

**SLOVENSKI STANDARD
SIST EN ISO 8835-5:2009****01-junij-2009****BUXca Yý U****SIST EN ISO 8835-5:2004****SIST EN ISO 8835-5:2004/AC:2005****SIST EN ISO 8835-5:2004/AC:2006**

Inhalacijski anestezijski sistemi - 5. del: Anestezijski ventilatorji (ISO 8835-5:2004)

Inhalational anaesthesia systems - Part 5: Anaesthesia ventilators (ISO 8835-5:2004)

Systeme für die Inhalationsanästhesie - Teil 5: Anästhesie-Beatmungsgeräte (ISO 8835-5:2004)
STANDARD PREVIEW
(standards.iteh.ai)Système d'anesthésie par inhalation - Partie 5: Ventilateurs d'anesthésie (ISO 8835-5:2004)
SIST EN ISO 8835-5:2009
<https://standards.iteh.ai/catalog/standards/sist/c2c87d67-58aa-4511-802f-4db737e501de/sist-en-iso-8835-5-2009>**Ta slovenski standard je istoveten z: EN ISO 8835-5:2009****ICS:**

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

SIST EN ISO 8835-5:2009**en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8835-5

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Supersedes EN ISO 8835-5:2004

English Version

Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004)

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 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
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 8835-5:2004 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 8835-5:2009 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 8835-5:2004.

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.

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Endorsement notice

The text of ISO 8835-5:2004 has been approved by CEN as a EN ISO 8835-5:2009 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	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 & this Standard	Not applicable	
-		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
4	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
4.101	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable	

Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	IEC 60601-1: 1988	1 to 6 as applicable	
6	IEC 60601-1: 1988 and IEC 60601-2-13:1998/ISO 8835-1,	1 (first paragraph) to 6 (except 6 a)) 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 (except 6 a)) 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 (except 6 a)) as applicable	
6.3	IEC 60601-1: 1988 and IEC 60601-2-13:1998/ISO 8835-1,	1 (first paragraph) to 6 (except 6 a)) 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 (except 6 a)) as applicable, 10.2, 10.3, and 12.9,	
6.3 bb)	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 10.2, 10.3, and 12.9,	
6.3 cc)	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 10.2, 10.3, and 12.9,	
6.3 dd)	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 10.2, 10.3, and 12.9,	
6.3 ee)	This Standard only	1 (first paragraph) to 6 (except 6 a)) 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 (except 6 a)) as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6 (except 13.6 q)	The relevant Essential requirement 13.3 a) is partly addressed
6.8.2 aa)	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6 (except 13.6 q)	The relevant Essential requirement 13.3 a) is partly addressed
6.8.2 bb)	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 13.1, to 13.5 as applicable, applicable parts of 13.6 (except 13.6 q)	The relevant Essential requirement 13.3 a) is partly addressed
7	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
8	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
9	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
10	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	

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Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
12	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
13	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
14	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
15	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
16	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
17	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
18	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
19	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
20	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 2nd dash, 12.6	
21	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 1st dash, 12.7.1	
22	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 1st dash, 12.7.1	
23	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2. 1st dash, 12.7.1	
24	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) 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 (except 6 a)) as applicable, 9.2. 1st dash, 12.7.1	

Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
29	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
30	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
31	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
32	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
33	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
34	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
35	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd dash, 11 as applicable	
36	IEC 60601-1: 1988 and this Standard	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2 2nd and 3 rd 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 (except 6 a)) as applicable, 7.1 (except, 3 rd dash), 9.3, 12.7.5	
43	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 7.1 (except, 3 rd dash), 9.3, 12.7.5	
43.101	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 7.1 (except, 3 rd dash), 9.3, 12.7.5	
44	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable , 7.2 , 7.5 (first sentence), 7.6, 8.1 to 8.7 as applicable	
44.3	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.6, 12.7.1	

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Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
44.8	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 8.1 to 8.7 as applicable	
45	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2, 12.7.1	
46	IEC 60601-1: 1988 and this standard	1 (first paragraph) to 6 (except 6 a)) as applicable	
47	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
48	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
49	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.6	
50	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
51	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable,	
51.101	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1, 12.4	
51.102	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.8.1	
51.103	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.8.1	
51.104	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.8.1	
52	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.6	
53	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.6	
54	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1 to 9.3 as applicable, 12.7.4	
55	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable	
56	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1 to 9.3 as applicable, 12.6, 12.7.4	
57	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1 to 9.3 as applicable, 12.6, 12.7.4	
58	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1 to 9.3 as applicable, 12.6, 12.7.4	

Clause(s)/sub-clause(s) of this EN	Where located	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
59	IEC 60601-1: 1988	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.1 to 9.3 as applicable, 12.6, 12.7.4	
101.1	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable,	
101.2	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.7.4	
101.3	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.9	
101.4	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 12.9	
101.5	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 8.1	
101.6	This Standard only	1 (first paragraph) to 6 (except 6 a)) as applicable, 9.2	

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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 Requirements (ERs) of Directive 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant Essential Requirement is not addressed in this EN
6, 46, 51, 60	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

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