Irish Standard
I.S. EN ISO 8835-4:2009

Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)

I.S. EN ISO 8835-4:2009

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EUROPEAN STANDARD

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English Version

Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)

Systèmes d'anesthésie par inhalation - Partie 4: Dispositifs d'administration de vapeur anesthésique (ISO 8835-4:2004)

Systeme für die Inhalationsanästhesie - Teil 4: Anästhesiemittelverdampfer (ISO 8835-4:2004)

This European Standard was approved by CEN on 21 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.

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Foreword

The text of ISO 8835-4:2004 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 8835-4:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 8835-4:2004.

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.

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 8835-4:2004 has been approved by CEN as a EN ISO 8835-4:2009 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 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
1	IEC 60601-1: 1988 & this Standard	Not applicable	
2	IEC 60601-1: 1988 & this Standard	Not applicable	
3	IEC 60601-1: 1988 , IEC 60601-2-13:1998/ISO 8835-1, ISO 4135 & this Standard	Not applicable	
4	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
4.101	This Standard only	1 (first paragraph) to 6 as applicable	
5	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
6	IEC 60601-1: 1988 and IEC 60601-2-13:1998/ISO 8835-1,	1 (first paragraph) to 6 as applicable , 13.1, to 13.5 as applicable	The relevant Essential requirement 13.3 a) is partly addressed
6.1 aa)	This Standard only	1 (first paragraph) to 6 as applicable , 13.1, to 13.5 as applicable	The relevant Essential requirement 13.3 a) is partly addressed
6.101	This Standard only	1 (first paragraph) to 6 as applicable	
6.3	IEC 60601-1: 1988 and IEC 60601-2-13:1998/ISO 8835-1,	1 (first paragraph) to 6 as applicable, 10.2, 10.3, 12.9, 13.1, to 13.5 as applicable	The relevant Essential requirement 13.3 a) is partly addressed

6.3 aa)	This Standard only	1 (first paragraph) to 6 as applicable, 10.2, 10.3, and 12.9,	
6.3 bb)	This Standard only	1 (first paragraph) to 6 as applicable, 10.2, 10.3, and 12.9,	
6.3 cc)	This Standard only	1 (first paragraph) to 6 as applicable, 10.2, 10.3, and 12.9,	
6.3 dd)	This Standard only	1 (first paragraph) to 6 as applicable, 10.2, 10.3, and 12.9,	
6.3 ee)	This Standard only	1 (first paragraph) to 6 as applicable, 10.2, 10.3, and 12.9,	
6.8.2	IEC 60601-1: 1988 and IEC 60601-2-13:1998/ISO 8835-1,	1 (first paragraph) to 6 as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6	The relevant Essential requirement 13.3 a) is partly addressed
6.8.2 aa)	This Standard only	1 (first paragraph) to 6 as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6	The relevant Essential requirement 13.3 a) is partly addressed
6.8.2 bb)	This Standard only	1 (first paragraph) to 6 as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6	The relevant Essential requirement 13.3 a) is partly addressed
7	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
8	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
9	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
10	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
11	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
12	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
13	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
14	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
15	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	

16	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
17	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
18	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
19	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
20	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 2nd dash, 12.6	
21	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
22	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
23	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
24	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
25	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
28	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2. 1st dash, 12.7.1	
29	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
30	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
31	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
32	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
33	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
34	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
35	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2 2nd dash, 11 as applicable	
36	IEC 60601-1: 1988 and this Standard	1 (first paragraph) to 6 as applicable, 9.2 2nd and 3rd dash, 11 as applicable, 12.5	
37	This Standard only		
38	This Standard only		

39	This Standard only		
40	This Standard only		
41	This Standard only		
42	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 7.1 (except, 3rd dash), 9.3, 12.7.5	
43	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 7.1 (except, 3rd dash), 9.3, 12.7.5	
43.101	This Standard only	1 (first paragraph) to 6 as applicable, 7.1 (except, 3rd dash), 9.3, 12.7.5	
44	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable , 7.2 , 7.5 (first sentence), 7.6, 8.1 (first paragraph) to 8.7 as applicable	
44.3	This Standard only	1 (first paragraph) to 6 as applicable, 12.6, 12.7.1	
44.8	This Standard only	1 (first paragraph) to 6 as applicable, 8.1 (first paragraph) to 8.7 as applicable	
45	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.2, 12.7.1	
46	IEC 60601-1: 1988 and this standard	1 to 6 as applicable	
47	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
48	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
49	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 12.6	
50	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
51	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable,	
51.101	This Standard only	1 (first paragraph) to 6 as applicable, 9.1, 12.4	
51.102	This Standard only	1 (first paragraph) to 6 as applicable, 12.8.1	
51.103	This Standard only	1 (first paragraph) to 6 as applicable, 12.8.1	
51.104	This Standard only	1 (first paragraph) to 6 as applicable, 12.8.1	
52	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 12.6	
53	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 12.6	

54	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.1 (first paragraph) to 9.3 as applicable, 12.7.4	
55	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable	
56	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.1 (first paragraph) to 9.3 as applicable, 12.6, 12.7.4	
57	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.1 (first paragraph) to 9.3 as applicable, 12.6, 12.7.4	
58	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.1 (first paragraph) to 9.3 as applicable, 12.6, 12.7.4	
59	IEC 60601-1: 1988	1 (first paragraph) to 6 as applicable, 9.1 (first paragraph) to 9.3 as applicable, 12.6, 12.7.4	
101.1	This Standard only	1 (first paragraph) to 6 as applicable,	
101.2	This Standard only	1 (first paragraph) to 6 as applicable, 12.7.4	
101.3	This Standard only	1 (first paragraph) to 6 as applicable, 12.9	
101.4	This Standard only	1 (first paragraph) to 6 as applicable, 12.9	
101.5	This Standard only	1 (first paragraph) to 6 as applicable, 8.1	
101.6	This Standard only	1 (first paragraph) to 6 as applicable, 9.2	
-		6a	This relevant Essential Requirement is not addressed in this European Standard
-		7.5 (1st paragraph, 2nd sentence and 2nd and 3rd paragraphs)	These relevant Essential Requirements are not addressed in this European Standard
		12.1a)	This relevant Essential Requirement is not addressed in this European Standard
-		13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

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

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
-	1.1.4	This relevant Essential Requirement is not addressed in this EN
51.102, 101	1.2.2	This relevant Essential Requirement is not fully addressed in this EN
6.3, 101.1	1.5.4	This relevant Essential Requirement is not fully addressed in this EN
-	1.6.1	This relevant Essential Requirement is not completely addressed in this EN; see also reference to IEC 60601-1
-	1.6.2	This relevant Essential Requirement is not addressed in this EN
-	1.6.3	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1
-	3.6.2	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1

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I.S. EN ISO 8835-4:2009

INTERNATIONAL STANDARD

ISO 8835-4

First edition
2004-06-01

Inhalational anaesthesia systems —

Part 4: Anaesthetic vapour delivery devices

Systèmes d'anesthésie par inhalation —

Partie 4: Dispositifs d'alimentation en vapeur anesthésique

Reference number
ISO 8835-4:2004(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 8835-4 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 was withdrawn and has been revised as IEC 60601-2-13:2003, *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 1 Definitions of Collateral Standards and Particular Standards 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 existing text 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: clauses, 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;

— test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2, or in this Particular Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

NOTE 2 Attention is drawn to ISO/TS 18835 concerning draw-over vaporizers.

Inhalational anaesthesia systems —

Part 4:
Anaesthetic vapour delivery devices

1 Scope

IEC 60601-1:1988, Clause 1 applies except as follows.

Addition:

This part of ISO 8835 specifies particular requirements for the essential performance of anaesthetic vapour delivery devices (AVDDs), as defined in 3.1. This part of ISO 8835 is applicable to AVDDs which are a component of an anaesthetic system and are intended to be continuously operator-attended. This part of ISO 8835 gives specific requirements for AVDDs which are supplementary to the applicable general requirements in IEC 60601-2-13.

This part of ISO 8835 is not applicable to AVDDs intended for use with flammable anaesthetics, as determined by Annex CC, and AVDDs intended for use within anaesthetic breathing systems (e.g. draw-over vaporizers).

The requirements of this part of ISO 8835 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 8835-3, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

ISO 11196, *Anaesthetic gas monitors*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres. Part 4: Method of test for ignition temperature*

IEC 60079-11, *Electrical apparatus for explosive gas atmospheres — Part 11: Intrinsic safety "i"*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*