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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

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

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

ISO/CEN PARALLEL PROCESSING

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 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.

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. 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. 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.

ISO 80601-2-61 was prepared by 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*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition of ISO 80601-2-61 cancels and replaces the first edition of ISO 80601-2-61[1][1] (2011). This edition of ISO 80601-2-61 constitutes a technical revision and includes an alignment with Amendment 1 of both the third edition of IEC 60601-1 and the second edition of IEC 60601-1-8, as well as the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-11 and IEC 60601-1-12.

[1] Numbers in square brackets refer to the Bibliography.

95 The most significant changes are the following modifications:

96 – Updated Rationale (Annex AA) and references related to advances in our understanding of hypoxia,
97 electronic health records and ALARM SYSTEMS;

98 and the following additions:

99 – Clause 211, requirements for use in the HOME HEALTHCARE ENVIRONMENT

100 – Clause 212, requirements for use in the emergency medical services (EMS) environment

101 – Annex HH, Data interface requirements

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European Foreword

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 7000 (database)	—	ISO 7000 (database)
ISO 14155:2011	EN ISO 14155:2011+AC:2011	ISO 14155:2011
ISO 14937:2009	—	ISO 14937:2009
ISO 15223-1:—[2]	prEN ISO 15223-1:—	ISO 15223-1:—
IEC 60068-2-27:2008+A1:2013	EN 60068-2-27:2009+A1:—	IEC 60068-2-27:2008+A1:2013
IEC 60068-2-31:2008	EN 60068-2-31:2008	IEC 60068-2-31:2008
IEC 60068-2-64:2008	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 60601-1:2005+A1:2012	EN 60601-1:2006+A1:2013 +AC:2014+A12:2014	IEC 60601-1:2005+A1:2012
IEC 60601-1-2:2014	EN 60601-1-2:—1	IEC 60601-1-2:2014
IEC 60601-1-6:2010 +A1:2013	EN 60601-1-6:2010+A1:—~~11~~	IEC 60601-1-6:2010 +A1:2013~~1~~
IEC 60601-1-8:2006+A1:2012	EN 60601-1-8:2007 +A1:2013 +AC:2014	IEC 60601-1-8:2006 +A1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:2015	IEC 60601-1-12:2014
IEC 60417 (database)	—	IEC 60417 (database)
IEC 60529:2013	EN 60529:—	IEC 60529:2013
IEC 60825-1:2014	EN 60825-1:2014	IEC 60825-1:2014

2 Under preparation. Stage at the time of publication: ISO FDIS 15223-1:2016.

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
IEC 60825-2:2004+A1:2006+A2:2010	EN 60825-2:2004+A1:2007 +A2:2010	IEC 60825-2:2004+A1:2006+A2:2010

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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 due to 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 committee 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.

Annex II contains Reference to the Essential Principles formerly found in Annex HH.

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

In this document, 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[3] IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS

In referring to the structure of this document, the term

[3] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

– “clause” means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201includes subclauses 201.7.1, 201.7.2, etc.) 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” means that compliance with a requirement or a test is mandatory for compliance with this document;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document; and

– “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 committees that the content of this document 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.

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, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

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 also apply to PULSE OXIMETER EQUIPMENT, including PULSE OXIMETER MONITORS, PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS, which have been REPROCESSED.

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 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 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard.

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.

This document is not applicable to pulse haemoglobin monitors.

NOTE 2 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/IEC 80601 series of standards.

201.1.2 Object

Subclause 1.2 of the general standard is replaced by:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.203] and its ACCESSORIES.

NOTE 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.

201.1.3 Collateral standards

IEC 60601-1:2005+AMD1:2012, subclause 1.3 applies with the following addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard[4] and Clause 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208, 211 and 212 respectively. IEC 60601-1-3[2] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

IEC 60601-1:2005+AMD1:2012, subclause 1.4 is replaced by:

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.

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

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

4 The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 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.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 2xx, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

IEC 60601-1:2005+AMD1:2012, Clause 2 applies, except as follows:

Replacement: