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Irish Standard
I.S. EN ISO 8835-2:2009

Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

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EUROPEAN STANDARD

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EN ISO 8835-2

April 2009

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Supersedes EN ISO 8835-2:2007

English Version

Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

Systèmes d'anesthésie par inhalation - Partie 2: Systèmes respiratoires d'anesthésie (ISO 8835-2:2007)

Systeme für die Inhalationsanästhesie - Teil 2: Anästhesie-Atemsysteme (ISO 8835-2:2007)

This European Standard was approved by CEN on 14 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.

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Foreword

The text of ISO 8835-2:2007 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 8835-2:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 8835-2:2007.

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.

Other European Standards relating to anaesthetic workstations and their components prepared by CEN/TC 215 which together with EN 60601-2-13:2006, replace appropriate portions of EN 740:1998, are:

– EN ISO 8835-2:2007, Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

– EN ISO 8835-3:2007, Inhalational anaesthesia systems – Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)

– EN ISO 8835-4:2004, Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)

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

Attention is also drawn to ISO/TS 18835:2004, Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment.

Annex RR of EN 740:1998 (Method of test for draw-over vaporizers used with emergency anaesthetic equipment) is not superseded.

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 8835-2:2007 has been approved by CEN as a EN ISO 8835-2:2009 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1 to 6	
4.1	1 to 6 and 7 (except 7.4 and 7.5, 2nd and 3rd paragraphs)	The relevant Essential Requirement 7.5, 1st paragraph, is not fully addressed in this EN. The relevant Essential Requirements 7.5 (2nd and 3rd paragraphs) are not addressed in this EN.
-	6a)	This relevant Essential Requirement is not addressed in this EN.
4.2	9.2	
4.3	12.6	
5	9, 12.7, 12.9	
5.2	9, 12.7	
6	9, 12.7	
7	9.2, 12.7, 12.8	
8.1	9, 12.9	
8.2 to 8.4	9, 12.8	
9.1	9, 12.7	
9.2, 9.3	9, 12.7, 12.8	
9.4	9	
10	9, 10	
11	9	

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Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
12	9 and 13 (except 13.6 h and 13.6q)	The relevant Essential Requirements 13.3 a) and 13.3 f) are not fully addressed in this EN.
13	9 and 13	The relevant Essential Requirements 13.3 a) and 13.3 f) are not fully addressed in this EN. The relevant Essential Requirements 13.6 h), 2nd paragraph, last two sentences and 13.6 q) are not addressed in this EN

WARNING - Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 8835-2:2009

INTERNATIONAL STANDARD

ISO 8835-2

Third edition
2007-08-15

Inhalational anaesthesia systems —

Part 2: Anaesthetic breathing systems

Systèmes d'anesthésie par inhalation —

Partie 2: Systèmes respiratoires d'anesthésie

Reference number
ISO 8835-2:2007(E)

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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 8835-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This third edition cancels and replaces the second edition (ISO 8835-2:1999), which has been technically revised.

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

— *Part 2: Anaesthetic breathing systems*

— *Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

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Introduction

An anaesthetic breathing system comprises an assembly of tubes and connectors and may include valves, a reservoir bag and a circle absorber assembly. Other items of equipment (e.g. humidifiers, filters, spirometers, thermometers, gas analysers) may be incorporated into an anaesthetic breathing system.

Its function is to convey mixtures of gases to and from the patient.

Annex A gives typical test arrangements and methods. Annex B gives the rationale for some of the requirements found within this part of ISO 8835.

Annex B contains rationale statements for some of the requirements of this part of ISO 8835. The clauses and subclauses marked with an asterix (*) before their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard.

Annex C lists the clauses of this part of ISO 8835 that address the environmental aspects of the device.

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Inhalational anaesthesia systems —

Part 2:
Anaesthetic breathing systems

* 1 Scope

This part of ISO 8835 specifies requirements for anaesthetic breathing systems that are supplied either assembled by the manufacturer or for assembly by the user in accordance with the manufacturer's instructions.

It also covers circle absorber assemblies, exhaust valves, inspiratory and expiratory valves and, in some designs, those parts of an anaesthetic breathing system that are incorporated within an inhalation anaesthetic system, including the expiratory gas pathway of an anaesthetic ventilator.

This part of ISO 8835 does not cover the performance of anaesthetic breathing systems regarding the elimination of expired carbon dioxide since this is complex and depends on the interaction of the patient, the fresh gas flow, the carbon dioxide absorbent and the anaesthetic breathing system itself.

This part of ISO 8835 does not apply to anaesthetic breathing systems intended for use with flammable anaesthetic agents/gases as determined by Annex DD of IEC 60601-2-13:2003.

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 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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 5362, *Anaesthetic reservoir bags*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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