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Anaesthetic vaporizers — Agentspecific 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).

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 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 editions (ISO \$5360:2012); of which it constitutes a minor revision with the following changes: 6c565a3a8af5/iso-5360-2016

- 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) te Geometrical tolerancing — Tolerances of form, orientation, location and run-out

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3 Terms and definitions

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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

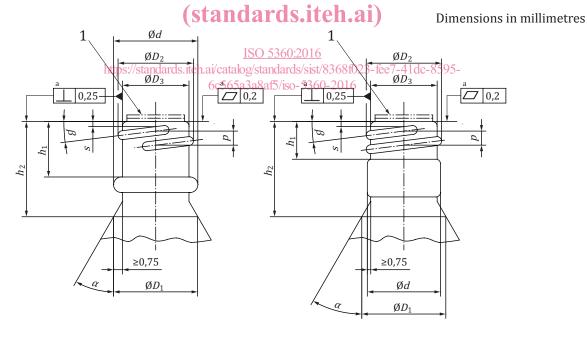
male adaptor

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 <u>Clause 5</u> and a threaded neck complying with <u>Figure 1</u> and <u>Table 1</u>, or a permanently attached bottle adaptor complying with <u>6.2</u>.



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 <u>Table 1</u>.

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	h2 ^a min. mm	s ±0,45 mm	β	$α$ min. at $ØD_1$	p mm	Thread turns min.	D_1^a nom.	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	23,9	23,5	21,5	28

NOTE See Figure 1.

5 Bottle collar iTeh STANDARD PREVIEW

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.

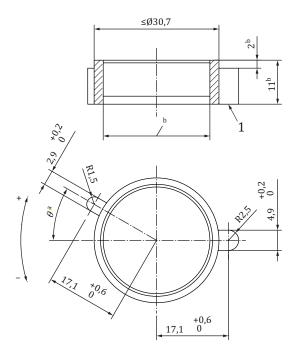
ISO 5360:2016

- 5.2 The position of the bottle collar relative to the screw thread of the bottle shall be as shown in $\frac{\text{Figure 3}}{6c565a3a8af5/\text{iso-}5360-2016}$
- **5.3** The bottle collar shall be attached to the bottle and shall be rotatable by hand.

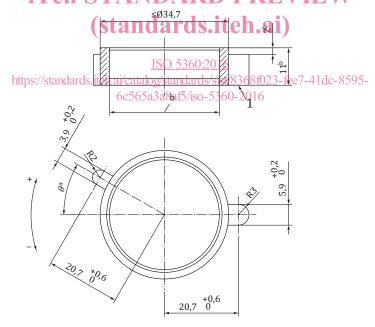
a Recommended values.

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

Key

- 1 face A
- a See <u>Table 2</u>.
- b May vary to suit bottle.

Figure 2 — Configuration of agent-specific bottle collars

	θa ±0° 30'	Specified colour ^b	Example of colour samples							
Anaesthetic agent			Federal Standard 595 colour[5]	BS 5252 colour[3]	Pantone colour ^[Z]	SS 01 91 02 colour ^[9]	M u n s e l l 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-flu- rane	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/Ae	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/Ae	24 E 53	254 C	NCS S 3055- R50B	7,5P4/12	11:4:4		
Spare	i	TetreyST	A16 251	00 A 09	Cool grey 9 C	NCS S 5502 B	5PB 5/1	N:0:4		

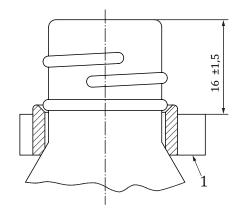
The sign "+" means clockwise rotation and sign "-" means counter-clockwise rotation, when viewed from the top.

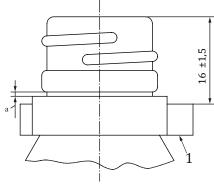
N.S. means not specified.

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N/A means not available.

Dimensions in millimetres





and transfer ring

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

Key

- face A (see Figure 2) 1
- Clearance to suit bottle.

Figure 3 — Alternative positions of agent-specific bottle collar

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 5360:2016

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

6 Bottle adaptor

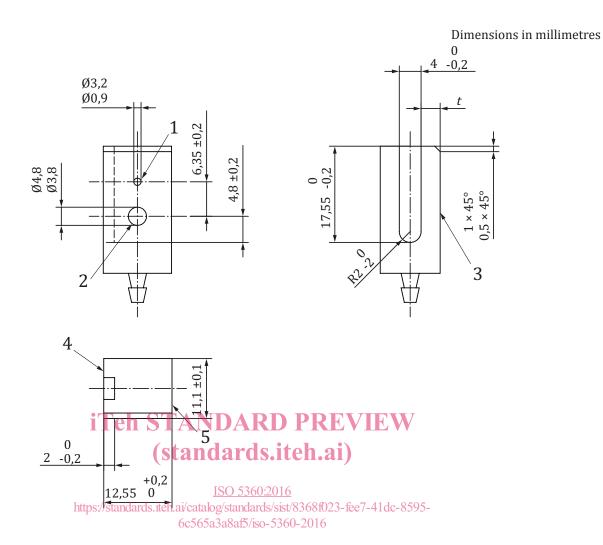
6.1 If the bottle adaptor is not permanently attached to the bottle or the vaporizer (see <u>Annex B</u>), it shall include an agent-specific bottle connector complying with the configuration and dimensions specified in <u>Figure 6</u> for the anaesthetic agent with which it is intended to be used. The 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 <u>Figure 4</u> or <u>Figure 5</u> 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 <u>Figure 4</u> or <u>Figure 5</u> 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 <u>Clause 4</u> b)] of an anaesthetic bottle, and <u>iTeh STANDARD PREVIEW</u>
- b) withstand, without visible damages 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 ards.iteh.ai/catalog/standards/sist/8368f023-fee7-41dc-8595-6c565a3a8af5/iso-5360-2016

- **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 port2 liquid port4 face A5 face B

3 sealing face

NOTE 1 See also <u>Table 3</u>.

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	В
Halothane	3,5	В
Spare	5,5	В
Spare	5,5	A