Inhalatsioonianesteesiasüsteemid. Osa 3: Aktiivanesteesigaasi puhastamissüsteemi ülekande- ja vastuvõtusüsteemid

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8835-3:2009 sisaldab Euroopa standardi EN ISO 8835-3:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8835-3:2009 consists of the English text of the European standard EN ISO 8835-3:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 18.03.2009.	Date of Availability of the European standard text 18.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: anesteesiaaparatuur, moodulid, ohutusnõuded, üksikasjalikud tehnilised andmed

EUROPEAN STANDARD

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EN ISO 8835-3

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 8835-3:2009: E

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)

– 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 (1st paragraph)	This relevant Essential Requirement is not completely addressed in this EN.
11, 12	1, 2nd paragraph, 1st and 2nd 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.

Contents

Page

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 asterix (*) before their number have corresponding rationale contained in Annex F, included to provide additional insight into the reasoning that led to the requirements and recommandations that have been incorporated in this International Standard.

Inhalational anaesthesia systems —

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

* 1 Scope

This part of ISO 8835 specifies requirements for transfer and receiving systems of active anaesthetic gas scavenging systems (active AGSSs) intended to reduce exposure of healthcare personnel to anaesthetic gases and vapours while providing patient protection (e.g. against excessive flow and pressure). This part of ISO 8835 also specifies requirements for transfer and receiving systems of active anaesthetic gas scavenging systems in which the power device is integral with the transfer and receiving system.

This part of ISO 8835 does not specify requirements for

— disposal systems which are covered by ISO 7396-2,

— non-active AGSSs (passive AGSSs),

— proximity gas extraction systems (i.e. systems not directly connected to the breathing system or associated equipment),

— transfer and receiving systems intended for use with flammable anaesthetic 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 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 connections*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases*

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

ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

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

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2:—[1)], *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 21647, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*