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- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 80601-2-61

Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Appareils électromédicaux —

Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls

ICS: 11.040.10; 11.040.55

ISO/TC 121/SC 3

Secretariat: **ANSI**

Voting begins on:
2024-11-18

Voting terminates on:
2025-02-10

This document is circulated as received from the committee secretariat.

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

ISO/CEN PARALLEL PROCESSING

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

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Reference number
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122 **Foreword**

123 ISO (the International Organization for Standardization) is a worldwide federation of national standards
 124 bodies (ISO member bodies). The work of preparing International Standards is normally carried out
 125 through ISO technical committee. Each member body interested in a subject for which a technical
 126 committee has been established has the right to be represented on that committee. International
 127 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO
 128 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of
 129 electrotechnical standardization.

130 The procedures used to develop this document and those intended for its further maintenance are
 131 described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the
 132 different types of ISO documents should be noted. This document was drafted in accordance with the
 133 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

134 Attention is drawn to the possibility that some of the elements of this document may be the subject of
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 136 patent rights identified during the development of the document will be in the Introduction and/or on
 137 the ISO list of patent declarations received (see www.iso.org/patents).

138 Any trade name used in this document is information given for the convenience of users and does not
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140 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
 141 expressions related to conformity assessment, as well as information about ISO's adherence to the World
 142 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see
 143 www.iso.org/iso/foreword.html.

144 This document was prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory
 145 equipment, Subcommittee SC 3, Respiratory devices and related equipment used for patient care and
 146 Technical Committee IEC/TC 62, Electrical equipment in medical practice, Subcommittee SC 62D, Electric
 147 equipment, in collaboration with the European Committee for Standardization (CEN) Technical
 148 Committee CEN/TC 215, Respiratory and anaesthetic equipment, in accordance with the Agreement on
 149 technical cooperation between ISO and CEN (Vienna Agreement).

150 This third edition cancels and replaces the second edition (ISO 80601-2-61:2018), which has been
 151 technically revised.

152 The main changes compared to the previous edition are as follows:

153 — alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012
 154 +AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013
 155 +AMD2:2020.

156 — increased disclosure requirements;

157 — increased the required number of participants in the clinical study and their diversity;

158 — reduced the maximum permissible A_{rms} ;

159 — required *disparate bias* determination;

160 — clarified that *accessories* need to be included in the clinical performance *verification* and conformity
 161 to the requirements of the document

162 — updated the reporting requirements for the clinical performance *verification*; and

163 — harmonization with ISO 20417, where appropriate.

164 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

165 Any feedback or questions on this document should be directed to the user's national standards body. A
166 complete listing of these bodies can be found at www.iso.org/members.html.

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 *SpO₂ 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.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *terms defined in Clause 3 of the IEC 60601-1:2005+AMD1:2012+AMD2:2020 in this document or as noted*: italic type; and
- 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.

In referring to the structure of this document, the term

- “clause” means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 201 includes subclauses 201.7.1, 201.7.2) and
- “subclause” means a numbered subdivision of a clause (e.g., 201.7.1, 7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;

208 – “can” indicates a possibility or capability; and

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

210 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

211 Any feedback or questions on this document should be directed to the user’s national standards body. A
212 complete listing of these bodies can be found at www.iso.org/members.html.

213

Medical electrical equipment —

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

201.1 Scope, object, and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of *pulse oximeter equipment* intended for use on humans, hereafter referred to as *ME equipment*. This includes any part necessary for *normal use*, including the *pulse oximeter monitor*, *pulse oximeter probe*, and *probe cable extender*.

These requirements apply to *pulse oximeter equipment*, including *pulse oximeter monitors*, *pulse oximeter probes* and *probe cable extenders* regardless of their origin (i.e., including *remanufactured* products).

The intended use of *pulse oximeter equipment* includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of *patients* in professional healthcare institutions as well as *patients* in the *home healthcare environment* and the *emergency medical services environment*.

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 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 8.4.1.

NOTE 2 See also IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document can also be applied to *ME equipment* and their *accessories* used for compensation or alleviation of disease, injury, or disability.

This document is not applicable to *pulse oximeter equipment* intended solely for foetal use.

This document is not applicable to remote or slave (secondary) equipment that displays SpO_2 values that are located outside of the *patient environment*.

NOTE 3 *ME equipment* that provides selection between diagnostic and monitoring functions is expected to meet the 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 and IEC 80601 series of standards.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *pulse oximeter equipment* [as defined in 201.3.254] and its *accessories*.

NOTE 1 *Accessories* are included because the combination of the *pulse oximeter monitor* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of *pulse oximeter equipment*.

NOTE 2 This document has been prepared to address the relevant *essential principles*^[25] and labelling^[26] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex LL.

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[27].

201.1.3 Collateral standards

Amendment (add after existing text):

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 and Clause 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11+AMD1:2020 and IEC 60601-1-12+AMD1:2020 apply as modified in Clauses 202, 206, 208, 211 and 212, respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace, or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

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

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following abbreviated words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

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

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

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

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

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

201.2 Normative references

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

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

NOTE 2 Informative references are listed in the Bibliography.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:

–Addition:

ISO 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 14155:2020, *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 15223-1:2021, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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

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

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

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

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

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

IEC 62366-1:2015+AMD1:2020, *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 IEC 60601-1:2005+AMD 1:2012+AMD1:2020, 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 following the Bibliography.

201.3.201

accompanying information

information accompanying or *marked* on a medical device or *accessory* for the user or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or *accessory*, particularly regarding safe use

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

Note 2 to entry: The *accompanying information* can consist of the label, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

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

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

201.3.202

accuracy

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

Note 1 to entry: Subclause 201.12.1.101.2 provides the method of calculating the *SpO₂ accuracy of pulse oximeter equipment*.

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

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

201.3.203

alarm condition delay

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

[SOURCE: IEC 60601-1-8:2006, 3.2]

201.3.204

alarm limit

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

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

201.3.205

alarm paused

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

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

201.3.206

alarm preset

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

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

201.3.207

alarm signal generation delay

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

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

201.3.208

audio paused

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

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

201.3.209

colour measurement site

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

201.3.210

controlled desaturation study

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

201.3.211

CO-oximeter

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

Note 1 to entry: The relevant CO-oximetry value is functional saturation of arterial blood, *SaO₂*, which *pulse oximeter equipment* estimates and reports as *SpO₂*.

201.3.212

data update period

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

Note 1 to entry: 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.

201.3.213

declared range

portion of the *displayed range* of *SpO₂* and pulse rate values over which there is specified *accuracy*

201.3.214**default alarm preset**

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

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

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

201.3.215**disparate bias**

bias that is meaningfully different when comparing between levels

Note 1 to entry: *Disparate bias* refers to a bias attributed to difference in SpO_2 due to skin pigmentation, which is too great. *Disparate bias* is assessed across pigmentation levels. See 201.12.1.101.6 h).

201.3.216**displayed range**

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

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

201.3.217**distributed alarm system****DAS**

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

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

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

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

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

201.3.218**EMS environment****emergency medical services environment**

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

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

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

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

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

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

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

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

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

201.3.219

essential function

function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the *manufacturer*, and operational availability for the medical device

Note 1 to entry: *Essential functions* include, but are not limited to, the safety instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the medical device safely with the most urgently needed performance (operational availability). The loss of *essential function* is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.220

essential principles

essential principles of safety and performance

fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

201.3.221

false positive alarm condition

presence of an *alarm condition* when no valid triggering event has occurred in the *patient*, the equipment or the *alarm system*

Note 1 to entry: A *false positive alarm condition* can be caused by spurious information produced by the *patient*, the *patient*-equipment interface, other equipment or the *alarm system* itself.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.21]

201.3.222

firecall

method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a *firecall* is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as "break glass" feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

201.3.223**fractional oxyhaemoglobin**DEPRECATED :FO₂Hb fractional saturationoxyhaemoglobin concentration *cO₂Hb* divided by the *total haemoglobin concentration, ctHb*, in the blood

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

Note 1 to entry: *cO₂Hb* 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. [O₂Hb]) was used.Note 5 to entry: CLSI^[3] uses the following notations:

- oxyhaemoglobin (O₂Hb);
- deoxyhaemoglobin (HHb);
- carboxyhaemoglobin (COHb);
- methaemoglobin (MetHb);
- sulphaemoglobin (SulfHb); and
- total haemoglobin (*ctHb*), which is derived by the cyanmethaemoglobin method of CLSI H15^[23].

201.3.224**functional oxygen saturation**percentage saturation given by the oxyhaemoglobin concentration (*cO₂Hb*) 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^[3] term for this ratio is haemoglobin oxygen saturation, and its notation is *SO₂*.Note 2 to entry: As related to *SpO₂*, this percent saturation is for arterial blood.**201.3.225****functional tester**test equipment which presents *pulse oximeter equipment* with a signal having a predictable value of *modulation ratio* so that the *operator* can observe the resulting displayed value of *SpO₂*, 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 *SpO₂* 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 *SpO₂ 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*.

201.3.226

healthcare professional

<adj> appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

[SOURCE: ISO 80601-2-12:2023, 201.3.247]

201.3.227

HF surgical equipment

medical electrical equipment which generates high frequency currents intended for the performance of surgical tasks, such as the cutting or coagulation of biological tissue by means of these high frequency currents

Note 1 to entry: *HF surgical equipment* is also variously known as surgical diathermy, electrosurgical equipment, electrosurgical generator, RF generator or HF generator.

Note 2 to entry: A footswitch is an example of an associated *accessory* that is part of *HF surgical equipment*.

[SOURCE: IEC 60601-2-2:2017, 3.224]

201.3.228

home healthcare environment

dwelling place in which a *patient* lives or other places where *patients* are present, excluding professional healthcare facility environments where *operators* with medical training are continually available when *patients* are present

EXAMPLE In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this collateral standard, nursing homes are considered *home healthcare environments*.

Note 3 to entry: Other places where a *patient* is present include the outdoor environment, while working and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1]

201.3.229

immunity

the ability of *ME equipment* or a *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.230

immunity test level

the level of a test signal used to simulate an electromagnetic disturbance when performing an *immunity test*

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.9]

201.3.231**individual typology angle****ITA**

objective colourimetry measurement of skin pigmentation that is inversely related to the amount of pigmentation

$$ITA = \left(\frac{180}{\pi} \right) \bullet \arctan \left(\frac{L^* - 50}{b^*} \right) \quad [8][46]$$

where

L^* is the luminance ranging from black (0) to white (100); and

b^* is the yellow/blue component.

Note 1 to entry: *ITA* is the vector direction on the L^* - b^* plane where *ITA* is given in degrees.

Note 2 to entry: *ITA* is collected with the use of equipment that provides the measure directly or derived from the parameters L^* and b^* according to Reference [46].

Note 3 to entry: For the purposes of this document, skin pigmentation and the quantification thereof by *ITA* only refers to melanin.

201.3.232**information for safety**

information provided to the user or *responsible organization* as a *risk control* measure

EXAMPLE 1 Warnings, precautions or contraindications.

EXAMPLE 2 *Instructions for the use* of a medical device to prevent use error or avoid a *hazardous situation*

EXAMPLE 3 Explanation of a safety feature of a medical device.

Note 1 to entry: *Information for safety* may be found in any or all types of *information supplied by the manufacturer*.

Note 2 to entry: *Information for safety* can be located on the display of a medical device or *accessory*.

[SOURCE: ISO 20417:2021, 3.10]

201.3.233**information supplied by the manufacturer**

information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the user or other relevant persons.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 4.]

201.3.234**instructions for use
IFU**

portion of the *accompanying information* that is essential for the safe and effective use of a medical device or *accessory* directed to the user of the medical device

Note 1 to entry: For the purposes of this document, a *user* can be either a *lay user* or professional *user* with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

Note 4 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 5 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.12, modified — deleted note 6.]

201.3.235**lay**

<adj> term referring to non-professional or professional without relevant specialized training

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.2]

201.3.236**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_i} or given by:

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

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;
and

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

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, 3.3.2, 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)'.]

201.3.237**marking**

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a medical device or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.17, modified — deleted note 3.]

201.3.238

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 .

201.3.239

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.

201.3.240

multiple patient multiple use

<medical device, accessory> intended by the *manufacturer* to be reused on multiple *patients* for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device* or *accessory* typically requires *processing* between *patients*.

Note 2 to entry: A *multiple patient multiple use medical device* or *accessory* may require *processing* between uses on a single *patient*.

[SOURCE: ISO 20417:2021, 3.18]

201.3.241

normalized

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

201.3.242

objective pigmentation measurement method

PMM that is independent of human interpretation

Note 1 to entry: *Objective pigmentation measurement methods* are generally based on spectroscopic or colorimetric methods that provide *ITA* values (or data such as RGB from which *ITA* can be derived) and are dependent on the use of proper measurement technique.

Note 2 to entry: An *objective pigmentation measurement method* typically is performed by the correct use of a calibrated scientific equipment as described in Reference [4].

201.3.243

operator interface

means by which the *operator* and the *ME equipment* interact

Note 1 to entry: The *accompanying documents* are considered part of the *ME equipment* and its *operator interface*.

Note 2 to entry: *Operator interface* includes all the elements of the *ME equipment* with which the *operator* interacts including the physical aspects of the *ME equipment* as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, the *manufacturer* may treat the combination of *ME equipment* and other equipment as a single *operator interface*.

Note 4 to entry: See IEC 62366-1:2015, 3.26.

[SOURCE: IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, 3.1]

201.3.244

operator settings

current state of any *pulse oximeter monitor* controls, including *alarm settings*

201.3.245

operator's position

intended position of the *operator* with respect to the *alarm signal* generating part of the *alarm system*

Note 1 to entry: A *distributed alarm system* can have multiple *operator's positions*.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.30]

201.3.246

percent modulation

%mod

indicator of pulsatile signal strength resulting only from tissue arterial blood content changes at the *pulse oximeter probe* site over the cardiac cycle

Note 1 to entry: *Percent modulation* may be approximated as AC/DC of the detected light signal, where "AC" refers to the modulating signal portion and "DC" refers to the baseline (non-modulating) signal portion.

Note 2 to entry: *Percent modulation* may be used in referring to different light signals independently, e.g., "infrared %mod" and "red %mod".

Note 3 to entry: When used to indicate an overall pulsatile signal strength at a *pulse oximetry probe* site, the infrared signal should be the primary factor used in determining the value of %mod.

201.3.247

physiological alarm condition

alarm condition arising from a monitored *patient*-related variable

EXAMPLE 1 High exhaled anaesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.31]

201.3.248

pigmentation measurement method

PMM

method for quantification or classification of skin pigment

201.3.249

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, SR_i .

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

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

201.3.250

primary operating function

function that involves user interaction that is related to the safety of the medical device

Note 1 to entry: Often a *primary operating function* is interacted with by a series of tasks that can be broken down into a series of user interactions.

Note 1 to entry: The concept of safety includes loss or degradation of performance resulting in an unacceptable *risk* to the *patient*, including use error that prevents the user from effectively using the medical device to achieve its intended medical purpose. In IEC 60601-1, this is referred to as *essential performance*.

[SOURCE: IEC 62366-1:2015+AMD1:2020, 3.11]

201.3.251

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* (e.g., standalone finger clip style).

Note 2 to entry: A *probe cable extender* can be an *applied part*.

201.3.252

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.

201.3.253

processing

<preparation of medical device, *accessory*> activity to prepare a new or used medical device and *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.21]

201.3.254

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.

201.3.255

pulse oximeter monitor

part of the *pulse oximeter equipment* that encompasses the electronics, display and *operator 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).

201.3.256

pulse oximeter probe

part of the *pulse oximeter equipment* that includes the *applied part* and transducer component

Note 1 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.

201.3.257

remanufacturing

DEPRECIATED: reprocessing

any activity, which is not specified in the *accompanying document*, which renders a used product suitable for use

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 “*remanufactured*” is used to designate the corresponding status.

Note 4 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

201.3.258

SaO₂

fraction of functional haemoglobin in arterial blood that is saturated with oxygen

Note 1 to entry: Subclause 201.12.1.101.3 provides the acceptable method for determining *SaO₂*.

Note 2 to entry: Additional information about *SaO₂* is found 201.3.224.

Note 3 to entry: *SaO₂* is normally expressed as a percentage (by multiplying the fraction by 100).

201.3.259

security level

level corresponding to the required set of countermeasures and inherent *cybersecurity* properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]

201.3.260

single patient multiple use

<medical device, accessory> intended by the *manufacturer* to be reused on an individual *patient* for multiple uses

Note 1 to entry: A *single patient multiple use medical device* or *accessory* may require *processing* between uses.

Note 2 to entry: For an implantable *medical device*, the duration of a *single use* is from implanting to explanting the *medical device*.

[SOURCE: ISO 20417:2021, 3.26]

201.3.261

single use

<medical device, accessory> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further *processed* and used again.

[SOURCE: ISO 20417:2021, 3.27]

201.3.262

SpO₂

estimate of *SaO₂* 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 *SaO₂*^{[24][104]}.

Note 2 to entry: *SpO₂* is normally reported as a percentage (multiplying the fraction by 100).

201.3.263

standardized skin colour scale

scale that defines a range of colours that captures a majority of colours seen in human skin and is used as a subjective *PMM*

Note 1 to entry: A *standardized skin colour scale* has a defined RGB or equivalent values that can be used by an observer using a properly calibrated printed colour swatch.

Note 2 to entry: The Monk Skin Tone scale (MST) is one such scale^[88].

201.3.264

sterile

free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.29]

201.3.265

symbol

graphical representation appearing on the label or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.30]

201.3.266

technical alarm condition

alarm condition arising from a monitored equipment-related or *alarm system*-related variable

EXAMPLE 1 An electrical, mechanical, or other failure.

EXAMPLE 2 A failure of a probe or component (unsafe voltage, high impedance, signal impedance, artefact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.36]

201.3.267

technical description

portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing* transport or storage for the expected lifetime of a medical device

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.31, modified — deleted note 2.]

201.3.268

total haemoglobin concentration

ctHb

sum of concentrations of all haemoglobin species in the blood including, but not limited to, oxyhaemoglobin (cO₂Hb), methaemoglobin (cMetHb), deoxyhaemoglobin (cHHb), sulphaemoglobin (cSHb) and carboxyhaemoglobin (cCOHb)^{Error! Reference source not found.}

201.3.269

transfer standard

DEPRECIATED: secondary standard

using a non-invasive estimate of *SaO₂* during *pulse oximeter accuracy* performance evaluation

Note 1: Bias and *precision* of the *transfer standard pulse oximeter equipment* are directly traceable to *CO-oximeter SaO₂* data and have been characterized to assess *accuracy* performance using an error transfer equation. The *transfer standard pulse oximeter equipment* is comprised of a *pulse oximeter monitor*, a *probe cable extender*, and a *pulse oximeter probe* (each component specially kept together as a single *transfer standard pulse oximeter equipment*). See Annex KK for details.

201.3.270

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 definition 3.8.13]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 4 applies, except as follows:

Additional subclauses:

201.4.3.101 Additional requirements for essential performance

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
For <i>pulse oximeter equipment</i> provided with an <i>alarm system</i> that includes the capability to detect a <i>physiological alarm condition</i> : <i>SpO₂ accuracy</i> , pulse rate <i>accuracy</i> and limit <i>alarm conditions</i> ^a	201.12.1.101 201.12.1.104 208.6.1.2.101
or generation of a <i>technical alarm condition</i>	201.11.8.101.1 201.12.4 201.13.101
For <i>pulse oximeter equipment</i> not provided with an <i>alarm system</i> that includes the capability to detect a <i>physiological alarm condition</i> : <i>SpO₂ accuracy</i> and pulse rate <i>accuracy</i> ^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 <i>SpO₂ accuracy</i> and pulse rate <i>accuracy</i> as acceptance criteria following specific tests required by this document.	

201.4.101 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 *SpO₂ accuracy* of 1,5 %, the *pulse oximeter equipment* is required to have 1,5 % *SpO₂ accuracy* for all requirements (e.g., during *immunity tests*).

201.4.102 Additional requirements for pulse oximeter equipment, parts and accessories

- a) The *pulse oximeter equipment*, as well as all individual parts and *accessories* specified for use with a *pulse oximeter monitor*, shall conform 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 This requirement applies independent of the *manufacturer* of the individual parts and *accessories* that, when combined, comprise the *pulse oximeter equipment*. *Pulse oximeter monitors* are frequently used with *pulse oximeter probes* and *probe cable extenders* from different *manufacturers*. This requirement ensures the compatibility of such combinations.

- b) 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+AMD2:2020, Clause 5 applies.

201.6 Classification of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 *ME equipment* identification, marking and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows:

Additional subclause:

201.7.1.101 Information to be supplied by the manufacturer

- a) The *information supplied by the manufacturer* of a *pulse oximeter equipment* and its *accessories* shall conform with ISO 20417:2021.

- b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+A1:2012+A2:2020 shall be used as follows.

1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.

2) The term "*medical device*" shall assume the same meaning as *ME equipment*.

3) The term "*user*" shall assume the same meaning as *operator*.

4) The term "*patient*" shall include animals.

Check conformity by application of ISO 20417:2021.

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 (see IEC 60601-1:2005/COR1:2006, Table D.2, Number 10).

Additional subclauses:

201.7.2.4.101 Additional requirements for *accessories*

- a) *Accessories* supplied separately shall:

1) fulfil the *marking* requirements of ISO 20417:2021, 6.1.1 c); and

2) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *pulse oximeter monitor*, if applicable. See also 201.7.2.101.

b) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

Check conformity by inspection, inspection of the *risk management file* for any limitations or adverse effects of the *accessory*, if applicable, and where necessary, inspection of the *instructions for use*.

201.7.2.9.101 IP classification

a) Notwithstanding the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.9, the *enclosure* of *ME equipment* shall be *marked* with the IP classification required by 201.11.6.5.101.

b) If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then:

1) the degree of protection provided by the *enclosure* shall be *marked* on the *enclosure*; and

2) 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.

c) An *enclosure* or a carrying case that is classified IPX0 need not be *marked* as such.

d) If an *enclosure* does not provide the minimum required degree of protection against the ingress of water, it shall be *marked*

1) 'keep dry'; or

2) with ISO 15223-1:2021, *Symbol* 5.3.4 (see Table 201.D.1.101, *Symbol* 1).

Check conformity by inspection and by application of the tests and criteria of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2 and 7.1.3.

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) If a *pulse oximeter monitor* is not provided with a low *SpO₂ alarm condition*, it shall be *marked* with a statement to the effect "No SpO₂ Alarms" or *Symbol* IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, Table C.1, *Symbol* 3).

b) A *remanufactured pulse oximeter probe* shall be *marked* as such.

c) These *markings* shall be *clearly legible*.

Check conformity by inspection.

201.7.4.3 Units of measurement

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

a) *Functional oxygen saturation* shall be expressed in units of percent SpO_2 and shall be marked as % SpO_2 or SpO_2 .

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

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

The *instructions for use* shall indicate the following:

a) that the *pulse oximeter equipment* is calibrated to estimate *functional oxygen saturation*;

b) 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 1 Clinicians performing photodynamic therapy.

c) description of the effect on displayed and transmitted SpO_2 and pulse rate data values, including the effects of any selectable operating mode that affects these properties, by:

1) the data averaging and other signal processing;

2) the *data update period*;

3) the *alarm condition delay*; and

4) *alarm signal generation delay*,

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

d) the *displayed ranges* of SpO_2 .

e) the *displayed ranges* of pulse rate.

f) for a *pulse oximeter monitor* without an *alarm system* that includes the capability to detect an SpO_2 or pulse rate *physiological alarm condition*, a statement to that effect; and

g) for a *pulse oximeter monitor*, the *pulse oximeter probes* and *probe cable extenders* with which the *pulse oximeter monitor* has been *verified* and tested for conformity with this document.

1) The list may be made available by electronic means.

NOTE 2 Additional information is found in 201.4.102.

Check conformity 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 *pulse oximeter monitor*, *pulse oximeter probe* and *probe cable extender* before use to prevent patient injury or inaccurate readings;

c) a warning statement to the effect that misapplication of a *pulse oximeter probe* with excessive pressure for prolonged periods can induce pressure injury;

d) a warning statement to the effect that artificial acrylic nails, gel-based manicures, nail jewellery, specific colours of nail polish, varied nail colour patterns, long nails and bruised nail beds interfere with the optical pathway and can cause inaccurate readings^{[49][117]}.

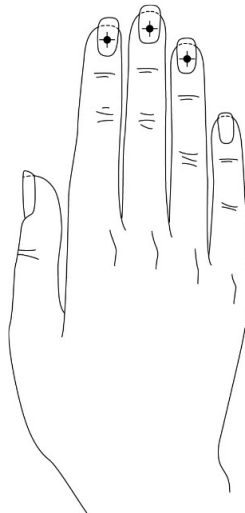
Check conformity by inspection of the *instructions for use*.

201.7.9.2.9.101 Additional requirements for operating instructions

The *instructions for use* shall indicate the following.

a) A description with graphic indicating proper orientation and placement of the *pulse oximeter probe*.

- 1) Proper positioning shall be visually confirmed by the user, which for a finger site typically is the emitter over the nailbed centrum. See Figure 201.101 for a typical example finger probe graphic.



Key

✦ Fingertip *probe* locations for optimal performance.

NOTE Artificial acrylic nails, gel-based manicures, nail jewellery, specific colours of nail polish, and varied nail colour patterns can result in finger-tip probe SpO_2 values that differ from SaO_2 , which could cause a missed detection of hypoxaemia or the initiation of unnecessary therapy. Many investigators who studied the phenomena concluded that these nail types should be routinely removed or an alternative *pulse oximeter probe* site should be sought^{[49][117]}. Additionally, when excessive nail length has the *pulse oximeter probe* optics no longer over an area of pulsing arterial blood, the SpO_2 value cannot reflect SaO_2 .

Figure 201.101 — Example finger *pulse oximeter probe* locations and orientation

b) A statement that the signal inadequacy indicator cannot identify all sources of error that result in potentially incorrect SpO_2 or pulse rate.

c) The recommended maximum application time for each type of *pulse oximeter probe* at a single site.

- d) The IP classification and meaning of the IP classification of the *pulse oximeter equipment enclosure* and,

- 1) if applicable, on any carrying case provided with the *pulse oximeter equipment*.

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

- e) *Pulse oximeter equipment* is not typically capable of, nor intended as a means for, the measurement of blood flow or blood volume.

- f) If the *pulse oximeter equipment* is provided with temperature capability such that the *pulse oximeter probe* can operate at a *pulse oximeter probe* contact surface temperature greater than 41 °C, specific instructions emphasizing the importance of proper *pulse oximeter probe* application, without excessive pressure.

- 1) In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C.

Check conformity by inspection of the *instructions for use*.

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 monitors* and *probe cable extenders* with which the *pulse oximeter probes* have been *verified* and tested for conformity with this document.

- 1) 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 monitors* and *pulse oximeter probes* with which the *probe cable extenders* have been *verified* and tested for conformity with this document.

- 1) The list may be made available by electronic means.

NOTE 2 Additional information is found in 201.4.102.

- 2) Any reasonably foreseeable adverse effect of any recommended *accessory* on the *basic safety* or *essential performance* of the *pulse oximeter monitor*.

NOTE 3 Additional requirements are found in 201.16.

Check conformity by inspection of the *instructions for use* and inspection of the *risk management file* for any adverse effect of any recommended *accessory*.

201.7.9.3.1.101 Additional general requirements

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) 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 2 Additional information is found in Annex FF.

- b) The *technical description* should provide descriptions on how the *responsible organization* can verify operation of the *pulse oximeter equipment*.

1104 1) If the use of a *functional tester* is specified, the *technical description* should indicate the *model*
 1105 *or type reference* and its software unique identifier, if applicable, of at least one *functional*
 1106 *tester* that is compatible with the basic functions of the *pulse oximeter equipment* (e.g., it can
 1107 ensure that the *pulse oximeter equipment* generates a display of SpO_2 and pulse rate).

1108 Check conformity by inspection of the *technical description*.

1109 201.8 Protection against electrical hazards from ME equipment

1110 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies, except as follows:

1111 *Additional subclause:*

1112 201.8.3.101 Additional requirements for classification of applied parts

1113 *Applied parts of pulse oximeter equipment* shall be:

1114 a) *type BF applied parts*; or

1115 b) *type CF applied parts*.

1116 Check conformity by inspection.

1117 201.9 Protection against mechanical hazards of ME equipment and ME systems

1118 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies.

1119 201.10 Protection against unwanted and excessive radiation hazards

1120 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies, except as follows:

1121 201.10.4 Lasers

1122 *Replacement:*

1123 aa) Depending on the light source used in a *pulse oximeter probe*, the relevant requirements of
 1124 IEC 60825-1:2014 shall apply to a *pulse oximeter probe*.

1125 bb) In the case of laser fibre optics, the requirements of IEC 60825-2:2021 shall apply.

1126 Check conformity by application of the requirements of IEC 60825-1:2014 and IEC 60825-2:2021, as
 1127 applicable.

1128 201.11 Protection against excessive temperatures and other hazards

1129 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows:

1130 201.11.1.2.2 Applied parts not intended to supply heat to a patient

1131 *Amendment (add at the end of subclause 11.1.2.2):*

1132 aa) The *pulse oximeter probe-tissue* interface shall be evaluated when the skin temperature is initially
 1133 at 35 °C for each *pulse oximeter monitor* and *pulse oximeter probe* indicated in the *instructions for*
 1134 *use*.

1135 NOTE 1 Additional information is found in Annex BB.

bb) If the surface temperature of the *pulse oximeter probe* at the tissue interface is capable of exceeding 41 °C, then

1) the *pulse oximeter equipment* shall have an *operator*-adjustable control for activating any elevated temperature mode that permits the tissue interface to exceed 41 °C.

i) A deliberate sequence of *operator* actions shall be required to activate this mode.

ii) The *instructions for use* shall describe this sequence of *operator* actions.

2) the *pulse oximeter equipment* shall provide a means to limit the duration of an elevated temperature mode that permits the tissue interface temperature to exceed 41 °C.

i) The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C.

3) 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.

4) the *pulse oximeter equipment* shall indicate when it is in the elevated temperature mode.

5) the *technical description* shall describe the test method used to measure the maximum temperature at the *pulse oximeter probe*-tissue interface.

i) When performing the temperature measurements for the *pulse oximeter probe*-tissue interface, as specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.1.3, the test method disclosed in the *technical description* may be utilized.

NOTE 2 Additional information is found in BB.3.

Check conformity by functional testing and inspection of the *technical description*.

Additional subclauses:

201.11.6.5.101 Additional requirements for ingress of water or particulate matter into ME equipment or ME system

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) 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*.

1) 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.

b) Notwithstanding a), *pulse oximeter equipment* incorporated as a module into an *enclosure* of another *ME equipment* (e.g., a multifunction *patient* monitor or ventilator) or a module is incorporated in a cable and connected to another *ME equipment*, the requirements for ingress protection of that other *ME equipment* shall apply.

NOTE 2 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 conformity 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

a) 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.

b) 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.

1) Any such switchover to an *internal electrical power source* shall be indicated by an *information signal* or a *low priority technical alarm condition*.

Check conformity 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, the following shall be preserved unchanged:

a) all settings; and

b) all stored *patient* data.

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 conformity 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, confirm that the above settings and stored data are 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 conformity 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+AMD2:2020, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 *SpO₂ accuracy of pulse oximeter equipment*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

201.12.1.101.1 *Specification of A_{rms}*

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

a) The *SpO₂ accuracy of pulse oximeter equipment* shall be a root-mean-square difference of less than or equal to 3,0% *SpO₂* over the range of 70 % to 100 % *SaO₂*.

1) The *SpO₂ accuracy* and *mean bias* over the range 70 % *SaO₂* to 100 % *SaO₂* for each combination of *pulse oximeter probe* and *pulse oximeter monitor* shall be disclosed in the *instructions for use*.

2) The 95% confidence interval for characterizing the uncertainty of the estimate of *SpO₂ accuracy* shall be disclosed in the *instructions for use*.

3) The *SpO₂* shall be indicated as *functional oxygen saturation*.

4) The *SpO₂* shall not be indicated as *fractional oxyhaemoglobin*.

5) *SpO₂ accuracy* information shall be accompanied by a disclosure indicating to the effect that because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within $\pm A_{rms}$ and about 95 % falling within ± 2 times A_{rms} of the value measured by a CO-oximeter.

6) *SpO₂ accuracy* information shall be accompanied by a disclosure indicating to the effect that the A_{rms} value is determined in a controlled desaturation study that is performed on healthy subjects and represents the best-case scenario with real-world clinical inaccuracy expected to be worse than the A_{rms} value disclosed from the controlled desaturation study.^[39]

7) When a *pulse oximeter monitor* is suitable for use with a variety of *pulse oximeter probes*, *SpO₂ accuracy* information shall be made available for each type of *pulse oximeter probe*.

b) A modified Bland-Altman plot (i.e., (*SpO₂* - *SaO₂*) versus *SaO₂*)^[75] with 95 % confidence intervals with each data point plotted identifying each participant and including numeric listing, upper 95 % limits of agreement, lower 95 % limits of agreement, using methods to account for repeated measurements for each combination of *pulse oximeter probe* and *pulse oximeter monitor* listed in the *instructions for use* shall at a minimum be provided to the *responsible organization* upon request. See Annex JJ for an example.

c) The *SpO₂ accuracy* and *mean bias* for each combination of *pulse oximeter probe* and *pulse oximeter monitor* shall be disclosed in the *instructions for use* over the *SaO₂* ranges:

1) 70 % to 80 %;

2) 80 % to 90 %; and

3) 90 % to 100 %.

d) Additional *SpO₂ accuracy* specifications over other ranges may also be provided in the *instructions for use* as long as the range is greater than 15 % *SpO₂*.

EXAMPLE 1 A specified *SpO₂ accuracy* of ± 3 % for 70 % to 90 % *SaO₂*.

1248 e) If *SpO₂ accuracy* claims below 65 % *SaO₂* are made, *SpO₂ accuracy* shall be stated in an additional
1249 range over a span of saturation not to exceed 20 % *SaO₂*.

1250 EXAMPLE 2 A specified *SpO₂ accuracy* range of 60 % to 80 % *SaO₂*.

1251 Check conformity by following the requirements of 201.12.1.101.3 and by inspection of the
1252 *accompanying document* as well as the information that is available to the *responsible organization*
1253 upon request.

1254 **201.12.1.101.2 Specification-disparate bias**

1255 a) The absolute differential bias of *pulse oximeter equipment* across populations should be less than
1256 or equal to 2,0 % for the interval between 85 % to 100 % *SaO₂*, and less than or equal to 4,0 %
1257 for the interval between 70 % to 85 %.

1258 NOTE A non-disparate bias is desirable as it implies a smaller difference in saturation between *ITA* levels.

1259 b) All aggregated differential bias data and *ITA* values taken at the forehead, inner bicep and *pulse*
1260 *oximeter probe* site shall be made available in numeric and graphical format:

1261 1) in the *accompanying document*; or

1262 2) on-line for the life of the *pulse oximeter probe*.

1263 Check conformity by following the requirements of 201.12.1.101.5 and by inspection of the
1264 *accompanying document* or information that is available on-line.

1265 **201.12.1.101.3 Data collection for determination of *SpO₂ accuracy***

1266 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

1267 a) The claims of *SpO₂ accuracy* shall be supported by *controlled desaturation study* measurements
1268 taken over the full range of *SaO₂* values +3 % of the lower value and -3 % of the upper value for
1269 which *SpO₂ accuracy* is claimed.

1270 EXAMPLE 1 A *controlled desaturation study* supporting a claimed range of *SpO₂ accuracy* from 70 % *SaO₂*
1271 to 100 % *SaO₂* can be supported with *SaO₂* data collected over the range of 73 % *SaO₂* to 97 % *SaO₂*.

1272 b) The *controlled desaturation study* shall conform with:

1273 1) Annex EE; and

1274 2) the requirements of ISO 14155:2020.

1275 c) The *residual risk* inherent in a controlled hypoxia study on healthy adult volunteers, can be
1276 reduced to a non-significant level by following recommended additional *procedures*^[38].

1277 d) The *accuracy of pulse oximeter equipment* for paediatric *patients* shall be supported via *controlled*
1278 *desaturation study* measurements on adult participants.

1279 NOTE 2 Paediatric participants are a vulnerable population.

1280 e) Data points should be collected with comparable density over the full range claimed.

1281 NOTE 3 Additional information is found in Annex EE.

1282 f) Any types of interference known to influence or affect the *SpO₂ accuracy*

1283 1) need not be stated as part of the *SpO₂ accuracy* specification but

2) shall be disclosed in the *instructions for use*.

EXAMPLE 2 Ambient light (including photodynamic therapy); physical movement (*patient's* voluntary or imposed motion); diagnostic testing; low perfusion; electromagnetic interference; *hfsurgical equipment*; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the *pulse oximeter probe*.

g) A summary of the test methods used to establish the *SpO₂ accuracy* claims shall be disclosed in the *technical description*.

h) *Functional testers* or *patient* simulators shall not be used for *verification* the *SpO₂ accuracy* of *pulse oximeter equipment*.

NOTE 4 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*. Additional information is found in Annex FF.

201.12.1.101.4 Data analysis for determination of *SpO₂ accuracy*

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

a) For each range specified, *SpO₂ 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).

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

NOTE 2 The concepts of bias and precision as given in ASTM E456-96^[12] and ambiguity as given in Reference^[107] also have value in representing the *accuracy* of *ME equipment*. The decision to require the form of *SpO₂ 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 *SpO₂ accuracy* of *pulse oximeter equipment* better than do bias and *precision*.

NOTE 3 Attention is also drawn to ISO/IEC Guide 99 (VIM)^[10] and ISO/IEC Guide 98-3 (GUM)^[4] as well as the documents of ISO/TC 69, *Applications of statistical methods*, for determination of *accuracy* and *precision*.

b) A linear regression (*SpO₂* versus *SaO₂*) plot from 70 % to 100 % *SaO₂* shall be generated and disclosed in the *technical description* with

1) the *mean bias* and *A_{rms}*, for the pooled participant data indicated.

2) the slope;

3) the intercept; and

4) the standard estimate of the error.

c) The standard reference for *SpO₂ accuracy* shall be traceable to *SaO₂* values obtained from *CO-oximeter* analysis of simultaneously time matched arterial blood specimens.

NOTE 4 Issues to consider in simultaneous time matching of values include physiological and signal processing delays.

NOTE 5 *SpO₂ accuracy* is theoretically possible against a *pulse oximeter* (*SpO₂*) instead of a *CO-oximeter* (*SaO₂*) 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}*).

- 1) 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.

NOTE 6 There is significant variation between types and brands of *CO-oximeters*^[54]. A claim of SpO_2 accuracy of less than 2% is not justifiable unless a *CO-oximeter* of an accuracy of 0,5% or better has been used as the reference for *verification* of the claim.

- 2) 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*.

- 3) Particular attention shall be given to the range for which the *manufacturer* makes SpO_2 accuracy claims.

NOTE 7 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 8 Additional information is found in Annex EE.

201.12.1.101.5 Data analysis for *disparate bias* determination

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

- a) For the SaO_2 ranges 70 % to 85 % and 85 % to 100 %, compute the mean of the paired $SpO_2 - SaO_2$ differences for each participant. This produces a nonparametric participant-level estimate of the $SpO_2 - SaO_2$ “bias” for each SaO_2 range.

- b) For the SaO_2 ranges 70 % to 85 % and 85 % to 100 %, regress the participant-level bias estimates on the *ITA* values to obtain an estimate of the relationship between mean $SpO_2 - SaO_2$ difference for each SaO_2 range and *ITA*.

- c) Using the linear regressions, estimate the “differential bias” between the values at an *ITA* of -50 and +50.

- d) Use the absolute differential bias values for characterizing the *disparate bias* in the two ranges 70 % SaO_2 to 85 % SaO_2 and 85 % SaO_2 to 100 % SaO_2 .

- 1) Differential bias shall be determined from the data collected in the *controlled desaturation study* for the determination of SpO_2 accuracy (see 201.12.1.101.3).

- 2) Differential bias shall be determined using *ITA* values at the *pulse oximeter probe* site. See 201.12.1.101.6 h) 8).

- i) If the *pulse oximeter probe* site is not accessible with a conforming colorimeter, take the *ITA* value from as near to the *pulse oximeter probe* site as practicable.

- 3) The *disparate bias* (i.e., absolute differential bias) shall be disclosed tabular and graphical format in the *instructions for use*. See Figure AA.1.

- i) The graphical format shall indicate each participant’s *mean bias* ($SpO_2 - SaO_2$) versus *ITA* for each range of:

I) 70 % SaO_2 to 85 % SaO_2 ; and

II) 85 % SaO_2 to 100 % SaO_2 .

201.12.1.101.6 Characteristics of the study population and collected data for the determination of SpO_2 accuracy

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

The study population and collected data of a *controlled desaturation study* data for the determination of SpO_2 accuracy shall include the following.

- a) Include a sample size of at least 24 participants.
 - 1) For a *single use or single patient multiple use pulse oximeter probe*, use a different *pulse oximeter probe* of the same design for each participant.
 - 2) For a *multiple patient multiple use pulse oximeter probe*, use multiple *pulse oximeter probes* of the same design across participants.
 - i) The number of *pulse oximeter probes* used shall be described in the study report.
 - 3) The study report shall detail the means by which participants were selected into the study population and included in data analysis according to EE 2.3.4.
- b) Include an average of 20 (± 4) data pairs per participant with a maximum data point range of 16 data points to 30 data points per participant.
 - 1) When more than 30 usable data pairs are collected for one participant, use the first valid 10 data pairs in each decade.
- c) Include an even distribution of data pairs, with total pairs evenly split across each desaturation decade between 70 % to 100 % saturations, with approximately 33 % in each decade. The data pairs comprising each decade are obtained from participants in each of the Monk Skin Tone and *ITA* cohorts. Each of these cohorts is expected to contribute an approximately equal number of data points in each SaO_2 decade in achieving the above distribution to ensure each cohort is nearly equally represented in each saturation decade.
- d) 90 % or greater of participants shall provide at least one useable data pair with an SaO_2 below 85 %.
 - 1) At least 69 % of participants shall also have provided at least one useable data pair with an SaO_2 between 70 % to 80 %.
- e) Include participants with diversity of skin pigment and gender as evidenced by the following.

NOTE 2 There is guidance or rationale for this list item contained in Clause AA.2.

- 1) Include at least 33 % of each biological sex.
- 2) Use a standardized perceived skin colour scale to assess the investigator perceived skin tone at the forehead to assure enrolment of skin tone diversity.
- 3) Ensure an overall study cohort is comprised of at least 25 % of the participants in each of the following Monk Skin Tone (MST) and *ITA* categories:

NOTE 3 There is guidance or rationale for this list item contained in Clause AA.2.

- i) MST from 1 to 3 and *ITA* greater than 30;
- ii) MST from 4 to 7 and *ITA* between 30 and -30; and

iii) MST from 8-10 and *ITA* less than -30 (with one half of *ITA* less than -30 having an *ITA* < less than -50).

4) Use *objective pigmentation measurement method ITA* to assess skin pigment at the forehead to assure skin tone distribution criteria are met as specified in Table 201.102.

5) If a subject has *ITA* and MST that do not place this subject in the same category, use the *ITA* categorization.

Table 201.102 — *ITA* and MST criteria for study enrolment

Category	MST on forehead ^a	<i>ITA</i> on forehead degrees
Light	A, B, C	> 30
Medium	D, E, F, G	$30 \geq ITA \geq -30$
Dark	H, I, J	< -30 ^b
^a If the MST criteria does not match the <i>ITA</i> criteria, use the <i>ITA</i> criteria.		
^b At least one half of the dark subjects have an <i>ITA</i> less than -50.		

6) The number of data pairs for a given *SaO₂* decile (i.e., 70 % to 80 %, 80 % to 90 % and 90 % to 100 %) should be derived approximately equally from participants across skin pigment categories, ensuring that >25 % of data points come from light, medium and dark participants by MST and *ITA*.

7) A *standardized skin colour scale* shall be represented by printed colour swatches.

8) *Standardized skin colour scale* printed colour swatches shall be *verified* using a calibrated colorimeter against target values and tolerances, prior to use.

EXAMPLE Representative colorimeters include the CM-700d from Konica-Minolta and Colorreader Pro from Datacolor.

NOTE 4 There is guidance or rationale for this list item contained in Clause AA.2.

NOTE 5 Benchmark values for printed MST scales are shown in Table 201.103 and used as target values for printed MST. Benchmark values for printed MST scales are derived from a sample of MST colour swatches printed on professional printers in different countries^[11]. It is recommended to use professional photo-grade printers with a large colour gamut. The *L** *a** *b** values in the Table 201.103 differ from the hexadecimal RGB equivalents by small amounts due to practical limitations in printing.

9) *L**, *a** and *b** values measured with a calibrated colorimeter shall be within the tolerances shown in Table 201.103 for all MST shades.

i) The *L** value of shade C shall be at least 3 units larger than that of shade D.

ii) The *L** value of shade G shall be at least 6 units larger than that of shade H.

10) If a factory printed MST scale is available, that may be used.

i) A factory printed MST scale can have *L**, *a**, *b** values for the MST shades that are closer to the defined MST values and thus may fall outside the tolerances of Table 201.103.

11) Use three observers, blinded to each other's readings. In the case of disagreement, when 2 of 3 values are the same, use that value. When three values are different, use the middle value.

1429

Table 201.103 —MST values and tolerances

MST shade	Hexadecimal code ^[88]	Targets ^[113]			Tolerances ^[113]		
		L*	a*	b*	L*	a*	b*
A	F7EDE4	88,3	2,0	-0,2	5,6	3,3	8,4
B	F3E7DA	86,4	1,9	2,0	6,5	3,3	8,4
C	F6EAD0	86,8	0,8	7,8	5,9	3,9	9,6
D	EAD9BB	81,8	1,5	11,0	7,4	3,5	10,7
E	D7BD96	73,3	3,2	18,1	8,4	3,9	10,7
F	9F7D54	52,4	5,9	21,5	8,2	5,8	10,3
G	815D44	41,6	7,8	14,5	7,6	5,2	7,4
H	604234	32,5	6,9	8,2	7,3	5,3	5,7
I	3A312A	25,4	1,1	2,5	8,0	4,1	4,4
J	2a2420	21,4	0,5	0,7	9,3	3,6	4,0

1430

1431 12) Ensure that the observers are not colour-blind as determined by optometric or on-line testing
1432 (e.g., EnChroma2 or equivalent).

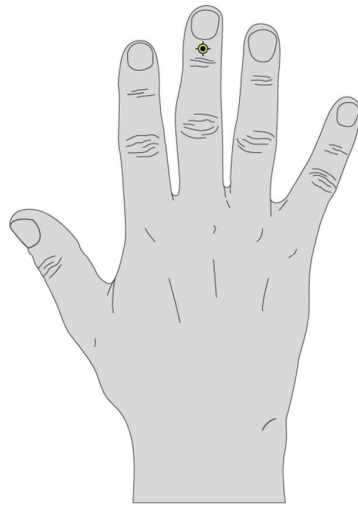
1433 13) Use a full spectrum lamp, colour temperature of 6 500 K and a CRI of 96 % for illumination.

1434 14) Measure the *ITA* values at the forehead, inner bicep and the *pulse oximeter probe*
1435 measurement site.

1436 NOTE 6 Forehead skin is sun exposed and inner bicep skin is typically not sun exposed.

1437 i) If measurement at the *pulse oximeter probe* site is not practical, then use a site that is
1438 most representative of the darkest skin tone of the *pulse oximeter probe* site.

1439 ii) In the case of a fingertip *pulse oximeter probe*, use the dorsal distal phalanx, (i.e., back of
1440 the finger between the fingernail and the most distal knuckle (see Figure 201.102).



The + in this figure indicates the dorsal distal phalanx (DP) as the location to measure skin pigment for finger *pulse oximeter probes*. The DP is the dorsal skin between the fingernail and the dorsal interphalangeal joint.

Figure 201.102 — Dorsal distal phalanx location

15) Use the *ITA* value at the *pulse oximeter probe* site for the *disparate bias* calculation.

16) Ensure that *ITA* colourimeter measurement specification conform with the following.

- i) *ITA* measured as defined by CIE. L^* and b^* .
- ii) If available, select a D65 illumination.
- iii) If a standard observer angle is available, select a standard observer equal to 2 degrees.
- iv) Use a measurement aperture between 3 mm and 8 mm.
- v) If a choice between specular reflection included or excluded is available, select the excluded setting.
- f) Participants who participated in the calibration study of the *pulse oximeter equipment* under test should be excluded.

NOTE 7 There is guidance or rationale for this list item contained in Clause AA.2.

- 1) Desaturation test facilities should make best efforts to limit the number of repeat participants in different *controlled desaturation studies* of the *pulse oximeter equipment* under test.

Check conformity by inspection of the *accompanying document* and the study report.

201.12.1.102 Accuracy under conditions of motion

NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

- a) 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*.