INTERNATIONAL STANDARD

ISO 80601-2-61

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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 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 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 of ISO 80601-2-61 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: SMALL CAPITALS 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 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:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— “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 committee that the content of this publication be adopted for implementation nationally not 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.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This standard covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements achievable within the limits of existing technology.

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.

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, Clause 1 applies, except as follows:

201.1.1 * Scope

Subclause 1.1 of The general standard is replaced by:

This International Standard 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.

This International Standard 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 standard are not covered by specific requirements in this standard except in 201.11 and in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard can also be applied to PULSE OXIMETER EQUIPMENT and their ACCESSORIES used for compensation or alleviation of disease, injury or disability.

This International Standard is not applicable to PULSE OXIMETER EQUIPMENT intended solely for foetal use.

This International Standard is not applicable to remote or slave (secondary) devices that display SpO_2 values that are located outside of the PATIENT ENVIRONMENT.

201.1.2 Object

Subclause 1.2 of The general standard is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.216] and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the PULSE OXIMETER MONITOR and the ACCESSORIES needs to be safe. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT.

201.1.3 Collateral standards

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

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

IEC 60601-1-3 does not apply.

NOTE Additional requirements for ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11.

201.1.4 Particular standards

Subclause 1.4 of The general standard is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

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

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the 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 particular standard.

"Addition" means that the text of this particular standard 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 particular standard.

Subclauses or figures which 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 which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

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

Where there is no corresponding section, clause or subclause in this particular standard, 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 standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the bibliography beginning on page 76.

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

Replacement:

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — 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*

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*

IEC 60825-1:2007, *Safety of laser products — Part 1: Equipment classification and requirements*

Addition:

ISO 7000/IEC 60417:2004, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 14937:2000, *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 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
ISO 15223-1:2007/Amd.1:2008

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

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2010, *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 60825-2:2004, *Safety of laser products — Part 2: Safety of optical fibre communication systems* (*OFCS*)
IEC 60825-2:2004/Amd.1:2006

IEC/TR 60878:2003, *Graphical symbols for electrical equipment in medical practice*

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows.

NOTE An alphabetized index of defined terms is found beginning on page 81.

Addition:

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

NOTE 1 Subclause 201.12.1.101.2.2 provides the method of calculating the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT.

NOTE 2 Additional information is found in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.1.

201.3.202
CONTROLLED DESATURATION STUDY
hypoxaemia induced in a human subject performed under laboratory conditions

NOTE This can also be referred to as a controlled hypoxaemia (breathdown) 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 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 SIGNAL INPUT/OUTPUT PART

NOTE 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
that 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 and pulse rate values that can be displayed by the PULSE OXIMETER EQUIPMENT

NOTE The DISPLAYED RANGE can extend beyond the DECLARED RANGE.

201.3.207
FRACTIONAL OXYHAEMOGLOBIN
FO_2Hb
fractional saturation (deprecated)
oxyhaemoglobin concentration cO_2Hb divided by the TOTAL HAEMOGLOBIN CONCENTRATION, ctHb, in the blood

$$FO_2Hb = \frac{cO_2Hb}{c\text{tHb}}$$

NOTE 1 cO_2Hb is the concentration of oxyhaemoglobin; ctHb is the concentration of total haemoglobin.

NOTE 2 This is sometimes reported as a percentage (multiplying the fraction by 100).

NOTE 3 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 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 CLSI[13] uses the following notations:

- oxyhaemoglobin (O_2Hb);
- deoxyhaemoglobin (HHb);
- carboxyhaemoglobin (COHb);
- methaemoglobin (MetHb);
- sulfhaemoglobin (SuHb); and
- total haemoglobin (tHb).

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)

$$\frac{100 \times cO_2Hb}{cO_2Hb + c\text{HHb}}$$

NOTE The CLSI[13] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2.

201.3.209
FUNCTIONAL TESTER
test device 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 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 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 the test results (SpO_2) and an accepted reference value (SaO_2)

NOTE 1 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 ith reference oxygen saturation value, S_{Ri}.

NOTE 2 Additional information is found with the term MEAN BIAS and in the discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.2.

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

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

NOTE 1 n is the number of data pairs in the sample within the range of interest, SpO_{2i} is the ith SpO_2 datum; S_{Ri} is the ith reference oxygen saturation value.

NOTE 2 Additional information also is found with the term LOCAL BIAS and in the discussion in Annex CC.

NOTE 3 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

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

NOTE 1 n is the number of data pairs in the sample within the range of interest; $(SpO_{2i} - SpO_{2\mathrm{fit},i})$ is the difference between the ith SpO_2 datum and the value of the fitted curve corresponding to the ith reference oxygen saturation value, S_{Ri}.

NOTE 2 Additional information is found in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.4.

201.3.215
PROBE CABLE EXTENDER
cable that connects a PULSE OXIMETER MONITOR to a PULSE OXIMETER PROBE

NOTE 1 Not every PULSE OXIMETER EQUIPMENT utilizes a PROBE CABLE EXTENDER.

NOTE 2 A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.216
PULSE OXIMETER EQUIPMENT
ME EQUIPMENT for the non-invasive estimation of FUNCTIONAL OXYGEN SATURATION of arterial haemoglobin (SpO_2) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow

NOTE 1 PULSE OXIMETER EQUIPMENT comprises a PULSE OXIMETER MONITOR, a PROBE CABLE EXTENDER, if provided, and a PULSE OXIMETER PROBE, which can be combined in a single assembly.

NOTE 2 Light is more technically referred to as electromagnetic radiation (optical radiation). This International Standard uses the common term.

201.3.217
PULSE OXIMETER MONITOR
part of the PULSE OXIMETER EQUIPMENT that encompasses the electronics, display and OPERATOR-EQUIPMENT INTERFACE, excluding the PULSE OXIMETER PROBE and PROBE CABLE EXTENDER

NOTE A PULSE OXIMETER MONITOR can consist of multiple pieces of hardware in separate locations, e.g. a telemetry system in which the APPLIED PART and primary display are in physically different locations.

201.3.218
PULSE OXIMETER PROBE
part of the PULSE OXIMETER EQUIPMENT that includes the APPLIED PART and transducer component

NOTE 1 The terms sensor and transducer have also been used for PULSE OXIMETER PROBE.

NOTE 2 The PULSE OXIMETER PROBE typically consists of a cable and a rigid or flexible assembly containing two photo emitters and a photo detector.

201.3.219
PULSE OXIMETER PROBE FAULT
abnormal condition of the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER, that, if not detected, could cause PATIENT HARM

NOTE PATIENT HARM can be caused by providing incorrect values, by exposing the PATIENT to high PULSE OXIMETER PROBE temperatures or by introducing a RISK of electric shock.

201.3.220
RATIO
MODULATION RATIO
RATIO OF RATIOS
R
basic quantity derived by PULSE OXIMETER EQUIPMENT from time-dependent light intensity measurements

NOTE PULSE OXIMETER EQUIPMENT uses an empirical calibration curve to derive SpO_2 from R. Additional information is found in FF.4.