SLOVENSKI STANDARD

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Inhalacijski anestezijski sistemi - 2. del: Anestezijski dihalni sistemi za odrasle (ISO 8835-2:2007)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 8835-2:2007**

ICS:

11.040.10

SIST EN ISO 8835-2:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8835-2

August 2007

ICS 11.040.10

Supersedes EN 740:1998

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 9 June 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

Ref. No. EN ISO 8835-2:2007: E

Foreword

This document (EN ISO 8835-2:2007) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 February 2008, and conflicting national standards shall be withdrawn at the latest by May 2009.

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.

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.

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

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 United Kingdom.

Endorsement notice

The text of ISO 8835-2:2007 has been approved by CEN as EN ISO 8835-2:2007 without any modifications.

ANNEX ZA
(informative)

Relationship between this 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 to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices (Medical Device Directive).

Once this European 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 European Standard given in Table ZA.1 confers, within the limits of the scope of this European Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1 to 6	
4.1	1 to 6, and 7	
4.2	1 to 6, and 9.2	
4.3	1 to 6, and 12.6	
4.4		
5	1 to 6, 9 and 12.7	
6	1 to 6, 9 and 12.7	
7	1 to 6, 9.2 and 12.7	
8.1	1 to 6, 9 and 12.7	
8.2	1 to 6, 9 and 12.9	
8.2.2	1 to 6, and 9	
8.2.3	1 to 6, 9 and 12.7	
9.1	1 to 6, and 9	
9.2	1 to 6, 9 and 12.7	
9.3	1 to 6, 9, 12.7 and 12.9	
9.4	1 to 6, and 9	
9.5.1	1 to 6, and 9	
9.5.2	1 to 6, and 9	
9.5.3	1 to 6, and 9	

9.5.4	1 to 6, and 9	
9.5.5	1 to 6, and 9	
10	1 to 6, 9 and 10	
11	1 to 6, and 9	
12	1 to 6, 9 and 13	
13	1 to 6, 9 and 13	

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

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*

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.