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 medizischen 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

oSIST prEN ISO 80601-2-61:2009 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 80601-2-61

May 2009

ICS 11.040.10

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)

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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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Contents

Page

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.

DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-61

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

Voting begins on **2009-05-21** Voting terminates on **2009-10-21**

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

(Revision of ISO 9919:2005)

ICS 11.040.10

Please see the administrative notes on page ii-2

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.

Contents

Page

107

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 and IEC shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 80601-2-61 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, *Electromedical equipment*.

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

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: bolded roman 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. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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