INTERNATIONAL STANDARD

ISO 5360

First edition
1993-02-15

Anaesthetic vaporizers — Agent-specific filling systems

Évaporateurs pour anesthésie — Systèmes de remplissage spécifiques d'agents

Reference number
ISO 5360:1993(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5360 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 1, *Breathing attachments and anaesthetic machines*.

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

This page intentionally left blank

Anaesthetic vaporizers — Agent-specific filling systems

1 Scope

This International Standard specifies the dimensions of agent-specific filling systems for agent-specific anaesthetic vaporizers.

This International Standard does not specify construction materials. Materials used for the parts of filling systems which come into contact with liquid anaesthetic agent should be selected with regard to:

a) toxicity;

b) compatibility with anaesthetic agents; and,

c) minimization of health risks due to substances leached from the materials.

Because of the unique properties of desflurane, dimensions for this agent have not been specified in this International Standard. Specifications for filling systems for this agent will be included in this Standard in due course.

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

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1101:1983, *Technical drawings — Geometrical tolerancing — Tolerances of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 anaesthetic vaporizer: Device designed to facilitate the change of an anaesthetic agent from a liquid to a vapour.

3.2 agent-specific: Having both a prescribed configuration and prescribed dimensions which are specific for a prescribed liquid anaesthetic agent.

3.3 bottle adaptor: Assembly which is intended to connect a bottle for liquid anaesthetic agent to an agent-specific anaesthetic vaporizer.

3.4 bottle collar: Agent-specific component on the neck of a bottle causing it to be agent-specific.

3.5 bottle neck: External threaded part of the bottle and the adjacent contour over which an agent-specific collar is fitted.

3.6 bottle connector: Agent-specific component which fits the thread on the bottle neck and mates with the agent-specific bottle collar.

3.7 male adaptor: Part of a bottle adaptor that mates with a filler receptacle on an agent-specific vaporizer.

3.8 filler receptacle: Receptacle for a bottle or a bottle adaptor on an agent-specific anaesthetic vaporizer.

3.9 agent-specific filling system: Functional system of agent-specific coded connections between an anaesthetic bottle and an agent-specific anaesthetic vaporizer, consisting of, for example, a threaded bottle neck with collar, bottle connector, male adaptor and filler receptacle.

NOTE 1 Different types of agent-specific filling systems are shown in annex B.

4 Bottle

Each bottle shall have

a) the name of the anaesthetic agent with which it is intended to be used marked on it; and,

b) either a bottle collar complying with clause 5 and a threaded neck complying with table 1 and figure 1, or a permanently attached bottle adaptor complying with 6.2.

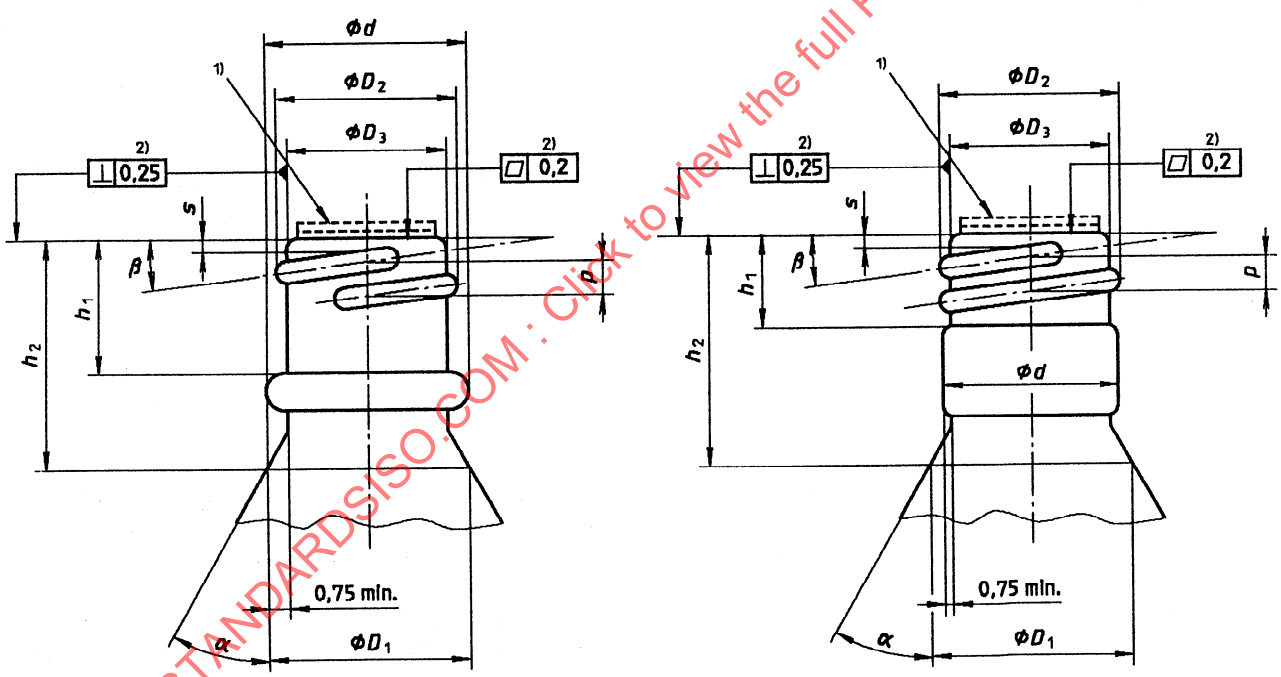
5 Bottle collar

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



1) Optional pouring lip (not dimensioned).
2) Flatness and perpendicularity tolerances according to ISO 1101.

NOTES

1 The dimensions shown form part of this International Standard: other features are for illustrative purposes only.

2 See also table 1.

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

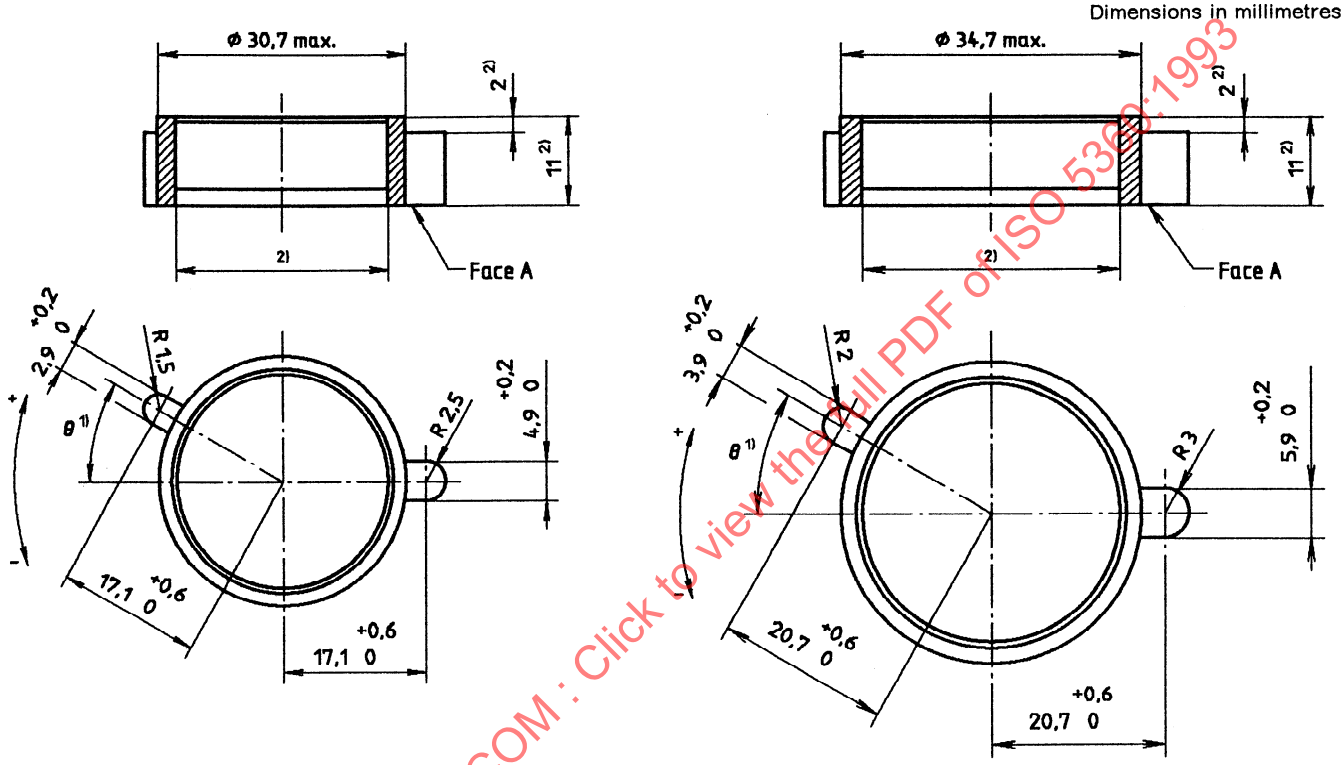
Table 1 — Dimensions of threaded necks of bottles for anaesthetic agents (see also figure 1)

Bottle type	Anaesthetic agent	h_1 ± 0,3 mm	h_2 [1] min. mm	s ± 0,45 mm	β	α min. at Ø D_1	p mm	Thread turns min.	D_1 [1] nom. mm	D_2 [2] ± 0,3 mm	D_3 [2] ± 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 (N. America)	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	Methoxyflurane	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	32

1) Recommended values.

2) 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.

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

1) See table 2.
2) 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[1] $\pm$ 0°30′	Specified colour[2]	Examples of colour samples					
			Federal Standard 595a colour	BS 5252 colour	Pantone colour	SS 019100-03 colour	Munsell colour [3]	DIN 6164 colour
Halothane	− 20°	Red	11105	04 E 56	200 C	1080 R	5R4/14	8:7:2
Enflurane	+ 20°	Orange	22510	06 E 55	151 C	0090-Y50R	2,5YR 6/16	5:5:1
Methoxyflurane	0°	Green	14187	14 E 53	334 C	2060-B90G	10G 5/10	21:6:3
Desflurane	N.S[4]	Blue	n.a.[5]	18 E 53	3015 C	3060 B	10B 4/10	18:4:3
Not for agent identification		White	37875	18 B 15	5455 C	1002 B	10B 9/1	N:0:0.5
Not for agent identification		Black	15042	00 E 53	Process black C	9500	N 0,5	N:0:9
Sevoflurane	+ 50°	Yellow	n.a.	10 E 53	108 C	0070-Y	6,25Y 8,5/12	2:6:1
Isoflurane	− 40°	Purple	n.a.	24 E 53	254 C	3060-R50B	7,5P4/12	11:4:4
Spare		Grey	16251	00 A 09	Cool grey 9 C	5502B	5PB 5/1	N:0:4

1) Sign "+" means clockwise rotation and sign "−" means counterclockwise rotation when viewed from the top.

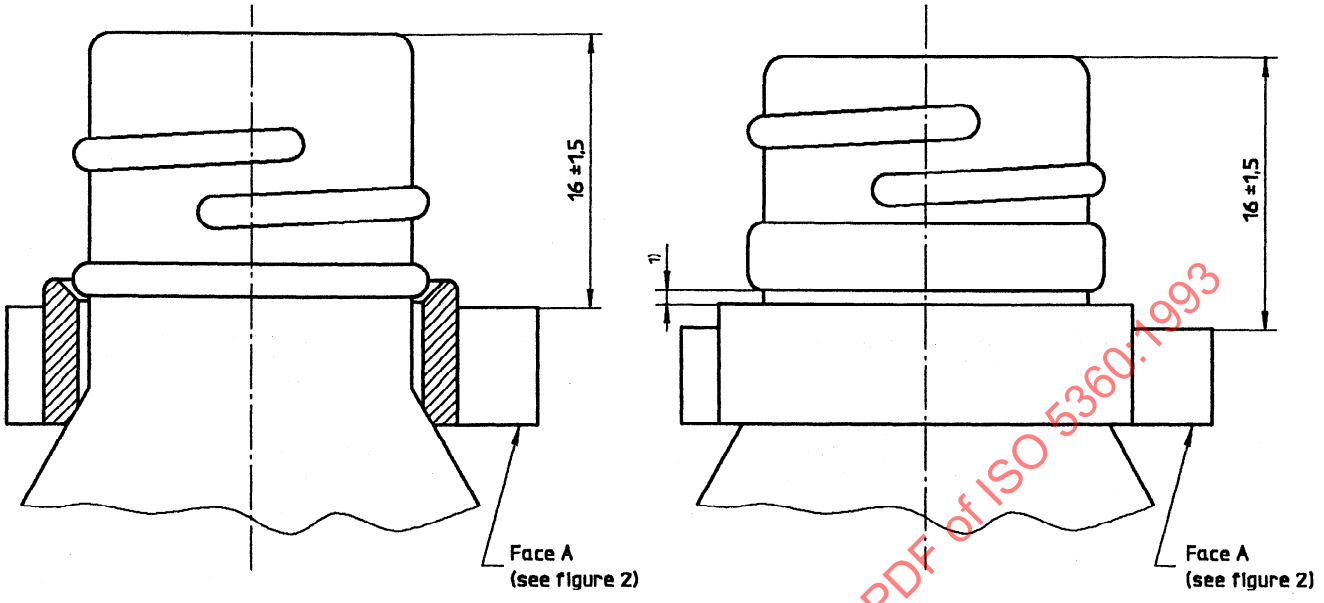
2) If a colour is used on a vaporizer, bottle or package label to facilitate correct identification, it is important that only the colour for the appropriate anaesthetic agent is used.

3) Munsell colour is the original. Other colour systems show nearest available colour sample.

4) N.S = not specified.

5) n.a. = not available.

Dimensions in millimetres



1) Clearance to suit bottle.

a) Position without clearance between collar and transfer ring

b) Position with clearance between collar and transfer ring

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 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 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,

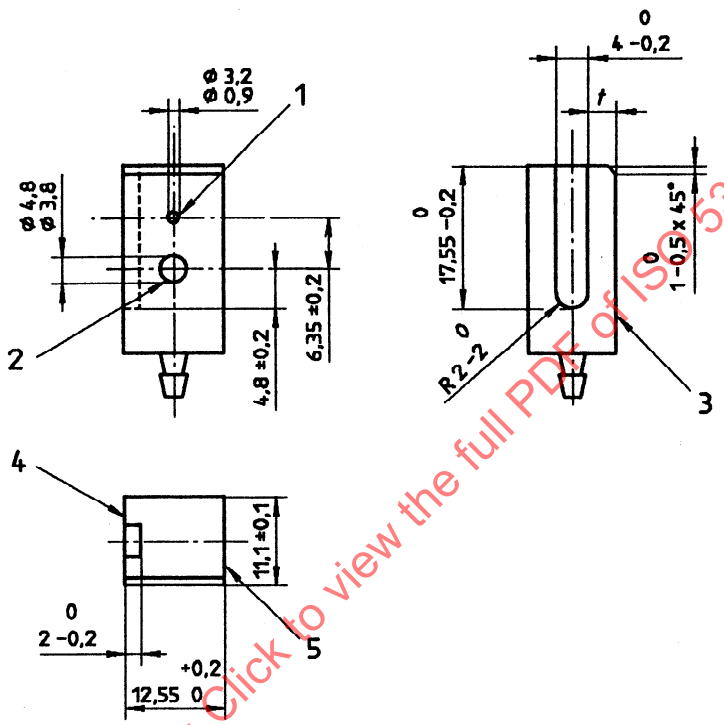
b) will withstand, without visible damage, a tightening torque of $(3 \pm 0{,}3)$ N·m, when fitted to an appropriate bottle.

NOTE 2 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 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



1 Air/vapour port.
2 Liquid port.
3 Sealing face.
4 Face A.
5 Face B.

NOTES

1 See also table 3.

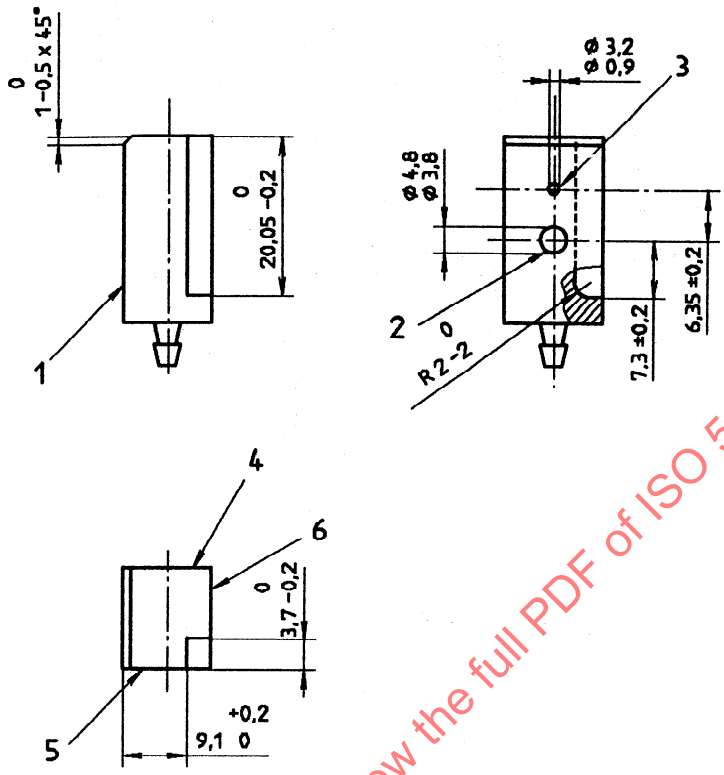
2 Port identification applies to filling procedure only.

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
Spare	1,5	A
Spare	1,5	B

Dimensions in millimetres



1 Sealing face.
2 Liquid port.
3 Air/vapour port.
4 Face A.
5 Face B.
6 Face C.

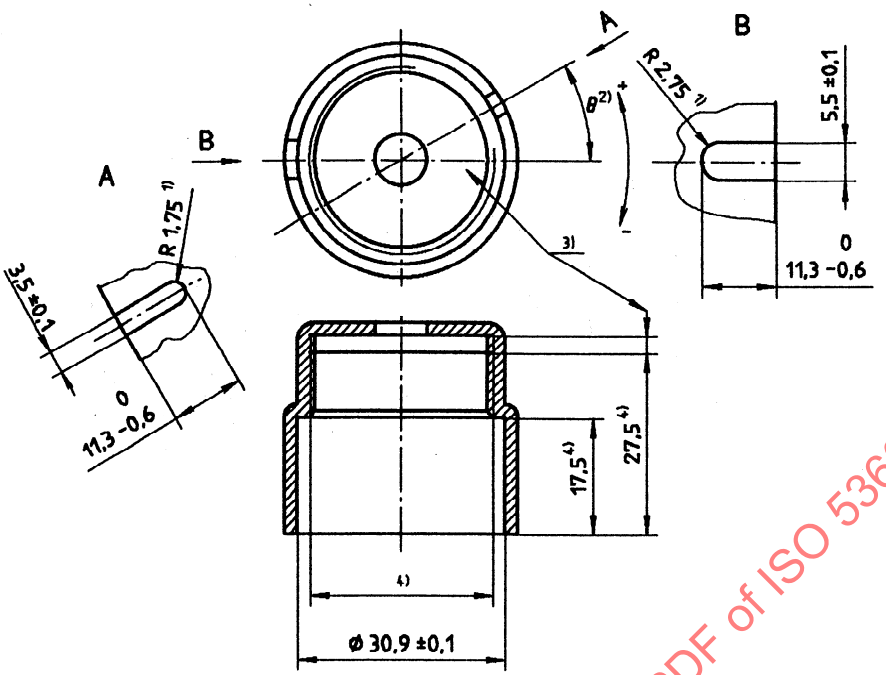
NOTE — See also table 4 and figure 4.

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

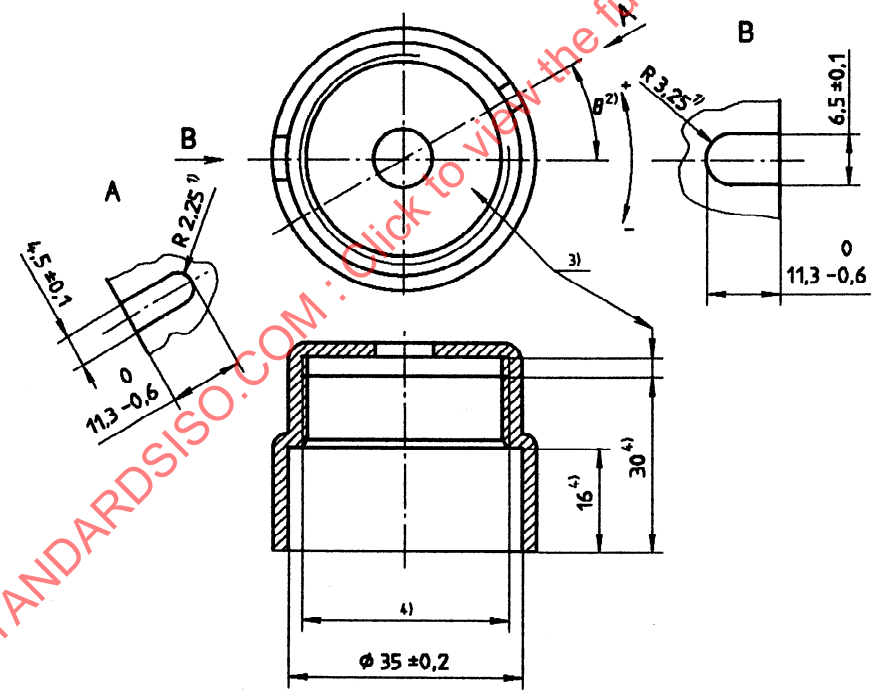
Table 4 — Details of male adaptors for use with isoflurane and sevoflurane

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

1) Square corners optional.
2) See table 2.
3) Space (not dimensioned) for sealing component.
4) May vary to suit bottle.

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

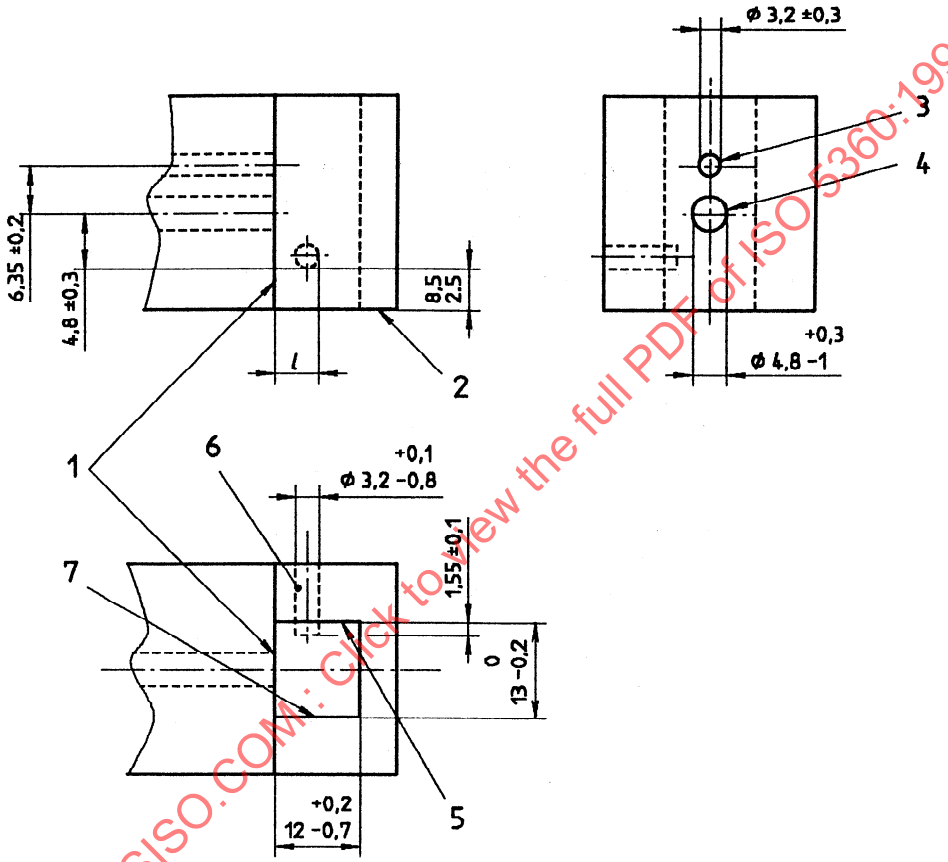
7 Filler receptacle

7.1 The filler receptacle of the vaporizer shall

a) comply with the configuration and dimensions shown in figure 7 or 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 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



1 Sealing face, space (not dimensioned) for sealing component.
2 Front face.
3 Air/vapour port.
4 Liquid port.
5 Face A.
6 Pin.
7 Face B.

NOTES

1 See also table 5.

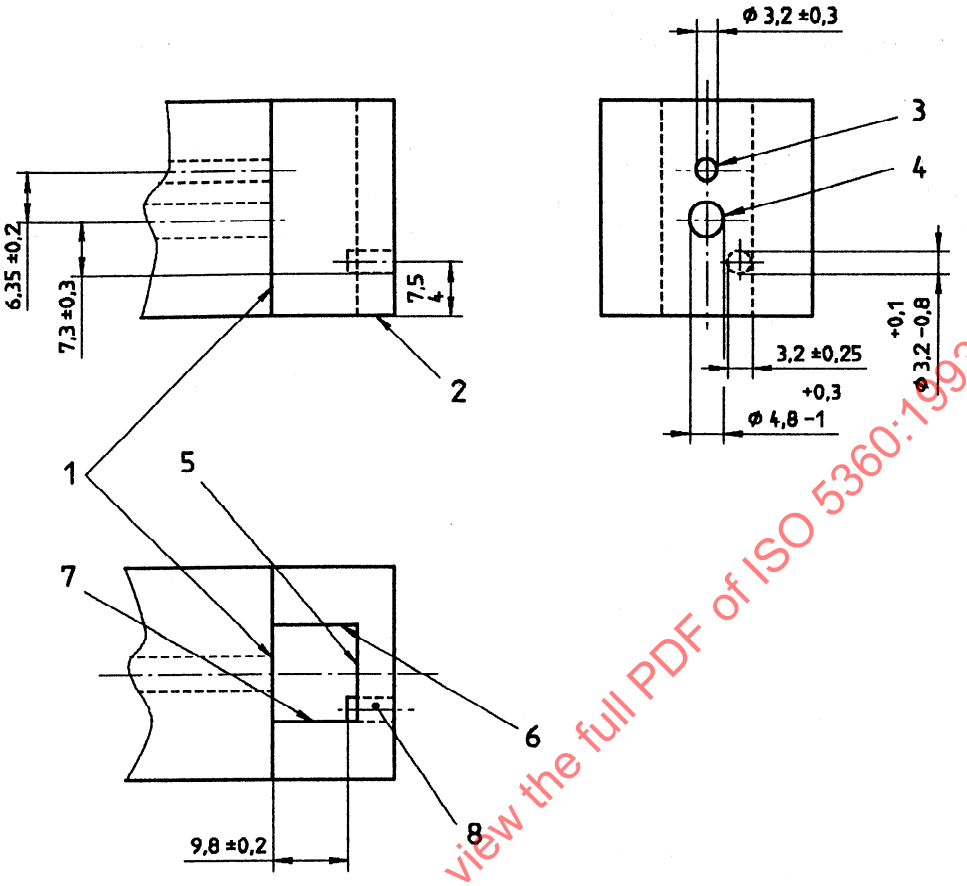
2 Port identification applies to filling procedure only.

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

Dimensions in millimetres



1 Sealing face, space (not dimensioned) for sealing component.
2 Front face.
3 Air/vapour port.
4 Liquid port.
5 Face C.
6 Face A.
7 Face B.
8 Pin.

NOTES

1 See also table 6.

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 installed in face C and adjacent to
Isoflurane	Face A
Sevoflurane	Face B

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

7.3 The filler receptacle shall be provided with means for 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.

9 Leakage

When measured according to annex A, the mean leakage into the atmosphere of liquid or vaporized anaesthetic agent shall not exceed 0,5 ml of liquid.

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 will escape to the environment. This should be noted in the user instruction manual.

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

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) the fluid level is no longer visible.

11 Colour coding

The bottle collar and the bottle connector shall incorporate the 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 Marking

Agent-specific filling systems or bottle collars, bottle adaptors or vaporizers supplied individually shall be marked with the manufacturer's name, the batch or serial number and the name of the anaesthetic agent with which it is intended to be used.

13 Accompanying documentation

Operating instructions for the recommended agent-specific filling system shall be provided by the vaporizer manufacturer.

Suppliers of agent-specific filling systems or components shall provide operating instructions for the system or the component respectively.

The compliance of the agent-specific filling system with this International Standard shall be stated in the operating instructions.

Annex A
(normative)

Determination of total leakage into atmosphere of anaesthetic agent during filling

A.1 Preparation of test samples

Carry out the tests and all preparatory steps at (20 ± 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 according to the operating instructions before testing.

A.2 Procedure

A.2.1 Prepare the vaporizer according to the operating instructions.

A.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.

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

A.2.4 Weigh the vaporizer and the full anaesthetic bottle with the adaptor affixed on a balance of an accuracy better than ± 0,25 g and a repeatability of better than ± 0,1 g.

A.2.5 Fill the vaporizer according to the operating instructions from the minimum liquid level until one of the following conditions is reached:

a) the maximum liquid level is reached;

b) the agent ceases to flow, if this is intended by the design of the vaporizer and the agent-specific filling system.

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

A.2.7 After (2 ± 1) min, weigh the vaporizer and the bottle with the bottle adaptor attached.

A.2.8 Empty the vaporizer to the minimum liquid level and re-fill the anaesthetic bottle.

A.2.9 Repeat A.2.2 to A.2.8 four times.

A.3 Calculation of results

Calculate the total leakage in millilitres of liquid anaesthetic agent from the difference in the masses measured in A.2.4 and A.2.7 and the appropriate density of the liquid. Calculate the mean result of the five tests.

A.4 Test report

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