EESTI STANDARD EVS-EN ISO 18779:2005

Hapniku ja hapnikusegude konserveerimiseks kasutatavad meditsiiniseadmed. Erinõuded

Medical devices for conserving oxygen and oxygen mixtures - Particular requirements

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-EN ISO 18779:2005 sisaldab Euroopa standardi EN ISO 18779:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 28.04.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 18779:2005 consists of the English text of the European standard EN ISO 18779:2005. This document is endorsed on 28.04.2005 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

NATIONAL FOREWORD

Käsitlusala: This International Standard specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices1) are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the patient's demand when used in home care applications. These devices are generally used without continual professional supervision.	**Scope:** This International Standard specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices1) are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the patient's demand when used in home care applications. These devices are generally used without continual professional supervision.

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Medical devices for conserving oxygen and oxygen mixtures - Particular requirements (ISO 18779:2005)

Economiseurs médicaux d'oxygène et de mélanges oxygénés - Exigences particulières (ISO 18779:2005)

Spargeräte für Sauerstoff und Sauerstoffgemische - Besondere Anforderungen (ISO 18779:2005)

This European Standard was approved by CEN on 28 January 2005.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN ISO 18779:2005) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

ANNEX ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42 EEC Medical devices

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC 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 normative 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.

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

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

Clause(s)/Subclause(s) of this International Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	All	
5	All	
6	13, 13.2	
6.1	13.1, 13.3, 13.4, 13.5	
6.3	10.2, 10.3, 12.8, 12.9	
6.8	13.1, 13.3, 13.4, 13.6	
6.101	12.9	
7	12.6	
8	12.6	
9	12.6	
10.1	5	
10.2	5	
13	12.6	
14	12.6	
15	12.6	

16	12.6, 12.7	
17	12.6	
18	12.6	
19	12.6	
20	12.6	
21	12.7	
22	12.7	
23	12.7	
24	12.7	
25	12.7	
26	12.7.2, 12.7.3	
27	12.8	
28	12.7	
29	11	
36	9.2, 12.5	
38	13	
39	9.2, 9.3, 12.6, 12.7	
40	9.2, 9.3, 12.6, 12.7	
41	9.2, 9.3, 12.6, 12.7	
42	12.7	
43	9.3, 12.7	
44.3	7.6, 12.6	
44.6	7.6, 12.6	
44.7	8.1	
44.8	7.1, 7.3, 7.5, 9.3	
45	12.7	
46	9, 10, 12.9	
47	12.5	
48	7.1, 7.5	
49	9.2, 12.8	
50	10	
51	10, 12.8	
52	12.1, 12.6, 12.7, 12.8	
53	5	

54	9	
55	9	
56	9	
56.3	9.1	
56.7	12.2	
57	12.6, 12.7	
58	12.6, 12.7	
101.2.1	9.2, 12.8	
101.2.3	12.8	
101.2.4	12.8	
101.2.6	12.8	
101.2.7	12.2	
101.2.8	9.3, 12.6, 12.8	
101.3	12.3, 12.8	

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Medical devices for conserving oxygen and oxygen mixtures — Particular requirements

Économiseurs médicaux d'oxygène et de mélanges oxygénés — Exigences particulières

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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 18779 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

This International Standard specifies requirements for oxygen and oxygen mixture saving devices (called here conserving devices) that are used to supply respiratory gases during therapy.

These devices are for domiciliary use only.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a requirement and to identify the hazards that the requirement addresses.

Clauses and subclauses marked with an asterisk (*) after their number have a corresponding rationale contained in Annex AA.

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 electrical 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 can be 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, 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 International 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 an existing element 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 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 Particular Standard: **bold type**.

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

Medical devices for conserving oxygen and oxygen mixtures — Particular requirements

1 * Scope

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

Amendment (add at end of 1.1):

1.1

This International Standard specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices[1)] are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the **patient's** demand when used in home care applications. These devices are generally used without continual professional supervision.

These devices are also used in health care facilities/institutions.

This International Standard covers two types of conserving devices (see 3.5 and 3.6): **conserving devices intended for continuous use** and those not intended for continuous use.

This International Standard covers active devices only, e.g. pneumatically or electrically controlled devices, and does not cover devices such as reservoir cannulas.

This International Standard also includes conserving devices which are part of a system, e.g. pressure regulators, oxygen concentrators or liquid oxygen vessels.

The requirements of this International Standard 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.

1.4

Addition:

NOTE Planning and design of products complying with this International Standard can have environmental impact during the product life cycle. Environmental aspects are addressed in Annex BB. Additional aspects of environmental impact are addressed in ISO 14971.

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.

1) Referred to as “conserving devices” throughout the document.

EN 980:2003, *Graphical symbols for use in the labelling of medical devices*

EN 1041:1998, *Information supplied by the manufacturer with medical devices*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

EN 13544-2:2003, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 60601-1:1988 + A1:1991 + A2:1995 and corrigendum 1995 mod), *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60529:2001, *Degree of protection provided by enclosures (IP code)*

IEC 60068-2-32:1975, *Environmental testing — Part 2: Tests — Test Ed: Free fall.* (A 1:1982 + A 2:1990)

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration broad-band random (digital control) and guidance*

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:1988, ISO 4135 and the following apply.

3.1
accuracy
quality that characterizes the ability of the conserving device to give indications approximating to the true value of the quantity measured

3.2
applied part
part of the conserving device intended to be connected to the **patient** and which in **normal use**:

— necessarily comes into physical contact with the **patient** for the conserving device to perform its function or

— can be brought into contact with the **patient** or

— needs to be touched by the **patient**

3.3
expected service life
period during which the performance of the conserving device or any of its components is expected to meet the requirements of this International Standard when used and maintained according to the **accompanying documents**

3.4
shelf life
period during which the conserving devices or any of its components are stored in its original container under conditions in accordance with the **accompanying documents**