SLOVENSKI STANDARD

SIST EN 1280-1:2000

01-januar-2000

Sistemi za nalivanje specifiļ nih hlapnih anestetikov v anestezijske hlapilnike (vaporizatorje) - 1. del: Sistemi s pravokotnimi vtikaļ i

Agent specific filling systems for anaesthetic vaporizers - Part 1: Rectangular keyed filling systems

Substanzspezifische Füllsysteme für Anästhesiemittelverdampfer - Teil 1: Rechteckige Kodierte Füllsysteme

Systemes de remplissage spécifiques a l'agent pour évaporateurs d'anesthésie - Partie 1: Systemes de remplissage a clavettes rectangulaires

Ta slovenski standard je istoveten z: **EN 1280-1:1997**

ICS:

11.040.10

SIST EN 1280-1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1280-1

March 1997

+A1

May 2000

ICS 11.040.10

Descriptors: Medical equipment, anaesthetic equipment, evaporators, filling devices, specifications

English version

Agent specific filling systems for anaesthetic vaporizers — Part 1: Rectangular keyed filling systems

(includes amendment A1:2000)

Systèmes de remplissage spécifiques à l'agent pour évaporateurs d'anesthésie — Partie 1: Systèmes de remplissage à clavettes rectangulaires (inclut l'amendement A1:2000)

Substanzspezifische Füllsysteme für Anästhesiemittelverdampfer — Teil 1: Rechteckige Kodierte Füllsysteme (enthält Änderung A1:2000)

This European Standard was approved by CEN on 1997-02-15. Amendment A1 was approved by CEN on 2000-04-10. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This European Standard is based on ISO 5360, prepared by Technical Committee ISO/TC 121 of the International Organization for Standardization (ISO). ISO/TC 121 participated in the preparation of this European Standard.

Annex B is normative and forms part of this European Standard. Annex A, Annex C and Annex ZA are for information only.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directives, see informative Annex ZA, which is an integral part of this standard.

Attention is drawn to the cautions given in clauses 13.2.2 and 13.3 b). See also informative references 11 and 12 in Annex C.

EN 1280 consists of the following Parts, under the general title *Agent specific filling systems for anaesthetic vaporizers:*

— *Part 1: Rectangular keyed filling systems;*

— *Part 2: Cylindrical keyed filling systems.*

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1997, and conflicting national standards shall be withdrawn at the latest by the 13th of June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Foreword to amendment A1

This amendment EN 1280-1:1997/A1:2000 to the EN 1280-1:1997 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This amendment to the European Standard EN 1280-1:1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2000, and conflicting national standards shall be withdrawn at the latest by November 2000.

This amendment to the European Standard EN 1280-1:1997 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom

Contents

blank

1 Scope

This Part of EN 1280 specifies requirements for agent-specific filling systems used with agent-specific anaesthetic vaporizers for anaesthetic agents excluding desflurane.

NOTE 1 When used according to the instructions for use. the side effects or undesirable conditions of agent-specific filling systems constitute an acceptable risk when weighed against the performance.

NOTE 2 Specifications for agent-specific filling systems for desflurane will be given in another Part of EN 1280.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 1041, *Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer of the medical devices.*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety.*

ISO 1101, *Technical drawings — Geometrical tolerancing — Tolerancing of form, orientation location and run-out — Generalities, definitions, symbols, indication on drawings.*

EN ISO 4135, *Anaesthesiology — Vocabulary.*

(ISO 4135:1995

3 Definitions

For the purposes of this Part of EN 1280 the following definitions apply in addition to those given in EN ISO 4135.

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 e.g. threaded bottle neck with collar, bottle connector, male adaptor and filler receptacle

NOTE Different configurations of agent-specific filling systems are shown in Annex A.

4 Bottle

Each bottle shall have either a bottle collar complying with clause **5** and a bottle neck complying with Table 1 and Figure 1, or a permanently attached bottle adaptor complying with **6.2**.

5 Bottle collar

5.1 The bottle collar shall comply with the configuration and dimensions shown in Figure 2 and with the value of 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 supplied attached to the bottle and shall be rotatable by hand.

6 Bottle adaptor

NOTE Three different configurations of agent-specific filling systems are shown in Figure A.1.

6.1 If the bottle adaptor is not permanently attached to the bottle or the vaporizer [see Figure A.1 a)], it shall include:

a) 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;

b) an agent-specific male adaptor permanently attached to the bottle connector complying 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 [see Figure A.1 b)], 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 [see Figure A.1 c)] 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 0,5 thread turns on a threaded neck (see clause **4**) of an anaesthetic bottle, and;

b) will withstand when fitted to an appropriate bottle, a tightening torque of 2,5 N·m applied for 2 s, loosened and reapplied after 10 s. This procedure shall be performed for a total of 10 times; thereafter the requirements of this standard shall still be met.

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

6.5 If the bottle adaptor is permanently attached to the bottle [see Figure A.1 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 comply with clauses **8** and **9** after being drop-tested as specified in **21.5** of EN 60601-1:1990.

NOTE 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.

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

7.2 If the filler receptacle is of the type specified in **7.1** a), 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 B the mean leakage into the atmosphere of liquid or vaporized anaesthetic agent shall not exceed 0,5 ml of liquid anaesthetic agent.

NOTE 1 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 instructions for use.

NOTE 2 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. It should be noted that open vaporizer filling systems cannot limit the spillage of liquid anaesthetic agent to atmosphere.

10 Overfilling protection

NOTE Attention is drawn to the requirements for protection against overfilling of agent-specific vaporizers that will be given in the future EN 740 (currently prepared for Formal Vote with the following intended title *Anaesthetic workstations and their modules — Particular requirements*).

11 Colour coding

The bottle collar and the bottle connector shall incorporate the colour coding 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 Constructional requirements

12.1 Alternative construction

Agent specific filling systems or part thereof, using material or having forms of construction different from those detailed in this Part of EN 1280, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

12.2 Materials used for the parts of the agent-specific filling system which come into contact with liquid anaesthetic agent shall be selected with regard to:

a) toxicity;

b) compatibility with anaesthetic agents; and

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

12.3 The components of the agent-specific filling system shall be designed, manufactured and packed such that they:

a) meet the requirements of this Part of EN 1280 after being transported and stored as specified in **10.1** of EN 60601-1:1990 or, if specified by the manufacturer, under the conditions stated by the manufacturer [see **13.2.1** f)]; and

b) minimize the risk due to contaminants and residues to all personnel involved in transport, storage and use, as well as to patients.

13 Information provided by the manufacturer

prEN 1041 applies with the following additions.

13.1 Marking

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

a) the manufacturer's name and/or trademark;

b) the batch code, prefixed by the word "LOT", or the serial number; and

c) the name of the anaesthetic agent with which it is intended to be used.

NOTE The use of the generic names of anaesthetic agents according to Table 2 is recommended.

13.2 Labelling

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

a) the name and address of the manufacturer;

b) the information necessary to identify the device or the contents of the package;

c) the anaesthetic agent with which the device is to be used;

d) if appropriate an indication of the time limit for using the device safely expressed in year/month;

e) an indication if the device is for single use only;

f) any relevant particular storage and/or handling requirements.

13.2.2 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".

13.3 Instructions for use

Instructions for use of the agent-specific filling systems shall include:

a) the details referred to in **13.2.1** with the exception of those in points c) and d);

b) the warning given in **13.2.2**;

c) the 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) a statement indicating compliance of the agent-specific filling system with this European Standard.

Table 1 — Dimensions of threaded bottle necks of anaesthetic agent bottles[a]

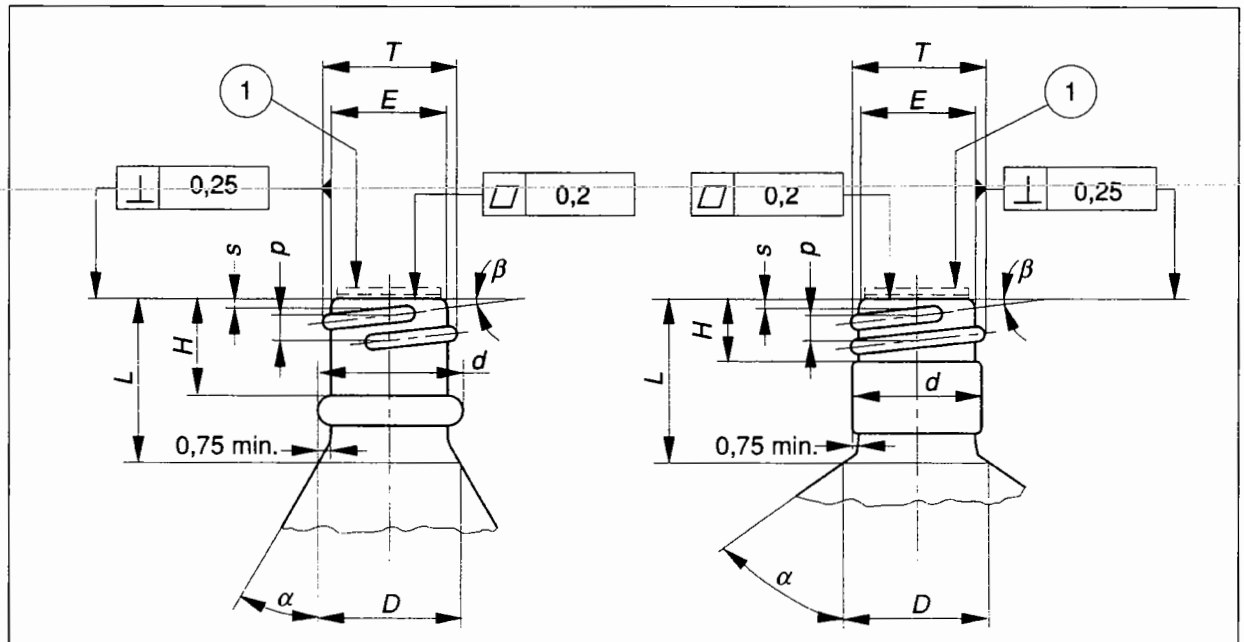
Bottle type	Anaesthetic agent	T^b ± 0.3 (mm)	E^b ± 0.3 (mm)	H ± 0,3 (mm)	S ± 0.45 (mm)	β	α (min) at dim. D	P (mm)	thread turns (min.)	L (min.) (mm)	D (nominal)	d (max.) (mm)
1	Isoflurane[c] Enflurane[c]	23,6	21,5	9,75	1,2	2° 35′	30°	3,2	1	23,0	28,0	28,0
2	Halothane	21,45	19,7	6,8	1,2	2° 15′	30°	2,54	1,25	18,7	24,0	28,0
3	Spare	21,7	19,5	15,0	1,0	2° 50′	30°	3,2	1,75	26,3	24,0	28,0
4	Spare	17,65	15,5	9,05	1,15	3° 30′	30°	3,2	1,25	20,0	20,0	28,0
5	Spare	19,65	17,5	9,05	1,15	3° 7′	30°	3,2	1,25	20,0	22,0	28,0
6	Methoxyflurane	27,3	24,9	9,8	1,15	2° 57′	30°	4,25	1,25	20,0	30,0	32,0
7	Spare	31,8	29,4	9,85	1,15	2° 31′	30°	4,25	1,25	20,0	34,0	32,0
8	Sevoflurane	23.5	21,5	8,9	1,3	2° 56′	30°	3,63	1,25	27,7	23,9	28.0
9	Desflurane	Will be given in another part of EN 1280										

[a] See also Figure 1.
[b] Summation of the tolerances of measures T and E shall be avoided. A maximum tolerance of ± 0.3 mm for (T-E) should be required, to avoid problems with the fitting of any bottle connector.
[c] Non-interchangeability achieved via different bottle collars and connectors (see Table 2).

Table 2 — Dimensions and colour of agent-specific bottle collars and connectors[a]

Anaesthetic agent	θ^b ± 0° 30′	Specified colour	Examples of colour samples: Federal Standard 595a Colour	BS 5252 colour	Pantone colour	SS 019100-03 Colour NCS: Exact Value	SS 019100-03 Colour NCS: Nearest Colour sample	Munsell colour	DIN 6164-2 colour
Halothane	– 20°	Red	11105	04 E 56	200 C	1375-R	1080-R	5A4/14	0:7:2
Enflurane	+ 20°	Orange	12510	06 E 55	151 C	0582-V453R	0090-V50R	2,5VR 6/16	5:5:1
Methoxyflurane	0°	Green	14187	14 E 53	334 C	2458-895G	2060-890G	10G 5/10	21:6:3
Desflurane	n.s.[c]	Blue	n.a.[d]	18 E 53	3015 C	2860-B	3040-G	10B 4/10	19:4:3
Not for agent identification	n.s.	White	37875	18 B 15	5455 C	0703-B25G	1002-G	108 9/1	N:0:0,5
Not for agent identification	n.s.	Black	15042	00 E 53	Process Black C	9000	9500	N 0,5	N:0:9
Sevoflurane	+ 50°	Yellow	n.a.	10 E 51	109 G	1080-Y	1080-Y	SY 8/14	2:6:1
Isoflurane	– 40°	Purple	n.a.	24 E 53	254 G	2854-A498	3060-R505	7 SP 4/12	11:4:4
Spare	n.s.	Grey	16251	00 A 09	Cool grey 9C	5204-A83G	5502G	SPE 5/1	N:0:4

[a] 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.
[b] Sign "+" means clockwise rotation and sign "–" means counterclockwise rotation when viewed from the top.
[c] n.s. = not specified.
[d] n.a. = not available.



1. Optional pouring lip (not dimensioned).

Dimensions in millimetres

NOTE 1 See also Table 1 for dimensions of threaded bottle necks.
NOTE 2 Flatness and perpendicularity tolerances according to ISO 1101.
NOTE 3 The dimensions shown form part of this European Standard; other features are for illustrative purposes only.

Figure 1 — Two examples of threaded bottle necks for anaesthetic agent bottles