

**Inhalatsioonianesteesiasüsteemid. Osa 2:  
Anesteesiahingamissüsteemid**

Inhalational anaesthesia systems - Part 2: Anaesthetic  
breathing systems

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 8835-2:2009 sisaldab Euroopa standardi EN ISO 8835-2:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 08.04.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 8835-2:2009 consists of the English text of the European standard EN ISO 8835-2:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 29.05.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 08.04.2009.

The standard is available from Estonian standardisation organisation.

ICS 11.040.10

**Võtmesõnad:** anesteesiaaparatuur, moodulid, ohutusnõuded, üksikasjalikud tehnilised andmed

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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)

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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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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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## 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.

# 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*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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

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