INTERNATIONAL STANDARD

ISO 8835-5

First edition
2004-05-15

Inhalational anaesthesia systems —

Part 5: Anaesthetic ventilators

Systèmes d'anesthésie par inhalation —

Partie 5: Ventilateurs d'anesthésie

Reference number
ISO 8835-5:2004(E)

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Published in Switzerland

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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 8835-5 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, *Medical electrical equipment — Part 1: Particular requirements for the safety of anaesthetic workstations,* was withdrawn in 1998 and replaced by the second edition of IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential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 Definitions of Collateral Standard and Particular Standard 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 an existing element 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: 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;

— description of type of document change, and test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2 and terms defined in this part of ISO 8835: **bold type**.

Throughout this part of ISO 8835, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Inhalational anaesthesia systems —

Part 5:
Anaesthetic ventilators

1 Scope

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

This part of ISO 8835 specifies particular requirements for the essential performance of **anaesthetic ventilators** (as defined in 3.1). This part of ISO 8835 is applicable to **anaesthetic ventilators** which are always a component of an **anaesthetic system** and are intended to be continuously attended by an **operator**.

This part of ISO 8835 is not applicable to **anaesthetic ventilators** intended for use with flammable anaesthetics, as determined by Annex BB.

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 407, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 8835-2:1999, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems for adults*

ISO 8835-3:1997, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

ISO 10524, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

EC 60079-11:1999, *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 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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 part of ISO 8835, the terms and definitions given in IEC 60601-1, ISO 4135 and IEC 60601-2-13 and the following apply.

3.1
anaesthetic ventilator
lung ventilator designed for use during anaesthesia with an anaesthetic breathing system

3.2
breathing system connection port
port which connects the ventilator to the breathing system

3.3
legible
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.

3.4
driving gas
gas which powers the ventilator but is not delivered to the **patient**

3.5
driving gas inlet port
port to which the **driving gas** is supplied

3.6
inflating gas
gas delivered to the **patient's** airway which is controlled by the **anaesthetic ventilator**

NOTE The **inflating gas** may also power the **anaesthetic ventilator**.

3.7
inflating gas inlet port
port to which the **inflating gas** is supplied

3.8
maximum limited pressure
$p_{\text{LIM max}}$
highest pressure at the **patient** connection port during **normal use** and under a **single fault condition**

NOTE Adapted from IEC 60601-2-12.

3.9
minimum limited pressure
$p_{LIM\ min}$
lowest pressure at the **patient** connection port during **normal use** and **under a single fault condition**

NOTE 1 Adapted from IEC 60601-2-12.

NOTE 2 This pressure may be sub-atmospheric.

3.10
maximum working pressure
$p_{W\ max}$
highest pressure which can be attained at the **patient** connection port during the inspiratory phase, with the ventilator operating normally

[ISO 4135]

3.11
minimum working pressure
$p_{W\ min}$
lowest (most negative) pressure which can be attained at the **patient** connection port during the expiratory phase, with the ventilator operating normally

[ISO 4135]

3.12
oxygen-rich environment
environment in which the partial pressure of oxygen is greater than 275 hPa

4 General requirements and general requirements for tests

IEC 60601-1:1988, 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 Clause 6 applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

Additions:

aa) If provided and **operator**-accessible, the following ports shall be legibly and durably marked:

— **driving gas inlet port;**

— **driving gas** exhaust port;

— **inflating gas** inlet port;

— **fresh gas** inlet;

— **anaesthetic breathing system** connection port;

— inspiratory port;

— expiratory port;

— exhaust port;

— bag port.

6.3 Marking of controls and instruments

Addition:

aa) The **operator**-adjustable means for pressure limitation shall be graduated in units or multiples of pascals and/or centimetres water.

6.8.2 Instructions for use

Additions:

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

1) an **anaesthetic breathing system** in accordance with ISO 8835-2, and

2) an anaesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3.

Unless the **anaesthetic ventilator** is an integral part of an **anaesthetic system**, the manufacturer/supplier of the **anaesthetic ventilator** shall provide information on how to connect the **anaesthetic breathing system** and the **anaesthetic gas scavenging transfer and receiving system**.

bb) The manufacturer/supplier of an **anaesthetic ventilator** shall provide the following information:

1) an instruction on how to perform a leak test of the **anaesthetic ventilator**;

2) the supply pressure range required for the driving gas(es) of the **anaesthetic ventilator**;

3) set-up, gas flow(s) and technique recommended for testing the **anaesthetic ventilator** before use;

4) a warning that the **anaesthetic ventilator** is not intended to be used with flammable anaesthetic agents;

5) inspiratory flow and pressure characteristics.

cc) The instructions for use shall contain a statement to the effect that flammable anaesthetic agents such as diethyl ether and cyclopropane shall not be used with the **anaesthetic ventilator**. Only anaesthetic agents which comply with the requirements for non-flammable anaesthetic agents as specified in Annex BB of this part of ISO 8835 are suitable for use with the **anaesthetic ventilator**.

dd) The instructions for use shall contain a description of the functioning of the **anaesthetic ventilator** after interruption of the power supply and, where applicable, the functioning of the **anaesthetic ventilator** after a switch-over to a reserve power supply.

6.8.3 Technical description

Addition:

aa) The technical description shall provide the operational characteristics of the **anaesthetic ventilator**, including, if appropriate, the following:

— range of delivered volumes (tidal and minute);

— range of breathing frequency;

— range of I:E ratios;

— range of values to which the **maximum working pressure** can be set and the means by which the maximum pressure is controlled (e.g. pressure cycling, pressure limitation);

— inspiratory flow and pressure characteristics;

— modes of cycling;

— minimum limited pressure;

— positive end-expiratory pressure (PEEP) range;

— if there is a facility for sub-atmospheric pressure in the expiratory phase, the limiting pressure and generated pressure;

— if provided, characteristics of the means of triggering;

— if applicable, interdependance of controls;

— any restrictions on the location and/or sequence of components within the **anaesthetic breathing system** supplied or recommended by the manufacturer (e.g. where such components are flow-direction-sensitive);

— the range of internal volume of any breathing attachments or other components or subassemblies recommended by the manufacturer.

6.101 Test method for legibility

Legible indications are correctly perceived by an operator with a visual acuity of 0 on the log MAR scale or 6-6 (20/20) vision (corrected if necessary) from a distance of 1 m ± 0,1 m 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 line of sight of the **operator**.

7 Power input

IEC 60601-1:1988, Clause 7 applies.