

Anaesthetic vaporizers — Agent-specific filling systems

The European Standard EN ISO 5360:2007 has the status of a British Standard

ICS 11.040.10

National foreword

This British Standard is the UK implementation of EN ISO 5360:2007. It supersedes BS EN 1280-1:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2008

© BSI 2008

ISBN 978 0 580 59003 0

Amendments/corrigenda issued since publication

Date	Comments

English Version

Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2006)

Evaporateurs d'anesthésie - Systèmes de remplissage
spécifiques à l'agent (ISO 5360:2006)

Anästhesiemittelverdampfer - Substanzspezifische
Füllsysteme (ISO 5360:2006)

This European Standard was approved by CEN on 19 November 2007.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of ISO 5360:2006 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5360:2007 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

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 June 2008, and conflicting national standards shall be withdrawn at the latest by June 2008.

This document supersedes EN 1280-1:1997.

This document 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 Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 5360:2006 has been approved by CEN as EN ISO 5360:2007 without any modifications.

INTERNATIONAL STANDARD

ISO
5360

Second edition
2006-10-01

Anaesthetic vaporizers — Agent-specific filling systems

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



Reference number
ISO 5360:2006(E)

AVA Documents
Document Sharing Hub

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.....	8
7 Filler receptacle.....	12
8 Filling rate	14
9 Leakage.....	16
10 Overfilling protection.....	16
11 Colour coding.....	16
12 Information provided by the manufacturer	16
Annex A (informative) Types of agent-specific filling systems	18
Annex B (normative) Determination of total leakage into atmosphere of anaesthetic agent during filling.....	19
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices.....	22
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 second edition cancels and replaces the first edition (ISO 5360:1993) which has been technically revised by virtue of incorporation of Technical Corrigendum 1:1998, inclusion of the changes presented and approved for ISO 5360:1993/Amd 1 (not published) and the need to update cross-references and other factual matters due to the passage of time.

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;
- 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.

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.

2 Normative references

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 1101:2004, *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 A.

- 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

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.