International Standard

ISO 80601-2-61

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) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

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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. In the IEC, see www.iec.ch/understanding-standards.

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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, 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 80601-2-61:2017), which has been technically revised.

The main changes 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 (a means to assure equal contributions across the range of skin pigmentation);

— reduced the maximum permissible A_{rms} to enhance measurement accuracy;

— required *differential bias* determination to enhance measurement accuracy;

— 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*;

— added an Annex describing the use of *transfer standard* for product development purposes;

— added an Annex mapping the requirements of this document to the IMDRF *essential principles*[25] and labelling[26] guidances; 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 and IEC websites.

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 and www.iec.ch/national-committees.

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 IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-12:2014+AMD1:2020, as well as IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-11:2015+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

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 the formulae used to evaluate the SpO_2 *accuracy* of *pulse oximeter equipment* measurements, *differential bias* and the names that are assigned to those formulae.

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

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

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

Annex GG describes data interface requirements.

Annex HH describing the clinical context of this document and its rationale;

Annex II describing the use of a *functional tester*;

Annex JJ describing the use of *transfer standard*;

Annex KK maps the requirements of this document to the IMDRF *essential principles*[25] and labelling[26] guidances

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;

– “can” indicates a possibility or capability; and

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

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 AA.2.1.

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*.

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 says 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 201.11.1.2.2, IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 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 for use in laboratory research applications nor to oximeters that require a blood sample from the *patient*.

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 appropriate requirements of this 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 to *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 201.3.253] 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 KK.

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 and IEC 60601-1-9 do 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.

"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+AMD2:2020, Clause 2 applies, except as follows:

Addition:

ISO 14155:2026, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 15223-1:2021+AMD1:2025, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 20417:2026, *Medical devices — Information to be supplied by the manufacturer*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008+AMD1:2019, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014+AMD1:2020, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

IEC 60825-2:2021, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS)*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD 1:2012+AMD1:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE An alphabetized index of defined terms is found following the Bibliography.

201.3.201
accompanying information
information supplied by the manufacturer with or *marked* on a medical device or *accessory* for the user or *responsible organization*, particularly regarding safe use

Note 1 to entry: The *accompanying information* is be regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, *technical description*, information shown on the packaging or graphical user interface (GUI), installation manual, quick reference guide, etc. and can address the installation, use, *processing*, maintenance and disposal of the medical device or *accessory.*

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but can involve auditory, visual, or tactile materials and multiple media types (e.g. CD-ROM, DVD-ROM, USB drive, website).

Note 4 to entry: Medical devices and *accessories* that can be used safely without *accompanying information* are exempted from having *accompanying information* by some *authorities having jurisdiction.*

[SOURCE: ISO 20417:2026, 3.2]

201.3.202
accuracy
closeness of agreement between a test result and an accepted reference value

Note 1 to entry: Subclause 201.12.1.101.4 provides the method of calculating the *SpO_2 accuracy* of *pulse oximeter equipment*.

Note 2 to entry: Additional information is found in Annex CC.

[SOURCE: ISO 3534-2:2006, 3.3.1, modified — Replaced note 1 to note 3 with new notes and ‘or measurement result and the true’ with ‘and an accepted reference ’.]

201.3.203
alarm condition delay
time from the occurrence of a triggering event either in the *patient*, for *physiological alarm conditions*, or in the equipment, for *technical alarm conditions*, to when the *alarm system* determines that an *alarm condition* exists

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.2]

201.3.204
alarm limit
threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

201.3.205
alarm paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate *alarm signals*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]

201.3.206
alarm preset
set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the *alarm system*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.6]

201.3.207
alarm signal generation delay
time from the onset of an *alarm condition* to the generation of its *alarm signal(s*)

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]

201.3.208
audio paused
state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an auditory *alarm signal*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]

201.3.209
colour measurement site
location on the body at which the skin pigmentation is assessed by *pigmentation measurement methods (PMMs)*

201.3.210
controlled desaturation study
hypoxaemia induced in a cohort of healthy adult human participants performed under well controlled, optimal or non-optimal laboratory conditions.

201.3.211
CO-oximeter
multiwavelength optical blood analyser that measures *total haemoglobin concentration* and the concentrations of various haemoglobin derivatives

Note 1 to entry: The relevant CO-oximetry value is functional saturation of arterial blood, SaO_2, which *pulse oximeter equipment* estimates and reports as SpO_2.

201.3.212
data update period
interval in which the *pulse oximeter equipment* algorithm provides new valid data to the display or the *functional connection*

Note 1 to entry: The *data update period* does not refer to the regular refresh period of the display, which is typically on the order of 1 s, but rather to the (typically longer) interval defined above.

201.3.213
declared range
portion of the *displayed range* of SpO_2 and pulse rate values over which there is specified *accuracy*

201.3.214
default alarm preset
alarm preset that can be activated by the *alarm system* without *operator* action

Note 1 to entry: *Manufacturer-* or *responsible organization-configured alarm presets* are possible types of *default alarm presets*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.16]

201.3.215
differential bias
measure of the overall dependence of participant-specific *mean bias* to a factor

201.3.216
displayed range
range of SpO_2 or pulse rate values that can be displayed by the *pulse oximeter equipment*

Note 1 to entry: The *displayed range* can extend beyond the *declared range*.

201.3.217
distributed alarm system
DAS
alarm system that involves more than one item of equipment of a *ME system* intended for delivery of *alarm conditions* with technical confirmation

Note 1 to entry: The parts of a *distributed alarm system* can be widely separated in distance.

Note 2 to entry: A *distributed alarm system* is intended to notify *operators* of the existence of an *alarm condition*.

Note 3 to entry: For the purposes of this document, technical confirmation means that each element of a *distributed alarm system* confirms or guarantees the successful delivery of the *alarm condition* to the next element or appropriate *technical alarm conditions* are created as described in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.11.2.2.1.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.17]

201.3.218
EMS environment
emergency medical services environment
actual conditions and settings, in which *operators* interact with the *ME equipment* or *ME system*, in and around the scene of an emergency outside of a professional healthcare facility where a *patient* can be given medical care, basic or advanced life support as well as during professional transport to a professional healthcare facility or between professional healthcare facilities

EXAMPLE 1 Responding to and providing life support at the scene of an emergency to a *patient* reported as experiencing injury or illness in a pre-hospital setting, and transporting the *patient*, while continuing such life support care, to an appropriate professional healthcare facility for further care.

EXAMPLE 2 Providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

Note 1 to entry: For the purposes of this document, use of equipment intended for the *EMS environment* and temporarily used in the *home healthcare environment* by emergency medical personnel is considered use in the *EMS environment*.

Note 2 to entry: For the purposes of this document, the *operators* of equipment intended for the *EMS environment* are presumed to be professional medical personnel or personnel with relevant specialized training.

Note 3 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms and multiple treatment facilities.

Note 4 to entry: Emergency medical services are known by various names in different countries and regions.

Note 5 to entry: For the purposes of this document, transport includes road, rotary and fixed-wing ambulances.

[SOURCE: IEC 60601-1-12:2014+AMD1:2020, 3.1]