SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-67:2012

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Elektromedicinska oprema - 2-67. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za shranjevanje kisika (ISO/DIS 80601-2-67:2012)

Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO/DIS 80601-2-67:2012)

Medizinische elektrische Geräte - Teil 2-67: Besondere Festlegungen für die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiersystemen (ISO/DIS 80601-2-67:2012)

Appareils électromédicaux - Partie 2-67: Exigences particulières pour la sécurité de base et performances essentielles de l'équipement de conservation de l'oxygène (ISO/DIS 80601-2-67:2012)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-67**

ICS:

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

oSIST prEN ISO 80601-2-67:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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DRAFT
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Will supersede EN ISO 18779:2005

English Version

Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (ISO/DIS 80601-2-67:2012)

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Medizinische elektrische Geräte - Teil 2-67: Besondere Festlegungen für die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale von Sauerstoff-Dosiersystemen (ISO/DIS 80601-2-67:2012)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (prEN ISO 80601-2-67:2012) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 18779:2005.

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).

Endorsement notice

The text of ISO/DIS 80601-2-67:2012 has been approved by CEN as a prEN ISO 80601-2-67:2012 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-67

ISO/TC **121**/SC **3** Secretariat: **ANSI**

Voting begins on **2012-01-26** Voting terminates on **2012-06-26**

Medical electrical equipment —

Part 2-67:
Particular requirements for basic safety and essential performance of oxygen-conserving equipment

Appareils électromédicaux —

Partie 2-67: Exigences particulières pour la sécurité de base et performances essentielles de l'équipement de conservation de l'oxygène

(Revision of ISO 18779:2005)

ICS 11.040.10

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

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/IEC 80601-2-67 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment.*

This first edition of ISO 80601-2-67 cancels and replaces the first edition of ISO 18779:2005. This edition of ISO 80601-2-67 constitutes a major technical revision of ISO 18779:2005 and includes an alignment with third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

- extending the scope to include not only the CONSERVING EQUIPMENT but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CONSERVING EQUIPMENT;
- identification of ESSENTIAL PERFORMANCE for a CONSERVING EQUIPMENT and its ACCESSORIES;

And the following additions:

- tests for oxygen delivery performance;
- new symbols;
- tests for cleaning and disinfection procedures; and
- consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Long term oxygen treatment prolongs survival in PATIENTS with hypoxic chronic respiratory disease, but is expensive. A equipment that delivers oxygen as a bolus, especially during the first part of inspiration when it is most likely to reach the alveoli, should conserve oxygen while allowing a satisfactory PATIENT arterial oxygen saturation (SaO_2) to be achieved.

This International Standard specifies requirements for oxygen and oxygen mixture saving devices (called CONSERVING EQUIPMENT in this standard) that are used to supply respiratory gas during oxygen therapy. The aim of oxygen therapy is to obtain the desired SaO_2. CONSERVING EQUIPMENT is intended to achieve the desired SaO_2 while minimizing usage of oxygen by controlling the delivery of oxygen to the PATIENT, particularly during the expiratory phase of the respiratory cycle.

CONSERVING EQUIPMENT delivers oxygen gas in a manner different than from continuous flow oxygen (CFO). Currently, most clinicians prescribe oxygen therapy in continuous oxygen flow (i.e. l/min). By nature CONSERVING EQUIPMENT are not "equivalent" to CFO over all breathing rates and anatomies. CONSERVING EQUIPMENT MANUFACTURERS have adopted many different methods for dosing, yet all equipment on the market at the time of the writing of this standard imply similarity to continuous flow by labelling with integer numbers that appear the same as CFO nomenclature of l/min (e.g. 1, 2, 3, 4, etc.). Different CONSERVING EQUIPMENT set to the same numerical setting can differ by 100 % or more in the actual dose delivered to the PATIENT.

The American Association for Respiratory Care along with several published studies [9][10][12][13] recommend individual PATIENT titration at rest and activity when prescribing oxygen using CONSERVING EQUIPMENT. The previous standard, ISO 18779:2005, requires a statement to this effect to be included in the instructions for use. Nonetheless, several studies have been published [14][16] that conclude that CONSERVING EQUIPMENT did not perform well when compared to CFO with the CONSERVING EQUIPMENT at equivalent numerical settings, not titrated settings. This standard is intended to reduce this ambiguity between CONSERVING EQUIPMENT models by requiring both standardized performance testing and labelling.

Medical Electrical Equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment

201.1 Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

IEC 60601-1:2005, 1.1 is replaced by:

This International Standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of oxygen CONSERVING EQUIPMENT, hereafter referred to as ME EQUIPMENT, in combination with its ACCESSORIES intended to conserve oxygen by delivering supplemental oxygen intermittently and synchronized to the PATIENT'S inspiratory flow, when used in the HOME HEALTHCARE ENVIRONMENT. Oxygen CONSERVING EQUIPMENT is typically used by a LAY OPERATOR.

NOTE 1 CONSERVING EQUIPMENT can also be used in professional health care facilities.

NOTE 2 CONSERVING EQUIPMENT can be used with an oxygen-enriched air supply produced from an oxygen concentrator.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to CONSERVING EQUIPMENT, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the CONSERVING EQUIPMENT.

This International Standard is only applicable to active devices (e.g., pneumatically or electrically powered) and is not applicable to non-active devices (e.g., reservoir cannulas).

NOTE 4 CONSERVING EQUIPMENT can be incorporated with other devices.

EXAMPLES CONSERVING EQUIPMENT combined with pressure regulators [2], oxygen concentrators [1] or liquid oxygen equipment [6], each of which has its own applicable standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 5 See also 4.2 of the General Standard.

This International Standard is a particular standard in the IEC 60601 series of standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by: