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Medicinska električna oprema - 2-61. del: Posebne zahteve za osnovno varnost in bistvene lastnosti pulznega oksimetra (ISO/DIS 80601-2-61:2024)

Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO/DIS 80601-2-61:2024)

Medizinische elektrische Geräte - Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten (ISO/DIS 80601-2-61:2024)

Appareils électromédicaux - Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls (ISO/DIS 80601-2-61:2024)

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Medical electrical equipment —

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Appareils électromédicaux —

Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls

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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 committee. 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee SC 3, Respiratory devices and related equipment used for patient care and Technical Committee IEC/TC 62, Electrical equipment in medical practice, Subcommittee SC 62D, Electric equipment, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-61:2018), which has been technically revised.

The main changes compared to the previous edition are as follows:

— alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012 +AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013 +AMD2:2020.

— increased disclosure requirements;

— increased the required number of participants in the clinical study and their diversity;

— reduced the maximum permissible A_{rms};

— required *disparate bias* determination;

— clarified that *accessories* need to be included in the clinical performance *verification* and conformity to the requirements of the document

— updated the reporting requirements for the clinical performance *verification*; and

— harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This document covers *basic safety* and *essential performance* requirements achievable within the limits of existing technology.

The committees recognized the need to revise the first edition of this document because of the publication of the first edition of IEC 60601-1-12, as well as the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-11 and the first Amendments to both the third edition of IEC 60601-1, the third edition of IEC 60601-1-6 and the second edition of IEC 60601-1-8.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the reasoning of the committees that led to a requirement and identifying the *hazards* that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a *pulse oximeter probe* and a *patient's* tissue.

Annex CC discusses both the formulae used to evaluate the *SpO_2 accuracy* of *pulse oximeter equipment* measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when in vitro blood calibration of *pulse oximeter equipment* is needed.

Annex EE presents a guideline for a *controlled desaturation study* for the calibration of *pulse oximeter equipment*.

Annex FF is a tutorial introduction to several kinds of testers used in pulse oximetry.

Annex GG describes concepts of *pulse oximeter equipment* response time.

Annex HH describes data interface requirements.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *terms defined in Clause 3 of the IEC 60601-1:2005+AMD1:2012+AMD2:2020 in this document or as noted*: italic type; and

– 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.

In referring to the structure of this document, the term

– "clause" means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 201 includes subclauses 201.7.1, 201.7.2) and

– "subclause" means a numbered subdivision of a clause (e.g., 201.7.1, 7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

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

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" indicates a requirement;

– "should" indicates a recommendation;

– "may" indicates a permission;

208 – “can” indicates a possibility or capability; and

209 – “must” is used express an external constraint.

210 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

211 Any feedback or questions on this document should be directed to the user’s national standards body. A
212 complete listing of these bodies can be found at www.iso.org/members.html.

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Medical electrical equipment —

Part 2-61:
Particular requirements for basic safety and essential performance of pulse oximeter equipment

201.1 Scope, object, and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of *pulse oximeter equipment* intended for use on humans, hereafter referred to as *ME equipment*. This includes any part necessary for *normal use*, including the *pulse oximeter monitor*, *pulse oximeter probe*, and *probe cable extender*.

These requirements apply to *pulse oximeter equipment*, including *pulse oximeter monitors*, *pulse oximeter probes* and *probe cable extenders* regardless of their origin (i.e., including *remanufactured* products).

The intended use of *pulse oximeter equipment* includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of *patients* in professional healthcare institutions as well as *patients* in the *home healthcare environment* and the *emergency medical services environment*.

This document is not applicable to *pulse oximeter equipment* intended for use in laboratory research applications nor to oximeters that require a blood sample from the *patient*.

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 physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in 201.11 and in 7.2.13 and IEC 60601-1:2005+AMD1:2012+AMD2:2020, 8.4.1.

NOTE 2 See also IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document can also be applied to *ME equipment* and their *accessories* used for compensation or alleviation of disease, injury, or disability.

This document is not applicable to *pulse oximeter equipment* intended solely for foetal use.

This document is not applicable to remote or slave (secondary) equipment that displays SpO_2 values that are located outside of the *patient environment*.

NOTE 3 *ME equipment* that provides selection between diagnostic and monitoring functions is expected to meet the requirements of the appropriate document when configured for that function.

This document is applicable to *pulse oximeter equipment* intended for use under extreme or uncontrolled environmental conditions outside the hospital environment or physician's office, such as in ambulances and air transport. Additional standards can apply *pulse oximeter equipment* for those environments of use.

This document is a particular standard in the IEC 60601-1 and ISO and IEC 80601 series of standards.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *pulse oximeter equipment* [as defined in 201.3.254] and its *accessories*.

NOTE 1 *Accessories* are included because the combination of the *pulse oximeter monitor* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of *pulse oximeter equipment.*

NOTE 2 This document has been prepared to address the relevant *essential principles*[25] and labelling[26] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex LL.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[27].

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 and Clause 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11+AMD1:2020 and IEC 60601-1-12+AMD1:2020 apply as modified in Clauses 202, 206, 208, 211 and 212, respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace, or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

A requirement of a particular standard takes priority over the general standard or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following abbreviated words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

