

SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-61:2009
01-september-2009

Elektromedicinska oprema - Posebne zahteve za osnovno varnost in bistvene lastnosti pulznega oksimetra za uporabo v medicini - 2-61. del (ISO/DIS 80601-2-61:2009)

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use - Part 2-61 (ISO/DIS 80601-2-61:2009)

Medizinische elektrische Geräte - Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoxymetern zur medizinischen Anwendung (ISO/DIS 80601-2-61:2009)

Appareils électromédicaux - Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls à usage médical - Partie 2-61 (ISO/DIS 80601-2-61:2009)

Ta slovenski standard je istoveten z: prEN ISO 80601-2-61

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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oSIST prEN ISO 80601-2-61:2009

en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN ISO 80601-2-61

May 2009

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Will supersede EN ISO 9919:2005

English Version

**Medical electrical equipment - Particular requirements for the
basic safety and essential performance of pulse oximeter
equipment for medical use - Part 2-61 (ISO/DIS 80601-2-
61:2009)**

Appareils électromédicaux - Exigences particulières pour la
sécurité de base et les performances essentielles pour les
oxymètres de pouls à usage médical - Partie 2-61 (ISO/DIS
80601-2-61:2009)

Medizinische elektrische Geräte - Teil 2-61: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Pulsoxymetern zur
medizinischen Anwendung (ISO/DIS 80601-2-61:2009)

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 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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN ISO 80601-2-61:2009) 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 9919:2005.

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 EC Directive(s).

Endorsement notice

The text of ISO/DIS 80601-2-61:2009 has been approved by CEN as a prEN ISO 80601-2-61:2009 without any modification.

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**DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-61**

ISO/TC 121/SC 3

Secretariat: **ANSI**Voting begins on
2009-05-21Voting terminates on
2009-10-21INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИСИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE**Medical electrical equipment — Particular requirements
for the basic safety and essential performance of pulse oximeter
equipment for medical use —****Part 2-61***Appareils électromédicaux — Exigences particulières pour la sécurité de base et les performances essentielles
pour les oxymètres de pouls à usage médical —**Partie 2-61*iteh STANDARD PREVIEW
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(Revision of ISO 9919:2005)

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

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

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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108 **Foreword**

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

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

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

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

121 ISO/IEC 80601-2-61 was prepared by a Joint Working Group of Technical Committee ISO/TC 121,
 122 *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and
 123 Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D,
 124 *Electromedical equipment*.

125 This first edition cancels and replaces the second edition of ISO 9919:2005, which has been revised to
 126 harmonize it with the third edition of IEC 60601-1:2005.

127 In this standard, the following print types are used: <https://standards.iteh.ai/catalog/standards/sist/1a167005-9922-451e-8b01-st-en-iso-80601-2-61-2011>

128 — Requirements and definitions: roman type.

129 — *Test specifications: italic type.*

130 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative
 131 text of tables is also in a smaller type.

132 — **Terms defined in Clause 3 of the general standard, in this particular standard or as noted: bolded**
 133 **roman type.**

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

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

137 — “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of
 138 Clause 7).

139 References to clauses within this standard are preceded by the term “Clause” followed by the clause number.
 140 References to subclauses within this collateral standard are by number only.

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

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

- 145 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this
146 standard;
- 147 — “should” means that compliance with a requirement or a test is recommended but is not mandatory for
148 compliance with this standard;
- 149 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.
- 150 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that
151 there is guidance or rationale related to that item in Annex AA.
- 152 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers
153 and testing organizations may need a transitional period following publication of a new, amended or revised
154 ISO or IEC publication in which to make products in accordance with the new requirements and to equip
155 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of
156 this publication be adopted for implementation nationally not earlier than 3 years from the date of publication
157 for equipment newly designed and not earlier than 5 years from the date of publication for equipment already
158 in production.
- 159

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