



BSI Standards Publication

Medical electrical equipment

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02)

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-61:2019. It is identical to ISO 80601-2-61:2017. It supersedes BS EN ISO 80601-2-61:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Date	Text affected
31 March 2019	Implementation of CEN correction notice 6 March 2019: Date of withdrawal for conflicting national standards corrected

English Version

Medical electrical equipment - Part 2-61: Particular
requirements for basic safety and essential performance of
pulse oximeter equipment (ISO 80601-2-61:2017,
Corrected version 2018-02)

Appareils électromédicaux - Partie 2-61: Exigences
particulières pour la sécurité de base et les
performances essentielles pour les oxymètres de pouls
(ISO 80601-2-61:2017, Version corrigée 2018-02)

Medizinische elektrische Geräte - Teil 2-61: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von
Pulsoximetriegeräten (ISO 80601-2-61:2017)

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This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 06 March 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 80601-2-61:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by January 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80601-2-61:2011.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-61:2017, Corrected version 2018-02 has been approved by CEN as EN ISO 80601-2-61:2019 without any modification.

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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 (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 STANDARD¹ 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 (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 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** **FO_2Hb fractional saturation (deprecated)**

oxyhaemoglobin concentration cO_2Hb divided by the TOTAL HAEMOGLOBIN CONCENTRATION, $ctHb$, in the blood

$$FO_2Hb = \frac{cO_2Hb}{ctHb}$$

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);
- sulphaemoglobin (SulfHb); and
- total haemoglobin (ctHb), 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:

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

where

$SpO_{2\text{fit},i}$ 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

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

where

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

SpO_{2i} is the i th 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

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

where

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

$(SpO_{2i} - SpO_{2\text{fit},i})$ 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

Note 1 to entry: 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.

201.3.217

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 to entry: 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 to entry: Light is more technically referred to as electromagnetic radiation (optical radiation). This document uses the common term.

201.3.218

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 1 to entry: 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 separated.

201.3.219

pulse oximeter probe

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

Note 1 to entry: The terms sensor and transducer have also been used for PULSE OXIMETER PROBE.

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

201.3.220

ratio

modulation ratio

ratio of ratios

R

basic quantity derived by PULSE OXIMETER EQUIPMENT from time-dependent light intensity measurements

Note 1 to entry: PULSE OXIMETER EQUIPMENT uses an empirical calibration curve to derive SpO_2 from R . Additional information is found in FF.4.

201.3.221

*** reprocessing**

any activity, which is not specified in the ACCOMPANYING DOCUMENT, that renders a product suitable for use or reuse

Note 1 to entry: Such activities are often referred to as refinishing, restoring, recycling, refurbishing, repairing or remanufacturing.

Note 2 to entry: Such activities can occur in healthcare facilities.

Note 3 to entry: The term "REPROCESSED" is used to designate the corresponding status.

201.3.222

SaO_2

fraction of functional haemoglobin in arterial that is saturated with oxygen

Note 1 to entry: Subclause 201.12.1.101.3 provides the method for determining acceptable methods of measurement of SaO_2 .

Note 2 to entry: SaO_2 is FUNCTIONAL OXYGEN SATURATION in arterial blood. Additional information is found 201.3.209.

Note 3 to entry: SaO_2 is normally expressed as a percentage (by multiplying the fraction by 100).

201.3.223

SpO_2

estimate of SaO_2 made by PULSE OXIMETER EQUIPMENT

Note 1 to entry: Two-wavelength PULSE OXIMETER EQUIPMENT cannot compensate for the interference caused by the presence of dyshaemoglobins in their estimation of SaO_2 ^{[6][7]}.

Note 2 to entry: SpO_2 is normally reported as a percentage (multiplying the fraction by 100).

201.3.224

total haemoglobin concentration

ctHb

sum of concentrations of all haemoglobin species in the blood including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin ($cMetHb$), deoxyhaemoglobin ($cHHb$), sulfhaemoglobin ($cSHb$) and carboxyhaemoglobin ($cCOHb$)^[8]

201.3.225

validation

confirmation, through the provision of OBJECTIVE EVIDENCE, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The OBJECTIVE EVIDENCE needed for a VALIDATION is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The term "VALIDATED" is used to designate the corresponding status.

Note 3 to entry: The use conditions for VALIDATION can be real or simulated.

[SOURCE: ISO 9000:2015^[9] definition 3.8.13]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+AMD1:2012, subclause 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

201.4.102 Additional requirements for acceptance criteria

Many of the clauses and subclauses within this document establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the MANUFACTURER specifies in the ACCOMPANYING DOCUMENT performance levels better than those specified within this document, these MANUFACTURER-specified levels become the acceptance levels.

EXAMPLE For a specified level of SpO_2 ACCURACY of 1 %, the PULSE OXIMETER EQUIPMENT is required to have 1 % SpO_2 ACCURACY for all requirements (e.g. during IMMUNITY tests).

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
For PULSE OXIMETER EQUIPMENT provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY, pulse rate ACCURACY and limit ALARM CONDITIONS ^a	201.12.1.101 201.12.1.104 208.6.1.2.101
or generation of a TECHNICAL ALARM CONDITION	201.11.8.101.1 201.12.4 201.13.101
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY and pulse rate ACCURACY ^a	201.12.1.101 201.12.1.104
or indication of abnormal operation	201.12.4 201.13.101
^a Subclause 202.8.2 indicates methods of evaluating SpO_2 ACCURACY and pulse rate ACCURACY as acceptance criteria following specific tests required by this document.	

201.4.103 Additional requirements for PULSE OXIMETER EQUIPMENT, parts and ACCESSORIES

The PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall comply with all requirements specified in this document. This includes all combinations of parts or ACCESSORIES that are specified by a MANUFACTURER for use in PULSE OXIMETER EQUIPMENT.

NOTE 1 This requirement ensures BASIC SAFETY and ESSENTIAL PERFORMANCE of parts and ACCESSORIES of the PULSE OXIMETER EQUIPMENT, in combination with their intended PULSE OXIMETER MONITORS.

NOTE 2 PULSE OXIMETER MONITORS are frequently used with PULSE OXIMETER PROBES and cables from different MANUFACTURERS. This requirement ensures the compatibility of such combinations.

All specified combinations of PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall be disclosed in the instructions for use.

NOTE 3 Additional information is found in 201.7.9.2.1.101 g) and 201.7.9.2.14.101 a) and b).

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+AMD1:2012, Clause 7 applies, except as follows:

201.7.2.3 Consult ACCOMPANYING DOCUMENTS

Replacement:

The PULSE OXIMETER EQUIPMENT shall be marked with the safety sign for the mandatory action: 'follow instructions for use', ISO 7010-M002.

NOTE Additional information is found in IEC 60601-1:2005+AMD1:2012, Table D.2, Number 10).

Additional subclause:

201.7.2.9.101 IP classification

IEC 60601-1:2005+AMD1:2012, subclause 7.2.9 applies, except as follows:

Notwithstanding the requirements of IEC 60601-1:2005, 7.2.9, the ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 201.11.6.5.101. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and the degree of protection provided by the carrying case shall be marked on the carrying case.

EXAMPLE If for PORTABLE ME EQUIPMENT, the ENCLOSURE provides the protection against the ingress of particulate matter and the carrying case provides the protection against the ingress of water, the ENCLOSURE of the ME EQUIPMENT would be marked IP2X and the carrying case would be marked IPX2.

An ENCLOSURE or a carrying case that is classified IPX0 need not be marked as such. If an ENCLOSURE does not provide the minimum required degree of protection against the ingress of water, it shall be marked 'keep dry' or with ISO 15223-1:2016, Symbol 5.3.4 (see Table 201.D.1.101, Symbol 1).

Check compliance by inspection and by application of the tests and criteria of IEC 60601-1:2005+AMD1:2012, 7.1.2 and 7.1.3.

201.7.2.13.101 Additional requirements for physiological effects

All latex-containing ACCESSORIES shall be marked as containing latex. The marking shall be CLEARLY LEGIBLE. Symbol ISO 7000-2725 (see Table 201.D.1.101, Symbol 5) may be used. All latex-containing components shall be disclosed as such in the instructions for use.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages of ME EQUIPMENT, parts or ACCESSORIES shall be marked

a) with the following:

- a description of the contents;
- an identification reference to the batch, type or serial number or Symbol 5.1.5, 5.1.6, 5.1.7 from ISO 15223-1:2016 (see Table 201.D.1.101, Symbol 2, Symbol 3 or Symbol 4); and
- for packages containing natural rubber latex, the word "LATEX", or Symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, Symbol 5);

- b) for those containing parts intended for single use, with the words "SINGLE USE", "DO NOT REUSE", "NOT FOR REUSE" or Symbol ISO 15223-1:2016, 5.4.2 (see IEC 60601-1:2005+AMD1:2012, Table D.1, Symbol 28). For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.

NOTE For the purposes of this document, repositioning the PULSE OXIMETER PROBE on the same PATIENT as indicated in the instructions for use is considered single use.

These markings shall be CLEARLY LEGIBLE.

Consideration should be given to the disposal of packaging waste.

Check compliance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT parts

ME EQUIPMENT, parts or ACCESSORIES shall be marked as follows.

- a) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with any particular storage, handling and operating instructions.
- b) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with regard to proper disposal, as appropriate.
- c) If a PULSE OXIMETER MONITOR is not provided with a low SpO_2 ALARM CONDITION, a statement to the effect "No SpO_2 Alarms" or Symbol IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006 +AMD1:2012, Table C.1, Symbol 3).
- d) For a REPROCESSED PULSE OXIMETER PROBE, marked as such.

These markings shall be CLEARLY LEGIBLE.

Check compliance by inspection.

201.7.4.3 Units of measurement

IEC 60601-1:2005+AMD1:2012, subclause 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

FUNCTIONAL OXYGEN SATURATION shall be expressed in units of percent SpO_2 and shall be marked as % SpO_2 or SpO_2 .

Pulse rate shall be expressed in units of reciprocal minutes (1/min).

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall indicate the following:

- a) for each PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE, the specified use of the PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE regarding:

- PATIENT population;

EXAMPLE 1 Age, weight

- part of the body or type of tissue applied to; and
- application;

EXAMPLE 2 Environment, frequency of use, location, mobility

- b) that the PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION;
- c) the range of the peak wavelengths and maximum optical output power of the light emitted by the PULSE OXIMETER PROBE and a statement to the effect that information about wavelength range can be especially useful to clinicians;

EXAMPLE 3 Clinicians performing photodynamic therapy.

- d) description of the effect on displayed and transmitted SpO_2 and pulse rate data values by:
 - data averaging and other signal processing;
 - the DATA UPDATE PERIOD;
 - the ALARM CONDITION DELAY; and
 - ALARM SIGNAL GENERATION DELAY,

including the effects of any selectable operating mode that affects these properties;

NOTE 1 Annex GG provides an example of how to assess and describe response time graphically.

- e) the DISPLAYED RANGES of SpO_2 and pulse rate;
- f) if no ALARM SYSTEM that includes the capability to detect an SpO_2 or pulse rate PHYSIOLOGICAL ALARM CONDITION is provided, a statement to that effect;
- g) for PULSE OXIMETER MONITORS, the PULSE OXIMETER PROBE(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER MONITOR has been VALIDATED and tested for compliance with this document. The list may be made available by electronic means; and

NOTE 2 Additional information is found in 201.4.103.

- h) if the PULSE OXIMETER EQUIPMENT or its parts are intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the PULSE OXIMETER EQUIPMENT or its parts would be re-used.

Check compliance by inspection of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include:

- a) for each PULSE OXIMETER PROBE and PROBE CABLE EXTENDER, a warning to the effect that probes and cables are designed for use with specific monitors;
- b) a warning statement to the effect that the responsible organization or operator needs to verify the compatibility of the monitor, probe and cable before use, or patient injury can result; and
- c) a warning statement to the effect that misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use shall indicate the following.

- a) A description of the signal inadequacy indicator and its function. If there is a waveform, a statement as to whether or not it is NORMALIZED shall be provided.

NOTE This statement is important in determining whether the pulse waveform meets the requirements of 201.12.4.102.

- b) The recommended maximum application time for each type of PULSE OXIMETER PROBE at a single site.
- c) The IP classification of the PULSE OXIMETER EQUIPMENT ENCLOSURE and, if applicable, on any carrying case provided with the PULSE OXIMETER EQUIPMENT along with a brief description of that classification's meaning.

EXAMPLE IPX2 means this pulse oximeter is protected against harmful effects of dripping water when tilted at 15° according to IEC 60529.

- d) If the PULSE OXIMETER EQUIPMENT is provided with temperature capability such that the PULSE OXIMETER PROBE can operate at greater than 41 °C, specific instructions emphasizing the importance of proper PULSE OXIMETER PROBE application, without excessive pressure. In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use shall include the following.

- a) For PULSE OXIMETER PROBES, the PULSE OXIMETER MONITOR(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER PROBES have been VALIDATED and tested for compliance with this document. The list may be made available by electronic means.

NOTE 1 Additional information is found in 201.4.103.

- b) For PROBE CABLE EXTENDERS, the PULSE OXIMETER MONITOR(S) and PULSE OXIMETER PROBES with which the PROBE CABLE EXTENDERS have been VALIDATED and tested for compliance with this document. The list may be made available by electronic means.

NOTE 2 Additional information is found in 201.4.103.

- c) Information regarding toxicity or the effect on tissues of materials with which the PATIENT or any other person can come into contact and information on RESIDUAL RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures.
- d) If a PULSE OXIMETER PROBE is delivered in sterile packaging, a description of how to re-sterilize it, if permissible, in the event of damage to the sterile packaging.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for the identification of any RESIDUAL RISKS and any adverse effect of any recommended ACCESSORY.

201.7.9.3.1.101 * Additional general requirements

The technical description shall include a statement to the effect that a FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR.

NOTE Additional information is found in Annex FF.

The technical description should provide descriptions on how the RESPONSIBLE ORGANIZATION can VERIFY operation of the PULSE OXIMETER EQUIPMENT. If the use of a FUNCTIONAL TESTER is specified, the technical description should indicate the MODEL OR TYPE REFERENCE and its software unique identifier, if applicable, of at least one FUNCTIONAL TESTER that is compatible with the basic functions of the PULSE OXIMETER EQUIPMENT (e.g. it can ensure that the PULSE OXIMETER EQUIPMENT generates a display of SpO_2 and pulse rate).

Check compliance by inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 8 applies, except as follows:

Additional subclause:

201.8.3.101 Additional requirements for classification of APPLIED PARTS

APPLIED PARTS of PULSE OXIMETER EQUIPMENT shall be TYPE BF or TYPE CF APPLIED PARTS.

Check compliance by inspection.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 10 applies, except as follows:

201.10.4 Lasers

Replacement:

Depending on the light source used in a PULSE OXIMETER PROBE, the relevant requirements of IEC 60825-1:2014 shall apply to a PULSE OXIMETER PROBE.

In the case of laser fibre optics, the requirements of IEC 60825-2:2004+AMD1:2006+AMD2:2010 shall apply.

Check compliance by application of the requirements of IEC 60825-1:2014, and IEC 60825-2:2004+AMD1:2006+AMD2:2010, as applicable.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 11 applies, except as follows:

201.11.1.2.2 APPLIED PARTS intended to supply heat to a PATIENT

Amendment (add at the end of subclause 11.1.2.2):

The PULSE OXIMETER PROBE-tissue interface shall be evaluated when the skin temperature is initially at 35 °C for each PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE indicated in the instructions for use.

NOTE Additional information is found in Annex BB.

If the surface temperature of the PULSE OXIMETER PROBE at the tissue interface is capable of exceeding 41 °C, then

- a) the PULSE OXIMETER EQUIPMENT shall have an OPERATOR-adjustable control for activating any elevated temperature mode that exceeds 41 °C. A deliberate sequence of OPERATOR actions shall be required to activate this mode. The instructions for use shall describe this sequence of OPERATOR actions.
- b) the PULSE OXIMETER EQUIPMENT shall provide a means to limit the duration of an elevated temperature mode in excess of 41 °C. The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C.
- c) the instructions for use shall include a statement to the effect that the use of temperature settings greater than 41 °C requires special attention in PATIENTS with susceptible skin, such as neonates, geriatric PATIENTS or burn victims.
- d) the PULSE OXIMETER EQUIPMENT shall indicate when it is in the elevated temperature mode.
- e) the technical description shall describe the test method used to measure the maximum temperature at the PULSE OXIMETER PROBE-tissue interface. When performing the temperature measurements for the PULSE OXIMETER PROBE-tissue interface, as specified in IEC 60601-1:2005, 11.1.3, the test method disclosed in the technical description may be utilized.

NOTE Additional information is found in BB.3.

Additional subclauses:

201.11.6.5.101 * Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM

The ENCLOSURE of TRANSPORTABLE PULSE OXIMETER EQUIPMENT shall provide a degree of protection to the harmful ingress of water of at least an IPX2 for PULSE OXIMETER EQUIPMENT. For PORTABLE ME EQUIPMENT that is only intended to be used within a protective case, this requirement may be met while the ME EQUIPMENT is inside the case.

Additional requirements for ingress of water or particulate matter into the ENCLOSURE of PULSE OXIMETER EQUIPMENT intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11 and in the EMERGENCY MEDICAL SERVICES ENVIRONMENT are found in IEC 60601-1-12.

Check compliance according to the tests of IEC 60529:2013 with the PULSE OXIMETER EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection. After these PROCEDURES, confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

201.11.8.101.1 TECHNICAL ALARM CONDITION for power supply failure

If PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION the ALARM SYSTEM shall provide at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION to indicate when the power supply falls outside the values specified for normal operation.

NOTE After the loss of power, the ALARM SYSTEM is not expected to repeat ALARM SIGNALS indefinitely.

If the function of the PULSE OXIMETER EQUIPMENT is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the supply failure MEDIUM PRIORITY TECHNICAL ALARM CONDITION shall not be activated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance by functional testing.

201.11.8.101.2 Settings and data storage following short interruptions or automatic switchover

When the SUPPLY MAINS to the PULSE OXIMETER EQUIPMENT is interrupted for less than 30 s or automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be preserved unchanged.

NOTE 1 The PULSE OXIMETER EQUIPMENT does not have to continue to operate during the interruption of the SUPPLY MAINS.

NOTE 2 Settings include OPERATOR SETTINGS, RESPONSIBLE ORGANIZATION settings, and the mode of operation.

Check compliance by observing the PULSE OXIMETER EQUIPMENT settings and stored PATIENT data and then interrupting the SUPPLY MAINS for a period of between 25 s and 30 s by disconnecting the POWER SUPPLY CORD. After reestablishment of power, the above settings and stored data shall be the same.

201.11.8.101.3 Operation following long interruptions

The instructions for use shall disclose the operation of the PULSE OXIMETER EQUIPMENT after the SUPPLY MAINS has been interrupted when the "on-off" switch remains in the "on" position and is restored after a period of time longer than 30 s.

Check compliance by inspection of the instructions for use.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+AMD1:2012, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 * SpO_2 ACCURACY OF PULSE OXIMETER EQUIPMENT

201.12.1.101.1 * Specification

The SpO_2 ACCURACY OF PULSE OXIMETER EQUIPMENT shall be a root-mean-square difference of less than or equal to 4,0 % SpO_2 over the range of 70 % to 100 % SpO_2 . The SpO_2 shall be indicated as FUNCTIONAL OXYGEN SATURATION and shall not be indicated as FRACTIONAL OXYHAEMOGLOBIN.

The DECLARED RANGES of SpO_2 and SpO_2 ACCURACY over those ranges shall be disclosed in the instructions for use. The SpO_2 ACCURACY shall be stated over the range 70 % to 100 % (additional information is found in 201.12.1.101.2). SpO_2 ACCURACY information shall be accompanied by a note reminding the reader that, because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within $\pm A_{rms}$ of the value measured by a CO-OXIMETER. When a PULSE OXIMETER MONITOR is suitable for use with a variety of PULSE OXIMETER PROBES, SpO_2 ACCURACY information shall be made available for each type of PULSE OXIMETER PROBE.

The modified Bland and Altman plot (i.e., $(SpO_2 - SaO_2)$ versus SaO_2)^{[10][11]} for each combination of PULSE OXIMETER PROBE and PULSE OXIMETER MONITOR listed in the instructions for use for all subjects pooled, including upper 95 % and lower 95 % limits of agreement shall at a minimum be provided to the RESPONSIBLE ORGANIZATION upon request. See Annex CC for an example:

Additional SpO_2 ACCURACY specifications over other ranges may also be provided as long as the range is greater than 15 % SpO_2 .

EXAMPLE 1 A specified SpO_2 ACCURACY of ± 4 % for 70 % to 90 % SaO_2 .

If SpO_2 ACCURACY claims below 65 % SaO_2 are made, SpO_2 ACCURACY shall be stated in an additional range over a span of saturation not to exceed 20 % SaO_2 .

EXAMPLE 2 A specified SpO_2 ACCURACY range of 60 % to 80 % SaO_2 .

Additional SpO_2 ACCURACY specifications over other ranges may also be provided.

Check compliance by following the requirements of 201.12.1.101.2 and by inspection of the ACCOMPANYING DOCUMENT as well as the information that is available to the RESPONSIBLE ORGANIZATION upon request.

201.12.1.101.2 * Data collection for determination of SpO_2 ACCURACY

The claims of SpO_2 ACCURACY shall be supported by CONTROLLED DESATURATION STUDY measurements taken over the full range of SaO_2 values ± 3 % of the lower value and ± 3 % of the upper value for which SpO_2 ACCURACY is claimed.

EXAMPLE 1 A CONTROLLED DESATURATION STUDY supporting a claimed range of SpO_2 ACCURACY from 70 % SaO_2 to 100 % SaO_2 can be supported with SaO_2 data collected over the range of 73 % SaO_2 to 97 % SaO_2 .

The CONTROLLED DESATURATION STUDY shall comply with the requirements of ISO 14155:2011.

The RESIDUAL RISK inherent in a controlled hypoxia study on healthy adult volunteers, can be reduced to a non-significant level by following recommended additional PROCEDURES^[12].

The ACCURACY of PULSE OXIMETER EQUIPMENT for paediatric PATIENTS shall be supported via CONTROLLED DESATURATION STUDY measurements on adult subjects. Paediatric subjects are a vulnerable population. Data points should be recorded with comparable density over the full range claimed.

NOTE 1 Additional information is found in Annex EE.

Any types of interference known to influence or affect the SpO_2 ACCURACY need not be stated as part of the SpO_2 ACCURACY specification, but shall be disclosed in the instructions for use.

EXAMPLE 2 Ambient light (including photodynamic therapy); physical movement (PATIENT and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; HF SURGICAL EQUIPMENT; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the PULSE OXIMETER PROBE.

A summary of the test methods used to establish the SpO_2 ACCURACY claims shall be disclosed in the technical description.

FUNCTIONAL TESTERS or PATIENT simulators shall not be used for VALIDATION the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT.

NOTE 2 Some FUNCTIONAL TESTERS or PATIENT simulators can be used to VERIFY aspects of design changes of a PULSE OXIMETER MONITOR but not a PULSE OXIMETER PROBE.

201.12.1.101.3 * Data analysis for determination of SpO_2 ACCURACY

For each range specified, SpO_2 ACCURACY of the PULSE OXIMETER EQUIPMENT shall be stated in terms of the root-mean-square (rms) difference between measured values (SpO_{2i}) and reference values (S_{Ri}), as given by Formula (1).

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^n (SpO_{2i} - S_{Ri})^2}{n}} \quad (1)$$

NOTE 1 The concepts of bias and precision as given in ASTM E456-96^[13] and ambiguity as given in Reference^[14] also have value in representing the ACCURACY of ME EQUIPMENT. The decision to require the form of SpO_2 ACCURACY stated above (which has been traditional in pulse oximetry, although under the misnomer “standard deviation”) is based on the belief that it will be more widely understood by the general community of clinical OPERATORS and on the recognition that in some cases it represents the overall SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT better than do bias and PRECISION.

NOTE 2 Attention is also drawn to ISO/IEC Guide 99 (VIM)^[15] and ISO/IEC Guide 98-3 (GUM)^[16] as well as the documents of ISO/TC 69, *Applications of statistical methods*, for determination of ACCURACY and PRECISION.

The standard reference for the SpO_2 ACCURACY as read by PULSE OXIMETER EQUIPMENT shall be traceable to SaO_2 values obtained from CO-OXIMETER analysis of simultaneously drawn arterial blood. The CO-OXIMETER shall have a specified SaO_2 performance of 1 % (1 standard deviation) or better over the range for which the MANUFACTURER makes SpO_2 ACCURACY claims. Quality assurance, including maintenance and calibration, PROCEDURES for assessing CO-OXIMETER performance that are required in laboratories reporting clinical data shall be utilized for the CO-OXIMETER. Particular attention shall be given to the range for which the MANUFACTURER makes SpO_2 ACCURACY claims.

NOTE 3 It is not appropriate to use SaO_2 values calculated from measurements made by blood gas analysers that actually measure PaO_2 (arterial oxygen pressure) rather than SaO_2 .

NOTE 4 Calibration is theoretically possible against a PULSE OXIMETER (SpO_2) instead of a CO-OXIMETER (SaO_2) but this technique requires extensive VALIDATION of the method and has not yet (as of this writing) been shown to successfully demonstrate ESSENTIAL PERFORMANCE (A_{rms}).

NOTE 5 Additional information is found in Annex EE.

201.12.1.101.4 Characteristics of the clinical study population for determination of SpO_2 ACCURACY

The summary of the clinical study report used to assess SpO_2 ACCURACY shall state whether the test subjects were sick or healthy and shall describe their skin colour, age and gender. This information shall be disclosed in the ACCOMPANYING DOCUMENT.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.12.1.102 ACCURACY under conditions of motion

If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate during motion, ACCURACY specifications during motion shall be disclosed in the instructions for use.

A summary of the test methods used to establish the ACCURACY claims during motion shall be disclosed in the technical description. The summary should include the average percentage modulation (of the infrared signal as an indicator of pulsatile signal strength) in quiescent and motion periods during the test.

Check compliance by inspection of the instructions for use and technical description.

201.12.1.103 ACCURACY under conditions of low perfusion

If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate under conditions of low perfusion, ACCURACY specifications under these conditions shall be disclosed in the instructions for use.

A summary of the test methods used to establish the ACCURACY claims under conditions of low perfusion shall be disclosed in the technical description. The summary should include percentage modulation of the infrared signal as an indicator of pulsatile signal strength.

Check compliance by inspection of the instructions for use and technical description.

201.12.1.104 Pulse rate ACCURACY

If equipped, pulse rate ACCURACY shall be disclosed in the instructions for use and stated as the root-mean-square (rms) difference between paired pulse rate data recorded with the PULSE OXIMETER EQUIPMENT and with a reference method. Pulse rate ACCURACY shall be stated either over the full claimed range of the PULSE OXIMETER EQUIPMENT or as separate pulse rate ACCURACY specifications over segments of that range. The reference method for the computation of pulse rate ACCURACY may be an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultation or a second PULSE OXIMETER EQUIPMENT which has been qualified by comparison to one of these references. The reference method for the determination of pulse rate ACCURACY shall be disclosed in the technical description.

Check compliance by inspection.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * DATA UPDATE PERIOD

There shall be an indication that SpO_2 or pulse rate data is not current when the DATA UPDATE PERIOD is greater than 30 s. The DATA UPDATE PERIOD time may be shorter than 30 s. A maximum DATA UPDATE PERIOD for saturation and pulse rate shorter than 30 s is recommended for continuous neonatal monitoring and diagnostic applications.

If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide at least a LOW PRIORITY ALARM CONDITION to indicate when the DATA UPDATE PERIOD exceeds 30 s.

PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITION shall indicate when the DATA UPDATE PERIOD exceeds 30 s. The indication shall be described in the instructions for use.

If the PULSE OXIMETER EQUIPMENT is equipped with a FUNCTIONAL CONNECTION (see 201.103.2), an indication that the DATA UPDATE PERIOD exceeds 30 s shall be included in the data stream.

Check compliance by inspection.

201.12.4.102 * Signal inadequacy

An indicator of signal inadequacy shall be provided to the OPERATOR when the displayed SpO_2 or pulse rate value is potentially incorrect. Symbol ISO 7000-0435 (see Table 201.D.1.101, Symbol 6) may be used for this indication. A description of the indicator and its function shall be provided in the ACCOMPANYING DOCUMENT.

EXAMPLE Signal inadequacy indicated by a visual INFORMATION SIGNAL or a LOW PRIORITY ALARM SIGNAL.

If the PULSE OXIMETER EQUIPMENT is equipped with a FUNCTIONAL CONNECTION (see 201.103.2), then signal inadequacy shall be included in the data stream (see Table HH.101).

NOTE A non-NORMALIZED pulse waveform display satisfies this requirement for a signal inadequacy indicator. A NORMALIZED waveform does not satisfy this requirement and can mask an unreliable signal.

Check compliance by inspection.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 13 applies, except as follows:

Additional subclauses:

201.13.101 Detection of PROBE FAULTS and PROBE CABLE EXTENDER faults

If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM to detect any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide a TECHNICAL ALARM CONDITION to indicate when any wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER is opened or shorted to any other wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER that causes other than normal operation.

PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS shall visually indicate the presence of PROBE FAULTS. The indication shall be described in the instructions for use.

EXAMPLE Indication of abnormal operation by blank display.

Check compliance with the following test:

- a) *Disconnect the PULSE OXIMETER PROBE from the PULSE OXIMETER EQUIPMENT and place it in series with a circuit with which each PULSE OXIMETER PROBE wire can be opened or shorted to any other PULSE OXIMETER PROBE wire. Do not test unused wires in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER.*
- b) *Repeat for any PROBE CABLE EXTENDER.*
- c) *Confirm either that a PROBE FAULT is indicated by the PULSE OXIMETER MONITOR or that the PULSE OXIMETER EQUIPMENT continues normal operation.*

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+AMD1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5.101 * Additional requirements for rough handling

201.15.3.5.101.1 * Shock and vibration

PULSE OXIMETER EQUIPMENT or its parts not intended for use during in the EMERGENCY MEDICAL SERVICES ENVIRONMENT or for use in the HOME HEALTHCARE ENVIRONMENT shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY EQUIPMENT is exempt from the requirements of this subclause.