



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

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.

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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.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-67

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on
2012-01-26Voting terminates on
2012-06-26INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИССИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE**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*

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(Revision of ISO 18779:2005)

ICS 11.040.10

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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.

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74 **Foreword**

75 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
 76 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO
 77 technical committees. Each member body interested in a subject for which a technical committee has been
 78 established has the right to be represented on that committee. International organizations, governmental and
 79 non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the
 80 International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

81 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

82 The main task of technical committees is to prepare International Standards. Draft International Standards
 83 adopted by the technical committees are circulated to the member bodies for voting. Publication as an
 84 International Standard requires approval by at least 75 % of the member bodies casting a vote.

85 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
 86 rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

93 The most significant changes are the following modifications:

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

98 And the following additions:

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

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

105 In this standard, the following print types are used:

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

112 In referring to the structure of this standard, the term

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

- 115 – “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are
116 all subclauses of Clause 201.7).
- 117 References to clauses within this standard are preceded by the term “Clause” followed by the clause number.
118 References to subclauses within this particular standard are by number only.
- 119 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of
120 the conditions is true.
- 121 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part
122 2. For the purposes of this standard, the auxiliary verb:
- 123 – “shall” means that compliance with a requirement or a test is mandatory for compliance with this
124 standard;
 - 125 – “should” means that compliance with a requirement or a test is recommended but is not
126 mandatory for compliance with this standard;
 - 127 – “may” is used to describe a permissible way to achieve compliance with a requirement or test.
- 128 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that
129 there is guidance or rationale related to that item in Annex AA.
- 130 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers
131 and testing organizations may need a transitional period following publication of a new, amended or revised
132 ISO or IEC publication in which to make products in accordance with the new requirements and to equip
133 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of
134 this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of
135 publication for equipment newly designed and not earlier than 5 years from the date of publication for
136 equipment already in production.

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137 Introduction

138 Long term oxygen treatment prolongs survival in PATIENTS with hypoxic chronic respiratory disease, but is
139 expensive. A equipment that delivers oxygen as a bolus, especially during the first part of inspiration when it
140 is most likely to reach the alveoli, should conserve oxygen while allowing a satisfactory PATIENT arterial
141 oxygen saturation (SaO₂) to be achieved.

142 This International Standard specifies requirements for oxygen and oxygen mixture saving devices (called
143 CONSERVING EQUIPMENT in this standard) that are used to supply respiratory gas during oxygen therapy. The
144 aim of oxygen therapy is to obtain the desired SaO₂. CONSERVING EQUIPMENT is intended to **achieve** the
145 desired SaO₂ while **minimizing** usage of oxygen by controlling the delivery of oxygen to the PATIENT,
146 particularly during the expiratory phase of the respiratory cycle.

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

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

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

164 **201.1 Scope, object and related standards**

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

166 **201.1.1 * Scope**

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

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

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

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

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

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

181 NOTE 4 CONSERVING EQUIPMENT can be incorporated with other devices.

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

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

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

190 NOTE 5 See also 4.2 of the General Standard.

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

192 **201.1.2 Object**

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