SLOVENSKI STANDARD

SIST EN ISO 8185:2008

01-april-2008

Nadomeġ a:

SIST EN ISO 8185:2000

SIST EN ISO 8185:2000/AC:2002

Vlažilniki dihalnega trakta za uporabo v medicini - Posebne zahteve za dihalne vlažilne sisteme (ISO 8185:2007)

Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)

Anfeuchter für Respirationsluft für medizinische Zwecke - Besondere Anforderungen an Anfeuchtersysteme für Respirationsluft (ISO 8185:2007)

Humidificateurs médicaux destinés a l'appareil respiratoire - Exigences particulieres relatives aux systemes d'humidification respiratoires (ISO 8185:2007)

Ta slovenski standard je istoveten z: **EN ISO 8185:2007**

ICS:

11.040.10

SIST EN ISO 8185:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8185

July 2007

ICS 11.040.10

Supersedes EN ISO 8185:1997

English Version

Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)

Humidificateurs respiratoires médicaux - Exigences spécifiques des systèmes d'humidification respiratoires (ISO 8185:2007)

Anfeuchter für Respirationsluft für medizinische Zwecke - Besondere Anforderungen an Anfeuchtersysteme für Respirationsluft (ISO 8185:2007)

This European Standard was approved by CEN on 24 June 2007.

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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 8185:2007) 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 January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN ISO 8185:1997.

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, 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.

Endorsement notice

The text of ISO 8185:2007 has been approved by CEN as EN ISO 8185:2007 without any modifications.

ANNEX ZA
(informative)

Relationship between this standard and the Essential Requirements of EU Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices (Medical Device Directive).

Once this International 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 International Standard given in Table ZA.1 confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4 [3.6 cc)]	12.1	
6	13.1, 13.2, 13.3	And via IEC 60601-1, Clause 6
6.1 aa)	13.1	
6.1 d)	13.1, 13.2, 13.3 b)	
6.1 e)	13.1, 13.3 a)	
6.1 f)	13.1, 13.3 b)	
6.3	10.1, 10.3, 12.9	And via IEC 60601-1, Subclause 6.3
6.4, 6.5	13.2	
6.6	9.1	And via IEC 60601-1, Subclause 6.6
6.7	12.9	And via IEC 60601-1, Subclause 6.7
6.8.2	13.1	
6.8.2 a)	2, 13.3 k), 13.3 m), 13.4, 13.5, 13.6 a),13.6 b), 13.6 c), 13.6 d), 13.6 i), 13.6 j),13.6 o)	
6.8.2 d)	13.6 h)	
10.1	5	And via IEC 60601-1, Subclause 10.1

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
10.2	4	
10.2.101	12.7.4	
15	12.6	Via IEC 60601-1, Clause 15
16	12.6	Via IEC 60601-1, Clause 16
17	12.6	Via IEC 60601-1, Clause 17
18	12.6	Via IEC 60601-1, Clause 18
19	12.6	Via IEC 60601-1, Clause 19
20	12.6	Via IEC 60601-1, Clause 20
21	4, 5, 9.2, 12.7.1	And via IEC 60601-1, Clause 21
22	12.7.1	Via 60601-1, Clause 22
23	4, 9.2, 12.7.1	Via IEC 60601-1, Clause 23
24	4, 12.7.1	And via IEC 60601-1, Clause 24
25	12.7.1	Via IEC 60601-1, Clause 25
26	12.7.2	Via IEC 60601-1, Clause 26
28	12.7.1	Via IEC 60601-1, Clause 28
29	11.3.1	Via IEC 60601-1, Clause 29
35	12.7.3	And via IEC 60601-1, Clause 35
35.101	4, 12.7.3	
36	4, 9.2, 12.5	And via IEC 60601-1, Clause 36
36.202.1	9.2	
37, 38, 39, 40, 41	9.3	
42	12.7.5	
42.101	4, 12.7.5, 12.8.1	
43	7.1, 9.3	And via IEC 60601-1, Clause 43
43.101	7.1, 7.3	
44	7.2, 7.5, 7.6	
44.2	7.2, 7.5	
44.3	7.6	
44.4	7.5	
44.6	7.6	
44.7	8.1, 8.4, 8.5	Via IEC 60601-1, Subclause 44.7

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
44.8	7.1, 7.2, 7.3	
45	9.2	Via IEC 60601-1, Clause 45
46	10.2	Via IEC 60601-1, Clause 46
48	7.1	Via IEC 60601-1, Clause 48
49	4, 9.2	And via IEC 60601-1, Clause 49
50	10.1, 12.8.1	
50.1	12.9	
50.2	10.1, 10.2	
50.2 aa)	2, 12.8.1	
50.2 bb)	2, 12.8.1	
50.2 cc)	2, 12.8.2	
51	12.8.1	Via IEC 60601-1, Clause 51
51	4	
51.101, 51.102, 51.103	2, 12.8.1	
52	7.2, 7.6, 9.2, 9.3, 12.7.1	Via IEC 60601-1, Clause 52
56	9.1, 12.6, 12.7.5	And via IEC 60601-1, Clause 56
56.3	9.1, 12.7.5	
56.7	9.3	Via IEC 60601-1, Subclause 56.7
56.101	7.2, 7.3, 9.1, 12.8.1, 12.8.2, 13.5	
56.102	7.5, 9.1, 13.5	
57	12.6, 12.7.4	Via IEC 60601-1, Clause 57
58	12.6	Via IEC 60601-1, Clause 58
59	9.3, 12.6	Via IEC 60601-1, Clause 59
101	3, 4	
102	3, 10.2	
103	2, 9.1, 12.7.3, 12.9, 13.1, 13.2, 13.6 d)	Via IEC 60601-1, Clause 6 and via IEC60601-8
201	2	Via IEC 60601-8

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

INTERNATIONAL STANDARD

ISO 8185

Third edition
2007-07-01

Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

Humidificateurs respiratoires médicaux — Exigences spécifiques des systèmes d'humidification respiratoires

Reference number
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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 8185 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This third edition cancels and replaces the second edition (ISO 8185:1997), which has been technically revised. It also incorporates the Technical Corrigendum, ISO 8185:1997/Cor. 1:2001.

Introduction

This International Standard 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 are found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

This International Standard uses the same main Clause titles and numbering as the General Standard, to facilitate cross-referencing of the requirements. The changes to the text of the General Standard 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 International Standard.

— "Addition" means that the relevant text of this International Standard is supplementary to the requirements of the General Standard.

— "Amendment" means that existing text of the General Standard is modified as indicated by the text of this International Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: 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 International Standard, 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 or in this International Standard: **bold type**.

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

Humidifiers are used to raise the water content of gases delivered to **patients**. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of **patients** whose upper airways have been bypassed. Reduction of the **relative humidity** at the **patient connection port** can cause desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, and consequently may cause narrowing or even obstruction of the airway [19]. Heat can be employed to increase the water output of the **humidifier**.

In addition, many **humidifiers** utilise heated **breathing tubes** in order to increase operating efficiency and reduce water and heat loss. Ventilator and anaesthesia **breathing tubes** in common use might not withstand the heat generated by **humidifiers** and heated **breathing tube** mechanisms.

Many **humidifier** manufacturers use off-the-shelf electrical connectors for their electrically-heated **breathing tubes**. However, since different manufacturers have used the same electrical connector for different power outputs, electrically-heated **breathing tubes** can be physically, but not electrically, interchangeable. Use of improper electrically-heated **breathing tubes** has caused overheating, circuit melting, **patient** and **operator** burns, and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between **humidifiers** and **breathing tubes** produced by different manufacturers.

Since the safe use of a **humidifier** depends on the interaction of the **humidifier** with its many **accessories**, this International Standard sets total-system performance requirements, applicable to **accessories** such as **breathing tubes** (both heated and non-heated), temperature sensors, and devices intended to control the environment within these **breathing tubes**.