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Standards

Irish Standard
I.S. EN ISO 8835-5:2009

Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004)

I.S. EN ISO 8835-5:2009

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English Version

Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004)

Systèmes d'anesthésie par inhalation - Partie 5:
Ventilateurs d'anesthésie (ISO 8835-5:2004)

Systeme für die Inhalationsanästhesie - Teil 5: Anästhesie-
Beatmungsgeräte (ISO 8835-5:2004)

This European Standard was approved by CEN on 1 March 2009.

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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.



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Foreword

The text of ISO 8835-5:2004 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 8835-5:2009 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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8835-5:2004.

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 EC Directive.

For relationship with EC Directive, 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 8835-5:2004 has been approved by CEN as a EN ISO 8835-5:2009 without any modification.

I.S. EN ISO 8835-5:2009

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**ISO
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Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators

*Systèmes d'anesthésie par inhalation —
Partie 5: Ventilateurs d'anesthésie*



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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*

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