INTERNATIONAL STANDARD

ISO 80601-2-61

Second edition
2017-12

Corrected version
2018-02

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

Reference number
ISO 80601-2-61:2017(E)

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

Published in Switzerland

Contents

Page

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 (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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by 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 (ISO 80601-2-61:2011), which has been technically revised. It 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.

The most significant changes are the following modifications:

– updated rationale (Annex AA) and references related to advances in the understanding of hypoxaemia, electronic health records and ALARM SYSTEMS;

– ingress protection changed from IPX1 to IPX2;

and the following additions:

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

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

– Annex HH, Data interface requirements.

This corrected version of ISO 80601-2-61:2017 incorporates the following correction:

– headers have been corrected.

A list of all the parts of the ISO/IEC 80601 series is available on the ISO website.

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.

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 [1] IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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).

---

[1] 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.

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.

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 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 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard. "The general standard" is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 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 201.3.217] 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 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.

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:

IEC 60417, *Graphical symbols for use on equipment*

IEC 60529:2013, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*
+ Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+ Amendment 1:2012

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

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock* + Amendment 1:2013

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, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1-11:2015, *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, *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 60825-2:2004, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS)* + Amendment 1:2006+ Amendment 2:2012

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3744:2010, ISO 4135:2001, IEC 60601-1:2005+AMD 1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD 1:2013, IEC 60601-1-8:2006+AMD 1:2012, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62366-1:2015 and the following apply.

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

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

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

NOTE An alphabetized index of defined terms is found in Annex JJ.

201.3.201
accuracy
closeness of agreement between a test result and an accepted reference value

Note 1 to entry: Subclause 201.12.1.101.2 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], 3.3.1, modified — Replaced note 1 to note 3 with new notes and 'or measurement result and the true' with 'and an accepted reference '.]

201.3.202
controlled desaturation study
hypoxaemia induced in a human subject performed under laboratory conditions

Note 1 to entry: This can also be referred to as a controlled hypoxaemia (breathedown) study. Additional information is found in Annex EE.

201.3.203
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.

201.3.204
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: This definition 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.

201.3.205
declared range
portion of the DISPLAYED RANGE of SpO_2 and pulse rate values over which there is specified ACCURACY

201.3.206
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.

201.3.207
fractional oxyhaemoglobin
***F*O₂Hb fractional saturation (deprecated)**
oxyhaemoglobin concentration cO_2Hb divided by the TOTAL HAEMOGLOBIN CONCENTRATION, ctHb, in the blood

$$FO_2\text{Hb} = \frac{cO_2\text{Hb}}{c\text{tHb}}$$

Note 1 to entry: cO_2Hb is the concentration of oxyhaemoglobin; ctHb is the concentration of total haemoglobin.

Note 2 to entry: This is sometimes reported as a percentage (multiplying the fraction by 100).

Note 3 to entry: FRACTIONAL OXYHAEMOGLOBIN is the term used by the Clinical and Laboratory Standards Institute (CLSI), (formerly NCCLS or National Committee for Clinical Laboratory Sciences) for this ratio.

Note 4 to entry: CLSI denotes “concentration” by a prefixed letter c, while in the past the convention of square brackets (e.g. [O_2Hb]) was used.

Note 5 to entry: CLSI[4] uses the following notations:

– oxyhaemoglobin (O_2Hb);

– deoxyhaemoglobin (HHb);

- carboxyhaemoglobin (COHb);methaemoglobin (MetHb);
- sulfhaemoglobin (SulfHb); and
- total haemoglobin (*c*tHb), which is derived by the cyanmethaemoglobin method of CLSI H15[5].

201.3.208
functional oxygen saturation
percentage saturation given by the oxyhaemoglobin concentration (cO_2Hb) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (cHHb)

$$\frac{100 \times cO_2Hb}{cO_2Hb + cHHb}$$

Note 1 to entry: The CLSI[4] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2.

Note 2 to entry: As related to SpO_2, this percent saturation is for arterial blood.

201.3.209
functional tester
test equipment which presents PULSE OXIMETER EQUIPMENT with a signal having a predictable value of RATIO so that the OPERATOR can observe the resulting displayed value of SpO_2, and compare it to the expected value derived from the calibration curve for that particular PULSE OXIMETER EQUIPMENT

Note 1 to entry: The ACCURACY of the SpO_2 value given by the PULSE OXIMETER EQUIPMENT depends in part on whether the calibration curve of the PULSE OXIMETER MONITOR properly reflects the optical characteristics of the PULSE OXIMETER PROBE and PULSE OXIMETER PROBE-tissue interaction. FUNCTIONAL TESTERS are not able to confirm the SpO_2 ACCURACY of the calibration curve or sufficiently assess the optical characteristics of PULSE OXIMETER PROBES to determine their proper calibration. Additional information is found in FF.4.

Note 2 to entry: Not all FUNCTIONAL TESTERS and PULSE OXIMETER EQUIPMENT are compatible. FUNCTIONAL TESTERS can vary in pulse simulation methods, pulse contours, and amplitude. A FUNCTIONAL TESTER might not accurately reproduce the calibration of the PULSE OXIMETER EQUIPMENT and can yield different results between PULSE OXIMETER EQUIPMENT.

201.3.210
local bias
b
difference between the expectation of a test result (SpO_2) and an accepted reference value (SaO_2)

Note 1 to entry: For PULSE OXIMETER EQUIPMENT, this is, at a given value of the reference oxygen saturation, the difference between the *y*-value of the regression line at that coordinate and the *y*-value of the line of identity, in a plot of SpO_2 versus S_R, or given by:

$$b_i = SpO_{2\,\mathrm{fit},i} - S_{Ri}$$

where

$SpO_{2\mathrm{fit},i}$ is the value of the curve fitted to the test data at the i^{th} reference oxygen saturation value, S_{Ri}.

Note 2 to entry: Additional information is found with the term MEAN BIAS and in the discussion in Annex CC.

[SOURCE: ISO 3534-2:2006[3], 3.3.2, modified — Replaced note 1 to note 3 with new notes and 'or measurement result and the true value' with '(SpO_2) and an accepted reference value (SaO_2)'.]

201.3.211
mean bias
B
mean difference between the test and reference values, preserving sign

$$B = \frac{\sum_{i=1}^{n}\left(SpO_{2i} - S_{Ri}\right)}{n}$$

where

n is the number of data pairs in the sample within the range of interest;

SpO_{2i} is the ith SpO_2 datum; and

S_{Ri} is the i^{th} reference oxygen saturation value.

Note 1 to entry: Additional information also is found with the term LOCAL BIAS and in the discussion in Annex CC.

Note 2 to entry: When defined in this way, MEAN BIAS is the average of all LOCAL BIAS values, b_i.

201.3.212
normalized
displayed at constant amplitude independent of the actual magnitude of the signal being displayed

201.3.213
operator settings
current state of any PULSE OXIMETER MONITOR controls, including ALARM SETTINGS

201.3.214
precision
closeness of agreement between independent test results obtained under stipulated conditions

$$s_{res} = \sqrt{\frac{\sum_{i=1}^{n}\left(SpO_{2i} - SpO_{2fit,i}\right)^2}{\left(n-2\right)}}$$

where

n is the number of data pairs in the sample within the range of interest;

$(SpO_{2i} - SpO_{2fit,i})$ is the difference between the i^{th} SpO_2 datum and the value of the fitted curve corresponding to the i^{th} reference oxygen saturation value, S_{Ri}.

Note 1 to entry: Additional information is found in Annex CC.

[SOURCE: ISO 3534-2:2006[3], 3.3.4, modified — Replaced note 1 to note 3 with a new note, deleted '/measurement results' and added formula.]

201.3.215
probe cable extender
cable that connects a PULSE OXIMETER MONITOR to a PULSE OXIMETER PROBE

Note 1 to entry: Not every PULSE OXIMETER EQUIPMENT utilizes a PROBE CABLE EXTENDER.

Note 2 to entry: A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.216
probe fault
abnormal condition of the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER, which if not detected, could cause PATIENT HARM