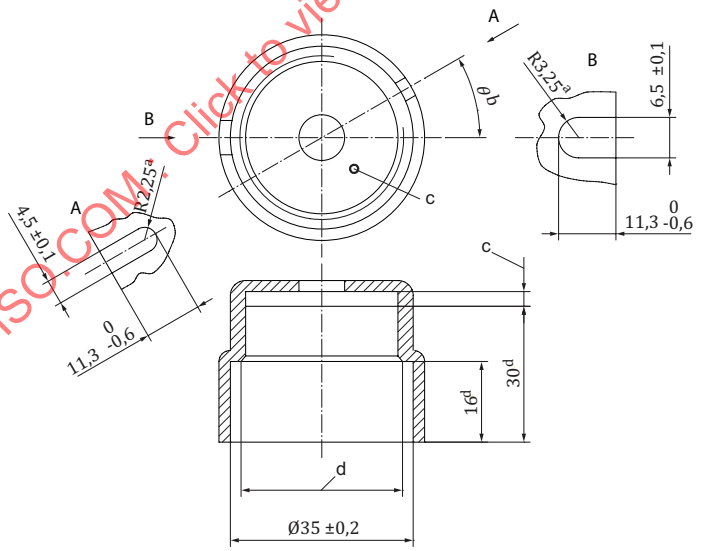
Table 4 — Details of male adaptors for use with isoflurane and sevoflurane

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

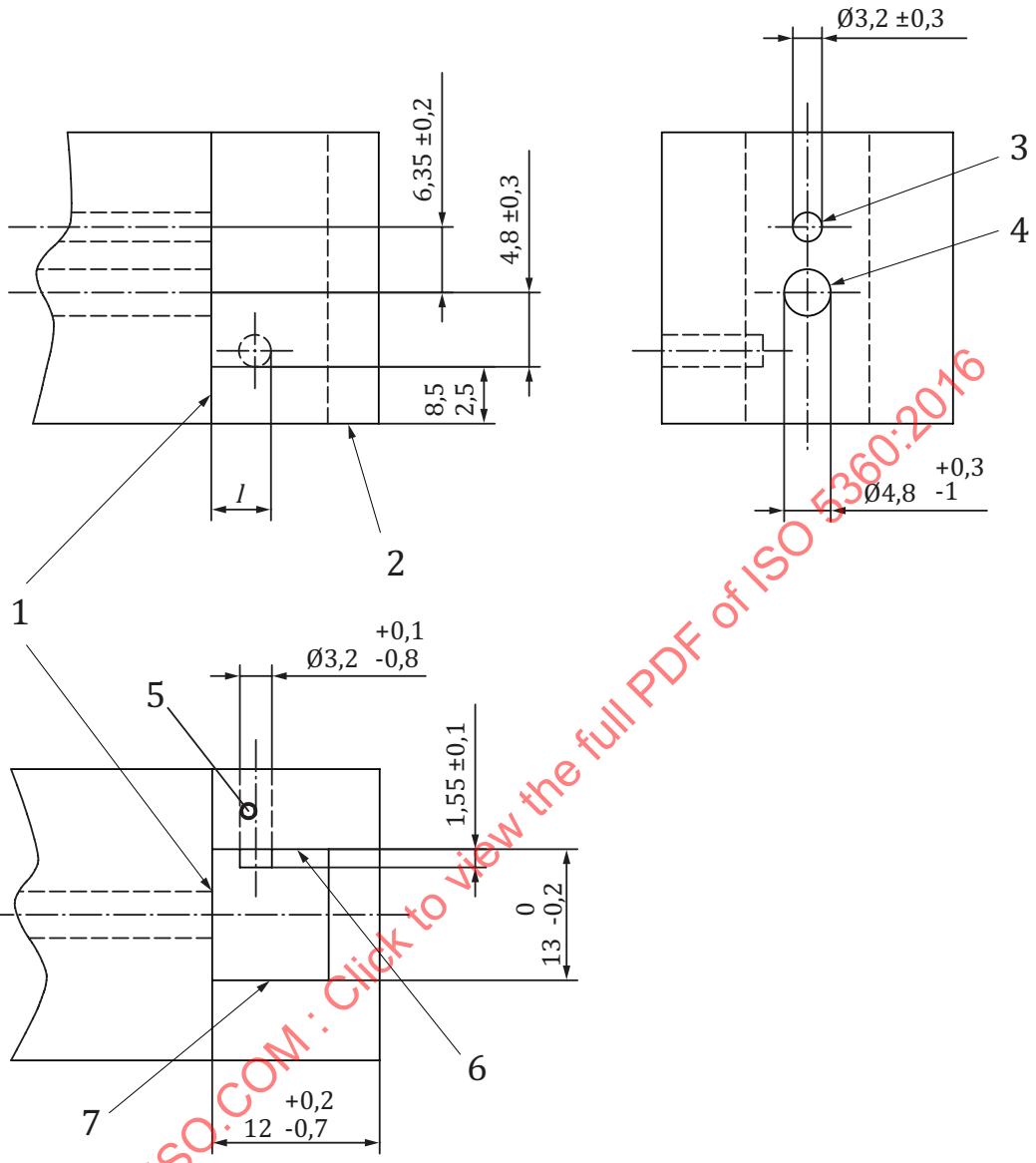
7 Filler receptacle

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, θ, specified in Table 2 for the anaesthetic agent with which it is intended to be used.

Dimensions in millimetres



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

Anaesthetic agent	l $^{+0,15}_{-0,10}$ mm	Pin in face
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

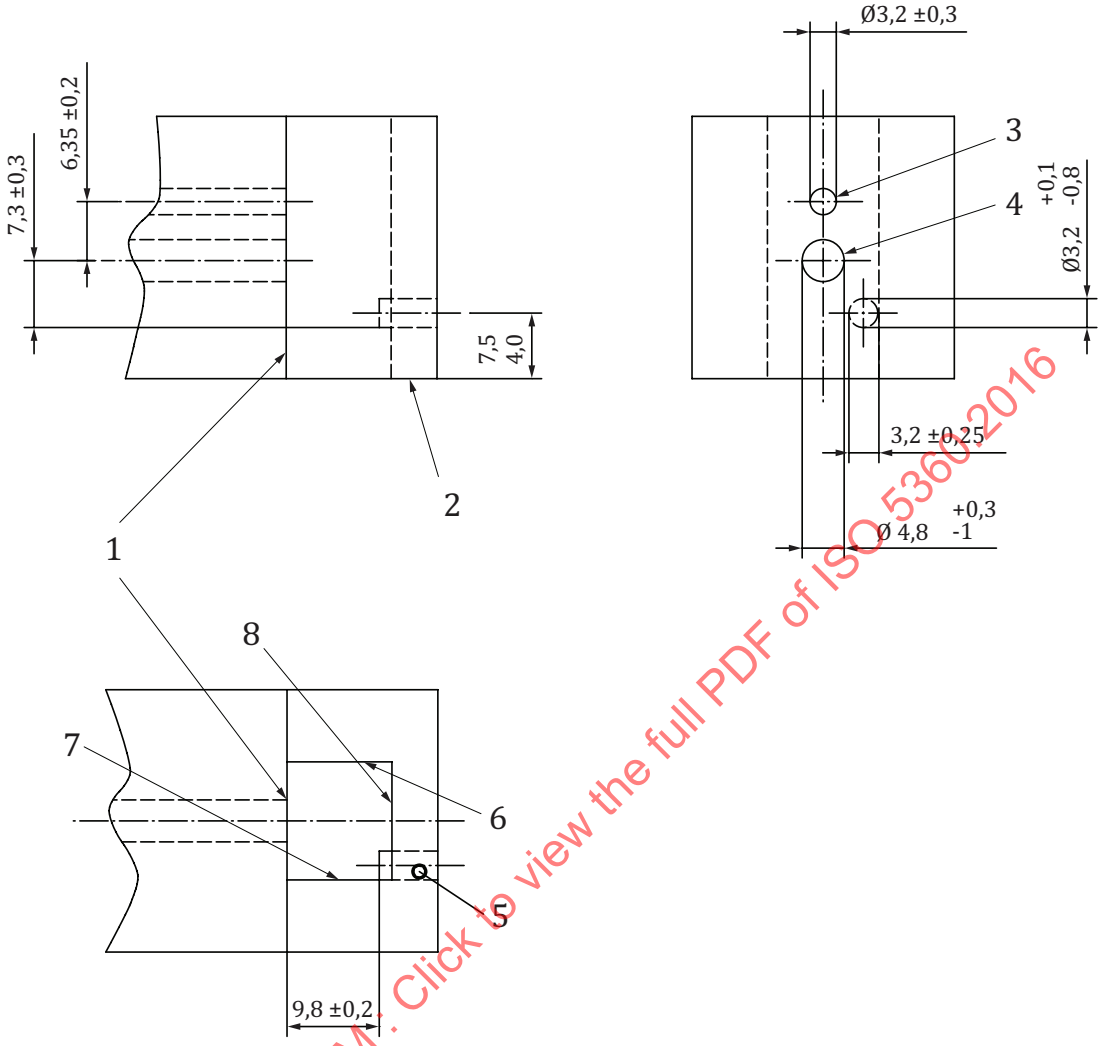
7.2 If the filler receptacle is of the type specified in 7.1 a), means for tightening the male adaptor against the receptacle seal(s) when the adaptor is inserted into the filler receptacle shall be provided.

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.

Dimensions in millimetres



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.