

BUXca Yý U.**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 à l'appareil respiratoire - Exigences particulières relatives aux systèmes 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

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 8185:2008

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>

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.

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>



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.

(standards.iteh.ai)

Endorsement notice

[SIST EN ISO 8185:2008](https://standards.iteh.ai/catalog/standards/sist/en-iso-8185-2008)

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

<https://standards.iteh.ai/catalog/standards/sist/en-iso-8185-2008>

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 IEC 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.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

SIST EN ISO 8185:2008

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>

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

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 8185:2008

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>



Reference number
ISO 8185:2007(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 8185:2008

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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

36	Electromagnetic compatibility	11
37	Locations and basic requirements	11
38	Marking, accompanying documents	11
39	Common requirements for category AP and category APG equipment	11
40	Requirements and tests for category AP equipment, parts and components thereof	11
41	Requirements and tests for category APG equipment, parts and components thereof	11
42	Excessive temperatures	11
43	* Fire prevention	12
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	12
45	Pressure vessels and parts subject to pressure	13
46	Human error	13
47	Electrostatic charges	13
48	Biocompatibility	13
49	Interruption of power supply	13
50	Accuracy of operating data	14
51	* Protection against hazardous output	14
52	Abnormal operation and fault conditions	15
53	Environmental tests	16
54	General	16
55	Enclosure and covers	16
56	Components and general assembly	16
57	Mains parts, components and layout	17
58	Protective earthing — Terminals and connections	17
59	Construction and layout	18
101	* Humidification system output	18
102	Liquid container	18
103	Alarm systems	18
	Annex AA (informative) Rationale	20
	Annex BB (normative) * Determination of the accuracy of the displayed temperature	27
	Annex CC (informative) Specific enthalpy calculations	29
	Annex DD (normative) Temperature sensors and mating ports	35
	Annex EE (normative) * Determination of humidification system output	36
	Annex FF (normative) * Standard temperature sensor	39
	Annex GG (informative) Environmental aspects	41
	Annex HH (informative) Reference to the essential principals of safety and performance	44
	Annex II (informative) Terminology — Index of defined terms	46
	Bibliography	48

STANDARD PREVIEW
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 8185:2008
<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>

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**.

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 8185:2008

<https://standards.iteh.ai/catalog/standards/sist/7d4745de-a99e-4aa3-9e54-638bd37703e2/sist-en-iso-8185-2008>