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

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

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## Contents

Page

Foreword .....	iv
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	1
4 Bottle .....	2
5 Bottle collar .....	4
6 Bottle adaptor .....	7
7 Filler receptacle .....	11
8 Filling rate .....	13
9 Leakage .....	15
10 Overfilling protection .....	15
11 Colour coding .....	15
12 Usability .....	15
13 Clinical evaluation .....	15
14 Information provided by the manufacturer .....	16
14.1 Marking .....	16
14.2 Labelling .....	16
14.3 Instructions for use .....	16
Annex A (informative) Recommendations on materials .....	18
Annex B (informative) Types of agent-specific filling systems .....	19
Annex C (normative) Determination of total leakage into atmosphere of anaesthetic agent during filling .....	20
Bibliography .....	21

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

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

This third edition cancels and replaces the second edition (ISO 5360:2006), of which it constitutes a minor revision. In particular, it

- indicates in the Scope that requirements of agent-specific filling systems for anaesthetic vaporizers (not merely the dimensions) are specified,
- transfers the recommendations on materials from the Scope to an informative annex,
- refers to substances which are carcinogenic, mutagenic or toxic to reproduction in Clause 9 (leakage),
- introduces new requirements on usability (Clause 12) and clinical evaluation (Clause 13), and
- amends the requirements on information provided by the manufacturer (renumbered Clause 14).

# 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.

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## 2 Normative references (standards.iteh.ai)

The following referenced documents are indispensable for the application of this document. 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 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 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 anaesthetic vaporizer

**3.5  
bottle collar**  
agent-specific component on the neck of a bottle causing it to be agent-specific

**3.6  
bottle connector**  
agent-specific component that fits the thread on the bottle neck and mates with the agent-specific bottle collar

**3.7  
bottle neck**  
external threaded part of the bottle and the adjacent contour over which an agent-specific collar is fitted

**3.8  
filler receptacle**  
receptacle for a bottle or a bottle adaptor on an agent-specific anaesthetic vaporizer

**3.9  
male adaptor**  
part of a bottle adaptor that mates with a filler receptacle on an agent-specific vaporizer

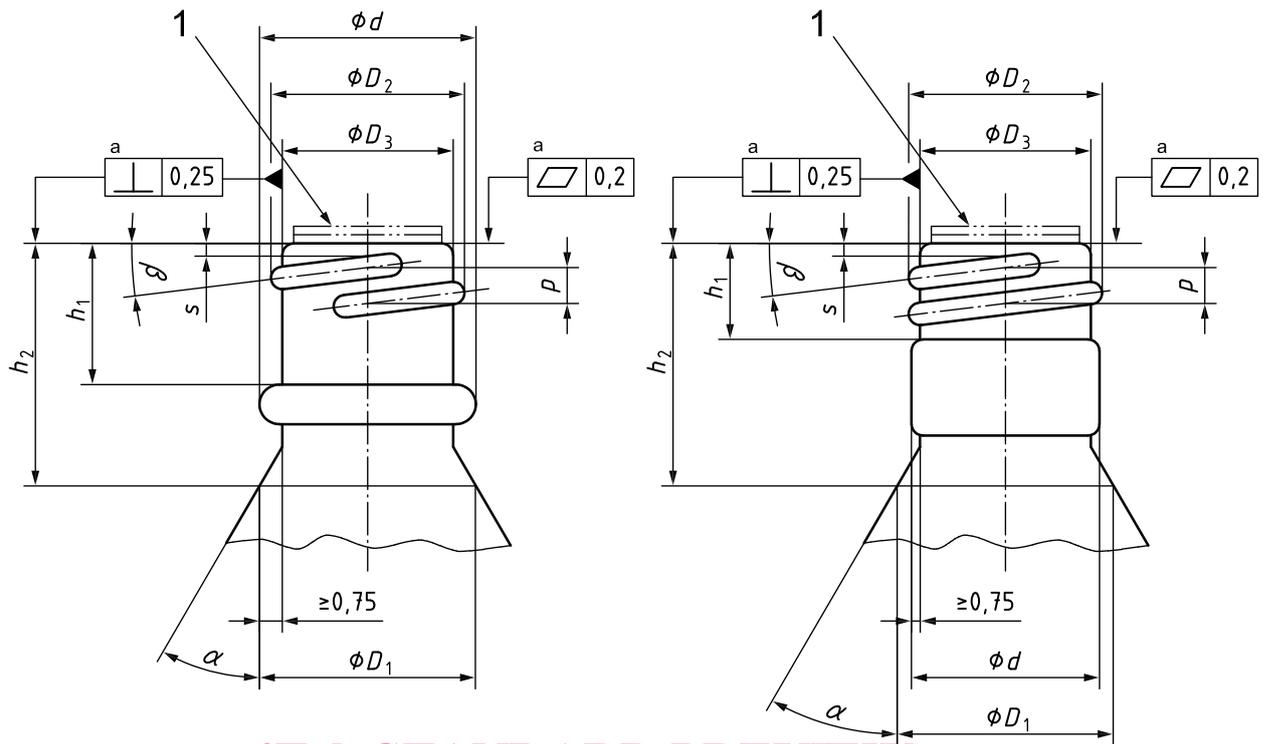
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**4 Bottle**

Each bottle shall have:

- a) the 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



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**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.

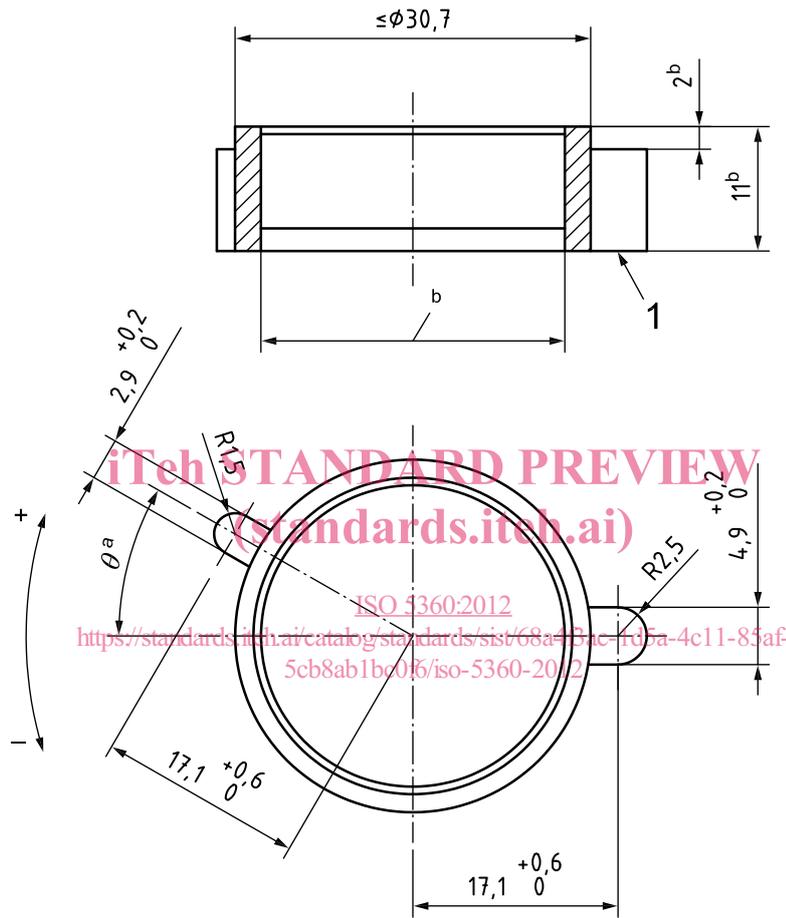
5 Bottle collar

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.

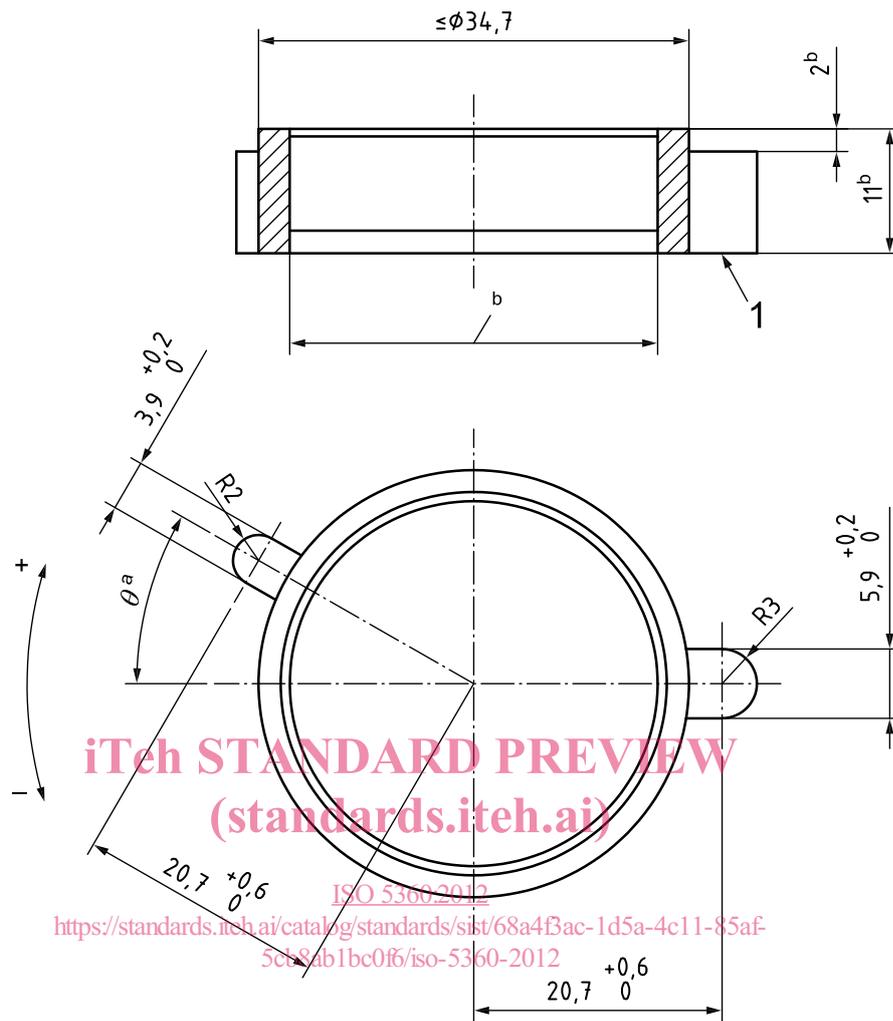
Dimensions in millimetres



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

Figure 2 — Configuration of agent-specific bottle collars (continued)

Dimensions in millimetres



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.

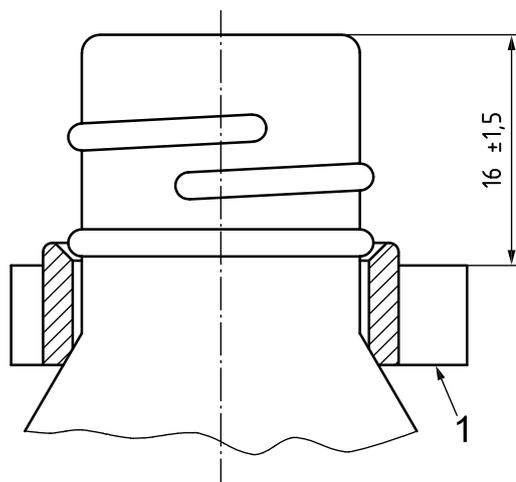
**Figure 2 — Configuration of agent-specific bottle collars**

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	BS 5252 colour	Pantone colour	SS 01 91 02 colour	Munsell colour <sup>c</sup>	DIN 6164-2 colour
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	3015 C	NCS S 3060 B	10B 4/10	18:4:3
Not for agent identification		White	37 875	18 B 15	5455 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 anticlockwise 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.

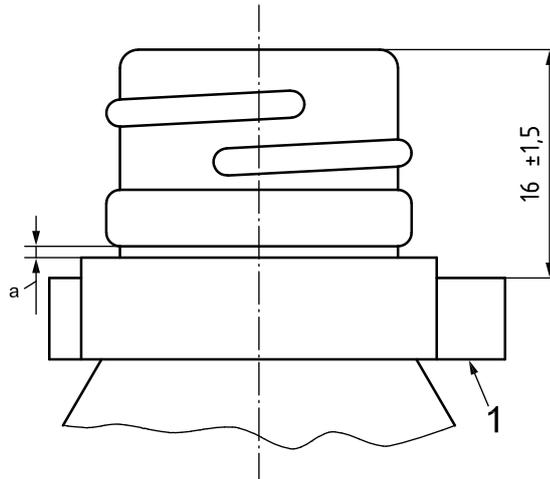
Dimensions in millimetres



a) Position without clearance between collar and transfer ring

Figure 3 — Alternative positions of agent-specific bottle collar (continued)

Dimensions in millimetres



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

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**6 Bottle adaptor**

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**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 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.