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Interested committees:

Title: BS EN ISO 80601-2-61 Medical electrical equipment

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

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- ii) affects other national standard(s)
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Responsible Committee Secretary: **Mr Paul Lambert (BSI)**

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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

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- 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
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (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.	



62D/2082/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

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2023-09-08

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62D/1945A/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

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Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

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

Appareils électromédicaux — Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oximètres de pouls

CD stage

Warning for WDs and CDs

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98 **Foreword**

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

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

110 Attention is drawn to the possibility that some of the elements of this document may be the subject of
 111 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any
 112 patent rights identified during the development of the document will be in the Introduction and/or on
 113 the ISO list of patent declarations received (see www.iso.org/patents).

114 Any trade name used in this document is information given for the convenience of users and does not
 115 constitute an endorsement.

116 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
 117 expressions related to conformity assessment, as well as information about ISO's adherence to the World
 118 Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see
 119 www.iso.org/iso/foreword.html.

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

126 This third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been
 127 technically revised.

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

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

132 — reformatted according to most recent Central Secretariat editing rules; and

133 — harmonization with ISO 20417, where appropriate.

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

135 Any feedback or questions on this document should be directed to the user's national standards body. A
 136 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;

- 178 – “can” indicates a possibility or capability; and
- 179 – “must” is used express an external constraint.

180 Summary of Current Changes in the ISO Draft:

- 181 1. The committees tightened the maximum allowed 70-100% $SaO_2 A_{rms}$ from 4 % to 3 %.
- 182 2. The committees included two acceptance criteria for *non-disparate bias*. These require that no
- 183 pigmentation group should have a bias difference of > 2% in the range >85 % to 100 % SaO_2 and not
- 184 > 4 % in the 70 % to 85 % SaO_2 range. Statistically, this means that a majority of the differential bias
- 185 will be no more than 1 % and 2 %, respectively.
- 186 3. The sample size for a *controlled desaturation study* was increased to a minimum of 24, which is more
- 187 than 2 times that required in the past.
- 188 4. The number of participants with dark skin was increased from 2 to 6 (≥ 25 % of the participants are
- 189 required be in the darkest skin category, which is now quantified in a standardized manner).
- 190 5. To assure inclusion of skin colour diversity, use of a subjective, visually perceived, skin tone
- 191 assessment method is required. This method allows identification of all levels of pigmentation, so
- 192 skin tones reported to be related to health care bias are included in the study population. At the time
- 193 of this writing, the Monk Skin Tone (MST) scale is the only known skin colour diversity tool to
- 194 facilitate the recruitment of test participants.
- 195 6. In addition to the above use of the MST as a tool for recruiting test participants, high resolution
- 196 quantification and assessment of *individual typology angle (ITA)* is required for enrolment. This
- 197 involves a technological tool that measures skin colour for enrolment-inclusion and objective
- 198 measurement of a continuous range of *ITA* that quantifies the skin tone with the use of a colourimeter
- 199 is necessary. This objective measure of melanin allows for the ability to regress skin colour, in the
- 200 form of *ITA* values, against $SpO_2 - SaO_2$ to show the different levels of reading bias across skin tones.

201 Overview and rationale of decisions made for summary items 4 and 5 above

202 The committees reviewed available evidence and identified multiple potential factors that may cause the

203 *pulse oximeter equipment* to not perform equally well for all *patients*. The first is that pigment at the probe

204 site absorbs significant levels of light, impacting the spectral content of detected signals, which may cause

205 the oximeter to generate inaccurate SpO_2 results [UCSF paper, Okunlola et al., Resp Care 2021.. Second

206 are disparities in health and health care related to skin colour, race, and ethnicity. Studies have shown

207 that people of colour often experience disparities in health and healthcare resulting from structural

208 racism. These inequities are experienced by *patients* with darker skin tones compared to lighter skinned

209 *patients*, regardless of their race or ethnicity. [Hamed S, Bradby H, Ahlberg BM, Thapar-Björkert S. Racism

210 in healthcare: a scoping review. BMC Public Health. 2022;22(1):988.] Thirdly, there also may be

211 significant population-level variation in factors that affect *pulse oximeter equipment accuracy*. However,

212 there are inadequate data at this time to confirm this link and such factors should not be misconstrued

213 as linked to race/ethnicity.

214 The committees believe the question most important to answer is: what is the impact of differences in

215 measured pigmentation on the *accuracy of pulse oximeter equipment*? To answer this, one needs to be

216 assured that the population sampled is diverse and be able to quantify skin colour as well as its influence

217 on performance of *pulse oximeter equipment*.

218 The most widely used probe site is the finger, which is the primary site of interest for this writing of the

219 standard. It has been noted that in darkly pigmented individuals, the palmar surface of the finger (i.e.,

220 finger pad) is usually much less pigmented than the rest of the person’s skin. Because of this, the *ITA* of

221 the finger pad does not reflect the ranges of skin colour diversity that are required.

222 For this reason, a compromise was considered which was to measure skin tone at the inner bicep. This

223 site is not affected by sun exposure and thus, would provide the benefit of not being affected by differing

224 sun-exposure-dependent levels of *ITA*. The drawbacks to this were twofold. First, the *ITA* of the inner

225 bicep does not closely match that of the forehead, which is where socially diverse, people are measured.

226 is observed. Second, the inner bicep is not representative of where the probe-pigmentation interaction
227 occurs.

228 The committees augmented the evaluation *process* by increasing the number of participants to 24 and
229 tightening the A_{rms} to $<3\%$. Criteria for *non-disparate bias* was also added with a requirement for a
230 maximum differential bias in two SaO_2 ranges, 70 % to 85 % and $>85\%$ to 100 %.

231 It is important to note that, as of this writing, an $A_{rms} >3\%$ is not allowed for any probe, including those
232 intended for use on sites other than the finger (e.g., cheek, chest, ear, forehead, nose, wrist). Based on the
233 committee's assessment of the maximum capability of current technology, alternative site probes may
234 not be capable of meeting an A_{rms} of 3 % or meeting the maximum differential bias in the two saturation
235 ranges. Therefore, a question remains, should larger acceptance criteria be allowed for special use cases
236 with probes intended for sites when the finger is not an option? In some situations, less *accuracy of pulse*
237 *oximeter equipment* may provide greater clinical utility than not having SpO_2 and *pulse rate* data.

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

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

241

**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*, which have been *remanufactured*.

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.

280 **201.1.2 Object**

281 *Replacement:*

282 The object of this document is to establish particular *basic safety* and *essential performance*
283 requirements for *pulse oximeter equipment* [as defined in 201.3.250] and its *accessories*.

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

287 NOTE 2 This document has been prepared to address the relevant *essential principles*^[21] and labelling^[22]
288 guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex JJ.

289 NOTE 3 This document has been prepared to address the relevant general safety and performance
290 requirements of European regulation (EU) 2017/745^[23].

291 **201.1.3 Collateral standards**

292 *Amendment (add after existing text):*

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

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

300 **201.1.4 Particular standards**

301 *Replacement:*

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

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

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

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

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

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

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

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

324 Subclauses or figures that are additional to those of the general standard are numbered starting from
325 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

326 Subclauses or figures that are additional to those of a collateral standard are numbered starting from
327 2xx, where "x" is the number of the collateral standard (e.g., 202 for IEC 60601-1-2, 203 for
328 IEC 60601-1-3, etc).

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

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

336 201.2 Normative references

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

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

343 NOTE 2 Informative references are listed in the Bibliography.

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

345 –Addition:

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

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

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

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

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

355 IEC 60068-2-27:2008+AMD1:2013, *Environmental testing — Part 2-27: Tests — Test Ea and*
356 *guidance: Shock*

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

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

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

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

367 IEC 60825-2:2004+AMD1:2006+AMD1:2010, *Safety of laser products — Part 2: Safety of optical fibre*
368 *communication systems (OFCS)*

369 IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to*
370 *medical devices*

371 201.3 Terms and definitions

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

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

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

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

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

378 201.3.201

379 accompanying information

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

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

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

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

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

389 201.3.202

390 accuracy

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

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

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

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

397 201.3.203

398 alarm condition delay

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

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

403 201.3.204

404 alarm limit

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

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

- 407 **201.3.205**
408 **alarm paused**
409 state of limited duration in which the *alarm system* or part of the *alarm system* does not generate
410 *alarm signals*
- 411 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.5]
- 412 **201.3.206**
413 **alarm preset**
414 set of stored configuration parameters, including selection of algorithms and initial values for use by
415 algorithms, which affect or modify the performance of the *alarm system*
- 416 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.6]
- 417 **201.3.207**
418 **alarm signal generation delay**
419 time from the onset of an *alarm condition* to the generation of its *alarm signal(s)*
- 420 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.10]
- 421 **201.3.208**
422 **audio paused**
423 state of limited duration in which the *alarm system* or part of the *alarm system* does not generate an
424 auditory *alarm signal*
- 425 [SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.13]
- 426 **201.3.209**
427 **colour measurement site**
428 location on the body at which the skin pigmentation is assessed by *pigmentation measurement*
429 *methods (PMMs)*
- 430 **201.3.210**
431 **constitutive skin pigmentation**
432 measurement of skin pigmentation, on skin that is hairless and is not routinely exposed to sunlight.
433 It is representative of an individual's baseline pigmentation.
- 434 Note 1 to entry: *Constitutive skin pigmentation* is typically measured on the upper inner bicep.
- 435 **201.3.211**
436 **controlled desaturation study**
437 hypoxaemia induced in a group of healthy adult human participants performed under well controlled,
438 optimal or non-optimal laboratory conditions.
- 439 Note 1 to entry: Optimal conditions are used to demonstrate maximum *accuracy* capability by isolating the
440 *pulse oximeter equipment* from confounding conditions such as low perfusion, movement, incorrect probe
441 placement, dyshaemoglobins, nail polish and high ambient light conditions. This method can also be used to
442 assess impact to *accuracy* during specifically targeted and defined non-optimal conditions such as participant
443 movement or low pulse-amplitude states (low perfusion).
- 444 **201.3.212**
445 **CO-oximeter**
446 multiwavelength, optical blood analyser that measures *total haemoglobin concentration* and the
447 concentrations of various haemoglobin derivatives
- 448 Note 1 to entry: The relevant CO-oximetry value is functional saturation of arterial blood, *SaO₂*, which *pulse*
449 *oximeter equipment* estimates and reports as *SpO₂*.

450 **201.3.213**
 451 **data update period**
 452 interval in which the *pulse oximeter equipment* algorithm provides new valid data to the display or
 453 the *functional connection*

454 Note 1 to entry: This definition does not refer to the regular refresh period of the display, which is typically on
 455 the order of 1 s, but rather to the (typically longer) interval defined above.

456 **201.3.214**
 457 **declared range**
 458 portion of the *displayed range* of SpO_2 and pulse rate values over which there is specified *accuracy*

459 **201.3.215**
 460 **default alarm preset**
 461 *alarm preset* that can be activated by the *alarm system* without *operator* action

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

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

465 **201.3.216**
 466 **displayed range**
 467 range of SpO_2 or pulse rate values that can be displayed by the *pulse oximeter equipment*

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

469 **201.3.217**
 470 **distributed alarm system**
 471 **DAS**
 472 *alarm system* that involves more than one item of equipment of a *ME system* intended for delivery of
 473 *alarm conditions* with technical confirmation

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

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

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

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

482 **201.3.218**
 483 **distribution of study participants**
 484 a statistically developed and powered distribution of participants across the required ranges of *ITA*
 485 values used to assess SpO_2 *accuracy*

486 Note 1 to entry: See “Characteristics of the clinical study population for determination of SpO_2 *accuracy*”.

487 **201.3.219**
 488 **EMS environment**
 489 **emergency medical services environment**
 490 actual conditions and settings, in which *operators* interact with the *ME equipment* or *ME system*, in
 491 and around the scene of an emergency outside of a professional healthcare facility where a *patient*
 492 can be given medical care, basic or advanced life support as well as during professional transport to
 493 a professional healthcare facility or between professional healthcare facilities

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

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

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

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

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

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

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

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

511 201.3.220

512 essential principles

513 essential principles of safety and performance

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

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

517 201.3.221

518 facultative skin pigmentation

519 a measurement of skin pigmentation on skin that is routinely exposed to sunlight

520 Note 1 to entry: *Facultative skin pigmentation* is typically measured on the forehead or below the nailbed of
 521 the dorsal side of the finger" (i.e., pad). It is subject to vary from baseline pigmentation due to factors such as
 522 sun exposure.

523 201.3.222

524 false positive alarm condition

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

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

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

530 201.3.223

531 fractional oxyhaemoglobin

532 DEPRECATED :FO₂Hb fractional saturation

533 oxyhaemoglobin concentration cO₂Hb divided by the *total haemoglobin concentration, ctHb*, in the
 534 blood

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

535

536 Note 1 to entry: cO₂Hb is the concentration of oxyhaemoglobin; ctHb is the concentration of total haemoglobin

- 537 Note 2 to entry: This is sometimes reported as a percentage (multiplying the fraction by 100).
 538 Note 3 to entry: *Fractional oxyhaemoglobin* is the term used by the Clinical and Laboratory Standards Institute
 539 (CLSI), (formerly NCCLS or National Committee for Clinical Laboratory Sciences) for this ratio.
 540 Note 4 to entry: CLSI denotes “concentration” by a prefixed letter *c*, while in the past the convention of square
 541 brackets (e.g. [O₂Hb]) was used.
 542 Note 5 to entry: CLSI^[3] uses the following notations:
 543 – oxyhaemoglobin (O₂Hb);
 544 – deoxyhaemoglobin (HHb);
 545 – carboxyhaemoglobin (COHb);
 546 – methaemoglobin (MetHb);
 547 – sulphaemoglobin (SulfHb); and
 548 – total haemoglobin (*ctHb*), which is derived by the cyanmethaemoglobin method of CLSI
 549 H15^[19].

550 **201.3.224**

551 **functional oxygen saturation**

552 percentage saturation given by the oxyhaemoglobin concentration (*cO₂Hb*) divided by the sum of the
 553 oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (*cHHb*)

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

554

555 Note 1 to entry: The CLSI^[3] term for this ratio is haemoglobin oxygen saturation, and its notation is *SO₂*.

556 Note 2 to entry: As related to *SpO₂*, this percent saturation is for arterial blood.

557 **201.3.225**

558 **functional tester**

559 test equipment which presents *pulse oximeter equipment* with a signal having a predictable value of
 560 *ratio* so that the *operator* can observe the resulting displayed value of *SpO₂*, and compare it to the
 561 expected value derived from the calibration curve for that particular *pulse oximeter equipment*

562 Note 1 to entry: The *accuracy* of the *SpO₂* value given by the *pulse oximeter equipment* depends in part on
 563 whether the calibration curve of the *pulse oximeter monitor* properly reflects the optical characteristics of the
 564 *pulse oximeter probe* and *pulse oximeter probe-tissue* interaction. *Functional testers* are not able to confirm the
 565 *SpO₂ accuracy* of the calibration curve or sufficiently assess the optical characteristics of *pulse oximeter probes*
 566 to determine their proper calibration. Additional information is found in FF.4.

567 Note 2 to entry: Not all *functional testers* and *pulse oximeter equipment* are compatible. *Functional testers* can
 568 vary in pulse simulation methods, pulse contours, and amplitude. A *functional tester* might not accurately
 569 reproduce the calibration of the *pulse oximeter equipment* and can yield different results between *pulse*
 570 *oximeter equipment*.

571 **201.3.226**

572 **HF surgical equipment**

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

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

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

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

580 201.3.227

581 home healthcare environment

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

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

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

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

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

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

594 201.3.228

595 immunity

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

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

599 201.3.229

600 immunity test level

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

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

604 201.3.230

605 individual typology angle

606 ITA

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

$$609 \quad ITA = \left(\frac{180}{\pi} \right) * \arctan \left(\frac{L^* - 50}{b^*} \right) \quad (1)$$

610 Where

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

612 b^* is the yellow/blue component.

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

614 Note 2 to entry: *ITA* is collected with the use of a device that provides the measure directly or derived from the
615 parameters L^* and b^* .

616 201.3.231

617 information for safety

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

619 EXAMPLE 1 Warnings, precautions or contraindications.

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

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

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

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

625 [SOURCE: ISO 20417:2021, 3.10]

626 201.3.232

627 **information supplied by the manufacturer**

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

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

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

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

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

639 201.3.233

640 **instructions for use**

641 **IFU**

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

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

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

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

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

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

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

655 201.3.234

656 **local bias**

657 ***b***

658 difference between the expectation of a test result (SpO_2) and an accepted reference value (SaO_2)

659 Note 1 to entry: For *pulse oximeter equipment*, this is, at a given value of the reference oxygen saturation, the
660 difference between the *y*-value of the regression line at that coordinate and the *y*-value of the line of identity,
661 in a plot of SpO_2 versus $S_{R,i}$ or given by:

$$662 \quad b_i = SpO_{2\text{fit},i} - S_{R,i}$$

663 Where:

664 $SpO_{2\text{fit},i}$ is the value of the curve fitted to the test data at the i^{th} reference oxygen saturation value, S_{Ri} .

665 Note 2 to entry: Additional information is found with the term *mean bias* and in the discussion in Annex CC.

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

668 **201.3.235**

669 **marking**

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

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

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

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

678 **201.3.236**

679 **mean bias**

680 ***B***

681 mean difference between the test and reference values, preserving sign

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

682

683 Where:

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

685 SpO_{2i} is the i^{th} SpO_2 datum; and

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

687 Note 1 to entry: Additional information also is found with the term *local bias* and in the discussion in Annex CC.

688 Note 2 to entry: When defined in this way, *mean bias* is the average of all *local bias* values, b_i .

689 **201.3.237**

690 **non-disparate bias**

691 bias that is not meaningfully different when comparing individuals in any of the multiple groups

692 **201.3.238**

693 **normalized**

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

695 **201.3.239**

696 **objective pigmentation measurement method**

697 *PMM* that is independent of human interpretation, typically by the correct use of a calibrated
698 scientific equipment as described in ISO/CIE 1166--1:2019 - Colourimetry — Part 1.

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

702 **201.3.240**

703 **operator interface**

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

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

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

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

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

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

714 **201.3.241**

715 **operator settings**

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

717 **201.3.242**

718 **operator's position**

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

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

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

722 **201.3.243**

723 **physiological alarm condition**

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

725 EXAMPLE 1 High exhaled anaesthetic agent concentration.

726 EXAMPLE 2 Low exhaled tidal volume.

727 EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

728 EXAMPLE 4 High arterial pressure.

729 EXAMPLE 5 High heart rate.

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

731 **201.3.244**

732 **pigmentation measurement method**

733 **PMM**

734 method for quantification or classification of skin pigment

735 **201.3.245**

736 **skin colour diversity testing**

737 using *PMM's* at a *colour measurement site*, which represents *facultative skin pigmentation*, to capture
738 the skin colour diversity in the study population needed for determination of *SpO₂ accuracy*

Note 1 to entry: colourimetry as part of *skin colour diversity testing* uses *colour measurement sites* on the forehead or below the fingernail bed to describe the participant pool of the clinical study for determination of *SpO₂ accuracy's facultative skin pigmentation*.

201.3.246

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.]

201.3.247

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]

201.3.248

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*.

201.3.249

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.

201.3.250

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]

- 779 **201.3.251**
 780 **pulse oximeter equipment**
 781 *ME equipment* for the non-invasive estimation of *functional oxygen saturation* of arterial haemoglobin
 782 (*SpO₂*) from a light signal interacting with tissue, by using the time-dependent changes in tissue
 783 optical properties that occur with pulsatile blood flow
- 784 Note 1 to entry: *Pulse oximeter equipment* comprises a *pulse oximeter monitor*, a *probe cable extender*, if
 785 provided, and a *pulse oximeter probe*, which can be combined in a single assembly.
- 786 Note 2 to entry: Light is more technically referred to as electromagnetic radiation (optical radiation). This
 787 document uses the common term.
- 788 **201.3.252**
 789 **pulse oximeter monitor**
 790 part of the *pulse oximeter equipment* that encompasses the electronics, display and *operator interface*,
 791 excluding the *pulse oximeter probe* and *probe cable extender*
- 792 Note 1 to entry: A *pulse oximeter monitor* can consist of multiple pieces of hardware in separate locations (e.g.,
 793 a telemetry system in which the *applied part* and primary display are in physically separated).
- 794 **201.3.253**
 795 **pulse oximeter probe**
 796 part of the *pulse oximeter equipment* that includes the *applied part* and transducer component
- 797 Note 1 to entry: The *pulse oximeter probe* typically consists of a cable and a rigid or flexible assembly containing
 798 two photo emitters and a photo detector.
- 799 **201.3.254**
 800 **ratio**
 801 **modulation ratio**
 802 **ratio of ratios**
 803 ***R***
 804 basic quantity derived by *pulse oximeter equipment* from time-dependent light intensity
 805 measurements
- 806 Note 1 to entry: *Pulse oximeter equipment* uses an empirical calibration curve to derive *SpO₂* from *R*. Additional
 807 information is found in FF.4.
- 808 **201.3.255**
 809 **remanufacturing**
 810 DEPRECIATED: reprocessing
 811 any activity, which is not specified in the *accompanying document*, which renders a used product
 812 suitable for use
- 813 Note 1 to entry: Such activities are often referred to as refinishing, restoring, recycling, refurbishing, repairing
 814 or *remanufacturing*.
- 815 Note 2 to entry: Such activities can occur in healthcare facilities.
- 816 Note 3 to entry: The term “*remanufactured*” is used to designate the corresponding status.
- 817 Note 4 to entry: There is guidance or rationale for this definition contained in Clause AA.2.
- 818
- 819 **201.3.256**
 820 **SaO₂**
 821 fraction of functional haemoglobin in arterial blood that is saturated with oxygen
- 822 Note 1 to entry: Subclause 201.12.1.101.3 provides the acceptable method for determining *SaO₂*.
- 823 Note 2 to entry: Additional information about *SaO₂* is found 201.3.209.
- 824 Note 3 to entry: *SaO₂* is normally expressed as a percentage (by multiplying the fraction by 100).

- 825 **201.3.257**
 826 **single use**
 827 <medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or
 828 specimen during a single *procedure* and then disposed of
- 829 Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further
 830 *processed* and used again.
- 831 [SOURCE: ISO 20417:2021, 3.27]
- 832 **201.3.258**
 833 **SpO₂**
 834 estimate of *SaO₂* made by *pulse oximeter equipment*
- 835 Note 1 to entry: Two-wavelength *pulse oximeter equipment* cannot compensate for the interference caused by
 836 the presence of dyshaemoglobins in their estimation of *SaO₂*^{[20][81]}.
- 837 Note 2 to entry: *SpO₂* is normally reported as a percentage (multiplying the fraction by 100).
- 838 **201.3.259**
 839 **standardized skin colour scale**
 840 a scale that defines a range of colours, measured by *PMMs*, that captures a majority of colours seen
 841 in human skin. It has a defined RGB, L*a*b* and *individual typology angle (ITA)* ranges.
- 842 Note 1 to entry: The Monk Skin Tone scale (MST) is considered the only such scale at the time of publication.
- 843 **201.3.260**
 844 **sterile**
 845 free from viable microorganisms
- 846 SOURCE: ISO 20417:2021, 3.29]
- 847 **201.3.261**
 848 **subjective pigmentation measurement method**
 849 *PMM* that is dependent on trained human observers interpretations of a person's skin pigmentation
 850 and sorting in comparison to a *standardized skin colour scale*.
- 851 Note 1 to entry: It can also represent a study participants perceived skin pigmentation.
- 852 **201.3.262**
 853 **symbol**
 854 graphical representation appearing on the label or associated documentation of a medical device that
 855 communicates characteristic information without the need for the supplier or receiver of the
 856 information to have knowledge of the language of a particular nation or people
- 857 Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar
 858 objects, including alphanumeric characters (with sufficient justification).
- 859 [SOURCE: ISO 20417:2021, 3.30]
- 860 **201.3.263**
 861 **technical alarm condition**
 862 *alarm condition* arising from a monitored equipment-related or *alarm system*-related variable
- 863 EXAMPLE 1 An electrical, mechanical, or other failure.
- 864 EXAMPLE 2 A failure of a probe or component (unsafe voltage, high impedance, signal impedance, artefact,
 865 noisy signal, disconnection, calibration error, tubing obstruction, etc.).
- 866 EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

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

868 **201.3.264**

869 **technical description**

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

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

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

875 **201.3.265**

876 **total haemoglobin concentration**

877 **ctHb**

878 sum of concentrations of all haemoglobin species in the blood including, but not limited to,
879 oxyhaemoglobin (cO₂Hb), methaemoglobin (cMetHb), deoxyhaemoglobin (cHHb), sulfhaemoglobin
880 (cSHb) and carboxyhaemoglobin (cCOHb)^[39]

881 **201.3.266**

882 **transfer standard**

883 DEPRECIATED: secondary standard

884 a pulse oximeter used as a non-invasive estimate of SaO₂ during *pulse oximeter accuracy* performance.

885 Note 1: Bias and *precision* of the *transfer standard* pulse oximeter are directly traceable to *CO-oximeter* SaO₂
886 data and have been characterized to assess *accuracy* performance using an error transfer equation. The *transfer*
887 *standard* pulse oximeter is *pulse oximeter equipment* comprised of a *pulse oximeter monitor*, a *probe cable*
888 *extender*, and a *pulse oximeter probe* (each component specially kept together as a single *transfer standard* pulse
889 oximeter). (see EE.5.3 for details)

890 **201.3.267**

891 **validation**

892 confirmation, through the provision of *objective evidence*, that the requirements for a specific
893 intended use or application have been fulfilled

894 Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of
895 determination such as performing alternative calculations or reviewing documents.

896 Note 2 to entry: The term “*validated*” is used to designate the corresponding status.

897 Note 3 to entry: The use conditions for *validation* can be real or simulated.

898 [SOURCE: ISO 9000:2015 definition 3.8.13]

899 **201.4 General requirements**

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

901 *Additional subclauses:*

902 **201.4.3.101 Additional requirements for essential performance**

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

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

905 **201.4.101 Additional requirements for acceptance criteria**

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



908 When the *manufacturer* specifies in the *accompanying document* performance levels better than
 909 those specified within this document, these *manufacturer*-specified levels become the acceptance
 910 levels.

911 EXAMPLE For a specified level of *SpO₂ accuracy* of 1 %, the *pulse oximeter equipment* is required to have
 912 1 % *SpO₂ accuracy* for all requirements (e.g., during *immunity tests*).

913 **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.	

914

915 **201.4.102 Additional requirements for *pulse oximeter equipment*, parts and**
 916 ***accessories***

917 a) The *pulse oximeter equipment*, as well as all individual parts and *accessories* specified for use with
 918 a *pulse oximeter monitor*, shall comply with all requirements specified in this document. This
 919 includes all combinations of parts or *accessories* that are specified by a *manufacturer* for use in
 920 *pulse oximeter equipment*.

921 NOTE 1 This requirement ensures *basic safety* and *essential performance* of parts and *accessories* of the *pulse*
 922 *oximeter equipment*, in combination with their intended *pulse oximeter monitors*.

923 NOTE 2 *Pulse oximeter monitors* are frequently used with *pulse oximeter probes* and cables from different
 924 *manufacturers*. This requirement ensures the compatibility of such combinations.

925 b) All specified combinations of *pulse oximeter equipment*, as well as all individual parts and
 926 *accessories* specified for use with a *pulse oximeter monitor*, shall be disclosed in the *instructions*
 927 *for use*.

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

929 **201.5 General requirements for testing of *ME equipment***

930 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies.

931 201.6 **Classification of *ME equipment* and *ME systems***

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

933 201.7 ***ME equipment* identification, marking and documents**

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

935 *Additional subclause:*

936 **201.7.1.101 Information to be supplied by the manufacturer**

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

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

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

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

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

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

946 Check conformity by application of ISO 20417:2021.

947 **201.7.2.3 Consult *accompanying documents***

948 *Replacement:*

949 The *pulse oximeter equipment* shall be *marked* with the *safety sign* for the mandatory action: "follow
950 instructions for use", ISO 7010-M002 (see IEC 60601-1:2005/COR1:2006, Table D.2, Number 10).

951 *Additional subclauses:*

952 **201.7.2.9.101 IP classification**

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

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

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

958 2) the degree of protection provided by the carrying case shall be *marked* on the carrying case.

959 **EXAMPLE** If for *portable ME equipment*, the *enclosure* provides the protection against the ingress of
960 particulate matter and the carrying case provides the protection against the ingress of water, the
961 *enclosure* of the *ME equipment* would be *marked* IP2X and the carrying case would be *marked* IPX2.

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

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

965 1) 'keep dry'; or

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

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

969 **201.7.2.101 Additional requirements for marking on the outside of ME equipment**
970 **parts**

971 *ME equipment, parts or accessories shall be marked as follows.*

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

975 c) For a *remanufactured pulse oximeter probe*, marked as such.

976 b) These *markings* shall be *clearly legible*.

977 Check conformity by inspection.

978 **201.7.4.3 Units of measurement**

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

980 a) *Functional oxygen saturation* shall be expressed in units of percent *SpO₂* and shall be *marked as*
981 *% SpO₂ or SpO₂*.

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

983 *Additional subclauses:*

984 **201.7.9.2.1.101 Additional general requirements**

985 The *instructions for use* shall indicate the following:

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

987 b) the range of the peak wavelengths and maximum optical output power of the light emitted by the
988 *pulse oximeter probe* and a statement to the effect that information about wavelength range can
989 be especially useful to clinicians;

990 EXAMPLE 1 Clinicians performing photodynamic therapy.

991 c) description of the effect on displayed and transmitted *SpO₂* and pulse rate data values by:

992 d) data averaging and other signal processing;

993 1) the *data update period*;

994 2) the *alarm condition delay*; and

995 3) *alarm signal generation delay*,

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

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

998 e) the *displayed ranges* of

- 999 1) SpO_2 and
- 1000 2) pulse rate;
- 1001 f) if no *alarm system* that includes the capability to detect an SpO_2 or pulse rate *physiological alarm*
- 1002 *condition* is provided, a statement to that effect; and
- 1003 g) for *pulse oximeter monitors*, the *pulse oximeter probes* and *probe cable extenders* with which the
- 1004 *pulse oximeter monitor* has been *verified* and tested for conformity with this document.
- 1005 1) The list may be made available by electronic means.

1006 NOTE 2 Additional information is found in 201.4.103.

1007 Check conformity by inspection of the *instructions for use*.

1008 **201.7.9.2.2.101 Additional requirements for warnings and safety notices**

1009 The *instructions for use* shall include:

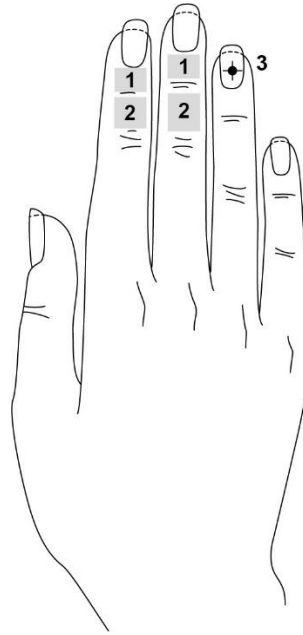
- 1010 a) for each *pulse oximeter probe* and *probe cable extender*, a warning to the effect that probes and
- 1011 cables are designed for use with specific monitors;
- 1012 b) a warning statement to the effect that the responsible organization or operator needs to verify
- 1013 the compatibility of the *pulse oximeter monitor*, *pulse oximeter probe* and *probe cable extender*
- 1014 before use, or patient injury can result; and
- 1015 c) a warning statement to the effect that misapplication of a *pulse oximeter probe* with excessive
- 1016 pressure for prolonged periods can induce pressure injury.
- 1017 d) a warning statement to the effect that nail polish, tattoos, artificial nails and bruised nail beds
- 1018 interfere with the optical pathway and can cause inaccurate readings.

1019 Check *conformity by inspection of the instructions for use*.

1020 **201.7.9.2.9.101 Additional requirements for operating instructions**

1021 The *instructions for use* shall indicate the following.

- 1022 a) A description with graphic indicating proper orientation and placement of the *pulse oximeter*
- 1023 *probe*. Proper positioning shall be visually confirmed by the user, which for a finger site shall be
- 1024 with the emitter over the nailbed centrum. See Figure 1 for an example.



Key

- 1 Site for hairless pigment measurement.
- 2 Site for hairless pigment measurement.
- 3 Fingertip *probe* location for optimal performance.

NOTE Long fingernails can interfere with proper placement of *probe*.

Figure 1 — Example *probe* locations and pigment measurement sites

b) A description of the signal inadequacy indicator and its function.

- 1) If there is a pulse waveform, a statement as to whether or not it is *normalized* shall be provided.

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

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

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

1050 Check conformity by inspection of the *instructions for use*.

1051 **201.7.9.2.14.101 Additional requirements for accessories, supplementary**
1052 **equipment, used material**

1053 The *instructions for use* shall include the following.

1054 a) For *pulse oximeter probes*, the *pulse oximeter monitors* and *probe cable extenders* with which the
1055 *pulse oximeter probes* have been *verified* and tested for conformity with this document.

1056 1) The list may be made available by electronic means.

1057 NOTE 1 Additional information is found in 201.4.103.

1058 b) For *probe cable extenders*, the *pulse oximeter monitors* and *pulse oximeter probes* with which the
1059 *probe cable extenders* have been *verified* and tested for conformity with this document.

1060 1) The list may be made available by electronic means.

1061 NOTE 2 Additional information is found in 201.4.103.

1062 Check conformity by inspection of the *instructions for use*.

1063 **201.7.9.3.1.101 Additional general requirements**

1064 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

1065 a) The *technical description* shall include a statement to the effect that a *functional tester* cannot be
1066 used to assess the *accuracy* of a *pulse oximeter probe* or a *pulse oximeter monitor*.

1067 NOTE 2 Additional information is found in Annex FF.

1068 b) The *technical description* should provide descriptions on how the *responsible organization* can
1069 verify operation of the *pulse oximeter equipment*.

1070 1) If the use of a *functional tester* is specified, the *technical description* should indicate the *model*
1071 *or type reference* and its software unique identifier, if applicable, of at least one *functional*
1072 *tester* that is compatible with the basic functions of the *pulse oximeter equipment* (e.g., it can
1073 ensure that the *pulse oximeter equipment* generates a display of *SpO₂* and pulse rate).

1074 Check conformity by inspection of the *technical description*.

1075 **201.8 Protection against electrical hazards from ME equipment**

1076 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies, except as follows:

1077 *Additional subclause:*

1078 **201.8.3.101 Additional requirements for classification of applied parts**

1079 *Applied parts of pulse oximeter equipment* shall be:

1080 a) *type BF applied parts*; or

1081 b) *type CF applied parts*.

1082 Check conformity by inspection.

1083 201.9 **Protection against mechanical hazards of ME equipment and ME systems**

1084 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies.

1085 201.10 **Protection against unwanted and excessive radiation hazards**

1086 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies, except as follows:

1087 **201.10.4 Lasers**

1088 *Replacement:*

1089 aa) Depending on the light source used in a *pulse oximeter probe*, the relevant requirements of
1090 IEC 60825-1:2014 shall apply to a *pulse oximeter probe*.

1091 bb) In the case of laser fibre optics, the requirements of IEC 60825-2:2004+AMD1:2006+AMD2:2010
1092 shall apply.

1093 Check conformity by application of the requirements of IEC 60825-1:2014 and
1094 IEC 60825-2:2004+AMD1:2006+AMD2:2010, as applicable.

1095 201.11 **Protection against excessive temperatures and other hazards**

1096 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows:

1097 **201.11.1.2.2 Applied parts intended to supply heat to a patient**

1098 *Amendment (add at the end of subclause 11.1.2.2):*

1099 aa) The *pulse oximeter probe*-tissue interface shall be evaluated when the skin temperature is initially
1100 at 35 °C for each *pulse oximeter monitor* and *pulse oximeter probe* indicated in the *instructions for*
1101 *use*.

1102 NOTE 1 Additional information is found in Annex BB.

1103 bb) If the surface temperature of the *pulse oximeter probe* at the tissue interface is capable of
1104 exceeding 41 °C, then

1105 1) the *pulse oximeter equipment* shall have an *operator*-adjustable control for activating any
1106 elevated temperature mode that exceeds 41 °C.

1107 i) A deliberate sequence of *operator* actions shall be required to activate this mode.

1108 ii) The *instructions for use* shall describe this sequence of *operator* actions.

1109 2) the *pulse oximeter equipment* shall provide a means to limit the duration of an elevated
1110 temperature mode in excess of 41 °C.

1111 i) The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at
1112 42 °C.

1113 3) the *instructions for use* shall include a statement to the effect that the use of temperature
1114 settings greater than 41 °C requires special attention in *patients* with susceptible skin, such
1115 as neonates, geriatric *patients* or burn victims.

1116 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 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) 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.

201.11.101.2 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

1156 b) all stored *patient* data.

1157 NOTE 1 The *pulse oximeter equipment* does not have to continue to operate during the interruption of the
1158 *supply mains*.

1159 NOTE 2 Settings include *operator settings*, *responsible organization* settings, and the mode of operation.

1160 Check conformity by observing the *pulse oximeter equipment* settings and stored *patient* data and
1161 then interrupting the *supply mains* for a period of between 25 s and 30 s by disconnecting the *power*
1162 *supply cord*. After reestablishment of power, confirm that the above settings and stored data are the
1163 same.

1164 201.11.101.3 Operation following long interruptions

1165 The *instructions for use* shall disclose the operation of the *pulse oximeter equipment* after the *supply*
1166 *mains* has been interrupted when the "on-off" switch remains in the "on" position and is restored
1167 after a period of time longer than 30 s.

1168 Check compliance by inspection of the *instructions for use*.

1169 201.12 Accuracy of controls and instruments and protection against hazardous 1170 outputs

1171 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 12 applies, except as follows:

1172 201.12.1 Accuracy of controls and instruments

1173 *Additional subclauses:*

1174 201.12.1.101 *SpO₂ accuracy of pulse oximeter equipment*

1175 NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

1176 201.12.1.101.1 Specification

1177 NOTE There is guidance or rationale for this subclause contained in Clause AA.2.

1178 a) The *SpO₂ accuracy of pulse oximeter equipment* shall be a root-mean-square difference of less than
1179 or equal to 3,0% *SpO₂* over the range of 70 % to 100 % *SaO₂*. The 95% confidence interval for
1180 characterizing the uncertainty of the estimate shall be disclosed.

1181 1) The *SpO₂* shall be indicated as *functional oxygen saturation*.

1182 2) The *SpO₂* shall not be indicated as *fractional oxyhaemoglobin*.

1183 b) *Non-disparate bias of pulse oximeter equipment* across populations shall have a mean of the
1184 measured *SpO₂-SaO₂* bias between groups of less than 2 % for the interval > 85 % to 100 % *SaO₂*,
1185 and less than 4 % for the interval of 70 % to 85 %.

1186 1) This shall be tested during the *controlled desaturation study* for the determination of *SpO₂*
1187 *accuracy* (see 201.12.1.101.4).

1188 2) *Non-disparate bias* shall be calculated based on the *distribution of study participants*.

1189 3) *Non-disparate bias* shall be measured using *ITA* at the *pulse oximeter probe* site.

1190 4) For *figertip pulse oximeter probes*, the dorsal distal index phalanges (dorsal DIP) shall be used
1191 to categorize the the *pulse oximeter probe* site colour.

c) The *declared ranges* of SpO_2 and SpO_2 accuracy over those ranges shall be disclosed in the *instructions for use*.

1) The SpO_2 accuracy shall be stated over the range 70 % to 100 % (additional information is found in 201.12.1.101.2).

2) SpO_2 accuracy information shall be accompanied by a note reminding the reader that, because *pulse oximeter equipment* measurements are statistically distributed, only about two-thirds of *pulse oximeter equipment* measurements can be expected to fall within $\pm A_{rms}$ of the value measured by a *CO-oximeter*, and that real-world performance under clinical conditions may be degraded.

3) When a *pulse oximeter monitor* is suitable for use with a variety of *pulse oximeter probes*, SpO_2 accuracy information shall be made available for each type of *pulse oximeter probe*.

d) The Bland-Altman plot (i.e., $(SpO_2 - SaO_2)$ versus SaO_2)^{[35][29]} for each combination of *pulse oximeter probe* and *pulse oximeter monitor* listed in the *instructions for use* for all participants pooled, including upper 95 % and lower 95 % limits of agreement shall at a minimum be provided to the *responsible organization* upon request. See Annex CC for an example:

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

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

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

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

g) Additional SpO_2 accuracy specifications over other ranges may also be provided.

h) All aggregated A_{rms} , bias data and *ITA* measurements taken at the forehead, inner bicep and *pulse oximeter probe* site shall be made available in numeric and graphical format upon request, in the product literature or on-line upon request for the life of the *pulse oximeter probe*.

Check conformity by following the requirements of 201.12.1.101.2 and by inspection of the *accompanying document* as well as the information that is available to the *responsible organization* upon request.

201.12.1.101.2 Data collection for determination of SpO_2 accuracy

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

a) The claims of SpO_2 accuracy shall be supported by *controlled desaturation study* measurements taken over the full range of SaO_2 values +3 % of the lower value and -3 % of the upper value for which SpO_2 accuracy is claimed.

EXAMPLE 1 A *controlled desaturation study* supporting a claimed range of SpO_2 accuracy from 70 % SaO_2 to 100 % SaO_2 can be supported with SaO_2 data collected over the range of 73 % SaO_2 to 97 % SaO_2 .

b) The *controlled desaturation study* shall comply with the requirements of ISO 14155:2011.

c) The *residual risk* inherent in a controlled hypoxia study on healthy adult volunteers, can be reduced to a non-significant level by following recommended additional *procedures*^[34].

1230 d) The *accuracy of pulse oximeter equipment* for paediatric patients shall be supported via *controlled*
1231 *desaturation study* measurements on adult participants.

1232 NOTE 2 Paediatric participants are a vulnerable population.

1233 e) Data points should be collected with comparable density over the full range claimed.

1234 NOTE 3 Additional information is found in Annex EE.

1235 f) Any types of interference known to influence or affect the *SpO₂ accuracy*

1236 1) need not be stated as part of the *SpO₂ accuracy* specification but

1237 2) shall be disclosed in the *instructions for use*.

1238 EXAMPLE 2 Ambient light (including photodynamic therapy); physical movement (*patient* and imposed
1239 motion); diagnostic testing; low perfusion; electromagnetic interference; *hfsurgical equipment*;
1240 dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the *pulse oximeter*
1241 *probe*.

1242 g) A summary of the test methods used to establish the *SpO₂ accuracy* claims shall be disclosed in
1243 the *technical description*.

1244 h) *Functional testers* or *patient* simulators shall not be used for *verification* the *SpO₂ accuracy* of *pulse*
1245 *oximeter equipment*.

1246 NOTE 4 Some *functional testers* or *patient* simulators can be used to verify aspects of design changes of a
1247 *pulse oximeter monitor* but not a *pulse oximeter probe*.

1248 201.12.1.101.3 Data analysis for determination of *SpO₂ accuracy*

1249 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

1250 a) For each range specified, *SpO₂ accuracy* of the *pulse oximeter equipment* shall be stated in terms
1251 of the root-mean-square (rms) difference between measured values (*SpO_{2i}*) and reference values
1252 (*S_{Ri}*), as given by Formula (1).

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

1254 NOTE 2 The concepts of bias and precision as given in ASTM E456-96^[10] and ambiguity as given in
1255 Reference^[84] also have value in representing the *accuracy of ME equipment*. The decision to require the
1256 form of *SpO₂ accuracy* stated above (which has been traditional in pulse oximetry, although under the
1257 misnomer “standard deviation”) is based on the belief that it will be more widely understood by the general
1258 community of clinical *operators* and on the recognition that in some cases it represents the overall *SpO₂*
1259 *accuracy of pulse oximeter equipment* better than do bias and *precision*.

1260 NOTE 3 Attention is also drawn to ISO/IEC Guide 99 (VIM)^[8] and ISO/IEC Guide 98-3 (GUM)^[4] as well as
1261 the documents of ISO/TC 69, *Applications of statistical methods*, for determination of *accuracy* and
1262 *precision*.

1263 b) The standard reference for *SpO₂ accuracy* shall be traceable to *SaO₂* values obtained from *CO-*
1264 *oximeter* analysis of simultaneously time matched arterial blood specimens.

1265 1) The *CO-oximeter* shall have a specified *SaO₂* performance of 1 % (1 standard deviation) or
1266 better over the range for which the *manufacturer* makes *SpO₂ accuracy* claims.

1267 2) Quality assurance, including maintenance and calibration, *procedures* for assessing *CO-*
1268 *oximeter* performance that are required in laboratories reporting clinical data shall be
1269 utilized for the *CO-oximeter*.

1270 3) Particular attention shall be given to the range for which the *manufacturer* makes *SpO₂*
1271 *accuracy* claims.

1272 NOTE 4 It is not appropriate to use *SaO₂* values calculated from measurements made by blood gas
1273 analysers that actually measure *PaO₂* (arterial oxygen pressure) rather than *SaO₂*.

1274 NOTE 5 Calibration is theoretically possible against a *pulse oximeter* (*SpO₂*) instead of a *CO-oximeter*
1275 (*SaO₂*) but this technique requires extensive *validation* of the method and has not yet (as of this writing)
1276 been shown to successfully demonstrate *essential performance* (*A_{rms}*).

1277 NOTE 6 Additional information is found in Annex EE.

1278 **201.12.1.101.4 Data analysis for non-disparate bias determination**

- 1279 a) For each participant, first obtain differences between all paired *SpO₂*/*SaO₂* measurements.
- 1280 b) For each *SaO₂* range, compute the mean of the paired *SpO₂*- *SaO₂* differences for each participant.
1281 This produces a nonparametric participant-level estimate of the *SpO₂*- *SaO₂* “bias” for each
1282 *SaO₂* range.
- 1283 c) For each *SaO₂* range, regress the participant-level bias estimates on the (also participant-level)
1284 *ITA* skin tone measurements to obtain an estimate of the relationship between skin tone and
1285 mean *SpO₂*- *SaO₂* difference for each *SaO₂* range. The regressions should be done using a method
1286 that allows for within-participant correlations.

1287 **Box Note 1**

1288 The statistics here have not met committees consensus; the National Member Bodies are requested
1289 to comment on both the method and acceptance criteria.

- 1291 d) Using the regressions, estimate the “differential bias” between dark and light pigmented skin at
1292 an *ITA* value of -50 and +50.

1293 **201.12.1.101.5 Demonstration of the characteristics of the clinical study** 1294 **population for determination of *SpO₂* accuracy**

1295 The study population of the *controlled desaturation study* data for the determination of *SpO₂* accuracy
1296 shall include the following.

- 1297 a) Include a sample size of at least 24 individuals.
- 1298 b) Include an average of 24 (+/-4) data points per participant with a maximum data point range of
1299 17 to 30 data points per participant.
- 1300 c) Include an even distribution of data points, with total points evenly split across each desaturation
1301 decade between 70 % to 100 % saturations, with ~33 % (±5 %) in each decade.
- 1302 d) Include only studies where 90 % or greater of participants can provide useable data points below
1303 85 %.
- 1304 1) At least 70 % of participants shall also have provided useable data in the 70 % to 80 %
1305 decade.

- 1306 e) Limit the number of repeat participants in different desaturation studies by enrolment of a
1307 variety of different individuals over time in subsequent studies.
- 1308 f) Include approximately 40% of each sex
- 1309 g) Exclude participants who participated in the calibration study of the *pulse oximeter equipment*
1310 under test
- 1311 NOTE 1 The number of repeat participants should be limited in different desaturation studies by
1312 enrolment of a variety of different individuals over time in subsequent studies.
- 1313 h) Exclude participants that are sick, incarcerated or pregnant
- 1314 i) Include diverse participants as evidenced by *skin colour diversity testing* that shall:
- 1315 1) Use the MST to visually assess skin pigment at the forehead, to assure enrolment of skin tone
1316 diversity.
- 1317 2) Enroll at least one individual in each of the 10 MST skin tone categories; at least 25 % of the
1318 total sample size shall be included in each of the following MST categories: 1 to 4, 5 to 7, 8 to
1319 10.
- 1320 3) The MST shall be represented by Pantone swatch, colour balanced computer screen, or
1321 comparable calibrated colour accurate printed colour chart.
- 1322 4) Three observers shall be used blinded to each other's readings. In the case of disagreement,
1323 when two of three values are the same, that value is used. When three values are different the
1324 middle value is used.
- 1325 5) Observers shall not be colour-blind (as determined by optometric or on-line testing (e.g.,
1326 EnChroma or equivalent).
- 1327 6) A full spectrum lamp, colour temperature of 6 500K and a CRI of 96 % shall be used for
1328 illumination.
- 1329 7) *ITA* shall be measured at the *pulse oximeter probe* site for the *non-disparate bias* calculation.
1330 In the case of a fingertip *pulse oximeter probe*, the dorsal distal index phalanx, (i.e., back of the
1331 finger between the fingernail and the most distal knuckle) shall be used, with *ITA*
1332 distributions as follows:
- 1333 i) At least 25% of enrollees shall meet the *ITA* requirements for each of the following MST
1334 categories and cut-offs: 1 to 4 (*ITA* > 25°), 5 to 7 (*ITA* ≤ 25° to > -35°), 8 to 10 (*ITA* ≤
1335 -35°).
- 1336 ii) At least 1 participant in MST category 1 to 4 shall have an *ITA* ≥ 50° and at least 2
1337 participants in MST category 8 to 10 shall have an *ITA* ≤ -45°.
- 1338 iii) Colourimeter measurement specification requirements
- 1339 I) *ITA* measured as defined by CIE. L* and b*
- 1340 II) Be computed with illumination equal to D65
- 1341 III) Use standard observer equal to 2 degrees or 10 degrees
- 1342 IV) Use a measurement aperture equal to 3mm to 8 mm

8) *ITA* values shall be recorded at the forehead (facultative), inner arm (constitutive), and the *pulse oximeter probe* site.

i) If the *pulse oximeter probe* site is intended to be used on a fingertip, the dorsal DIP (excluding the fingernail and cuticle bed) shall be used.

NOTE 1 The goal is to include participants that are representative of a diverse range of populations/ethnicities/races, but specific distributions are not required.

j) Report results using 201.12.1.101.10.6

1) This information shall be disclosed in the *accompanying document*.

Check conformity by inspection of the *accompanying document*.

201.12.1.101.6 Components of the clinical study report

a) Components of the clinical study report shall include:

1) Table of Contents

2) Study Summary

3) Purpose

4) Participant demographics

5) Methods

6) Table of measured *accuracy* specification results

7) Conclusions

8) Ethics committee identification and approval process

9) Copy of a blank informed consent

10) Investigational device and methods

11) *Pulse oximeter equipment* description

12) Gas delivery methods/description

13) Method for *SpO₂* or calculated *SaO₂* stability determination

14) Safety equipment

15) Reference equipment description and number of *CO-oximeters* used to measure each blood sample

16) Overall description of the study *process*

17) Record of all equipment used in the study

18) Results

19) *Diversity testing* including detailed participant demographics with tabular and graphic description for each participant including: