



SLOVENSKI STANDARD SIST EN ISO 8835-3:2009

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BUXca Yý U
SIST EN ISO 8835-3:2008

Inhalacijski anestezijski sistemi - 3. del: Sistemi za prenos in sprejem sistemov za odstranjevanje anestezijskih plinov (ISO 8835-3:2007)

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

Systeme für die Inhalationsanästhesie - Teil 3: Weiterleitungs- und Aufnahmesysteme von aktiven Anästhesiegas-Fortleitungssystemen (ISO 8835-3:2007)

Systemes d'anesthésie par inhalation - Partie 3: Systèmes de transfert et de réception des systèmes d'évacuation des gaz d'anesthésie (ISO 8835-3:2007)

Ta slovenski standard je istoveten z: EN ISO 8835-3:2009

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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EUROPEAN STANDARD

EN ISO 8835-3

NORME EUROPÉENNE

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March 2009

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English Version

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

Systèmes d'anesthésie par inhalation - Partie 3: Systèmes de transfert et de réception des systèmes d'évacuation des gaz d'anesthésie (ISO 8835-3:2007)

Systeme für die Inhalationsanästhesie - Teil 3: Weiterleitungs- und Aufnahmesysteme von aktiven Anästhesiegas-Fortleitungssystemen (ISO 8835-3:2007)

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

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
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Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
Foreword.....	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC.....	4

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Foreword

The text of ISO 8835-3:2007 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 8835-3:2009 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 8835-3:2007.

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 EN 740:1998 in total, are:

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

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– 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.

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 8835-3:2007 has been approved by CEN as a EN ISO 8835-3:2009 without any modification.

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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	2, 12.7.4	
4.1	7.5 (1 st paragraph)	This relevant Essential Requirement is not completely addressed in this EN.
11, 12	1, 2 nd paragraph, 1 st and 2 nd dash	These relevant Essential Requirements are not fully addressed in this EN
11, 12	13.1	
11, 12	13.3 b)	
11 d)	13.6 h)	
	13.6 q)	This relevant Essential Requirement is not addressed in this EN
12 b)	13.3 a)	This relevant Essential Requirement is not completely addressed in this EN

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

INTERNATIONAL STANDARD

ISO
8835-3

Second edition
2007-08-15

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

Systèmes d'anesthésie par inhalation —

*Partie 3: Systèmes de transfert et de réception des systèmes
d'évacuation des gaz d'anesthésie*

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ISO 8835-3:2007(E)

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
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Contents

Page

Foreword.....	iv
Introduction	v
* 1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 General requirements and alternative test methods.....	4
4.1 Materials	4
4.2 Means of pressure relief	4
4.3 Alternative test methods.....	4
* 5 Patient and environmental protection	4
5.1 Normal operating conditions.....	4
5.2 Single fault conditions	5
* 6 Connectors	5
* 7 Transfer systems.....	5
7.1 Inlet of transfer systems.....	5
7.2 Outlet of transfer systems.....	6
* 8 Receiving systems.....	6
8.1 General.....	6
8.2 Inlet of receiving systems.....	6
8.3 Outlet of receiving systems.....	7
8.4 Visual indicator	7
8.5 Particle filter	7
8.6 Receiving hoses.....	7
9 Extract flow resistance.....	7
9.1 Low-flow transfer and receiving systems	7
9.2 High-flow transfer and receiving systems	7
10 Electrical requirements	8
* 11 Information to be supplied by the manufacturer.....	8
12 Marking	8
* 13 Colour coding.....	8
Annex A (informative) Typical test arrangement and method for pressure measurement at inlet to AGSS.....	9
Annex B (informative) Typical test arrangement and method for sub-atmospheric pressure limitation	13
Annex C (informative) Typical test arrangement and method for testing of induced flow.....	14
Annex D (informative) Typical test arrangement and method for resistance to extract flow.....	15
Annex E (informative) Typical test arrangement and method for spillage.....	17
Annex F (informative) Rationale	20
Annex G (informative) Environmental aspects	22
Bibliography	23

ISO 8835-3:2007(E)

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 8835-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This second edition cancels and replaces the first edition (ISO 8835-3:1997), 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

This part of ISO 8835 is intended to ensure that, for all practical purposes, an active AGSS will remove essentially all gases delivered to it and thereby reduce atmospheric pollution to a small fraction of the uncontrolled level.

It is recognized that there are many factors affecting conditions within the operator's working environment, which are outside the control of manufacturers of active AGSSs. These include room ventilation, leakage from equipment and the choice of anaesthetic technique, all of which are variable. Furthermore, the amount of pollutant taken up by personnel will be affected by other factors, such as the duration of exposure, their position in relation to any source of pollution, etc.

Atmospheric pollution by anaesthetic gases is the subject of considerable discussion, and opinions differ as to the limits that should be allowed in the working environment. Recommendations on permissible levels are therefore not included in this part of ISO 8835 but can be specified in national standards.

The committee responsible for this part of ISO 8835 has been primarily concerned with limiting the risks to the patient, which the transfer and receiving systems of AGSS can introduce by altering the function of breathing systems. The wide range of anaesthetic machines, ventilators and related equipment in general use today has been taken into account.

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

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