



SLOVENSKI STANDARD
SIST EN ISO 8185:2000
01-januar-2000

Vlažilniki za uporabo v medicini - Splošne zahteve za vlažilne sisteme (ISO 8185:1997)

Humidifiers for medical use - General requirements for humidification systems (ISO 8185:1997)

Anfeuchter für medizinische Zwecke - Allgemeine Anforderungen an Anfeuchtungssysteme (ISO 8185:1997)

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Humidificateurs médicaux - Exigences générales relatives aux systèmes d'humidification (ISO 8185:1997)

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Ta slovenski standard je istoveten z: EN ISO 8185:1997

ICS:

11.040.10

SIST EN ISO 8185:2000

en

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ICS 11.040.10

Descriptors: see ISO document

English version

Humidifiers for medical use - General requirements for humidification systems (ISO 8185:1997)

Humidificateurs médicaux - Exigences générales relatives aux systèmes d'humidification (ISO 8185:1997)

This European Standard was approved by CEN on 26 September 1997.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Page 2
EN ISO 8185:1997

Foreword

The text of the International Standard ISO 8185:1997 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 May 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard 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 standard.

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

Endorsement notice

The text of the International Standard ISO 8185:1997 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZB (normative).

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Annex ZB (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 3744	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane	EN ISO 3744	1995

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TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All clauses	1	
Section 2	9.2	
Sections 2 to 10	2	
Section 3	12.6	
Section 4	12.7.1, 9.2	
Section 5	11.1	
Section 6	7.1	
7.3 to 7.8	9.2	
1.7	12.9, 13.1, 13.2	
1.7	2, 13.3 a)	
1.7	8.3	
1,7	12.9, 13.1	
1.7	9.2	
1.7	12.9	
1.7	13.6 a)	
1.7	2, 7.2, 7.3, 13.6 d)	
1.7	7.5, 9.1, 13.1, 13.3 j), k), 13.4, 13.6 a), b), c)	
1.7	13.6 i)	
1.7	13.6 h)	
1.7	2, 13.4, 13.6 d)	
1.7	7.2	

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TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
1.8	7.3	
2.3	5	
3.4	13.6 i)	
4.4	4, 7.5	
4.6	4, 12.7.2, 12.7.3	
4.7	12.7.1	
Section 5	12.7.3	
5.1	4, 9.2	
5.1	9.2	
5.1	9.2	
6.1	7.1, 7.3, 9.3, 13.3 k)	
6.2	13.1	
6.3	9.3	
6.4	9.3	
6.5	9.3	
7.1	7.3, 9.2, 12.7.5	
7.1	12.7.5	
7.2	7.1, 7.3, 9.3	
7.3	4, 7.3, 7.5, 7.6, 8.1	
7.3	8.6	
7.7	7.1	
8.2	12.8.1, 12.8.2	
8.2	7.5, 12.8.1, 12.8.2	
8.2	12.8.1	
8.2	7.3	
8.2	12.8.2	
9.1	12.6	
10.1	7.3	

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EN ISO 8185:2000
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TABLE ZA.1 - Correspondence between this European Standard and EU Directives

Clause/subclause/annex of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
10.3	9.1, 12.7.4	
10.3	9.1	
10.3	12.7.4	
10.4	12.6	
10.4	12.7.4	
10.4	12.7.4	
10.5	12.6	
11.2	9.2	
11.3	7.6	
11.3.1	7.5	
11.4.1	12.7.3	
11.4.2	12.7.3	
11.5	9.1	
Appendix M	7.1	
Appendix Q	9.1	

Clause numbers in **bold type** refer to clauses in EN ISO 8185-1. Clause numbers in ordinary type refer to the clauses, amended or original, of IEC 601-1 to which reference is made in EN ISO 8185-1

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**Humidifiers for medical use — General
requirements for humidification systems**

*Humidificateurs médicaux — Exigences générales relatives aux systèmes
d'humidification*

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Foreword

ISO (the International Organization for Standardization) is a world-wide 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 nongovernmental, 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.

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.

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

This second edition cancels and replaces the first edition (ISO 8185:1988), which has been technically revised.

Annexes M, N, P, Q and R form an integral part of this International Standard. Annexes O, S and T are for information only.

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Printed in Switzerland

Introduction

Humidifiers are used to raise the water content of gases delivered to patients. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract or desiccate secretions of patients whose supraglottic airways have been by-passed. Heat may be employed to increase the water output of the humidifier.

In addition, many humidifiers utilize heated delivery tubes in order to increase operating efficiency and reduce excessive water and heat loss. Ventilator and anaesthesia delivery tubes in common use may not withstand the heat generated by humidifiers and heated delivery tubes mechanisms.

Many humidifier manufacturers use off-the-shelf electrical connectors for their electrically heated delivery tubes. However, since different manufacturers have used the same electrical connector for different power outputs, electrically heated delivery tubes may be physically, but not electrically, interchangeable. Improper electrically heated delivery tubes use has caused overheating, circuit melting, patient and care-giver burns, and fires. Reduction of the relative humidity at the patient connection port may cause desiccation of tracheo-bronchial secretions (see reference [20], annex T). It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between humidifiers and delivery tubes produced by different manufacturers.

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

A rationale for the most important requirements is given in annex S. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revision.

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Humidifiers for medical use — General requirements for humidification systems

Section 1: General

1.1 Scope

Clause 1 of IEC 60601-1:1988 applies with the following amendment:

ISO 8185 is one of a series of International Standards based on IEC 60601-1; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 60601-1:1988, the requirements of this International Standard take precedence over those of IEC 60601-1.

Humidifiers may be gas-powered, electrically powered, or both. However, this International Standard has been prepared as a Particular Standard based on IEC 60601-1, which gives general requirements for all aspects of safety, not only electrical safety, and many of the requirements are therefore applicable to humidifiers not powered by electricity. Where this International Standard specifies that a clause of IEC 60601-1 applies, it means that the clause applies only if the requirement is relevant to the humidifier system under consideration.

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This International Standard includes requirements for the safety and performance of humidifiers, as defined in 1.3.107, suitable for inclusion in breathing systems.

This International Standard also includes some requirements for delivery tubes, including heated delivery tubes (heated-wire delivery tubes), and devices intended to control these heated delivery tubes, heated delivery tube controllers.

This International Standard is not applicable to heat and moisture exchangers (HMEs).

This International Standard is not applicable to devices commonly referred to as "room humidifiers" and humidifiers used in heating, ventilation and air conditioning systems, and humidifiers incorporated into infant incubators.

This International Standard is not applicable to nebulizers used for the delivery of drugs to patients

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

ISO 10524:1995, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems.*

ISO 10651-1:—¹⁾, *Lung ventilators for medical use — Part 1: Particular requirements for critical care ventilators.*

IEC 60079-3:1990, *Electrical apparatus for explosive gas atmospheres — Part 3: Spark-test apparatus for intrinsically-safe circuits.*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

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

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility — Requirements and tests.*

IEC 60601-2-19:1990, *Medical electrical equipment — Part 2: Particular requirements for safety of baby incubators.*

IEC 60801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

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SIST EN ISO 8185:2000

<https://standards.iteh.ai/catalog/standards/sist/bd7bdb21-aa6e-47a6-8d02-01ad76576684/sist-en-iso-8185-2000>

1.3 Definitions

NOTE — Attention is drawn to the definitions given in ISO 4135.

The definitions given in clause 2 of IEC 60601-1:1988 and the following definitions apply.

1.3.101 accessible surface temperature: Temperature of any surface which can be touched by a hand or finger during normal use, which includes filling and refilling of the humidifier.

1.3.102 delivery tube: Tube conveying humidified gas from a humidifier outlet.

NOTE — The delivery tube may be heated.

1.3.103 delivered gas temperature: Temperature of the gas, or aerosol, or both, measured at the patient connection port.

1.3.104 heated delivery tube controller: Device which controls the heating of a delivery tube.

NOTE — The controller can be either stand-alone or part of the humidifier.

1.3.105 humidification chamber: That part of the humidifier which vaporizes or nebulizes water or water-based medicament.

1.3.106 humidification system: Delivery tube, heated delivery tube controller (if applicable), humidifier and any other accessories which when used together are intended to meet the requirements of this International Standard.

1) To be published. (Revision of ISO 10651-1:1993)

1.3.107 humidifier: Device to add water in the form of droplets or vapour, or both, to the inspired gas.

NOTE — This term includes vaporizing, bubble-through and ultrasonic humidifiers.

1.3.108 humidifier outlet: Outlet port of the humidifier which delivers the humidified gases.

1.3.109 humidifier output: Total mass of water (in the form of liquid and vapour) per unit volume of gas normalized to Body Temperature, Atmospheric Pressure and Saturated (BTSP), i.e. at 37 °C, 101,3 kPa (760 mmHg) and saturated with water vapour, at the patient connection port.

1.3.110 liquid container: That portion of the humidifier which holds the liquid.

NOTE — The liquid container may be detachable for filling.

1.3.111 liquid reservoir: A portion of the humidifier which replenishes the liquid container.

1.3.112 maximum operating pressure: Maximum pressure in the humidification chamber.

1.3.113 measured gas temperature: Temperature of the gas, or aerosol, or both, that the humidification system is measuring and, if applicable, displaying.

1.3.114 operating volume: Volume accessible to the breathing gas of the liquid container when operated between the maximum and minimum levels, if so marked.

1.3.115 patient connection port: That opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adapter, a face mask or a face mask angle-piece, or a laryngeal mask.

NOTE — For the purposes of this International Standard, for delivery tubes that do not connect directly to a patient (e.g. tracheal tubes, face masks), the patient end of a delivery tube will be considered the patient connection port.

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1.3.116 relative humidity: Water vapour pressure at a particular temperature, expressed as a percentage of the saturation vapour pressure.

1.3.117 set temperature: Temperature at which the humidifier system attempts to maintain delivered gas temperature.

NOTE — This temperature may be operator-adjustable.

1.3.118 thermal hazard: Hazard resulting from fire, excessive surface temperature or excessive delivered gas temperature.

NOTE — Any toxic materials resulting from abnormal temperatures also constitute a thermal hazard. See also annex N.

1.4 General requirements

The requirements given in clause 3 of IEC 60601-1:1988 apply, with the following additions:

3.6 k) Operation of the humidifier without any liquid

3.6 l) If the humidifier includes a temperature sensor, any single fault condition with the temperature sensor. For example:

- temperature sensor single open-circuit
- temperature sensor single short-circuit
- temperature sensor disconnected from the temperature control system

3.6 m) A safety hazard (e.g. thermal injury to the patient) resulting from software error.