INTERNATIONAL STANDARD

ISO 8835-4

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Inhalational anaesthesia systems —

Part 4: Anaesthetic vapour delivery devices

Systèmes d'anesthésie par inhalation —

Partie 4: Dispositifs d'alimentation en vapeur anesthésique

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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 8835-4 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

ISO 8835 consists of the following parts, under the general title *Inhalational anaesthesia systems*:

— *Part 2: Anaesthetic breathing systems for adults*

— *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

NOTE ISO 8835-1 was withdrawn and has been revised as IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13, Particular requirements for the safety and essential performance of anaesthetic systems.*

Introduction

This part of ISO 8835 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE 1 Definitions of Collateral Standards and Particular Standards can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 8835, the following drafting conventions have been applied.

This part of ISO 8835 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard [as supplemented by the Collateral Standards], are specified by the use of the following words:

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.

— “Amendment” means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this part of ISO 8835: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this part of ISO 8835, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2, or in this Particular Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

NOTE 2 Attention is drawn to ISO/TS 18835 concerning draw-over vaporizers.

Inhalational anaesthesia systems —

Part 4:
Anaesthetic vapour delivery devices

1 Scope

IEC 60601-1:1988, Clause 1 applies except as follows.

Addition:

This part of ISO 8835 specifies particular requirements for the essential performance of anaesthetic vapour delivery devices (AVDDs), as defined in 3.1. This part of ISO 8835 is applicable to AVDDs which are a component of an anaesthetic system and are intended to be continuously operator-attended. This part of ISO 8835 gives specific requirements for AVDDs which are supplementary to the applicable general requirements in IEC 60601-2-13.

This part of ISO 8835 is not applicable to AVDDs intended for use with flammable anaesthetics, as determined by Annex CC, and AVDDs intended for use within anaesthetic breathing systems (e.g. draw-over vaporizers).

The requirements of this part of ISO 8835 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 8835-3, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

ISO 11196, *Anaesthetic gas monitors*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres. Part 4: Method of test for ignition temperature*

IEC 60079-11, *Electrical apparatus for explosive gas atmospheres — Part 11: Intrinsic safety "i"*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, IEC 60601-2-13 and the following apply.

3.1
anaesthetic vapour delivery device
AVDD
device which provides the vapour of an anaesthetic agent in a controllable concentration

3.2
legible
property of displayed qualitative or quantitative information, values, functions and markings that can be discriminated and identified under a specific set of environmental conditions

NOTE See 6.101 for testing for legibility.

4 General requirements and general requirements for tests

IEC 60601-1:1998, Clauses 3 and 4 apply, except as follows.

Addition:

4.101 Other test methods

Test methods other than those specified in this part of ISO 8835, but of equal or greater accuracy, may be used to verify compliance with requirements.

5 Classification

IEC 60601-1:1988, Clause 5 applies.

6 Identification, marking and documents

IEC 60601-2-13:2003, Clause 6 applies, except as follows.

Additions:

6.1 aa) The **AVDD** shall be labelled with the words “before use read instructions for use”, or Symbol #14 from IEC 60601-1:1988, Table D.1.

6.3 Marking of controls and instruments

Additions:

aa) Controls for anaesthetic vapour output shall be marked with an indication how to increase vapour output. (See 101.3 for rotary controls)

bb) Either the maximum and minimum filling levels shall be marked on the liquid level indicator, or the actual usable volume shall be displayed.

cc) The filling port shall be marked with the generic name of the anaesthetic agent. The control activating the delivery of a specific anaesthetic agent shall be marked with the generic name in full spelling or in abbreviated form as given in the following list:

- Desflurane: “DES”
- Enflurane: “ENF”
- Halothane: “HAL”
- Isoflurane: “ISO”
- Sevoflurane: “SEV”

If colour coding is used, it shall be in accordance with Annex BB.

dd) The units in which the control of the **AVDD** is graduated shall be indicated.

ee) Graduated controls shall be marked with “0” or “Off”, or with both if the “0” position is not also the “Off” position, or with “Standby” if the “Off” position is not provided.

NOTE If the **AVDD** is set at “Off” or “Standby”, no anaesthetic vapour is intentionally being added to the output flow. “Standby” set on an electrically operated **AVDD** indicates that the **AVDD** is enabled. “0” setting indicates that no more than the manufacturer's prescribed tolerance of anaesthetic vapour is being added to the output flow.

6.8.2 Instructions for use

Additions:

aa) The instructions for use of the **AVDD** shall contain a statement to the effect that the **AVDD** is intended to be used with

- an anaesthetic agent monitor complying with ISO 11196, and
- an anaesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3.

bb) The instructions for use of the **AVDD** shall contain

1) instructions for fitting the **AVDD**, if appropriate,
2) the performance of the **AVDD**, if applicable, including the effects of variation in ambient temperature, ambient pressure, resistance to flow, tilting, back-pressure, sub-atmospheric pressure, input flow and gas mixture over the range of operating conditions specified by the manufacturer,
3) instructions for filling the **AVDD**,
4) the volume of anaesthetic agent required to fill the reservoir of the **AVDD** from the minimum to the maximum filling level, and the total capacity,

NOTE The anaesthetic agent bottle can be used as the anaesthetic agent reservoir.

5) if the **AVDD** should not be used at a setting between “Off” and the first graduation above zero, a statement to this effect,

6) the carrier gas, gas flowrate(s) and analytical technique(s) recommended for measuring the output of the **AVDD**,

7) advice on handling, transportation and storage.

6.101 Test method for legibility

Legible indications shall be correctly perceived by an **operator** with a visual acuity of 0 on the log MAR scale or 66 (20/20) vision (corrected if necessary) from a distance of 1 m ± 10 % at a light level of 215 lux ± 65 lux, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the normal line of sight of the **operator**.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies.

11 Not used

IEC 60601-1:1988, Clause 11 applies.

12 Not used

IEC 60601-1:1988, Clause 12 applies.

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.