

Inhalational anaesthesia systems —

Part 5: Anaesthetic ventilators

The European Standard EN ISO 8835-5:2004 has the status of a British Standard

ICS 11.040.10

National foreword

This British Standard is the official English language version of EN ISO 8835-5:2004, including Corrigenda December 2004 and January 2006. It is identical with ISO 8835-5:2004. Together with BS EN ISO 8835 Parts 1 to 4 (when published) this supersedes BS EN 740:1999, which will remain current until 30 November 2009.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/1, Breathing attachments and anaesthetic machines, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

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Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO Foreword page, the ISO title page, pages ii to vi, pages 1 to 16, five Annex ZA pages and a back cover.

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Amendments issued since publication

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English version

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Systèmes d'anesthésie par inhalation - Partie 5:
Ventilateurs d'anesthésie (ISO 8835-5:2004)

Systeme für die Inhalationsanästhesie - Teil 5: Anästhesie-
Beatmungsgeräte (ISO 8835-5:2004)

This European Standard was approved by CEN on 6 May 2004.

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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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This document (EN ISO 8835-5:2004) 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 November 2004, and conflicting national standards shall be withdrawn at the latest by November 2009.

This document partially supersedes EN 740:1998.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8835-5:2004 has been approved by CEN as EN ISO 8835-5:2004 without any modifications.

INTERNATIONAL STANDARD

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Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators

*Systèmes d'anesthésie par inhalation —
Partie 5: Ventilateurs d'anesthésie*



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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and general requirements for tests	3
5 Classification	3
6 Identification, marking and documents	3
7 Power input	5
8 Basic safety categories	6
9 Removable protective means	6
10 Environmental conditions	6
11 Not used	6
12 Not used	6
13 General	6
14 Requirements related to classification	6
15 Limitation of voltage and/or energy	6
16 Enclosures and protective covers	6
17 Separation	6
18 Protective earthing, functional earthing and potential equalization	6
19 Continuous leakage currents and patient auxiliary currents	7
20 Dielectric strength	7
21 Mechanical strength	7
22 Moving parts	7
23 Surfaces, corners and edges	7
24 Stability in normal use	7
25 Expelled parts	7
26 Vibration and noise	7
27 Pneumatic and hydraulic power	7
28 Suspended masses	7
29 X-Radiation	7
30 Alpha, beta, gamma, neutron radiation and other particle radiation	8
31 Microwave radiation	8
32 Light radiation (including lasers)	8
33 Infra-red radiation	8

34	Ultraviolet radiation.....	8
35	Acoustical energy (including ultrasonics).....	8
36	Electromagnetic compatibility	8
37	Locations and basic requirements	8
38	Marking and accompanying documents.....	8
39	Common requirements for category AP and category APG equipment	8
40	Requirements and tests for category AP equipment, parts and components thereof	9
41	Requirements and tests for category APG equipment, parts and components thereof	9
42	Excessive temperatures	9
43	Fire prevention.....	9
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	9
45	Pressure vessels and parts subject to pressure	10
46	Human errors	10
47	Electrostatic charges	10
48	Biocompatibility.....	10
49	Interruption of the power supply	10
50	Accuracy of operating data	10
51	Protection against hazardous output.....	10
52	Abnormal operation and fault conditions.....	11
53	Environmental tests	11
54	General	11
55	Enclosures and covers	11
56	Components and general assembly.....	11
57	Mains parts, components and layout.....	12
58	Protective earthing — Terminals and connections	12
59	Construction and layout	12
101	Additional requirements for anaesthetic ventilators	12
102	Appendices of IEC 60601-1:1988	13
	Annex AA (informative) Rationale.....	14
	Annex BB (normative) Test for flammability of anaesthetic agents.....	15
	Bibliography.....	16

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 8835-5 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

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

- *Part 2: Anaesthetic breathing systems for adults*
- *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*
- *Part 4: Anaesthetic vapour delivery devices*
- *Part 5: Anaesthetic ventilators*

NOTE ISO 8835-1, *Medical electrical equipment — Part 1: Particular requirements for the safety of anaesthetic workstations*, was withdrawn in 1998 and replaced by the second edition of IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*.

Introduction

This part of ISO 8835 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 8835, the following drafting conventions have been applied.

This part of ISO 8835 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

- “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.
- “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, Note, table, figure) additional to the General Standard.
- “Amendment” means that an existing element of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this part of ISO 8835: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this part of ISO 8835, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- notes and examples: smaller roman type;
- description of type of document change, and test methods: *italic type*;
- terms defined in the General Standard IEC 60601-1:1988, Clause 2 and terms defined in this part of ISO 8835: **bold type**.

Throughout this part of ISO 8835, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).