INTERNATIONAL STANDARD

ISO 9919

Second edition
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Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Appareils électromédicaux — Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical

Reference number
ISO 9919:2005(E)

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 9919 (IEC 60601-2-54) was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 9919:1992), which has been technically revised.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This International Standard covers basic safety and essential performance requirements achievable within the limits of existing technology.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the committee's reasoning that led to a requirement and identifying the hazards that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a **pulse oximeter probe** and a **patient's** tissue.

Annex CC discusses both the formulae used to evaluate the **SpO_2 accuracy** of **pulse oximeter equipment** measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when *in vitro* blood calibration of **pulse oximeter equipment** is needed.

Annex EE presents a guideline for **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.

This International Standard is a Particular Standard, based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— "Replacement" means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— "Addition" means that the relevant text of this Particular Standard is a new element (e.g. subclause, list element, note, table, figure) additional to the General Standard.

— "Amendment" means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change, and test specifications*: italic type*;

— terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold type.**

Throughout this Particular Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

1 Scope

IEC 60601-1:1988, Clause 1 applies, except as follows.

Amendment (add at the end of 1.1):

This International Standard specifies particular requirements for the basic safety and essential performance of **pulse oximeter equipment** intended for use on humans. This includes any part necessary for **normal use**, e.g. the **pulse oximeter monitor**, **pulse oximeter probe**, **probe cable extender**.

These requirements also apply to **pulse oximeter equipment,** including **pulse oximeter monitors**, **pulse oximeter probes** and **probe cable extenders,** that has been **reprocessed**.

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

* This International Standard is not applicable to **pulse oximeter equipment** intended for use in laboratory research applications nor to oximeters that requires a blood sample from the **patient**.

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

This International Standard is not applicable to remote or slave (secondary) devices that display $\mathbf{SpO_2}$ values that are located outside of the **patient environment**.

The requirements of this International Standard which replace or modify requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14937:2000, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*
Amendment 1:2002.
Amendment 2:2004.

IEC 60068-2-6:1995, *Environmental testing — Part 2-6: Tests — Test Fc. Vibration (sinusoidal)*

IEC 60068-2-27:1987, *Environmental testing — Part 2-27: Tests — Test Ea and guidance. Shock*

IEC 60068-2-32:1975, *Environmental testing — Part 2-32: Tests — Test Ed. Free fall*
Amendment 1:1982
Amendment 2:1990

IEC 60068-2-64:1993, *Environmental testing — Part 2-64: Test methods — Test Fh. Vibration, broad-band random (digital control) and guidance*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*
Amendment 1:1995

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

IEC 60601-1:1988[1)], *Medical electrical equipment — Part 1: General requirements for safety*
Amendment 1:1991
Amendment 2:1995

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral Standard: Programmable electrical medical systems*
Amendment 1:1999

IEC 60601-1-6:2004, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

IEC 60825-2:2000, *Safety of laser products — Part 2: Safety of optical fibre communication systems* (OFCS)

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in IEC 60601-1:1988, Clause 2, as amended by the Collateral Standards, and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex JJ.

1) Currently under revision as IEC/CDV 60601-1:2004.

3.1
accuracy
closeness of agreement between a test result and an accepted reference value

NOTE 1 See 50.101.2.2 for the method of calculating the **SpO_2 accuracy** of **pulse oximeter equipment**.

NOTE 2 See also discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.2
controlled desaturation study
hypoxaemia induced in a human subject performed under laboratory conditions

NOTE This can also be referred to as a controlled hypoxaemia (breathdown) study. See also Annex EE.

3.3
CO-oximeter
multiwavelength, optical blood analyser that measures **total haemoglobin concentration** and the concentrations of various haemoglobin derivatives

NOTE The relevant CO-oximetry value is functional saturation of arterial blood, **SaO_2**, which **pulse oximeter equipment** estimates and reports as **SpO_2**.

3.4
data update period
interval in which the **pulse oximeter equipment** algorithm provides new valid data to the display or the **signal output port**

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

3.5
declared range
that portion of the **displayed range** (3.7) of **SpO_2** and pulse rate values over which there is specified **accuracy**

3.6
demonstration mode
mode in which simulated **patient**-numbers or **patient**-waveforms are displayed

NOTE The display in the **demonstration mode** can be mistaken for real-time **patient** data if not properly identified.

3.7
displayed range
range of **SpO_2** and pulse-rate values that can be displayed by the **pulse oximeter equipment**

NOTE This range can extend beyond the **declared range** (3.5).

3.8
fractional oxyhaemoglobin
fractional saturation (obsolete)
FO_2Hb
oxyhaemoglobin concentration cO_2Hb divided by the **total haemoglobin concentration, ctHb**

NOTE 1 This is represented mathematically as:

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

where

cO_2Hb is the concentration of oxyhaemoglobin;

ctHB is the concentration of total haemoglobin.

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

NOTE 2 **Fractional oxyhaemoglobin** is the term used by the National Committee for Clinical Laboratory Sciences (NCCLS) for this ratio.

NOTE 3 NCCLS denotes "concentration" by a prefixed letter c, while in the past the convention of square brackets, e.g. $[O_2Hb]$, was used.

NOTE 4 NCCLS[5] uses the following notations:

— oxyhaemoglobin (O_2Hb);

— deoxyhaemoglobin (HHb);

— carboxyhaemoglobin (COHb);

— methaemoglobin (MetHb);

— sulfhaemoglobin (SuHb); and

— total haemoglobin (tHb).

3.9
functional oxygen saturation
percentage saturation given by the oxyhaemoglobin concentration (cO_2Hb) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (cHHb)

NOTE 1 This is represented mathematically as:

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

NOTE 2 The NCCLS[5] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2.

3.10
functional tester
test device which presents **pulse oximeter equipment** with a signal having a predictable value of **ratio** (3.22) so that the **operator** can observe the resulting displayed value of $\mathbf{SpO_2}$, and compare it to the expected value derived from the **manufacturer's** calibration curve for that particular **pulse oximeter equipment**

NOTE The **accuracy** of the $\mathbf{SpO_2}$ value given by the **pulse oximeter equipment** depends in part on whether the calibration curve of the **pulse oximeter monitor** properly reflects the optical characteristics of the **pulse oximeter probe** and **pulse oximeter probe**-tissue interaction. **Functional testers** are not able to confirm the $\mathbf{SpO_2}$ **accuracy** of the calibration curve or sufficiently assess the optical characteristics of **pulse oximeter probes** to determine their proper calibration. See also FF.4.

3.11
local bias
b
difference between the expectation of the test results ($\mathbf{SpO_2}$) and an accepted reference value ($\mathbf{SaO_2}$)

NOTE 1 For **pulse oximeter equipment,** this is, at a given value of the reference oxygen saturation, the difference between the y-value of the regression line at that coordinate and the y-value of the line of identity, in a plot of $\mathbf{SpO_2}$ versus S_R, or given by:

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

where $SpO_{2fit,\,i}$ is the value of the curve fitted to the test data at the ith reference oxygen saturation value, $S_{R\,i}$

NOTE 2 See also **mean bias** (3.13) and discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.12
manufacturer
natural or legal person with responsibility for the design, the manufacture, the packaging, the reprocessing, the marking, or the **accompanying documents** of **pulse oximeter equipment, pulse oximeter monitors, pulse oximeter probes, probe extender cables** or the adaptation of those items, regardless of whether these operations are carried out by that person him/herself or on his/her behalf by a third party

NOTE Adapted from IEC/CDV2 60601-1:2004, definition 3.54.

3.13
mean bias
B
mean difference between the test and reference values, preserving sign

NOTE 1 For **pulse oximeters,** this is represented mathematically as:

$$B = \frac{\sum_{i=1}^{n} \left(\mathrm{SpO}_{2i} - S_{\mathrm{R}i} \right)}{n}$$

where

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

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

$S_{\mathrm{R}i}$ is the ith reference oxygen saturation value.

NOTE 2 See also **local bias** (3.11) and discussion in Annex CC.

NOTE 3 When defined in this way, **mean bias** is the average of all **local bias** values, b_i.

3.14
normalized
displayed at constant amplitude, independent of the actual magnitude of the signal being displayed

3.15
operator settings
current state of any **pulse oximeter monitor** controls, including **alarm settings**

3.16
precision
closeness of agreement between independent test results obtained under stipulated conditions

NOTE 1 For **pulse oximeter equipment**, it is expressed as the standard deviation of the residuals, s_{res}, represented mathematically as:

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

where

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

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

NOTE 2 See also discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.17
probe cable extender
cable that connects **pulse oximeter monitor** to **pulse oximeter probe**

NOTE 1 Not every **pulse oximeter equipment** utilizes a **probe cable extender**.

NOTE 2 A **probe cable extender** can be an **applied part**.

3.18
pulse oximeter equipment
medical electrical equipment for the non-invasive estimation of **functional oxygen saturation** of arterial haemoglobin (**SpO_2**) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow

NOTE 1 **Pulse oximeter equipment** comprises a **pulse oximeter monitor**, a **probe cable extender**, if provided, and a **pulse oximeter probe**, which can be combined in a single assembly.

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

3.19
pulse oximeter monitor
part of the **pulse oximeter equipment** that encompasses the electronics, display and user interface, excluding the **pulse oximeter probe** and **probe cable extender**

NOTE The **pulse oximeter monitor** can consist of multiple pieces of hardware in separate locations, for example, a telemetry system in which the **applied part** and primary display are in physically different locations.

3.20
pulse oximeter probe
part of the **pulse oximeter equipment** that includes the **applied part** and transducer component

NOTE 1 The terms sensor and transducer have also been used for **pulse oximeter probe**.

NOTE 2 The **pulse oximeter probe** typically consists of a cable and a rigid or flexible assembly containing two photo emitters and a photo detector.

3.21
pulse oximeter probe fault
abnormal condition of the **pulse oximeter probe** or **probe cable extender**, that, if not detected, could compromise **patient** safety

NOTE **Patient** safety can be compromised by providing incorrect values, by exposing the **patient** to high **pulse oximeter probe** temperatures or by introducing a risk of electric shock.

3.22
ratio
Modulation Ratio
Ratio of Ratios
R
basic quantity derived by **pulse oximeter equipment** from time-dependent light intensity measurements

NOTE **Pulse oximeter equipment** uses an empirical calibration curve to derive **SpO_2** from R. See also FF.4.

3.23
*** reprocessing**
any activity, not specified in the **accompanying documents,** that renders a used product ready for re-use

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

NOTE 2 Such activities can occur in healthcare facilities.

3.24
SaO_2
fraction of functional haemoglobin in arterial blood that is saturated with oxygen

NOTE 1 See 50.101.2.2 for requirements on acceptable methods of measurement of **SaO_2**.

NOTE 2 **SaO_2** is **functional oxygen saturation** in arterial blood (see 3.9).

NOTE 3 This is normally expressed as a percentage (multiplying the fraction by 100).

3.25
SpO_2
estimate of **SaO_2** made by **pulse oximeter equipment**

NOTE 1 Two-wavelength **pulse oximeter equipment** cannot compensate for the interference caused by the presence of dyshaemoglobins in their estimation of **SaO_2** [56].

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

3.26
total haemoglobin concentration
ctHb
sum of concentrations of all haemoglobin species including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin (cMetHb), deoxyhaemoglobin (cHHb), sulfhaemoglobin (cSuHb) and carboxyhaemoglobin (cCOHb)

NOTE See also reference [16].

4 General requirements and requirements for tests

IEC 60601-1:1988, Clauses 3 and 4 apply, except as follows.

Addition:

4.101 Other test methods

The **manufacturer** may use type tests different from those detailed within this International Standard if a degree of safety and performance equivalent to that defined in this International Standard is obtained. In the event of dispute, the methods specified herein shall be used as the reference methods.

4.102 Acceptance criteria

Many of the test clauses within this International Standard establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the **manufacturer** specifies in the **accompanying documents** performance levels better than those specified within this International Standard, these **manufacturer**-specified levels become the acceptance levels.

EXAMPLE For a specified level of **SpO_2 accuracy** of 1 %, the **pulse oximeter equipment** is required to have 1 % **SpO_2 accuracy** for all requirements, e.g. during EMC tests.

4.103 Pulse oximeter equipment, parts and accessories

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

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

NOTE 2 **Pulse oximeter monitors** are frequently used with **pulse oximeter probes** and cables from different **manufacturers**. This requirement is intended to ensure compatibility of such combinations.

All specified combinations of **pulse oximeter equipment,** as well as all individual parts and **accessories** specified for use with a **pulse oximeter monitor,** shall be disclosed in the instructions for use. See also 6.8.2 aa) 11) and 6.8.2 aa) 12).

5 Classification

IEC 60601-1:1988, Clause 5 applies.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6 applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

d) *Minimum requirements for marking on **equipment** and on interchangeable parts*

If the size of the **pulse oximeter equipment** does not permit all the markings specified in this clause in the General Standard (IEC 60601-1:1988) and this International Standard, at least the following shall be marked on the **pulse oximeter equipment**:

— the name of the **manufacturer**; and

— a serial number (or Symbol 3.16 from ISO 15223:2000) or lot identifying number or batch identifying number (or Symbol 3.14 from ISO 15223:2000); and

— the words “Attention, consult **accompanying documents**” or Symbol ISO 7000-0434;

— if not provided with an **SpO_2** alarm, a statement to the effect “No SpO_2 Alarms” or Symbol IEC 60417-5319.

Replacement:

f) Model or type reference

— a serial number (or Symbol 3.16 from ISO 15223:2000) or lot or batch (or Symbol 3.14 from ISO 15223:2000) identifying number

— detachable **pulse oximeter probes** shall be marked with type number and a batch (or Symbol 3.14 from ISO 15223:2000) or serial number (or Symbol 3.16 from ISO 15223:2000) on them or on the packaging as appropriate.

— **reprocessed pulse oximeter probes** shall be marked as such.

Addition:

aa) Displayed values

The **pulse oximeter monitor** shall display **functional oxygen saturation** in units of percent **SpO_2** and shall be marked as % **SpO_2** or **SpO_2**. Display of pulse rate shall be in units of reciprocal minutes (1/min), for example, beats/min. All other displayed measured values shall be marked in appropriate units

bb) Do not re-use

If the **pulse oximeter probe** is not for re-use, the package or the **pulse oximeter probe** itself shall be marked with an indication that the **pulse oximeter probe** is not for re-use, or with Symbol 3.2 from ISO 15223:2000.

If the **pulse oximeter probe** is for single **patient** use, the package or the **pulse oximeter probe** itself shall be marked with an indication that the **pulse oximeter probe** is for single **patient** use.

cc) Sterile

Packages shall be marked with Symbols 3.20 through 3.24 from ISO 15223:2000, where appropriate.

dd) Expiration date

Where appropriate, an indication of the time limit for safe use with Symbol 3.12 from ISO 15223:2000. The date shall be expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day. The date shall be adjacent to the symbol.

ee) The **pulse oximeter monitor** and its parts shall be marked with regard to proper disposal, as appropriate.

6.8.1 General

Amendment, add after the first sentence:

The documents may be made available by electronic means provided that the **user** is afforded the opportunity to request the **accompanying documents** in paper form.

6.8.2 Instructions for use

Addition:

aa) Additional general information:

The instructions for use shall indicate the following:

1) that the **pulse oximeter equipment** is calibrated to display **functional oxygen saturation**;

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

   EXAMPLE Clinicians performing photodynamic therapy.

3) any types of interference known to influence the function or **accuracies** of the **pulse oximeter equipment;**

   EXAMPLES Ambient light (including photodynamic therapy); physical movement (**patient** and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; electrosurgical units; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the **pulse oximeter probe.**

4) the **displayed ranges** of $\mathbf{SpO_2}$ and pulse rate;

5) description of the **data update period,** the effect of data averaging and other signal processing on the displayed and transmitted data values of $\mathbf{SpO_2}$ and pulse rate, along with the **alarm condition delay** and **alarm signal generation delay** in any selectable operating mode that affects these properties;

   NOTE See also Annex GG for an example of how to assess and describe response time graphically.

6) if **physiological alarm conditions** are provided and automatic self-test of **alarm signal** generation is not provided, the method for **operator**-initiated testing of **alarm signal** generation;

7) if the **pulse oximeter equipment** requires in-service calibration, a suitable calibration procedure;

8) a description of the signal inadequacy indicator and its function. If there is a waveform, the 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 Clause 101.

9) if the **pulse oximeter equipment** is provided with adjustable **alarm limits**, the range of adjustment of the **alarm limits**;

10) if no $\mathbf{SpO_2}$ or pulse rate **alarm condition** is provided, a statement to that effect;

11) for **pulse oximeter monitors**, the **pulse oximeter probe(s)** with which the **pulse oximeter monitor** has been validated and tested for compliance with this International Standard. The list may be made available by electronic means (see also 4.103);

12) for **pulse oximeter probes** and **probe cable extenders**, the **pulse oximeter monitor(s)** with which they have been validated and tested for compliance with this International Standard. The list may be made available by electronic means (see also 4.103);

13) the recommended maximum application time for each type of **pulse oximeter probe** at a single site;

14) if the **pulse oximeter equipment** is provided with temperature capability such that the **pulse oximeter probe** can operate at greater than 41 °C, specific instructions emphasizing the importance of proper **pulse oximeter probe** application, without excessive pressure. In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C;

15) a description of the sequence of actions required by the **operator** for permitting temperatures greater than 41 °C (see 42.3);

16) the maximum temperature that can be obtained at the **pulse oximeter probe**-tissue interface if the **pulse oximeter equipment** is provided with an **operator**-adjustable control for permitting temperatures greater than 41 °C (see 42.3);

17) if the **pulse oximeter equipment** is provided with temperature capability such that the **pulse oximeter probe** can operate at greater than 41 °C, a statement to the effect that temperature settings greater than 41 °C shall not be used on patients less than one year of age.

18) all necessary information, as regards toxicity and/or action on tissues, about materials with which the **patient** or any other person can come into contact;

19) if **pulse oximeter probes** are delivered in sterile packaging, the instructions for use shall contain the necessary information regarding how to re-sterilize in the event of damage to the sterile packaging, if re-sterilization is permissible;

20) for each **pulse oximeter probe** and **probe cable extender**, a caution statement to the effect that probes and cables are designed for use with specific monitors. The user and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result;

21) the specified use of the **pulse oximeter probe** regarding:

— **patient** population (e.g. age, weight);

— part of the body or type of tissue applied to; and

— application (e.g. environment, frequency of use, location, mobility);

22) information concerning the disposal of the **pulse oximeter equipment** or components thereof.

6.8.3 Technical description

Addition:

aa) Additional general information:

The technical description shall include the following:

1) * a statement to the effect that a functional tester cannot be used to assess the accuracy of a **pulse oximeter probe** or a **pulse oximeter monitor** (see also Annex FF);

2) a statement to the effect that, if there is independent demonstration that a particular calibration curve is accurate for the combination of a **pulse oximeter monitor** and a **pulse oximeter probe**, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular **pulse oximeter monitor** is reproducing that calibration curve. See also Annex FF.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows.

10.1 Transport and storage

Amendment (add at end of paragraph):

Packaging of sterile **equipment** or **equipment** parts shall ensure sterile conditions until opened or damaged or until its expiration date is reached.

Consideration should be given to the disposal of packaging waste.

11 Not used

12 Not used

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies, except as follows.

14.6 Types B, BF and CF equipment

Amendment [add at the end of the list element c)]:

Applied parts of **pulse oximeters** shall be **type BF** or **type CF applied parts**.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies, except as follows.

19.4 Tests

Amendment:

h) 9)

Replace the second sentence of the first paragraph "Alternatively...immersed" with:

Pulse oximeter probes marked for temporary immersion using the IP code second characteristic numeral 7 of IEC 60529 shall be **patient leakage current** tested as follows:

*Immerse that part of the **pulse oximeter probe** marked for temporary immersion in a normal saline (0,9 g/l NaCl in H_2O) solution that is maintained at a temperature between 20 °C and 25 °C, for 60 s. While the **pulse oximeter probe** is still immersed, measure **patient leakage current**.*

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies, except as follows.

20.4 Tests

Addition:

aa) **Pulse oximeter probes** marked for temporary immersion using the IP code second characteristic numeral 7 of IEC 60529 shall be dielectrically tested as follows:

*Immerse only that part of the **pulse oximeter probe** marked for temporary immersion in a normal saline (0,9 g/l NaCl in H_2O) solution that is maintained at a temperature between 20 °C and 25 °C. After 60 s and while that part of the **pulse oximeter probe** is still immersed, perform the tests for dielectric strength as specified in 20.4 a) of IEC 60601-1:1988.*

21 * Mechanical strength

IEC 60601-1:1988, Clause 21 applies, except as follows.

21.5

*Amendment (add between "**safety hazard**" and "as a"):*

and shall function normally

Addition:

21.101 * Shock and vibration

Pulse oximeter equipment or its parts not intended for use during **patient** transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by **normal use,** pushing, impact, dropping and rough handling. **Stationary equipment** is exempt from the requirements of this subclause.

After the following tests, **pulse oximeter equipment** shall not cause a **safety hazard** and shall function normally.

a) Shock test in accordance with IEC 60068-2-27, using the following conditions:

- peak acceleration: 150 m/s^2 (15,3 g);
- duration: 11 ms;
- pulse shape: half-sine;
- number of shocks: 3 shocks per direction per axis (18 total).

NOTE **Pulse oximeter equipment** tested and complying with the requirements in 21.5 of IEC 60601-1:1988 is considered to comply with this requirement.

b) Broad-band random vibration test in accordance with IEC 60068-2-64, using the following conditions:

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration amplitude:
  - 10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;
  - 100 Hz to 200 Hz: −3 db per octave;
  - 200 Hz to 2 000 Hz: 0,5 (m/s^2)^2/Hz;
- duration: 10 min per perpendicular axis (3 total).

21.102 * Shock and vibration for transport

Pulse oximeter equipment or its parts, intended for use during **patient** transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by **normal use,** pushing, impact, dropping, and rough handling.

After the following tests, **pulse oximeter equipment** shall not cause a **safety hazard** and shall function normally.

NOTE **Equipment** tested and complying with the requirements in 21.102 in total or part, is considered to comply with the corresponding requirements of 21.101.

a) Shock test in accordance with IEC 60068-2-27, using the following conditions:

- peak acceleration: 1 000 m/s^2 (102 g);
- duration: 6 ms;
- pulse shape: half-sine;
- number of shocks: 3 shocks per direction per axis (18 total);

b) Broad-band random vibration test in accordance with IEC 60068-2-64, using the following conditions:

- frequency range: 10 Hz to 2 000 Hz;

— resolution: 10 Hz;

— acceleration amplitude:

  — 10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$;

  — 100 Hz to 200 Hz: −7 db per octave;

  — 200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$;

— duration: 30 min per perpendicular axis (3 total).

c) For **mobile pulse oximeter equipment**, free fall to IEC 60068-2-32, using Procedure 1 and the following conditions:

— height: 0,1 m;

— number of falls: one;

— direction: vertical, (normal operating position).

d) For **portable pulse oximeter equipment**, free fall to IEC 60068-2-32, using Procedure 2 and the following conditions:

— height: 0,25 m;

— number of falls: one;

— direction: on each of the six surfaces.

For **portable pulse oximeter equipment** that is intended to be used with a carrying case, that case may be applied to the **equipment** during this test.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 text does not apply.

Replacement:

The relevant requirements of IEC 60825-1 apply. If laser light barriers or similar products are used within **pulse oximeter equipment**, they shall comply with the requirements of IEC 60825-1. In the case of laser fibre optics, the requirements of IEC 60825-2 shall apply.

33 Infra-red radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultraviolet radiation

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

36 * Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies, except as follows.

Addition:

Pulse oximeter equipment shall meet the requirements of IEC 60601-1-2.

NOTE 1 **Pulse oximeter equipment** is not considered **life-supporting equipment or system** as defined in IEC 60601-1-2.

For the purposes of IEC 60601-1-2:2001, 36.202.1 j) Compliance criteria, the **pulse oximeter equipment** shall operate within its specified **SpO_2 accuracy** limits and pulse rate **accuracy** limits during immunity testing. The **pulse oximeter equipment** shall be tested at an **SpO_2** reading within the calibrated range that is at least 5 % different from that of a noise-induced value and less than (100 % minus the **SpO_2 accuracy** of the **pulse oximeter equipment**).

NOTE 2 The noise-induced value could be a value, for example, where R = 1 or R = the ratio of the gain from the IR channel to the gain from the red channel. Other noise-induced values have been observed.

The pulse rate shall be different from that of the noise-induced signal frequency and within the specified range of the pulse rate display.

In the event of disruption during transient tests as defined by IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5 and IEC 61000-4-11, the **pulse oximeter equipment** shall recover from any disruption within 30 s. The **SpO_2** and pulse rate signal may be derived from a **patient** simulator device for these tests.

In addition to these requirements, **pulse oximeter equipment** intended for use during **patient** transport outside the healthcare facility shall comply with IEC 60601-1-2:2001, 36.202.3 a) 1) at the **immunity test level** of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2 500 MHz (see IEC 60601-1-2:2001, Table 209).

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 applies.

38 Marking, accompanying documents

IEC 60601-1:1988, Clause 38 applies.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 applies.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies, except as follows.

Replacement:

42.3 * In **normal condition** and **single fault-condition,** the default limit for maximum power delivered to the energized **pulse oximeter probe** shall not be sufficient to produce a temperature exceeding 41 °C at the **pulse oximeter probe**-tissue interface when the skin temperature is initially at 35 °C. See also Annex BB.

If **pulse oximeter equipment** is provided with a mode (or means) to provide sufficient power to its energized **pulse oximeter probe** to produce a temperature exceeding 41 °C at the **pulse oximeter probe**-tissue interface when the skin temperature is initially at 35 °C, then:

a) the **pulse oximeter equipment** shall have an **operator**-adjustable control for permitting this mode. There shall be a deliberate sequence of **operator** actions needed to activate this mode;

b) there shall be an indication when the **pulse oximeter equipment** is in this mode;

c) in **normal condition** and **single fault-condition,** the maximum power delivered to an energized **pulse oximeter probe** in this mode shall not be sufficient to produce a temperature exceeding 43 °C at the **pulse oximeter probe**-tissue interface when the skin temperature is initially at 35 °C;

d) the **pulse oximeter equipment** shall provide a means to limit the duration of continuous operation at temperatures above 41 °C. The application times at elevated temperatures shall not exceed a continuous 4 h at 43 °C or a continuous 8 h at 42 °C;

e) the **accompanying documents** shall disclose the maximum temperature possible at the **pulse oximeter probe**-tissue interface; and

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

*Check the compliance by measuring the maximum surface temperature of the **pulse oximeter probe**-tissue interface, under **normal condition** and **single fault-condition**, by using the procedure disclosed in the technical description. See also BB.3.*

43 Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows.

Addition:

43.101 * Pulse oximeter equipment used in conjunction with oxidants

43.101.1 Ignitable material

In order to reduce the risk to **patients**, to other persons or to the surroundings due to fire, ignitable material, under **normal condition** and **single fault-condition**, shall not, at the same time, be subjected to conditions in which

— the temperature of the material is raised to its minimum ignition temperature, and

— an oxidant, for example nitrous oxide, is present.

NOTE For oxygen concentrations up to 25 % or partial pressures up to 27,5 kPa, when no other oxidants are present, the requirements in IEC 60601-1:1988 are considered to be sufficient.

The minimum ignition temperature is determined in accordance with IEC 60079-4 using the oxidizing conditions present under **normal condition** and **single fault-condition**.

*Check the compliance by determining the temperature to which the material is raised under **normal condition** and **single fault-condition**.*

43.101.2 Sparking

If sparking can occur under **normal condition** or **single fault-condition**, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

*Check the compliance by observing if ignition occurs under the most unfavourable combination of **normal conditions** with a single fault.*

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

IEC 60601-1:1988, Clause 44 applies, except as follows.

44.6 * Ingress of liquids

Amendment (add as second sentence, first paragraph):

Pulse oximeter equipment shall not cause a **safety hazard** and shall function normally after undergoing

— the tests in IEC 60529 for IPX2, or

— the tests in IEC 60529 for IPX1 and the spillage test of 44.3 in IEC 60601-1:1988.

Add at the end of test requirement last sentence:

*and the **pulse oximeter equipment** shall continue to function normally.*

44.7 Cleaning, sterilization and disinfection

Amendment (add before the compliance test):

Pulse oximeter equipment or accessories labelled sterile shall have been sterilized using an appropriate, validated method in accordance with ISO 14937.

Packaging for non-sterile **pulse oximeter equipment** or accessories shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness, and shall be designed to minimize the risk of contamination.

Amendment (add at the end of the compliance test):

*If a sterility claim is made, review the **accompanying documents** for methods of sterilization and disinfection, and compare to the relevant validation reports.*

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

46 Human errors

IEC 60601-1:1988, Clause 46 does not apply.

Replacement:

NOTE Attention is drawn to IEC 60601-1-6.

47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, except as follows.

Addition:

49.101 Power-failure alarm condition

If **pulse oximeter equipment** is provided with a **physiological alarm condition**, it shall provide at least a **medium priority alarm signal** when the power falls below the minimum value for normal operation.

NOTE After the loss of power, the **alarm system** is not expected to repeat **alarm signals** indefinitely.

Check the compliance by functional testing.

49.102 Pulse oximeter equipment operation following interruption of the power supply

49.102.1 Settings and data storage following short interruptions or automatic switchover

When the **supply mains** to the **pulse oximeter equipment** is interrupted for less than 30 s or automatic switchover to an **internal electrical power source** occurs, all settings and all stored **patient** data shall not be changed.

NOTE 1 The **pulse oximeter equipment** does not have to be operating during the interruption of the **supply mains**.

NOTE 2 Settings include **operator settings**, **user** settings, and the mode of operation.

*Check the compliance by observing the **pulse oximeter equipment** settings and stored **patient** data and then interrupting the **supply mains** for a period of between 25 s and 30 s by disconnecting the **power supply cord**. After reestablishment of power, the above settings and stored data shall be the same.*

49.102.2 Operation following long interruptions

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

*Check the compliance by inspection of the **accompanying documents**.*

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies, except as follows.

Addition:

50.101 * SpO_2 accuracy of pulse oximeter equipment

50.101.1 * Specification

The **SpO_2 accuracy** of **pulse oximeter equipment** shall be a root-mean-square difference of less than or equal to 4,0 % **SpO_2** over the range of 70 % to 100 % **SaO_2**.

The **declared ranges** of **SpO_2** and **SpO_2 accuracy** over those ranges shall be disclosed in the instructions for use. The **SpO_2 accuracy** shall be stated over the range 70 % to 100 % (see 50.101.2.1). **SpO_2 accuracy** information shall be accompanied by a note reminding the reader that, because **pulse oximeter equipment** measurements are statistically distributed, only about two-thirds of **pulse oximeter equipment** measurements can be expected to fall within $\pm A_{rms}$ of the value measured by a **CO-oximeter**. When a **pulse oximeter monitor** is suitable for use with a variety of **pulse oximeter probes**, **SpO_2 accuracy** information shall be made available for each type of **pulse oximeter probe**. Additional **SpO_2 accuracy** specifications over other ranges may also be provided.

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

EXAMPLE 1 A specified **SpO_2 accuracy** range of 60 % to 80 % **SpO_2**.

EXAMPLE 2 A specified **SpO_2 accuracy** range of 60 % to 70 % **SpO_2**.

*Check the compliance by following the requirements of 50.101.2 and by inspection of the **accompanying documents**.*

50.101.2 Determination of SpO_2 accuracy

50.101.2.1 * Data collection

The claims of **SpO_2 accuracy** shall be supported by clinical study measurements taken over the full range, ± 3 %, of **SaO_2** values for which **SpO_2 accuracy** is claimed. The clinical study shall comply with the requirements of ISO 14155-1 and ISO 14155-2.

Data points should be recorded with comparable density over the full range claimed.

NOTE See also Annex EE.

Conditions which adversely affect the **SpO_2 accuracy** need not be stated as part of the **SpO_2 accuracy** specification, but shall be disclosed in the **accompanying documents**, as required by 6.8.2 aa) 3.

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

Functional testers or **patient** simulators shall not be used to validate the **SpO_2 accuracy** of **pulse oximeter equipment**.

50.101.2.2 * Data analysis

For each range specified, **SpO_2 accuracy** of the **pulse oximeter equipment** shall be stated in terms of the root-mean-square (rms) difference between measured values (SpO_{2i}) and reference values (S_{Ri}), as given by the following formula:

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

NOTE 1 The concepts of bias and **precision** as given in reference [3] and ambiguity as given in reference [54] also have value in representing the **accuracy** of **medical electrical equipment**. The decision to require the form of **SpO_2 accuracy** stated above (which has been traditional in pulse oximetry, although under the misnomer "standard deviation") is based on the belief that it will be more widely understood by the general community of clinical **operators** and on the recognition that in some cases it represents the overall **SpO_2 accuracy** of **pulse oximeter equipment** better than do bias and **precision**.

NOTE 2 Attention is also drawn to VIM [64] and the GUM (*Guide to the Expression of Uncertainty in Measurement*) [65] as well as the documents of ISO/TC 69, *Applications of statistical methods*, for determination of accuracy and precision.

The standard reference for the **SpO_2 accuracy** as read by **pulse oximeter equipment** shall be traceable to **SaO_2** values obtained from **CO-oximeter** analysis of simultaneously drawn arterial blood. The **CO-oximeter** should have a **SaO_2 accuracy** of 1 % (1 standard deviation) or better over the range for which the **manufacturer** makes **SpO_2 accuracy** claims. Quality assurance procedures for verifying **CO-oximeter accuracy** that are required in laboratories reporting clinical data should be utilized.

EXAMPLE Available procedures are available for example from NCCLS [5] and the College of American Pathologists [18].

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

NOTE 4 See also Annex EE.

50.101.2.3 Characteristics of the clinical study population

The summary of the clinical study report used to access **SpO_2 accuracy** shall state whether the test subjects were sick or healthy and shall describe their skin colour, age and gender. This information shall be disclosed in the **accompanying documents**.

50.102 Accuracy under conditions of motion

If a **manufacturer** claims that the **pulse oximeter equipment** is accurate during motion, **accuracy** specifications during motion shall be disclosed in the instructions for use.

A summary of the test methods used to establish the **accuracy** claims during motion shall be disclosed in the technical description.

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

50.103 Accuracy under conditions of low perfusion

If a **manufacturer** claims that the **pulse oximeter equipment** is accurate under conditions of low perfusion, **accuracy** specifications under these conditions shall be disclosed in the instructions for use.

A summary of the test methods used to establish the **accuracy** claims under conditions of low perfusion shall be disclosed in the technical description.

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

50.104 Pulse rate accuracy

Pulse rate **accuracy** shall be stated as the root-mean-square (rms) difference between paired pulse rate data recorded with the **pulse oximeter equipment** and with a reference method. Pulse rate **accuracy** shall be stated either over the full claimed range of the **pulse oximeter equipment** or as separate pulse rate **accuracy** specifications over segments of that range. The reference method for the computation of pulse rate **accuracy** may be, for example, an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultation or a second **pulse oximeter equipment** which has been qualified by comparison to one of these references.

Check the compliance by inspection.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows.

Addition:

51.101 * Data update period

There shall be an indication that **SpO_2** or pulse rate data is not current when the **data update period** is greater than 30 s. There shall be at least a **low priority alarm condition** generated when the **data update period** exceeds 30 s.

These times may be shorter than 30 s and shall be disclosed in the instructions for use. A maximum update period of saturation and pulse rate data shorter than 30 s is recommended for continuous neonatal and diagnostic applications.

Check the compliance by inspection.

51.102 Detection of pulse oximeter probe and probe cable extender fault

If **pulse oximeter equipment** is provided with any **physiological alarm conditions**, it shall be provided with an **alarm system** that monitors for **pulse oximeter probe faults**. That **alarm condition** shall be activated when any wire in the **pulse oximeter probe** cable or **probe cable extender** is opened or shorted to any other wire in the **pulse oximeter probe** cable or **probe cable extender** that causes other than normal operation.

If **pulse oximeter equipment** is not provided with any **physiological alarm conditions**, it shall provide indication of abnormal operation (e.g. blank display) for **pulse oximeter probe faults**. The indication shall be described in the instructions for use.

It shall be the **manufacturer's** responsibility to perform a **risk analysis** to determine whether a given fault (open or short) will result in a **safety hazard** and requires **operator** awareness.

NOTE Unused wires in the **pulse oximeter probe** cable or **probe cable extender** are not required to be tested.

Check the compliance with the following test:

*Disconnect the **pulse oximeter probe** from the **pulse oximeter equipment** and place in series with it a circuit with which each **pulse oximeter probe** wire can be opened or shorted to any other **pulse oximeter probe** wire. Repeat for any **probe cable extender.** Verify that either a **pulse oximeter probe fault** is indicated or that the **pulse oximeter equipment** continues normal operation.*

52 Abnormal operation and fault-conditions

IEC 60601-1:1988, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies, except as follows.

Addition (add at the end of Clause 54):

Planning and design of products applying this International Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex II.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

Addition:

101 * Signal inadequacy

An indicator of signal inadequacy (e.g. a visual **information signal** or a **low priority alarm signal**) shall be provided to the **operator** that the **SpO_2** or pulse rate value displayed is potentially incorrect. Symbol ISO 7000-0435 may be used for this indication. A description of the indicator and its function shall be provided in the **accompanying documents**.

NOTE A **normalized** waveform does not satisfy this requirement and is more likely to mask an unreliable signal. A non-**normalized** pulse waveform display does satisfy this requirement for a signal inadequacy indicator.

Check the compliance by inspection.

102 * Pulse oximeter probes and probe cable extenders

102.1 General

All **pulse oximeter probes** and **probe cable extenders** shall comply with the requirements of this International Standard, whether they are produced by the **manufacturer** of the **pulse oximeter monitor** or by another entity ("third party manufacturer" or healthcare provider) or are **reprocessed**.

Manufacturers of **reprocessed pulse oximeter probes** and **probe cable extenders** shall conduct tests to ensure that all **pulse oximeter equipment** specifications are met with each model of **pulse oximeter monitor** with which the **pulse oximeter probe** or **probe cable extender** is intended to be used. In the **accompanying documents,** the **manufacturer** shall list all **pulse oximeter monitors** with which compatibility is claimed.

It is the responsibility of the **manufacturer** to validate their processes to ensure that any new or **reprocessed** product complies with the requirements of this International Standard.

Check the compliance by the tests of this International Standard.

102.2 Labelling

The model or type reference of at least one **pulse oximeter monitor** shall be supplied with each **pulse oximeter probe,** compliant with 102.1.

Statements shall be included with each **pulse oximeter probe** or cable to the effect that

— probes are designed for use with specific monitors,

— the operator is responsible for checking the compatibility of the monitor, probe and cable before use, and

— incompatible components can result in degraded performance.

See also 102.1.

*Check the compliance by inspection of the **accompanying documents**.*

103 Saturation pulse information signal

If a variable-pitch auditory **information signal** is provided to indicate the pulse signal, the pitch change shall follow the **SpO_2** reading, that is, as the **SpO_2** reading lowers, the pitch shall also be lowered.

Check the compliance by inspection.

104 Alarm systems

The requirements of IEC 60601-1-8:2003 apply, except as follows.

201.1.2 * Assignment of priority

Amendment (add after the Note):

If **pulse oximeter equipment** is provided with a **physiological alarm condition**, there shall be an **alarm condition** for low **SpO_2** level of at least **medium priority**.

NOTE In certain clinical applications, such as neonatal monitoring, the provision of a high **SpO_2** level **alarm condition** can provide an additional safety feature.

201.5.4 * Default alarm preset

201.5.4.1 General requirements

Amendment (add before the first sentence):

If the **pulse oximeter monitor** is equipped with a low $\mathbf{SpO_2}$ level **physiological alarm condition,** this **alarm limit** in the **manufacturer**-configured **alarm preset** shall not be less than 85 % $\mathbf{SpO_2}$.

Addition:

aa) Unless the low $\mathbf{SpO_2}$ **alarm limit** is displayed continuously, the low $\mathbf{SpO_2}$ **alarm limit** of any **operator**-configured **alarm preset** shall not be less than the low $\mathbf{SpO_2}$ **alarm limit** stored in the **default alarm preset**.

201.8 Alarm signal inactivation states

201.8.3 Indication and access

Amendment (add at the end of the third paragraph):

The **manufacturer**-configured default **audio-paused** or **alarm-paused** interval of **pulse oximeter equipment** shall not exceed 2 min.

105 Appendices of IEC 60601-1:1988

The Appendices of IEC 60601-1:1988 apply.

Addition:

The subsequent annexes form an additional element of this International Standard.

Annex AA
(informative)

Rationale

This annex provides a rationale for some requirements of this International Standard and is intended for those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this International Standard necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this International Standard. The numbering is, therefore, not consecutive.

Pulse oximetry facilitates **patient** care management by providing an approximation of arterial haemoglobin saturation with oxygen, and allows for the possibility of early detection of the catastrophic events associated with **patient** hypoxaemia.

The present technology requires an adequate concentration of haemoglobin, a pulsatile change in blood flow, and light transmission through a tissue bed in order to provide effective *in vivo* approximation of human haemoglobin saturation with oxygen. **Pulse oximeter equipment** is not typically capable of functioning effectively during cardiopulmonary bypass or at extreme low-flow states, and is not at present intended as a means for the measurement of blood flow or blood volume.

With the limitations of the present technology, **pulse oximeter equipment** does not permit a **precision** measurement. The presently marketed *in vivo* **pulse oximeter equipment** is not a replacement for measurement of blood samples by *in vitro* optical oximeters. The values derived from pulse oximetry are not a measurement of blood or solid-tissue oxygen tension. Pulse oximetry provides no direct indication of oxygen delivery to tissue, or of tissue oxygen consumption.

AA.1 Scope

Devices used in laboratory research applications are often experimental or intended primarily for non-medical uses. Imposition of the requirements of this International Standard on devices used for research might unduly limit development of beneficial new techniques or devices.

AA.3.23 Reprocessing

The term **reprocessing** was chosen, instead of terms such as remanufacturing or refurbishing, because the committee was looking for the widest possible term. Any activity, outside the instructions given by the **manufacturer**, for subsequent reuse is considered **reprocessing**. This includes cleaning and reuse of a single-use **probe**, as well as using a used single-use **probe** as the raw material for a remanufacturing process to create a "new" **probe** for use.

AA.6.8.3 Technical description

aa) 1)

The appropriate application of **functional testers** has been misunderstood by some **operators** or **users**. See Annex FF for a discussion of this issue.

AA.21 Mechanical strength

Equipment, including **pulse oximeter equipment,** in **normal use** will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, **equipment** needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in **normal use**.

These tests were chosen by first qualitatively assessing the relative severity of the scenarios within various environments [i.e. home, hospital and transport (wings and wheels)] on various sizes and types of **equipment** (i.e. **hand-held, portable** and **mobile equipment**). The result of the committee's analysis is shown in Table AA.1 for the various types of shock and vibration which can be experienced.

Table AA.1 — Qualitative assessment of pulse oximeter equipment shock and vibration environment

Equipment category	Location															
	Standard environment								Transport vehicle							
	Home				Hospital				Wheels				Wings/Rotary			
Mobile	D1	S1	V1	B1	D1	S2	V1	B1	D1	S3	V2	B3	D1	S3	V3	B1
Portable	D1	S2	V0	B0	D1	S2	V1	B1	D1	S3	V2	B3	D1	S3	V3	B1
Hand-held	D3	S0	V0	B0	D3	S0	V1	B0	D3	S3	V2	B3	D3	S3	V3	B1
Stationary	None				None				Not applicable							
S = shock; V = vibration; D = drop; B = bump Rating: 0 = no test, 1 = least severe; 2 = moderate severity; 3 = most severe																

Rationale for combining home and hospital environments: the committee recognized that for the case of shock, vibration and bump, the environment in the home should be slightly less severe than that expected in the hospital. The committee chose to combine these two categories, both for simplicity and because many pieces of **medical electrical equipment** are routinely moved from the hospital to the home environment and vice versa.

After qualitative assessment, the committee assessed the International Standards in the IEC 60068 series relevant for environmental testing, and their respective rationales, as well as the IEC 60721 series of guidance documents.

In selecting the requirements, the committee reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance[23] for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with IEC 60721-3-7. This International Standard mapped well to the requirements defined in Table AA.1. There is also a guidance document, IEC/TR 60721-4-7, that helps to correlate environmental condition classes of IEC 60721-3 to environmental tests according the IEC 60068 series. The aforementioned International Standards specify 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. The committee found the classes 7M1 and 7M3 to best represent the conditions seen during **patient** transport within healthcare facilities and **patient** transport outside healthcare facilities, respectively. The committee agreed that different tests and test levels should be applied to **equipment** intended for use in a healthcare facility versus **equipment** intended for use during **patient** transport outside the healthcare facility.

Verifying that the **equipment** is functioning within the **manufacturer's** specifications while the vibration (random and sinusoidal) tests are being conducted is not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety to the **equipment** that would not outweigh the costs. Verifying proper functioning after completion of the tests is believed adequate.

AA.21.101 Shock and vibration

Equipment, including **pulse oximeter equipment,** in **normal use,** used within a healthcare facility, or home environment will be subjected to these mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, **equipment** intended to be used in healthcare and home environments needs to be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M1. IEC 60721-3-7 indicates that this class applies to use at, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

AA.21.102 Shock and vibration for transport

Equipment, including **pulse oximeter equipment,** in **normal use,** used for **patient** transport outside a healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump and drop) and could randomly be subjected to additional stresses. Therefore, **equipment** intended to be used for **patient** transport outside a healthcare facility needs to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high-level shocks. Rough handling and transfer of **equipment** is expected in these environments.

There are no established generalized test programmes that exactly reproduce the range of vibration and shock conditions that **equipment** can meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this clause have been chosen on the basis that **equipment** tested to these levels are likely to withstand the normal dynamic disturbances that they can meet when used in the range of vehicles and aircraft (including helicopters) likely to be used for carrying **patients**.

The use of **equipment** in road ambulances, fixed wing and rotary wing aircraft, naval vessels, etc. can require additional tests and verification of safety when used in these different environments.

For free-fall testing described in IEC 60068-2-32, the committee used the rationale for the various levels to gauge the severity of the test based on Table AA.1 of this rationale. The category of the test level chosen for **portable equipment** was portable cases. The committee agreed that **pulse oximeter equipment** should be required to meet a level of drop-testing for the transport environment. The committee also agreed that much **pulse oximeter equipment** is likely to be supplied with a protective or carrying case for use in transport environments. It was agreed among the committee that it would be an adequate test for **portable equipment** to be dropped while in their carrying cases, as this would be most like the real world environment. For **mobile equipment**, a less severe level was chosen since wheeled **equipment** is typically heavier.

AA.36 Electromagnetic compatibility

The radiated immunity environment during **patient** transport outside the healthcare facility (e.g. land and air ambulances) is harsher than the typical in-hospital environment. The main cause of this difference is the presence of multiple two-way radio communication systems that intentionally radiate electromagnetic energy. In both of these environments, **pulse oximeter equipment** meeting the requirements of IEC 60601-1-2:2001 is adequately protected from unintentional sources of electromagnetic interference. The additional testing needed to qualify **pulse oximeter equipment** for the transport environment outside the healthcare facility needs to address only this additional threat.

Two-way communication devices are used to transmit both voice and **patient** data. Experience has shown that typical field strengths[13] measured in this environment can be as high as 20 V/m. Voice and **patient** data typically have modulation bandwidths that exceed 1 kHz with a centre-point of voice modulation of 1 kHz. The committee chose a single test point to represent the typical information modulation band. A signal with 80 % amplitude modulation at 1 kHz was chosen, and is consistent with the base radiated immunity standard IEC 61000-4-3 that also uses 80 % amplitude-modulated signal at 1 kHz. A 20 V_{rms}/m 80 % amplitude-modulated signal has a peak-to-peak amplitude of 90,5 V.

The change to 20 V/m is also compatible with the requirements of the FDA reviewer's guidance [23].

AA.42.3

IEC 60601-1:1988 specifies that **applied parts** of **equipment** not intended to supply heat to a **patient** shall not have surface temperatures exceeding 41 °C. There are no known national deviations to this limit.

The following text appears in draft IEC/CDV 60601-1:2004:

11.1.2.2 **Applied parts** not intended to supply heat to a **patient**

> The limits of Table 22 shall apply. If the surface temperature of an **applied part** exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use and the clinical effects with respect to characteristics such as body surface, maturity of **patients**, medications being taken or surface pressure shall be determined and documented in the **risk management file**. Where 41 °C is not exceeded, no justification is required.

After reviewing the published experimental studies, this committee came to believe that under some circumstances it is safe to permit temperatures higher than 41 °C for **pulse oximeter probes**, and that the potential benefit of permitting higher-current operation of **pulse oximeter probes** warrants making this option available to the clinician. This rationale explains our decision, and points out areas where new experimental data could lead to still more forgiving limits.

Today's **pulse oximeter equipment** is very safe. Between 1996 and 1997, the FDA's Medical Device Report system shows only 14 reports of suspected burns by **pulse oximeter probes**. Each year, in this same period, there were many millions of long-term applications of **pulse oximeter probes** to **patients** in the United States. Furthermore, it is the unanimous experience of the industry experts of this committee that, at least for **pulse oximeter equipment** manufactured in the last several years and used with the **manufacturer's** recommended **pulse oximeter probes**, investigation of these rare cases of suspected burns has always produced the conclusion that either

— there was no thermal injury (the most common alternative explanation of observed symptoms is that they are pressure sores caused by improper **pulse oximeter probe** application), or that

— some component of the **pulse oximeter equipment** malfunctioned, causing more current to flow through the **pulse oximeter probe** than was intended in the design.

Table AA.2 — Allowable maximum temperatures for skin contact with medical electrical equipment applied parts (adapted from Table 22, IEC/CDV 60601-1:2004)

Contact time of applied part with patient skin t min	**Maximum temperature** [a] [b] °C		
	Material of applied part		
	Metal and liquids	**Glass, porcelain, vitreous material**	**Moulded material, plastic, rubber, wood**
$t < 1$	51	56	60
$1 \leqslant t < 10$	48	48	48
$10 \leqslant t$	43	43	43

[a] These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10% of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10% of the head surface. Where this is the case, appropriate limits shall be determined and documented in the **risk management file.**

[b] Where it is necessary for **applied parts** to exceed the temperature limits of this table in order to provide clinical benefit, the **risk management file** shall contain documentation showing that the resulting benefit exceeds any associated increase in **risk**.

While efforts should continue to reduce even further the frequency of malfunctions, it is worth re-examining the temperature threshold in the design rules. Increasing the permissible temperature allows an increase in the power that can be supplied to the **pulse oximeter probe**'**s** light sources. This results in a greater light output, which enhances the signal-to-noise ratio. In borderline cases, this can make the difference between having a useful measurement of oxygen saturation and having none.

It is possible to increase the signal output of **pulse oximeter probes** without increasing maximum skin temperature, by using more efficient light-emitting diodes (LEDs) or larger detectors. However, for any **pulse oximeter probe** design, it will usually be possible to increase signal by increasing LED drive current, and this will tend to increase skin temperature.

In recommending the temperature limits in 42.3, the committee wished to avoid any significant increase in the risk of burns. **Pulse oximeter probes** designed to the 41 °C limit can deliver useful **accuracy** on most **patients**. While some **patients** will benefit from the better performance available at higher temperatures, we feel that this performance enhancement would not be justified if there were a significant increase in the risk of burns. We have therefore attempted to interpret the available data conservatively, to recommend acceptance thresholds that will continue to make the occurrence of burns extremely rare.

There is no practical concern about thermal injury by a **pulse oximeter probe** that is used for brief tests (so-called "spot checking"). Our intent is to ensure that **pulse oximeter probes** used for long-term continuous monitoring of **patients** do not cause burns. Depending on the mode of attachment to the **patient**, the instructions for use of **pulse oximeter probes** typically call for inspection of the application site after either 4 h or 8 h. We therefore sought to extract from available literature the best available estimates of safe temperature thresholds for these periods.

It is well-accepted by students of thermal injury that the threshold temperature for injury is a function of exposure time. When exposure time is increased by a factor of 2, the safe temperature reduces by about 1 °C. Thus, if 44 °C is known to be safe for 4 h, 43 °C can be estimated to be safe for 8 h. At sufficiently low temperatures, the factor-of-two rule becomes overly conservative; there is some temperature low enough that no injury will ever occur, no matter how long the exposure. Moritz and Henriques [45] put it this way:

> "…for each degree rise in surface temperature, between 44 °C and 51 °C, the time required to produce [irreversible damage to epidermal cells] was reduced by approximately one-half… Below 44 °C there is a rapid decrease in the rate at which burning occurs and the time-temperature curve is asymptotic in the direction of the time axis. This is probably due to the increased effectiveness of the cellular reparative processes as the hyperthermic level approaches the temperature range that is normal for the tissue."

The existence of equilibrium between damage and repair is expressed in this way by Moncrief [44]:

> "Below 44 °C local cellular damage does not occur to a significant degree unless the exposure is for protracted periods of time. That this must be for prolonged periods is attested to by the fact that in many countries this is the temperature range of the thermal bath in which individuals purposely immerse themselves for many hours.
>
> At a temperature of 44 °C, the rate of local tissue damage and recovery is in such delicate balance that although equilibrium can be maintained for a period of approximately six hours, beyond this time irreversible damage as deep as the basal cells of the epidermis occurs."

To qualify a **pulse oximeter probe** design, the highest local skin temperature induced by the **pulse oximeter probe** is measured with the **pulse oximeter probe** in contact with skin (or with a properly designed thermo-mechanical simulator). Because most of the heat dissipated by the **pulse oximeter probe's** light emitters is normally conducted away through the skin, an oximeter **pulse oximeter probe** lying open to air on a lab bench will typically run warmer than it does on a **patient's** skin. When an energized **pulse oximeter probe** is applied to the skin, the temperature at the **pulse oximeter probe**-skin interface drops within seconds or minutes to a quasi-equilibrium value that will fluctuate as local perfusion changes. The quasi-equilibrium value is what needs to be measured, since this is the thermal condition that might, during long exposure, cause injury. Any exposure to higher temperatures during the equilibration period is brief enough to present no likelihood of injury. If a **pulse oximeter probe** is applied to the skin before being energized, there is never a period of above-equilibrium exposure.

When local blood flow is strong, the moving blood does a good job of carrying away heat from the **pulse oximeter probe**, so that the temperature rise induced by the **pulse oximeter probe** is low. The task of the **pulse oximeter probe** designer is therefore to discover the skin temperature increase caused by the **pulse oximeter probe** when perfusion is poor. On the other hand, poor perfusion also reduces the skin temperature that would exist without the **pulse oximeter probe** (i.e. people with poor circulation have cold hands), so that the temperature rise induced by the **pulse oximeter probe** will be less likely to produce an injurious final temperature. Thinking about these opposing influences of poor perfusion, we conclude that for the greatest chance of injury, an external source of heat (e.g. the warmer used in an infant incubator) that raises the skin temperature of a **patient** who has poor perfusion is required. Under this condition, the external warmer produces a high base temperature and the temperature rise produced by the **pulse oximeter probe** above that base is maximized.

One idea implicit in this discussion is that skin temperature is the key parameter that determines whether skin will be injured. Burning is a chemical process. The rates of chemical processes are dominated by temperature.

Also implicit is an idea familiar to those who have studied heat flow calculations, yet sometimes surprising to others. If a given flow of heat is delivered to a given area of a substrate of constant thermal conductivity, this causes a calculable temperature rise above the temperature which the substrate would have had without the extra heat source (i.e. the surface temperature achieved is x degrees warmer than whatever the substrate temperature was without the extra heat source). The amount of the rise depends on the area of dissipation (a parameter controllable by the **pulse oximeter probe** designer) and on the effective thermal conductivity of the substrate. For maximum rise, the effective conductivity is poor (i.e. there is not much blood flow to carry away heat). For maximum local temperature, the beginning temperature of the skin (before the **pulse oximeter probe** is energized) is high; for this to occur when perfusion is poor, there is an external heat source.

AA.43.101 Pulse oximeter equipment used in conjunction with oxidants

Reports of fire caused by **medical electrical equipment** are unusual. However, when such fires occur in the hospital environment they can have tragic consequences. The risk of fire is fundamentally determined by the three elements that are necessary in order to start a fire:

— ignitable material (fuel);

— temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials; and

— an oxidant.

Therefore, following the basic safety concepts of the General Standard, the objective in the design of **equipment** is to ensure that under **normal condition** and **single fault-condition**, and under the oxidizing conditions to which the material can be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition can occur, provided it is self-limiting (e.g. a fuse or a resistor within a sealed compartment) so that no **hazard** is created.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature can be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these can be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that can accumulate during prolonged use, for example, airborne particles of paper or cotton.

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, whilst in environments containing oxidants, thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs, but there is at present no documented evidence as to the power level at which this

might occur for different materials and environments. Therefore, where the potential spark power dissipation deviates from the well-established safe practice, specific spark tests should be conducted simulating the most unfavourable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen, which is given in reference [6] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in **medical electrical equipment** with oxygen-enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. Simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power can be dissipated and the proximity and type of any ”fuel” present.

It is therefore, now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials, and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under **single fault-conditions** in a typical electrical circuit, the possible number of failure modes is very high. In this case full assurance of safety can only be possible with the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, that is, material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air-ignition temperature under **normal conditions** and seal compartments, or might add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under **single fault-condition**.

Alternatively, it can be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under **single fault-condition**.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.44.6 Ingress of liquids

When used within the operating room, any **pulse oximeter equipment** resting on the anaesthesia machine faces the possibility of being wetted by IV or body fluids. When used outside of the operating room, it can face the additional hazard of being wetted by coffee, soda, etc. **Pulse oximeter equipment** for use in the home or in emergency vehicles is highly likely to experience "rain". The committee considered requiring an IPX2 rating for all **pulse oximeter equipment**, but this was considered too severe. A compromise was developed to allow either

— an IPX2 rating (hard rain or large hole in an IV bag), or

— an IPX1 rating (rain or dripping IV bag) and the traditional 200-ml spill test (spilled cup of coffee or large hole in IV bag).

AA.50.101 SpO_2 accuracy of pulse oximeter equipment

It is important to note that **SpO_2 accuracy** is not simply a property of the **pulse oximeter monitor**, but is a property of the **pulse oximeter equipment**, the combination of the **pulse oximeter monitor**, the **pulse oximeter probe**, any cable, and human tissue. See also FF.6, which gives an example of a **pulse oximeter probe** that degrades **pulse oximeter equipment SpO_2 accuracy** by causing great variability in calibration among different test subjects.

AA.50.101.1 Specification

There was considerable discussion about the minimum acceptable **SpO_2 accuracy** specification of pulse oximeters. Ideally, **pulse oximeter equipment** would deliver high saturation measurement **SpO_2 accuracy** ($<$ 1 %) with all **pulse oximeter probe** and application sites. However, due to well-known limitations in current pulse oximetry technology, that level of **SpO_2 accuracy** is not routinely achievable.

Therefore, the committee had to consider: “What is the minimum acceptable **SpO_2 accuracy** for safe and effective use of **pulse oximeter equipment**?”

Due to the diverse applications of **pulse oximeter equipment**, minimum performance requirements are not universal. Two general categories of use can be described as monitoring and diagnosis.

— Monitoring can be defined as the use of trends and/or **alarm signals** to facilitate the early detection of saturation or pulse rate changes.

— Diagnosis – or diagnostic use – can be defined as measurement of **SpO_2** to obtain an accurate estimate of **SaO_2** to facilitate diagnosis or guide therapy.

Diagnostic applications usually require higher **SpO_2 accuracy**. Regardless of the specified **SpO_2 accuracy** of the **pulse oximeter monitor**, inherent limitations in **SpO_2 accuracy** can necessitate arterial blood sample analysis.

Based on clinical experience and the historical use of **pulse oximeter equipment**, **SpO_2 accuracy** not worse than 4 % is acceptable for many monitoring applications. Clinicians on the committee expressed concerns that **pulse oximeter equipment** specified with **SpO_2 accuracy** in excess of 4,0 % at 1 standard deviation (8,0 % at 2 standard deviations) could cause mistreatment in clinical practice. Even though greater **SpO_2 accuracy** is usually more desirable, and frequently attainable, this figure represents a clinically acceptable tradeoff between lower **SpO_2 accuracy** and greater flexibility in **pulse oximeter probe** placement and performance.

The committee agreed that it is important to provide a uniform basis for comparing different **pulse oximeter equipment** and for this reason, elected to require that **SpO_2 accuracy** be specified over the single range, 70 % to 100 % in every case. This Particular Standard explicitly allows **SpO_2 accuracy** specifications over additional ranges to be published (e.g. 1 % over the range 90 % to 100 % **SpO_2**).

The **SpO_2 accuracy** of **pulse oximeter equipment** is dependent, in part, on the **SaO_2** of the **patient** [52]. Currently designed **pulse oximeter equipment** is generally more accurate at **SaO_2** levels above 90 % than they are below 80 %. By limiting the span over which the **SpO_2 accuracy** is stated, the performance in the range of interest will be more realistically communicated. For **pulse oximeter equipment** with specified **SpO_2 accuracy** below 65 %, the span is limited to 20 %. This prevents averaging in the better performance of the higher ranges, thereby avoiding misrepresenting the low saturation **SpO_2 accuracy**.

AA.50.101.2.1 Data collection

During a desaturation test, it is often difficult to achieve a target **SaO_2**, particularly at the lower end of the **SaO_2** range. Attempts should be made at least to achieve a measured **SaO_2** within 3 % **SpO_2** of the stated range of **SpO_2 accuracy**.

The **SpO_2 accuracy** of **pulse oximeter equipment** depends strongly on the optical interaction of the **pulse oximeter probe’s** emitted and collected light and the **patient’s** blood-perfused tissues. The correlation of the measured pulsatile change in light transmission through blood-perfused tissues and the underlying arterial

oxygen saturation depends, among other things, on the spectral content of the **pulse oximeter probe's** emitted light and interaction of the **pulse oximeter probe** optics and the skin surface. Since these complex wavelength-dependent interactions are not assessed nor reproduced by **pulse oximeter equipment functional testers** and simulators, such devices are incapable of characterizing or validating the true **accuracy** of the **pulse oximeter probe/pulse oximeter monitor** combinations. **Functional testers** can be appropriately used for verifying the proper functionality of **pulse oximeter monitors** and the electrical integrity of the **pulse oximeter probes**. (See also Annex FF.)

AA.50.101.2.2 Data analysis

CO-oximeters have an inherent inaccuracy that will influence **SpO_2 accuracy** assessment[11] [26]. **CO-oximeters** and **pulse oximeter equipment** are used to measure arterial oxygen saturation and both have inherent uncertainty. To reduce **pulse oximeter equipment** inaccuracy, one needs to control the inaccuracy of the reference **CO-oximeter's** measurement of **SaO_2**.

The committee is not aware that a practical or traceable procedure exists for the **manufacturer** or **user** to verify **SaO_2 accuracy** of a **CO-oximeter**. To minimize the influence of the **CO-oximeter** inaccuracy in the A_{rms} measurement, careful attention should be paid to ensure that the **CO-oximeter** is performing within its specified performance capability. Verification of correct operation by use of the **CO-oximeter** manufacturer's recommended maintenance procedures is necessary, but is not sufficient to ensure a traceable, accurate measurement. Further quality assurance procedures for verifying **CO-oximeter accuracy** are needed.

EXAMPLE 1 NCCLS [5].

EXAMPLE 2 College of American Pathologists [18].

AA.51.101 Data update period

Pulse oximeter equipment is required to provide an indication that the displayed **SpO_2** value is not current if the **data update period** of **SpO_2** exceeds 30 seconds. Subclause 6.8.2 includes a requirement to disclose the **data update period** in the **accompanying documents**. However, there is no requirement that limits the duration of the **data update period**. The additional requirement that "there shall be an indication that the displayed value is not current" was added by the committee based on potentially significant delays that can occur between an event that activates an **alarm condition**, and the actual generation of the **alarm signals**. The displayed **SpO_2** value does not reflect changes in the measured **SpO_2** value until completion of each update period. If an event that activates an **alarm condition**, such as **patient** desaturation, occurs just after the display is updated, a significant delay could occur between the event and the generation of the **alarm signals**. This could create a hazardous situation for the **patient** if the update period is long.

To mitigate this potentially hazardous situation, the committee believes it is important for the **pulse oximeter equipment** to provide an indication to the **operator** when the displayed **SpO_2** value has not been updated in the last 30 seconds, and as such, can be invalid. This provides the **operator** timely information to assess the **patient's** condition and take appropriate action, if necessary.

AA.101 Signal inadequacy

Clinicians assume that pulse oximetry **accuracy** degrades under various physiological and environmental conditions, and they wish to see an indicator of performance degradation. Furthermore, it is generally assumed that the plethysmographic display will reveal the performance degradation when it is caused by motion and poor pulsatile signal strength. Consequently, clinicians have expressed a desire to require the display of the non-**normalized** plethysmogram. (It is also assumed that the plethysmograms that are **normalized** in amplitude will hide significant changes in signal strength. Signal strength is the time varying component of the infrared waveform.)

In fact, many factors contribute to degradation of signal adequacy with potential loss of **accuracy**. Changes of the plethysmogram can be sensitive to noise and changes in signal strength, but plethysmographic changes are not specific to factors that degrade **accuracy** versus factors that corrupt the plethysmogram but do not degrade **accuracy**. These factors can include but are not limited to: signal strength, noise frequency and

amplitude, source of noise, plethysmographic morphology, ambient light intensity and sensor positioning and alignment.

Ideally, it would be beneficial to provide means for assessment of signal adequacy as it relates to general performance, including confidence in measurement **accuracy**. Although this would best be accomplished by a comprehensive real-time assessment of signal adequacy and visual indication of said status, it can also be accomplished in a clinically acceptable manner, for example, with an appropriately scaled plethysmographic display.

A non-scaled plethysmographic display can lack the resolution to reveal clinically significant changes in signal strength in the low range. Therefore, scaling of the plethysmographic display to increase resolution in the low signal-strength range can enhance the utility of the plethysmogram for assessing changes in signal strength.

AA.102 Pulse oximeter probes and probe cable extenders

Pulse oximeter probes and **probe cable extenders** are as important in establishing the safety and **accuracy** of the complete **pulse oximeter equipment** as is the **pulse oximeter monitor** itself. Clause 102 establishes that the **manufacturer** of the **pulse oximeter probe** or **probe cable extender** (including a **manufacturer** of a **reprocessed pulse oximeter probe** or **probe cable extender**) is responsible not only for the separately testable properties (such as biocompatibility) of the **pulse oximeter probe** or **probe cable extender** itself, but also for the affected combined properties (such as **accuracy**, electromagnetic compatibility, electrical safety, and protection against excessive temperature at the **pulse oximeter probe**-tissue interface) of the **pulse oximeter equipment** that the manufacturer specifies that the **pulse oximeter probe** or **probe cable extender** can be used with. As an example of a possible effect of **reprocessing** on biocompatibility, glutaraldehyde sterilization of silicone rubber materials can result in impregnation of the material with solvent, which if not sufficiently removed by subsequent processing can cause a chemical burn when that process is not described (and therefore validated) in the **accompanying documents**.

AA.201.1.2 Assignment of priority

The language in the previous version of this International Standard is similar, except that the introductory phrase is “If intended for continuous monitoring….” This language led to extended discussion among committee members and their advisors as to just what were the circumstances in which low $\mathbf{SpO_2}$ level **alarm signals** are required. Terms such as “continuous monitoring” and “unattended monitoring” are sufficiently ambiguous to require extensive clarification, and might be interpreted to include sleep studies, which do not require **alarm signals** at all. The committee finally agreed that **operators** and **users** know when they require a **pulse oximeter monitor** to have **alarm signals**, so that the useful contribution of this Particular Standard would be to ensure that **pulse oximeter monitors** having no **physiological alarm conditions** are labelled appropriately (see 6.1 and 6.8.2), and that if such **alarm conditions** are included, there is an **alarm condition** for the parameter that is usually most important, i.e. low $\mathbf{SpO_2}$.

Some **pulse oximeter monitors** can have **technical alarm conditions** for **equipment**-related variables, such as low battery, but no **physiological alarm conditions**. Such **pulse oximeter monitors** are not required to have a low $\mathbf{SpO_2}$ level **alarm condition**.

AA.201.5.4 Default alarm preset

85 % $\mathbf{SpO_2}$ is a generally accepted lower **alarm limit** for most clinical situations; however lower **alarm limits** can be desirable in particular clinical conditions. The **operator** is permitted to set lower **alarm limits** during **normal use**.

In selecting 85 % as the minimum **manufacturer**-configured default **alarm limit** for the low $\mathbf{SpO_2}$ level **alarm condition**, a compromise was made between two clinical requirements. One requirement was that **pulse oximeter equipment** should act as an early indicator of distress in a **patient** with relatively normal oxygenation. In this situation, it would be good clinical practice to select a default **alarm limit** above the “knee” of the oxyhaemoglobin dissociation curve that provides as much margin of safety as is practical. The second requirement is to avoid frequent **alarm signals** not necessarily requiring clinical intervention, that might

"desensitize" caregivers to **alarm signals**. In this case, one might argue for a default **alarm limit** low enough to guarantee that most **alarm conditions** would be meaningful by anyone's measure. It was acknowledged that in both clinical situations, many, if not most, **operators** were likely to rely on the default low **SpO_2 alarm limit**.

Another factor that was considered is that many examples of **pulse oximeter equipment** intended for continuous monitoring allow **user-**configured or **operator-**configured default **alarm limits** and that for specific monitoring settings, default **alarm limits** could be selected that were more closely tailored to the needs of the **patients** and **operators** in that setting. Given these considerations, a lower limit of 85 % for the **manufacturer**-configured default **alarm limit** was felt to be an acceptable compromise that best met both clinical requirements.

Annex BB
(informative)

Skin temperature at the pulse oximeter probe

BB.1 Summary

A literature review relating to temperature requirements leads to the conclusion that it is appropriate and conservative to retain the 41 °C limit for infants (**patients** up to 1 year of age) and to apply the limits of 42 °C for 8 h and 43 °C for 4 h for older **patients**.

BB.2 Literature review

The committee has taken the use of *external* heat to produce a 35 °C surface temperature, in the *absence* of strong peripheral circulation, as being worst case. Although strong local perfusion can lead to skin temperature of 35 °C or above, forced convective heat transfer by blood increases the effective thermal conductivity of the skin. Thus, if the 35 °C temperature is endogenously produced, a given heat input from the **pulse oximeter probe** will produce less temperature rise.

In this International Standard, the committee has adopted the FDA's 35 °C rule for the test environment, and have made explicit an interpretation that "ambient" temperature, as used in the FDA guidance[23], can be taken as local skin temperature when the **pulse oximeter probe** is not energized. The most important route by which heat leaves the **pulse oximeter probe** is through the skin of the **patient**, not through the surrounding air. Thus the **patient's** skin temperature (without the **pulse oximeter probe**) is much more important in determining the temperature to which the **pulse oximeter probe**/skin interface eventually rises than is the temperature of the surrounding air. It is therefore appropriate for skin temperature, rather than air temperature, to be specified.

The same 35 °C maximum skin temperature appears in this International Standard for neonates as it does for adults. 35 °C is a sufficient maximum, even though infant incubators can be adjusted to raise abdominal skin temperature as high as 37 °C. In the absence of strong local perfusion, the skin of the extremities is several degrees cooler than the skin of the abdomen, as indicated in the following literature:

— Templeman and Bell [58] showed mean heel temperatures near 33 °C, while abdominal temperature was regulated in the 36 °C to 37 °C range, in both air-heated incubators and radiant warmers;

— Malin and Baumgart [41] showed, in a radiant warmer environment, mean heel temperatures were 4,5 °C below mean rectal temperature when the abdominal wall temperature was 35,5 °C, and about 2 °C below at 37,5 °C abdominal temperature;

— Topper and Stewart [59] studying the use of heated water pads to supplement radiant warmers, found mean foot temperatures about 2,6 °C below the nearly-equal temperatures of back and abdomen when the heating pad was off, and 2,1 °C below when it was on;

— Seguin [53] studied the distorting effects on incubator servo control of heated transcutaneous sensors. During the control phase, with the transcutaneous sensor not in use, he measured mean foot temperature of 33,4 °C, while oesophageal temperature was at 36,9 °C. This work was in radiant warmers, servo-controlled for abdominal skin **pulse oximeter probe** temperature of 36,5 °C to 37 °C;

— Harpin *et al.* [29] studying the responses of newborns to overheating, in air-heated incubators, showed a consistent pattern in which hand temperature was 1,5 °C to 5 °C below rectal temperature when the baby was at the low end of the "thermoneutral" range, to about 0,5 °C below when the baby was overheated. The authors interpreted higher hand temperatures as consistent with stronger local circulation.

The possibility that the natural damage-repair mechanism of the skin might be weaker when circulation is poor, which might lead to a lower threshold temperature for thermal injury, has not been accounted for explicitly[62]. There is little experimental literature bearing on this point. An early direct experiment [46] was done on pigs. That test showed no effect of local perfusion on injury threshold. More recent experiments, also on pigs[37] [34], showed that in the presence of high local pressure (100 mmHg) over a large area (51 mm to 57 mm diameter) it is hard to define a threshold temperature for injury. Greater injury occurred, for example, at 35 °C than at 25 °C, and some injury occurred even at 25 °C. Any recommended safe temperature threshold for **pulse oximeter probes** should be accompanied by the usual caution that **pulse oximeter probes** need to be applied to avoid excessive pressure. Given this precaution, we have recommended temperature thresholds that appear safe in view of the most pessimistic literature values. In this way, the effects of poor perfusion that probably existed in some of the experimental subjects who were studied have been included.

The following table shows our best estimates of the safe skin temperature thresholds implied by each of many reports in the journal literature. The inconsistencies among these reports arise from at least two causes.

— All the available data for neonates come from studies of transcutaneous blood gas monitoring, in which the observed variable is usually the temperature of the transcutaneous sensor core. Skin temperature is an uncontrolled variable, which we have estimated as being 1 °C below transcutaneous sensor core temperature, but which can actually vary more widely [21] [32] [35] [36].

— There are important variables in many of these experiments that are not addressed consistently, including at least the accuracy of temperature measurements and the varying physiology of **patients**.

To interpret each report, the threshold safe temperature was taken to be the level at which no blisters were observed. Erythema, which might just imply heat-induced hyperaemia, or might imply thermal damage to part of the thickness of epidermis (commonly called a first-degree burn), was taken as marginally acceptable, since recovery from simple reddened skin is typically rapid. Blisters are unambiguously recognizable as injuries and imply damage to basal cells in the epidermis (a second-degree burn). If the duration of exposure was less than 8 h, we have estimated the safe 8-h temperature using Moritz and Henriques [45]'s rule of thumb that doubling exposure time reduces the safe temperature by 1 °C.

The literature references fall, for the most part, into two groups. There are many citations of work with transcutaneous monitors, which apply for the most part to neonates. Another group of documents represent burn-threshold studies with adult volunteers. Only a few references apply to subjects in the intermediate age group.

Reviewing the estimates in Table BB.1 led to the following conclusions:

— 42 °C can be entirely safe for infants (including neonates), but there are enough conflicting results to warrant caution. For this reason, it is recommended that the traditional 41 °C limit for infant applications not be increased and that the default setting of 41 °C be retained.

— 43 °C for 8 h can well be safe for adults, but there have been few studies since the classic work of Moritz *et al.;* and the results of Wienert *et al.* suggest caution. For that reason, it was concluded that the justifiable limit for adults is 42 °C for 8 h, and (using Moritz' rule), 43 °C for 4 h.

It is appropriate and conservative to retain the 41 °C limit for infants (**patients** up to 1 year of age) and to apply the adult limits (42 °C for 8 h, 43 °C for 4 h) for older **patients**, based on the observation that dermal circulation is immature before 1 year of age [50] and that in other structural respects the skin is adult-like by this age [49].

Table BB.1 — Pulse oximeter probe safe application time and source

Reference	Safe skin temperature for n hours	Safe skin temperature for 8 h
Neonates		
Boyle 1980 [14]	43 °C for 4 h to 7 h	> 42 °C
Bucher 1986 [15]	41 °C for 24 h	> 42 °C
Cabal 1981 [17]	42,5 °C for 4 h	> 41,5 °C
Eberhard 1975 [20]	41 °C for up to 84 h	> 42 °C
Eberhard 1976 [21]	43 °C for 4 h "eliminate[d] the risk of blister formation *almost* entirely". 42 °C was "tolerated well [for] up to 24 h."	42 °C
Fanconi 1996 [22]	41 °C for up to 24 h, in the absence of eugenol	> 41 °C
Golden 1981 [27]	< 42 °C for 2 h.	< 40 °C
Huch 1981 [33]	44 °C for 1 h (appears to be a purposely conservative guess. No data presented)	41 °C
Laptook 1981 [38]	43 °C for 4 h	42 °C
Löfgren 1983 [39]	< 43 °C for 8 h	42 °C
Monaco 1981 [43]	43 °C, 3 h to 4 h	42 °C
Schachinger 1983 [51]	< 43 °C, 2 h. No original data presented.	< 41 °C
Venus 1981 [60]	44 °C, up to 6 h	43 °C
Intermediate ages		
Poler 1992 [48]	43 °C for period of application of pulse oximeter	43 °C
Adults		
Manzinger 1990 [42]	Rats, not humans. Water baths at 60 °C, 75 °C, and 90 °C, for 4 s, 10 s, or 15 s.	Results generally support Moritz
Moncrief 1979 [44]	44 °C for 6 h (this is a review article, not an experimental report, and might actually be based on Moritz [45] [46])	> 43 °C
Moritz 1947 [45]	44 °C for 5 h.	> 43 °C
Poler 1992 [48]	43 °C for period of application of pulse oximeter	43 °C
Vyas 1988 [61]	43 °C for 8 h	43 °C
Wienert 1983 [62]	< 43 °C for 8 h	< 43 °C

BB.3 Test methods

This International Standard does not require a particular method of measuring the skin temperature beneath the **pulse oximeter probe**. There are many different widely known and accepted methods of measuring surface temperatures. Different **pulse oximeter probe manufacturers** have evolved their own methods of measuring temperature, using either human test subjects or thermo-mechanical simulators. It would be impractical today to find a single universally acceptable test method, and the excellent thermal safety record of pulse oximetry suggests that such a method is not necessary. **Pulse oximeter probe** designers who wish to take advantage of the higher temperatures should keep the following cautions in mind.

— Measurement tolerances are required to be evaluated carefully. The **manufacturer** should know the true **accuracy** of temperature measurement when designing **pulse oximeter probes** for use at temperatures above 41 °C since a higher temperature reduces the margin of safety.

— Temperature sensors are required to be small enough so as not to distort the measurement. The largest temperature sensors that have been found acceptable have characteristic dimensions near 0,5 mm (e.g. the bead of a thermocouple welded from 0,25 mm wire). Often still smaller temperature sensors are used.

— The temperature sensor is required to not reduce the measured peak temperature by conducting a significant amount of heat away from the measurement region. Thus, it would usually be inappropriate to use the copper-constantan Type T thermocouples that are common in medical investigation, since the high thermal conductivity of the copper wire could cause a false low temperature measurement.

— The temperature sensor is required to be located precisely at the warmest point on the interface between skin and **pulse oximeter probe**. This is often, but not invariably, a point on the **pulse oximeter probe** that is midway between the two LED chips that are typically used in emitters. The warmest point is found by testing.

— Experimental methods are required to be adequate to ensure that recommended temperature limits are met under “reasonable worst case” conditions. As an example, reasonable worst case for neonatal **pulse oximeter probes** might include the following conditions.

  — The **patient** has poor peripheral circulation. There is therefore little forced-convection heat transfer by blood to increase the effective thermal conductivity of surface tissue.

  — The LEDs in the **pulse oximeter probe** are driven at the maximum current which the **pulse oximeter monitor** is capable of providing during normal operation (this condition can occur when the **patient** has very dark skin or a thick foot).

  — An active heat source is in use to raise the baby's abdominal skin temperature artificially to 37 °C.

It is not our intention to require that every model of **pulse oximeter probe** be tested directly on “worst-case” **patients**. The **manufacturer** should select methods for evaluation of the thermal performance of the **pulse oximeter probe** that lead to confident prediction of thermal safety on such **patients**.

Annex CC
(informative)

Determination of accuracy

CC.1 General

This annex discusses both the formulas used to evaluate the quality of **pulse oximeter equipment** measurements, and the names that are assigned to those formulas.

It has been common for the **SpO_2 accuracy** specifications of **pulse oximeter equipment** to be stated in terms such as "$\pm$ 2 %, one standard deviation." In this International Standard, the committee has chosen a different name for the recommended **SpO_2 accuracy** measure, while retaining essentially the same formula (a value of $n-1$ is replaced with n) that has been in common use. We recommend definitions of **local bias**, **mean bias**, and **precision** that are consistent with common engineering usage, but slightly different from the meanings of these terms, as they have sometimes been used in the pulse oximetry literature. The reasons for our recommendations are explained in this Annex. We also discuss the term "ambiguity," which was introduced by Severinghaus *et al.* [54], and explain our belief that the term **accuracy** can perform a similar function.

CC.2 Accuracy, bias and precision

CC.2.1 Definitions

The terms **accuracy**, bias and **precision** have all been used in a variety of ways. The Compilation of ASTM Standard Definitions (ASTM, 7th ed., 1990) assembles 11 definitions of accuracy, 9 of bias, and 19 of precision, all taken from ASTM documents. We have chosen specific definitions that are consistent with the general definitions appearing in ASTM E456-96[3], "Standard terminology relating to quality and statistics." The definitions in ASTM E456-96, with their associated notes, are as follows:

Accuracy: the closeness of agreement between a test result and an accepted reference value.

NOTE 1 The term accuracy, when applied to a set of test results, involves a combination of a random component and of a common systematic error or bias component.

Bias: the difference between the expectation of the test results and an accepted reference value.

NOTE 2 Bias is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

NOTE 3 Expectation is a statistical term which can be interpreted approximately as the mean of the values that would be obtained if the measurement were made many times.

Precision: the closeness of agreement between independent test results obtained under stipulated conditions.

NOTE 4 Precision depends on random errors and does not relate to the true value or the specified value.

NOTE 5 The measure of precision usually is expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

NOTE 6 "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of **precision** depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions.

CC.2.2 Effects of offset and linearity errors

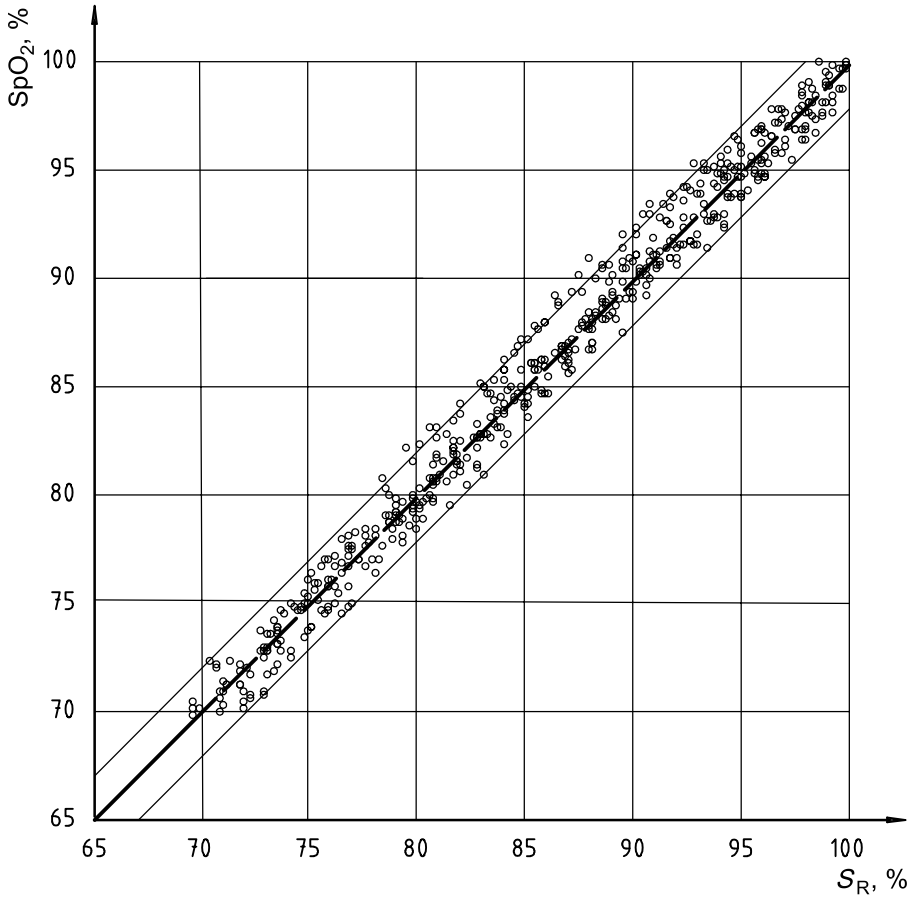
The committee choice of definitions was influenced by considering three synthesized data sets, which might have resulted from a **controlled desaturation study**, that are shown in Figures CC.1 through CC.3. The horizontal axis in each of these figures represents oxygen saturation readings S_{Ri} taken from a reference system, and the vertical axis represents oxygen saturation readings SpO_{2i} from the **pulse oximeter equipment** under test. Reference lines shown on the chart are the line of identity (at which test and reference devices give equal readings) and two dashed lines representing deviations of ± 2 % from the line of identity.

The three figures differ only in the nature of the simple modifications made to one basic data set:

— Figure CC.1, the base case, was created so that a regression line fitted to the data falls almost perfectly on the line of identity (slope = 1,00 and mean offset = 0).

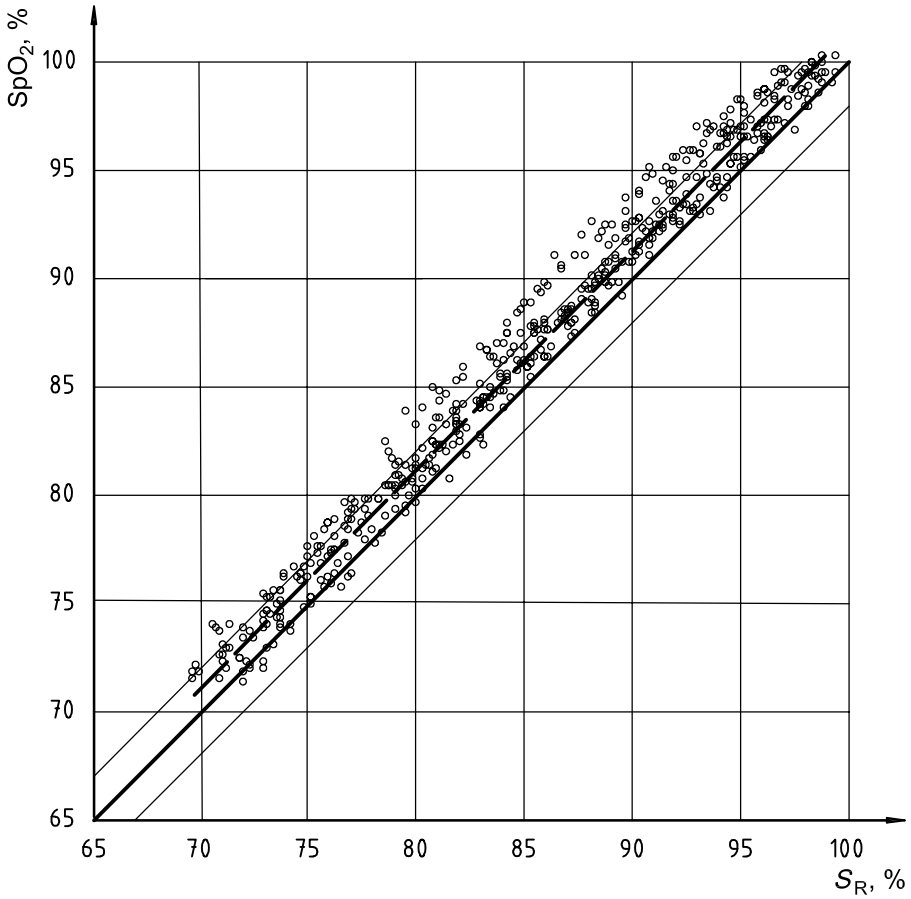
— Figure CC.2 was created from Figure CC.1 by adding a constant 1,5 unit offset to each y value.

— Figure CC.3 was created from Figure CC.1 by adding an x-dependent error to each value: $y\,(x) = 0{,}1x - 8{,}652\,3$, so that the added error is zero near the centre of the chart, positive at the right, and negative at the left. The adjustment formula was chosen to give zero mean additional error.



Test sensor **SpO_2** as a function of reference S_R
Negligible **mean bias** (0,02 %).
Regression line slope = 1,000
s_{res} = 1,034 % B_S = 0
A_{rms} = 1,033 % P_S = 1,033
Trend line formula: y = 1,000 2·x + 0,02

Figure CC.1 — Synthesized calibration data (base case)



Test sensor **SpO_2** as a function of reference S_R

Mean bias 1,5 %

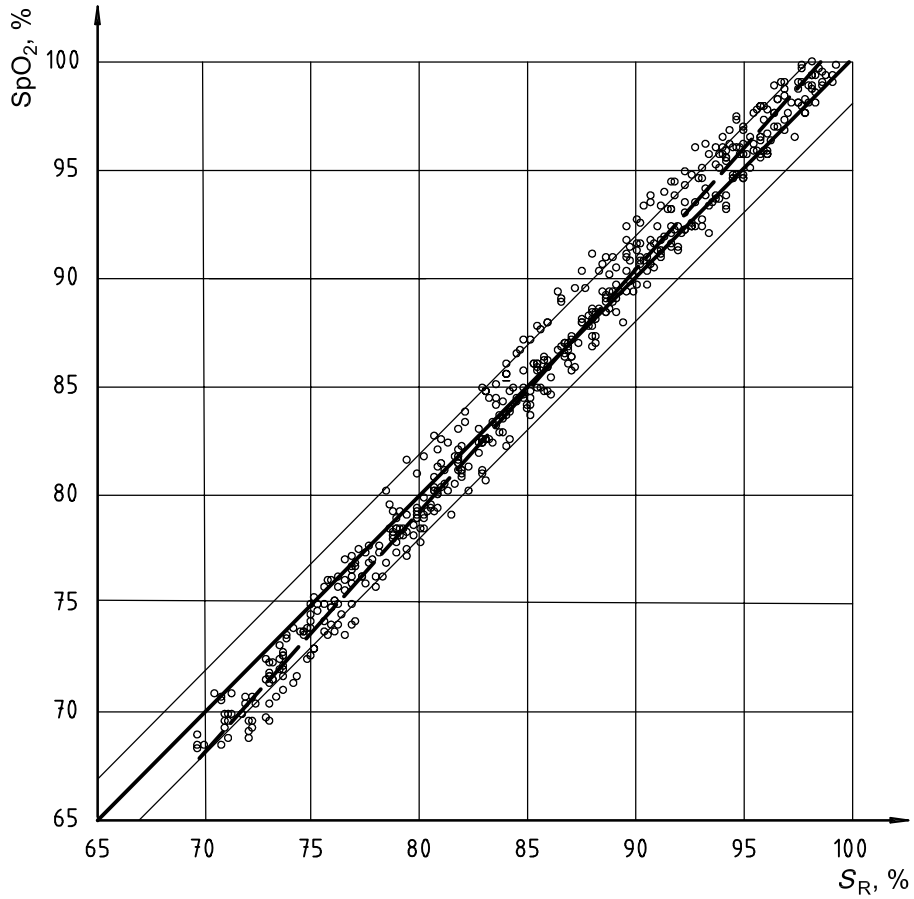
Regression line slope is still 1,000

s_{res} = 1,035 %. B_S = 1,5

A_{rms} = 1,823 % P_S = 1,033

Trend line formula: $y = 1{,}000\ 2 \cdot x + 1{,}48$

Figure CC.2 — Constant offset has been added to base case



Test sensor **SpO_2** as a function of reference S_R
Negligible **mean bias** (0,001 %)
Regression line slope is now 1,100
s_{res} = 1,034 % $B_S = 0$
A_{rms} = 1,332 % P_S = 1,333
Trend line formula: $y = 1{,}100\ 2 \cdot x - 8{,}67$

Figure CC.3 — Tilt has been added to base case

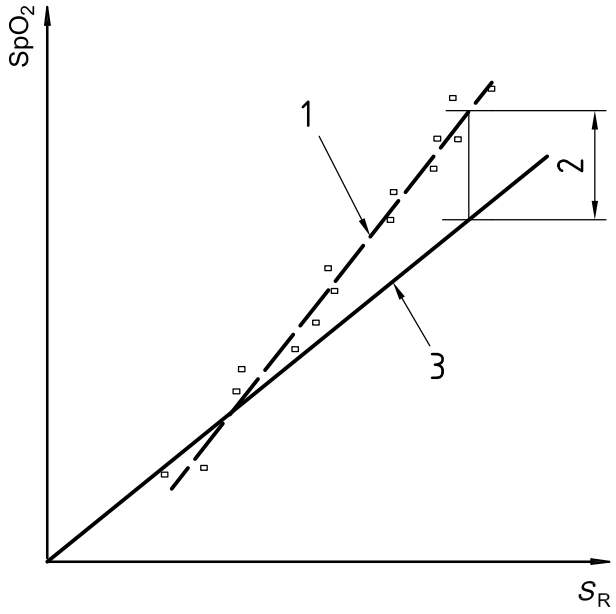
CC.2.3 Bias (see Figures CC.4 and CC.5)

Local bias (indicated here by a lower case "b") at a given value of x, is the difference between the y-value of the regression line at that coordinate and the y-value of the line of identity, i.e.

$$b_i = \mathrm{SpO}_{2\mathrm{fit},i} - S_{\mathrm{R}i} \qquad i = 1, \ldots, n$$

Mean bias is a single number (indicated here with a capital "B"), representing the whole data set. It is the mean difference of the test and reference values, preserving sign;

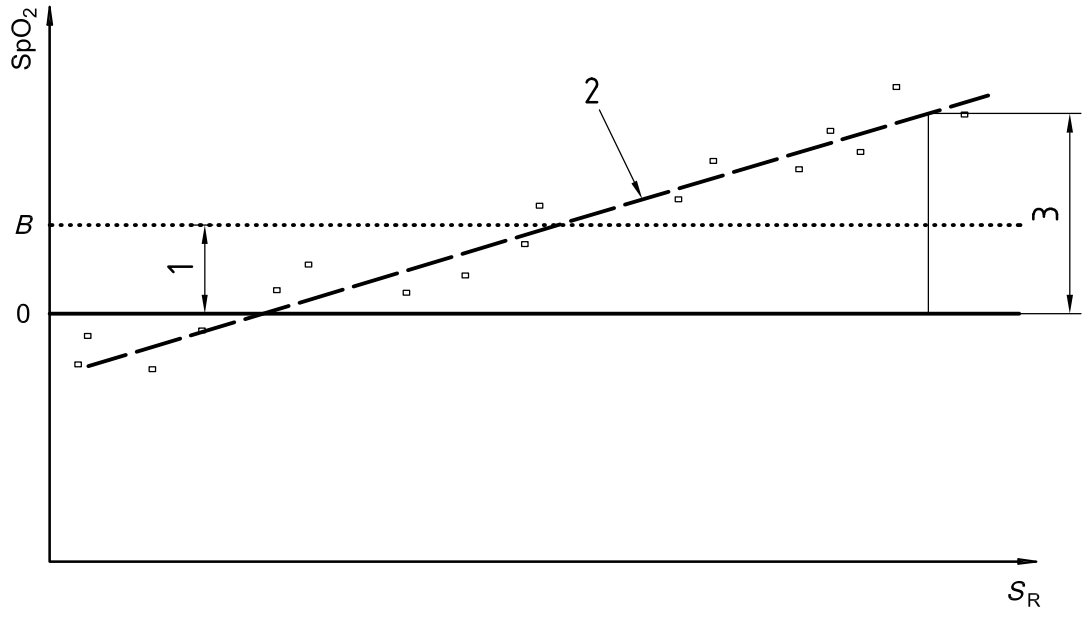
$$B = \frac{\sum_{i=1}^{n} (\mathrm{SpO}_{2i} - S_{\mathrm{R}i})}{n}$$



Key

1 regression line
2 **local bias**
3 line of identity

Figure CC.4 — Graphical representation for the definition of local bias
(Test sensor **SpO_2** as a function of reference S_R)



Key

1 **mean bias**
2 regression line
3 **local bias**

Figure CC.5 — Graphical representation for the definition of local bias and mean bias
(Test sensor **SpO_2** as a function of reference S_R)

When defined in this way, **mean bias** is, as it should be, the average of all **local bias** values, as shown in the following development:

$$B = \frac{\sum_{i=1}^{n}(\mathrm{SpO}_{2i} - S_{\mathrm{R}i})}{n} = \frac{\sum_{i=1}^{n}\left[(\mathrm{SpO}_{2i} - \mathrm{SpO}_{2\mathrm{fit},i}) + (\mathrm{SpO}_{2\mathrm{fit},i} - S_{\mathrm{R}i})\right]}{n} = 0 + \frac{\sum_{i=1}^{n} b_i}{n}$$

The zero term on the right hand side results from the regression that defines $\mathrm{SpO}_{2\mathrm{fit}}$, and the second term simply recognizes the definition of "b" shown above.

Figures CC.1 and CC.3 both exhibit a **mean bias** of zero, while Figure CC.2 has a **mean bias** of 1,5 units. The value of **local bias** is everywhere zero in Figure CC.1, consistently 1,5 units in Figure CC.2, and in Figure CC.3 follows the formula $b = 0{,}100\ 2 \cdot x - 8{,}67$.

CC.2.4 Precision

Figure CC.3 represents a case that sometimes occurs in pulse oximetry, especially when a new model of **pulse oximeter probe** is being developed for use with the calibration curves that are built into an existing **pulse oximeter monitor**. The fact that there is a variable offset between test and reference values in this data set implies that it is useful to make a distinction between **local bias** and **mean bias**. Real data sets can have more complex dependencies of bias on S_{R}, but this example will suffice to show what happens to various data-characterization formulae when **local bias** varies with saturation.

We support defining **precision** as the standard deviation of the residuals (s_{res}), given by the following formula[31]:

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

where n is the number of data pairs in the sample, and ($\mathrm{SpO}_{2i} - \mathrm{SpO}_{2\mathrm{fit},i}$) is the difference between the ith **SpO_2** datum and the value of the fitted curve corresponding to the ith reference value, $\mathrm{S}_{\mathrm{R}i}$. s_{res} can intuitively be recognized as the scatter of data points about the best-fit calibration curve. It is a measure of the scatter to be expected in multiple measurements made with the same **pulse oximeter equipment** at a given oxygen saturation, taking into account both variations among **patients** and repeatability of the **equipment** electronics and software.

NOTE In Figures CC.1, CC.2, and CC.3, the s_{res} has a consistent value near 1,034 %. All three data sets have the same scatter of data points with respect to the best-fit regression line, and the nearly-identical values of s_{res} reflect that fact. The presence of bias in two of these figures has no effect on our measure of **precision**, which is as it should be.

CC.2.5 Accuracy

As suggested by the definition that appears in ASTM E 456-96, we want **accuracy** to represent a combination of the systematic and random components of error. The definition which has long been used by many **manufacturers** is the root-mean-square (rms) difference between measured values ($\mathrm{SpO}_2 i$) and reference values ($S_{\mathrm{R}i}$), as given by the following formula:

$$A_{\mathrm{rms}} = \sqrt{\frac{\sum_{i=1}^{n}\left(\mathrm{SpO}_{2i} - S_{\mathrm{R}i}\right)^2}{n}}$$

We believe that most **manufacturers**, when stating **pulse oximeter equipment SpO_2 accuracy** as a "standard deviation," have actually been computing A_{rms}. At least one **manufacturer** has internally used the abbreviation SDI, meaning "standard deviation with respect to the line of identity". This is a misnomer, since

A_{rms} is not a standard deviation. What is important is that the measure itself is useful. Engineers will recognize A_{rms} as being very similar to the common measurement "rms error," or "root mean square error." It is a way of averaging the absolute values of errors over the full measurement range.

NOTE Note the use of n in the denominator of the expression for A_{rms} rather than (n – 1), which would be used if A_{rms} were a standard deviation. The difference in the numerical value is typically trivial. The appearance of (n – 1) in the definition of standard deviation arises from the fact that only (n – 1) of the samples that comprise the standard deviation can be freely chosen (statisticians say that there are n – 1 "degrees of freedom"). The nth sample is constrained in value because the definition of standard deviation includes the difference from a mean, implying that the nth sample is chosen so that the mean has the known value. There is no such constraint on the calculation of A_{rms} because the expression does not include any predetermined parameter, such as a mean.

Understanding that A_{rms} is not a standard deviation is important in avoiding error in calculating oximeter **SpO_2 accuracy**. If one were to create a spreadsheet column containing all the differences, ($SpO_{2i} - S_{Ri}$), and instruct the spreadsheet software to calculate the standard deviation of the data, the result would not be A_{rms} (in fact, as noted below, it would be P_S, a measure of **precision** developed by Severinghaus *et al.*) [54]. Standard deviation, for any variable x, is

$$s_x = \sqrt{\frac{\sum_{i=1}^{n}\left(x_i - \bar{x}\right)^2}{n-1}}$$

where $\bar{x}$ is the mean of all the x_i. Comparing this to the expression for A_{rms}, you can see that in A_{rms} there is no subtraction of a mean value. A_{rms} does *not* measure scatter about a mean value. It measures the difference between test values and reference values. The numerical differences between A_{rms} and P_S can be seen in the captions of Figures CC.1 through CC.3.

A_{rms} is affected both by random scatter and by **mean bias** and **local bias**.

In Figure CC.1, because **local bias** is negligible over the entire range (resulting in negligible **mean bias** as well), A_{rms} = 1,033 %, which is nearly equal to s_{res}. The fact that A_{rms} and s_{res} are close to 1 % is consistent with the visual observation that most data in Figure CC.1 lie within the ± 2 % reference lines on the chart. In a normal distribution, we expect 95 % of observations to lie within two standard deviations of the mean.

In Figure CC.2, with a consistently large offset (i.e. a constant **local bias** resulting in a non-zero **mean bias**), A_{rms} has increased to 1,823 %.

In Figure CC.3, with *zero* **mean bias** but a varying **local bias**, A_{rms} has the intermediate value of 1,332 %. Because the **local bias** in Figure CC.3 is almost everywhere less in absolute magnitude than the constant offset in Figure CC.2, it is appropriate that our measure of overall **SpO_2 accuracy** be lower in Figure CC.3 than in Figure CC.2 (i.e. Figure CC.3 exhibits better **SpO_2 accuracy** that Figure CC.2).

CC.2.6 Analysis

Now we wish to discuss the relationship between the definitions used above and the terms used by two respected sources that have been influential in the journal literature of pulse oximetry. Bland and Altman [12] campaigned effectively against the misuse of correlation coefficients in comparing two methods of measurement, and introduced a useful graphical method of examining the data from comparison experiments. Severinghaus *et al.* [54] introduced definitions of bias and **precision** that were based in the Bland and Altman method, and also defined the new term, ambiguity, as the sum of **precision** and bias.

In the following paragraphs, we use the symbols B_S and P_S, for the definitions of bias and **precision** that were used by Severinghaus. He defined bias as the mean difference of the test and reference values, preserving sign [57]:

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

By no coincidence, this is identical to our definition of **mean bias**. We have adopted Severinghaus's language for the definition, with the additional recognition that **pulse oximeter equipment** calibration studies sometimes exhibit variation of bias with saturation, so that it is useful to distinguish between **local bias** and **mean bias**.

Severinghaus *et al.* defined **precision** as the "standard deviation of the bias";

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

This measure is different from our recommended definition of **precision**. One perspective is that P_S is the root-mean-square (rms) deviation of differences from **mean bias**, while s_{res} is the rms deviation of differences from **local bias**. Recall that s_{res} was the same in Figures CC.1 through CC.3. Compare what happens to P_S in these three cases:

— in Figure CC.1, P_S = 1,033 (identical to s_{res});

— in Figure CC.2, P_S = 1,033 (in this case, P_S has the desirable property of a "precision" measure, of responding to scatter about the regression line but not responding to the constant offset reflected in the non-zero value of **mean bias**);

— in Figure CC.3, P_S = 1,333 (P_S has increased, to match A_{rms}. Because **local bias** is variable, it causes an increase in P_S, even though the random component of error, as measured by s_{res}, has not changed.)

Bland and Altman, in discussing the example in their Figure 2, say "…there is no obvious relation between the difference and the mean. Under these circumstances we can summarize the lack of agreement by calculating the bias, estimated by the mean difference $\bar{d}$ and the standard deviation of the differences (s)". Thus, Bland and Altman's $\bar{d}$ equivalent to Severinghaus' B_S, and their s is equivalent to his P_S. Bland and Altman have pointed out that the utility of the standard deviation of differences appears when there is no obvious relation between the difference and the mean. As our Figure CC.3 illustrates, the presence of variable local offset makes it preferable to use a different measure of random error.

Finally, we consider the term ambiguity, which Severinghaus *et al.* [54] introduced, as the sum of bias and **precision**:

$$A_S = B_S + P_S$$

The value of this term as a figure of merit is that it combines in single number components of both systematic and random error. It can be shown that our recommended **SpO_2 accuracy** measure, A_{rms}, has a similar property, so that it should not be necessary to use both A_{rms} and ambiguity in analysing the results of a particular experiment. The proof begins with the mathematical identity:

$$\sum_{i=1}^{n} x_i^2 = \sum_{i=1}^{n}\left(x_i - \bar{x}\right)^2 + \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n}$$

For x_i we use the difference ($SpO_{2i} - S_{Ri}$). Expansion and substitution lead to a demonstration that

$$A_{rms} \cong \sqrt{{P_S}^2 + {B_S}^2}$$

Some readers can find it convenient to use this formula as a route to computing A_{rms}. If the differences between test and reference oximeter readings are entered in one column of a spreadsheet, B_S will be the mean of that column and P_S will be its standard deviation.

Annex DD
(informative)

Calibration standards

Some previously published standards appear to mandate that **pulse oximeter equipment** be calibrated directly against *in vitro* blood analysis using **CO-oximeters**. This annex presents two such published documents and explains when we think *in vitro* analysis is required and when it is not.

The American Association for Respiratory Care (AARC) *Clinical Practice Guideline: Pulse Oximetry*[7] says:

> "7.2 To validate pulse oximeter equipment readings, incorporate or assess agreement between SpO_2 and arterial oxyhaemoglobin saturation (SaO_2) obtained by direct measurement, these measurements should be initially performed simultaneously and then periodically re-evaluated in relation to the patient's clinical state."

We read the AARC position as a clinical practice guideline that does not address the issue as to how the original calibration of **pulse oximeter equipment** should be established. This committee believes that the AARC's guideline is appropriate in the clinical context. For a variety of reasons, **pulse oximeter equipment** readings on individual **patient**s can differ from **CO-oximeter** readings, so that it is always appropriate in clinical use to confirm $\mathbf{SpO_2}$ readings using a more accurate measurement. This statement is consistent with the point of view expressed in AA.1.

The FDA's *General Guidance Document: Non-Invasive Pulse Oximeter* [23] directly addresses the issue of **manufacturer's** original calibration. It says, in Section III.M.e.:

> "Clinical testing should be submitted to support the accuracy specifications issued by the manufacturer. During this testing, the oximeter under review should be used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood samplings with a **CO-oximeter**…."

This committee has taken the position that the use of secondary-standard **pulse oximeter equipment** is permissible. When data are taken on multiple **patients**, so that statistics can be developed, we feel that it is appropriate to use **pulse oximeter equipment** that have been calibrated against **CO-oximeters** as secondary standards for the calibration of other **pulse oximeter equipment**. This is done with proper attention to error propagation, so that the $\mathbf{SpO_2}$ **accuracy** claims that are made are clearly justified. In the clinical laboratory conditions under which secondary-standard calibrations are conducted, many of the known sources of error in pulse oximetry are virtually eliminated. Examples of such sources of error are low perfusion, EMI, motion, nail polish, **pulse oximeter probe** mispositioning and ambient light. The efficacy of the secondary-standard calibration process is demonstrated by the fact that secondary-standard testing of **pulse oximeter probes** of a given type over many years has consistently produced identical results and has resulted in a 20-year history of safe and increasing utilization of pulse oximetry.

Annex EE
(informative)

Guideline for evaluating and documenting SpO_2 accuracy in human subjects

EE.1 General

This annex is provided as a guideline for evaluating and documenting the **SpO_2 accuracy** of **pulse oximeter equipment**. The methods described in this annex are applicable to both new **pulse oximeter equipment** and modified **pulse oximeter equipment** or parts whenever human testing is required.

NOTE 50.101.2.1 requires that any study conducted to evaluate the **SpO_2 accuracy** of **pulse oximeter equipment** shall comply with ISO 14155-1 and ISO 14155-2.

This annex is intended to describe the testing methods for assessing the **SpO_2 accuracy** of **pulse oximeter equipment**. It is not intended to prescribe medical practice, proper safety procedures or institutional review board (IRB) or ethics committee (EC) processes.

Two types of tests in which human subjects are used for evaluating **SpO_2 accuracy** of **pulse oximeter equipment** are described. Either type can be performed in the laboratory or the intended environment of use.

a) Invasive testing: the **SpO_2 accuracy** of **pulse oximeter equipment** is measured by comparing **SpO_2** readings of the **pulse oximeter equipment** to values of **SaO_2** determined with a **CO-oximeter**. Two types of individual could participate in invasive studies:

   — healthy volunteers who consent to induced hypoxia and arterial blood sampling as part of the experimental procedure (see EE.2); or

   — **patients** in whom arterial blood samples are available for analysis (see EE.4.1).

b) Non-invasive testing: the **SpO_2 accuracy** of **pulse oximeter equipment** is measured by comparing **SpO_2** readings of the **pulse oximeter equipment** to values obtained with a secondary-standard **pulse oximeter equipment**. Two types of individuals could participate in non-invasive studies:

   — healthy volunteers who consent to induced hypoxia as part of the experimental procedure; or

   — **patients.**

Since the calibration of the secondary-standard **pulse oximeter equipment** is directly traceable to a **CO-oximeter**, the secondary-standard **pulse oximeter equipment** can be used as a transfer standard.

EE.2 Procedure for invasive laboratory testing on healthy volunteers

EE.2.1 Purpose of an invasive controlled desaturation study

The general purpose of invasive **controlled desaturation studies** is to validate the **SpO_2 accuracy** of **pulse oximeter equipment** in comparison to "gold-standard" measurements of blood **SaO_2** by a **CO-oximeter**. This is achieved through paired observations of **SpO_2** and **SaO_2** values over the specified **SpO_2 accuracy** range (e.g. 70 % to 100 % **SaO_2**) of the **pulse oximeter equipment** on a group of healthy adult volunteers. The fraction of inspired oxygen (FiO_2) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods. Arterial blood samples are periodically taken from an indwelling arterial catheter for use in the comparison.

The method described below involves procedures that have to be undertaken and supervised by qualified personnel. Subjects have an artery cannulated and then are exposed to inspired oxygen concentrations lower than room air. Accordingly, this study method generally requires protocol approval by an IRB or EC, including informed consent of the subjects.

EE.2.2 Scope of an invasive controlled desaturation study

This invasive **controlled desaturation study** method is used to validate the **SpO_2 accuracy** of **pulse oximeter equipment** under well-controlled, optimal laboratory conditions on healthy adult subjects. This method can be used during specifically defined non-optimal conditions such as subject movement or low pulse-amplitude states.

EE.2.3 Methods

EE.2.3.1 Study population

The following parameters should be considered.

a) Number and source of subjects

— The study should include a sufficient number of subjects to attain the statistical significance necessary to demonstrate a specified **SpO_2 accuracy**.

— Subjects should be healthy adult volunteers.

— For the broadest application to the largest group of **patients**, the subjects should vary in their physical characteristics to the greatest extent possible.

NOTE The characteristics of the subjects can be limited due to safety reasons or availability, for example, only female subjects being available to validate a paediatric finger **pulse oximeter probe** due to their meeting the criteria for finger size.

b) Subject inclusion/exclusion criteria

— The study protocol should define the inclusion/exclusion criteria.

— Subjects participate in the study on a voluntary basis.

— All subjects should be in good health at the time of the study. Unless specified otherwise in the protocol, the following values could be applied: COHb < 3 %, MetHb < 2 %, ctHb > 10 g/dl; these values are not intended to be a comprehensive determination of “good health”.

— Inclusion criteria should serve the purpose of the study. (Examples are not intended to be comprehensive.)

EXAMPLE 1 Both male and female subjects.

EXAMPLE 2 Specific finger size.

EXAMPLE 3 Healthy adult subjects capable of undergoing controlled hypoxaemia to the levels called for in the protocol with minimal medical risk.

— Examples of exclusion criteria (not intended to be comprehensive).

EXAMPLE 1 Smokers or individuals exposed to high levels of carbon monoxide that result in elevated carboxyhaemoglobin levels, unless specific dyshaemoglobins are called for in the study protocol.

EXAMPLE 2 Individuals subject to conditions that result in elevated levels of methaemoglobin, unless specific dyshaemoglobins are called for in the study protocol.

EXAMPLE 3 Subjects who would be placed at undue medical risk associated with any procedures called for in the protocol (e.g. arterial cannulation or hypoxia).

EXAMPLE 4 Age.

c) Criteria for study termination

— Study protocol should define circumstances and/or subject response to the procedure that becomes grounds for study termination.

EXAMPLE The subject is discovered to meet one of the pre-defined exclusion criteria (e.g. elevated methaemoglobin levels).

EE.2.3.2 Apparatus

EE.2.3.2.1 CO-oximeter for measuring $\mathbf{SaO_2}$ and **CO-oximeter** manufacturer-recommended procedures and supplies.

EE.2.3.2.2 Materials for arterial catheterization and blood sampling.

EE.2.3.2.3 Means for recording $\mathbf{SpO_2}$ values, which can be manual or automated.

EE.2.3.2.4 Pulse oximeter equipment to be tested. See also EE.2.3.4 c).

EE.2.3.2.5 Means for delivering a medical grade oxygen-nitrogen mixture of varying FiO_2 levels to the subject (e.g. pre-mixed high-pressure cylinders or gas-mixing device).

EE.2.3.3 Procedure

a) The study protocol should describe the specific conditions of the test (e.g. optimal laboratory conditions, subject motion, low pulse amplitude, etc.). The use of warmers or other warming means can be utilized to improve circulation and pulse amplitude at a **pulse oximeter probe** site.

b) After a catheter is placed in the artery, **pulse oximetry probes** to be evaluated are attached to the subject's fingers, forehead, nose, ears or other body surfaces as appropriate. **Pulse oximeter probes** can be covered with opaque material to prevent optical interference (light from one **pulse oximeter probe** or any other source reaching the photodetector of an adjacent **pulse oximeter probe**).

NOTE Further details of the proper techniques and maintenance of the arterial line are beyond the scope of this International Standard. The radial artery is typically used.

c) The protocol should specify criteria and methods for determining stability of the $\mathbf{SaO_2}$ at the **pulse oximeter probe** site.

EXAMPLE 1 A stable plateau on the **pulse oximeter equipment** under test.

EXAMPLE 2 A stable plateau on a reference **pulse oximeter equipment**.

EXAMPLE 3 A real-time measurement of expired respiratory gases.

d) The breathing circuit is fitted to the subject and the subject breathes a mixture of oxygen and nitrogen. Carbon dioxide can be added to the inspired gas mixture to maintain normal carbon dioxide levels and to prevent respiratory alkalosis secondary to hypoxic hyperventilation.

e) FiO_2 is reduced or increased to bring the subject near target levels. Desaturation to the lowest level (e.g. 70 % $\mathbf{SaO_2}$) is conducted in a stepwise process targeting a number of saturation plateaus (periods in

which the saturation is relatively stable). The number of saturation plateaus finally accepted as valid is represented by a value M.

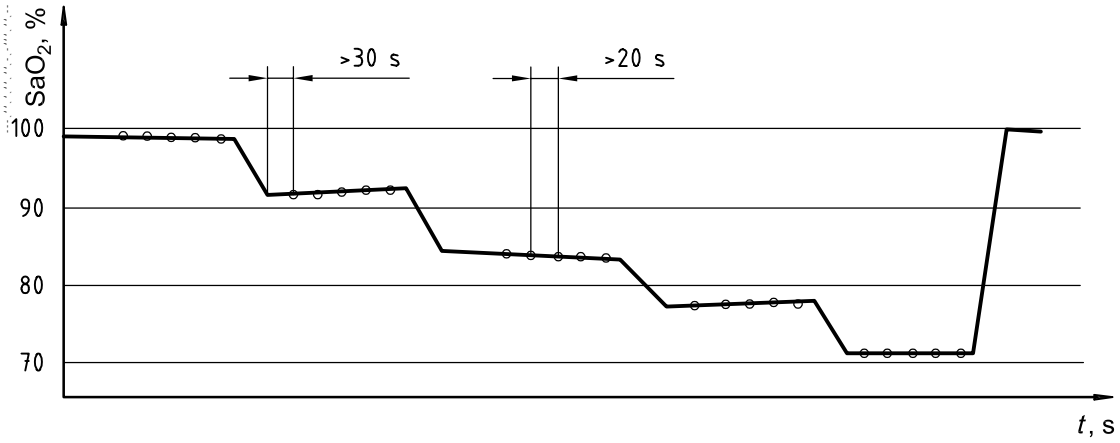
f) When combined across subjects, these M plateaus should result in a distribution of collected and pooled data pairs spanning the specified **SaO_2** range. See also EE.2.3.4 b) and EE.2.3.4 g).

g) Within each saturation plateau level, draw N blood samples and pair with the corresponding **SpO_2** values.

EXAMPLE A study design is shown in Table EE.1 and Figure EE.1. In this example, $M = 5$ and $N = 5$. The values in this example are not intended to be limiting in the number of plateaus or numbers of samples per plateau.

Table EE.1 — Example of target plateaus and ranges

SaO_2 plateau range %	**Target number of samples**
100 to 97	5
97 to 92	5
92 to 85	5
84 to 78	5
77 to 70	5
Total	25



Points are **SaO_2** values at the time of the blood draws.

Figure EE.1 — Example of desaturation-time profile

h) For each subject, $M \times N$ blood draws provide (**SaO_2**, **SpO_2**) data pairs for analysis [see EE.2.3.4 f)]. These data pairs are either acquired simultaneously or correlated in time to accommodate physiological and **pulse oximeter equipment** delays.

NOTE The values of M and N can vary by subject, given the ability to reach and maintain the targeted plateau levels.

i) When the reference system's blood saturation stabilizes at an acceptable plateau level, blood sampling can begin. After a change in plateau level, readings should be allowed to stabilize for at least 30 seconds to allow **SaO_2** to reach equilibrium at the **pulse oximeter probe** site.

j) Care should be taken for the sampling, handling and analysis of blood to ensure the **SpO_2 accuracy** of the **CO-oximetry** measurement. Procedures for the sampling, handling and analysis of blood are found elsewhere [9].

k) To assure the independence of samples, time intervals between the end of one sampling period and the beginning of the next should be sufficient to allow monitor averaging time (e.g. $\geqslant$ the averaging time of the **pulse oximeter equipment**) and blood circulation at the **pulse oximeter probe** site time to refresh. This time interval should be defined in the protocol.

EE.2.3.4 Data analysis

a) Paired **SpO_2** and **SaO_2** data points are pooled for all subjects and the A_{rms} is calculated using the formula given in 50.101.2.2.

b) The pooled data values are required to include **SaO_2** levels within 3 % of the endpoints of the **SpO_2 accuracy** range, e.g. 70 % to 100 % **SpO_2 accuracy** specifications must include data pairs with **SaO_2** values that span at least 73 % to 97 % (per 50.101.2.1).

c) For **pulse oximeter monitors** that place an upper limit on displayed **SpO_2** (e.g. 99 % or 100 %), a means should be used that does not bias the A_{rms} result.

EXAMPLE 1 Include only observations where **SpO_2** readings are less than the upper display limit.

EXAMPLE 2 Statistically down-weight those values with **SpO_2** = 100 % (e.g. treat observations of 100 % as censored, as is done in the analysis of survival data).

EXAMPLE 3 Configure the data-collection system to record **SpO_2** values > 100 %.

NOTE A_{rms} describes the combined bias and **precision** of **SpO_2** readings, and by limiting display values, the assumptions of a normal distribution are violated.

d) Points collected with **SaO_2** values beyond the specified **SpO_2 accuracy** range are excluded, unless specifically defined in the protocol to be included (within 3 % of the endpoints).

NOTE If including such points were to be optional, they can be advantageously included or excluded.

e) Data pairs can be rejected if, determined retrospectively, they were taken during conditions that were outside of the scope of the testing as defined in the protocol.

EXAMPLE 1 An unstable **SpO_2** plateau.

EXAMPLE 2 If it were annotated that the blood draw experienced difficulties (excessive bubbles).

EXAMPLE 3 The **CO-oximeter** experienced abnormal or error conditions.

f) The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified **SpO_2 accuracy**. For example, about 20 blood samples are acquired in each of at least 10 subjects, resulting in at least 200 data pairs. Specific numbers of samples and subjects can vary, if properly justified using statistical methods.

g) The distribution of **SaO_2** values in the pooled data set needs to be made with comparable density over the full claimed range. For example, approximately 1/3 of the data should fall between the ranges 70 % to 79 %, 80 % to 89 %, and 90 % to 100 % **SaO_2**.

EE.3 Procedure for non-invasive laboratory testing on healthy volunteers

In non-invasive testing, the **SpO_2 accuracy** of **pulse oximeter equipment** is measured by comparing **SpO_2** readings of the **pulse oximeter equipment** to values obtained with secondary-standard **pulse oximeter**

equipment. This method utilizes healthy volunteers who consent to induced hypoxia as part of the experimental procedure.

Since the calibration of the secondary-standard **pulse oximeter equipment** is directly traceable to a **CO-oximeter,** the secondary-standard **pulse oximeter equipment** can be used as a transfer standard.

The method for non-invasive laboratory testing on healthy volunteers follows the protocol described in EE.2 for invasive tests with the following exceptions.

a) The reference values are $\mathbf{SpO_2}$ readings obtained from a secondary-standard **pulse oximeter equipment** replacing the $\mathbf{SaO_2}$ values measured with a **CO-oximeter**.

b) Blood sampling is not utilized.

c) The calibration of the secondary-standard **pulse oximeter equipment** and the treatment of the data analysis are traceable to a **CO-oximeter**.

d) The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified $\mathbf{SpO_2}$ **accuracy**.

   — For example, one possible profile for acquiring data follows the plateau scheme described in EE.2.3.3 e) through EE.2.3.3 h), i.e. about 20 sampling periods, during plateaus, are achieved in each of at least 10 subjects, resulting in at least 200 sets of data pairs.

   — Other profiles are possible, i.e. continuous data collection during gradual changes in saturation, independent of plateaus, relating sample pairs in time.

   Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

e) The procedures for item c) and item d) are described in the test report.

f) The A_{rms} value, as defined in 50.101.2.2, is expressed relative to the “gold-standard” **CO-oximeter** and includes the error of the secondary-standard **pulse oximeter equipment**.

EE.4 Procedure for testing on patients

EE.4.1 Invasive testing on patients

The $\mathbf{SpO_2}$ **accuracy of pulse oximeter equipment** is measured by comparing $\mathbf{SpO_2}$ readings of the **pulse oximeter equipment** to values of $\mathbf{SaO_2}$ determined by a **CO-oximeter**.

In a clinical environment, the primary responsibility is **patient** care. The $\mathbf{SpO_2}$ measurement from **patients** in that environment when compared to measurements from a **CO-oximeter** in that environment can be degraded because data collection cannot always be well controlled. Both measurements are better controlled under laboratory conditions.

In a clinical environment, measurements from **pulse oximeter equipment** and **CO-oximeters** are often subject to non-optimal conditions and are difficult to match reliably due to circulatory instabilities or dynamics.

The **patient’s** clinical condition should be considered when placing any **pulse oximeter probe** in relation to the arterial sampling site. Whenever possible, the **pulse oximeter probe** should be observing blood that is part of the same circulatory stream as the artery from which blood is taken.

Generating the number of data pairs sufficient to demonstrate statistically the specified $\mathbf{SpO_2}$ **accuracy** over the specified range can require a large number of **patients**.

NOTE 1 Blood samples can be withdrawn either as a needed part of clinical care or solely for the purposes of the study, as specified in an approved study protocol.

NOTE 2 Using single needle punctures as a source of arterial blood is likely to result in unstable **SpO_2** values.

The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified **SpO_2 accuracy**. The distribution of reference values in the pooled data set needs to be made with comparable density over the full claimed range. Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

EE.4.2 Non-invasive testing on patients

The **SpO_2 accuracy** of **pulse oximeter equipment** is measured by comparing **SpO_2** readings of the test **pulse oximeter equipment** to values obtained with secondary-standard **pulse oximeter equipment** that is traceable to **CO-oximeter SaO_2** values.

In a clinical environment, the primary responsibility is **patient** care. **SpO_2** measurements from **patients** in that environment can be degraded because data collection cannot always be well controlled. **SpO_2** measurements are better controlled under laboratory conditions.

In a clinical environment, measurements from **pulse oximeter equipment** are often subject to non-optimal conditions and are difficult to match reliably, due to circulatory instabilities or dynamics.

The **patient's** clinical condition should be considered when placing **pulse oximeter probes**. Whenever possible, the test and secondary-standard **pulse oximeter probes** should be observing blood that is part of the same regional circulation.

Generating the number of data pairs sufficient to demonstrate statistically the specified **SpO_2 accuracy** over the specified range can require a large number of **patients** or observations.

The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified **SpO_2 accuracy**. The distribution of reference values in the pooled data set needs to be made with comparable density over the full claimed range. Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

The A_{rms} value is expressed relative to the "gold-standard" **CO-oximeter** and includes the error of the secondary-standard **pulse oximeter equipment**.

Annex FF
(informative)

Simulators, calibrators and functional testers for pulse oximeter equipment

FF.1 General

The committee felt that **functional testers** have become commonly available and are incorrectly perceived by some **users** as being calibrators. This annex addresses appropriate uses of each type of tester.

A variety of devices can be used to test **pulse oximeter equipment**. Some of these devices are provided by the **manufacturers** of **pulse oximeter equipment**, some by independent tester **manufacturers**, and some by research laboratories. The committee felt that it would be helpful to suggest standard terms that can be used in describing these devices, in the interest of improving **users**' understanding of the capabilities of particular testers. The need for this discussion is made greater by two somewhat unusual characteristics of **pulse oximeter equipment**.

— Unlike many other types of **medical electrical equipment**, **pulse oximeter equipment** is not designed to be calibrated after it leaves the factory.

— There is today no accepted method of verifying the correct calibration of a **pulse oximeter probe/pulse oximeter monitor** combination other than testing on human beings.

All available tools for testing **pulse oximeter equipment**, at this writing, are properly called **functional testers**. 6.8.3 aa) 1) requires the instruction manuals of **pulse oximeter equipment** to state that **functional testers** cannot in general be used to measure the **SpO_2 accuracy** of **pulse oximeter probes** and **pulse oximeter monitors**. An intention of this annex is to clarify the reasons for this requirement. Another intention is to clarify semantic issues. Terms such as simulator, calibrator and tester have a variety of common meanings, which can contribute to misunderstanding of the actual capability of a particular device. We have recommended particular uses of the terms "calibrator" and "functional tester," when these terms are applied to pulse oximetry. This annex explains the difference between **functional testers** and other types of testing devices, and will suggest the correct sphere of use of **functional testers**. It also explains why it is inappropriate to use measurements made with **functional testers** to support **SpO_2 accuracy** claims for **pulse oximeter probes** or **pulse oximeter monitors**, with the limited exception permitted by the text of 6.8.3 aa) 2).

FF.2 What is a simulator?

In conventional usage, a simulator is a test device that stands in for the human **patient**. There are, for example, simulators for invasive and non-invasive blood pressure, and for electrocardiograph signals, which are well-accepted as accurate substitutes for a **patient**, in the sense that the **equipment** can be predicted confidently to display the same measurement **accuracy** on human **patients** that it displays when tested with the simulator (with some additional stated component of inaccuracy contributed by errors in the simulator).

There is, at this writing, no **simulator** for pulse oximetry that reproduces the optical properties of a **patient** well enough to warrant its use in determining the **SpO_2 accuracy** of any **pulse oximeter monitor/pulse oximeter probe** combination. There exist various simulators, useful in development and testing of **pulse oximeter equipment**, which suffice for particular engineering purposes.

FF.3 What is a calibrator?

A calibrator, as the term is conventionally used, is a test device that can be used in adjusting **equipment** to make that **equipment** accurate. Typically, a calibrator for use with **equipment** is a high-**accuracy** simulator, and the **equipment's** calibration is capable of adjustment. Although the second condition cannot be met for **pulse oximeter equipment**, we feel that the least of semantic evils is to recommend a special use of the term "calibrator." A pulse oximetry calibrator (POC) would be a high-**accuracy** simulator, capable of producing signals or optical responses indistinguishable from those that come from a human **patient** or test subject. When **pulse oximeter equipment**/**pulse oximeter probe** combination is tested with a POC, it is, in general, not possible, with **pulse oximeter equipment** as they are manufactured today, to adjust the **equipment** to improve the **accuracy** of calibration. The POC is used to measure the error with which the oximeter measures oxygen saturation on one or more simulated **patients**. If the error is found to be unacceptable, the cure typically is replacement of defective components or redesign of **equipment**. Another difference between the POC and other sorts of calibrators is the difficulty of reducing the error contribution of the POC to the level expected of calibrators. It is commonly expected that a calibrator will deliver four to ten times the **accuracy** of the **equipment** being calibrated. Given the common **pulse oximeter equipment SpO_2 accuracy** of ± 2 saturation points, a POC should preferably characterize the **accuracy** of any **pulse oximeter monitor/pulse oximeter probe** combination with error not exceeding 0,5 points.

FF.4 How are pulse oximeter equipment calibrated presently?

Pulse oximeter equipment are unlike other **medical electrical equipment,** in that

— at this writing, no simulators have been proven adequate for use as **pulse oximeter equipment** calibrators. The interaction of light and human tissue upon which pulse oximetry depends is complex. At least one effort is underway to produce a properly-validated POC [30] [31] that would model at least some of the optical intricacies, but no such effort has yet been completed successfully.

Thus, the primary available method of determining the **SpO_2 accuracy** of **pulse oximeter equipment** is to compare its readings with the readings of a **CO-oximeter** (which determines by optical measurements *in vitro* the concentration of several forms of haemoglobin in arterial blood). See also EE.2.

Pulse oximeter equipment, as manufactured to date, is never subject to calibration in the same sense that an invasive blood pressure transducer can be calibrated. There can be various manual or automatic adjustments in the **pulse oximeter equipment**, for example to set gains or cancel amplifier offsets, but these are all adjusted against ordinary electronic reference standards (e.g. an offset adjustment will be set to bring to zero the reading of a voltmeter). The basic relationship between optical signals derived from the **patient** and the displayed value of **SpO_2** is determined by the **manufacturer** for a particular combination of **pulse oximeter monitor** and **pulse oximeter probe.** The relationship is stored permanently in firmware, and is never adjusted. In particular, many contemporary **pulse oximeter equipment** observe a quantity sometimes called the Modulation Ratio or the Ratio of Ratios, which can be approximated as follows:

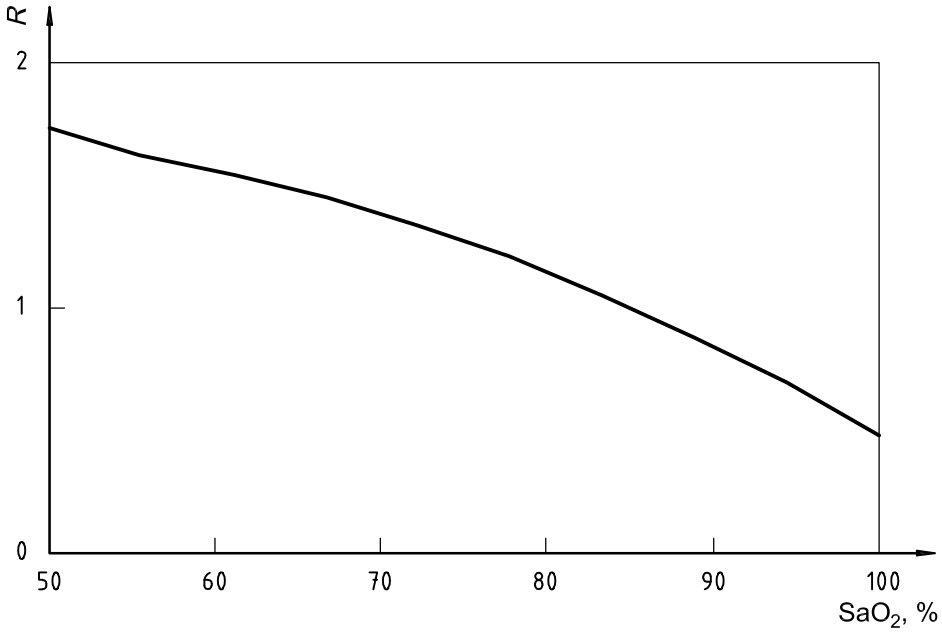
$$R = \frac{\log_{10}(\max._{\text{red}} / \min._{\text{red}})}{\log_{10}(\max._{\text{IR}} / \min._{\text{IR}})} \approx \frac{\dfrac{AC_{\text{red}}}{DC_{\text{red}}}}{\dfrac{AC_{\text{IR}}}{DC_{\text{IR}}}}$$

where AC_{red} is the maximum (pulsatile) red wavelength signal, AC_{IR} is the maximum (pulsatile) infrared wavelength signal, DC_{red} is the minimum (non-pulsatile) red wavelength signal, and DC_{IR} is the minimum (non-pulsatile) infrared wavelength signal.

NOTE This approximate formula is cited only to provide a concrete example to support the following calibration curve discussion; accurate oximeters are designed around a variety of mathematical approaches, each of which requires some sort of empirical calibration curve.

An empirically-determined calibration curve, such as that illustrated in Figure FF.1, allows the oximeter to derive the displayed **SpO_2** from the observed R. The procedure to determine the calibration curve is called a **controlled desaturation study**. It typically involves providing healthy volunteer test subjects with breathing

mixtures having reduced oxygen content. Arterial blood samples are drawn and measured with a **CO-oximeter**, and the **CO-oximeter** readings are plotted against R values observed during the interval when the blood is being drawn. The process should be carefully conducted, to avoid a wide variety of possible errors. **Controlled desaturation studies** can also be conducted by comparing the readings of **pulse oximeter equipment** under test to "secondary standard" **pulse oximeter equipment** that have previously been calibrated against **CO-oximeters**. This approach avoids the need to draw arterial blood but still always requires the use of human test subjects.



Red/IR modulation ratio, R, as a function of arterial oxygen saturation

Figure FF.1 — Sample calibration curve for pulse oximeter equipment

This curve displays the observed value of R for various values of $\mathbf{SaO_2}$ determined with a **CO-oximeter**. When installed in **pulse oximeter equipment** software, the curve will establish the displayed value of $\mathbf{SpO_2}$, given an observed value of R.

FF.5 What is a functional tester?

Every **pulse oximeter equipment** tester on the market at this writing is a **functional tester**. Two principal characteristics of **functional testers** are as follows.

— A **functional tester** allows the **user** to determine whether the **pulse oximeter monitor** is performing as the **manufacturer** designed it to perform, without in any way determining whether the design was correct.

— A **functional tester** has limited ability to determine whether any **pulse oximeter probe** is performing as the **manufacturer** designed it to perform (more will be said about the limitations below) and can never determine whether the design was correct.

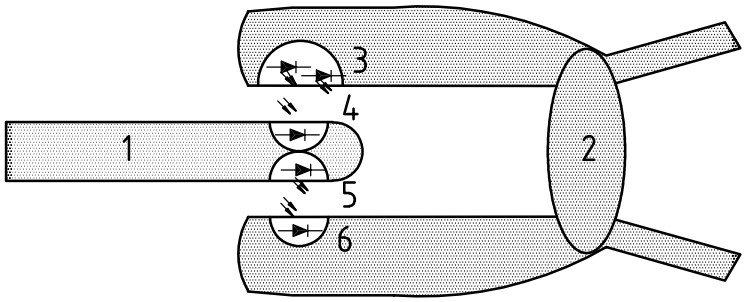
A **functional tester** presents the **pulse oximeter monitor** with a signal having a predictable value of R, so that the **user** can observe the resulting displayed value of $\mathbf{SpO_2}$, and evaluate it in comparison to expectations for that particular **pulse oximeter monitor** model. If the tester **manufacturer** knows the calibration curve that has been designed into a particular **pulse oximeter monitor**, he can be able to produce accurately the R value which ought to lead to a particular value of $\mathbf{SpO_2}$, e.g. 85 %. Then the **pulse oximeter equipment** can be evaluated for its ability to reproduce the calibration curve that was designed into it. Any error exceeding the combined error specifications of the **pulse oximeter monitor** and the tester suggests that either the **pulse oximeter monitor** or the tester requires repair.

An accurate reading of **SpO_2** on a **functional tester** never implies that the **pulse oximeter equipment** is accurate on human beings. All that is being evaluated by the tester is the **pulse oximeter monitor's** ability to reproduce the calibration curve that the **manufacturer** designed into it; this calibration curve can or cannot be accurate. The following detailed observations are chosen to emphasize this point.

— Some **functional testers** are designed to connect electrically to the input of the **pulse oximeter equipment** in place of the **pulse oximeter probe**. It is clear in the design of such a tester that the optical properties of the **pulse oximeter probe**, which have tremendous importance in calibration, are not being evaluated (calibration is always a property of the **pulse oximeter monitor/pulse oximeter probe** combination). The purely electronic character of this family of testers is not so much a disadvantage as a frank admission of the limitations of **functional testers**, which have only limited ability to test the optical properties of **pulse oximeter equipment**.

— Some **functional testers** are electronic modulators having an optical interface to the **pulse oximeter equipment** — the oximeter's **pulse oximeter probe** is applied to an optomechanical "finger" of some sort, and modulated optical signals are delivered to the detector of the oximeter **pulse oximeter probe**. While such testers can give the impression that the **pulse oximeter probe** is being evaluated, in fact only the most basic properties of the **pulse oximeter probe** are usually tested; that its light sources and detector are active and that no disabling shorts or open circuits exist. The same determination can be made by applying the **pulse oximeter probe** to the **user**'s own finger and observing that the **pulse oximeter equipment** displays some value of **SpO_2**. This type of **functional tester** simply uses the **pulse oximeter probe** as a tool to deliver a desired test signal to the electronics of the **pulse oximeter equipment**.

— Several brands of **functional tester** have an optomechanical "finger" containing a detector, which picks up light from the oximeter **pulse oximeter probe**'s light emitter, and a light-emitting diode (LED) which delivers modulated light to the oximeter **pulse oximeter probe**'**s** detector (see Figure FF.2). This is one example of the optically-interfaced tester described above. If the oximeter **pulse oximeter probe**'s red LED were of the wrong wavelength for the calibration curve in use, this would definitely cause the oximeter to be inaccurate in actual use on **patients**. The **functional tester** would be entirely unaware of this error, as would the **pulse oximeter equipment** under test, so that inaccurate **pulse oximeter equipment** might well appear to be accurate. Some oximeter vendors provide **pulse oximeter probes** with a variety of different wavelengths; depending on the wavelength that is used, the oximeter is instructed to select the correct calibration curve from a variety of available curves. The instruction for selection of the correct curve is given to the oximeter by means of a coding device, such as a resistor, that is carried by the **pulse oximeter probe**. An important quality control requirement in new or **reprocessed pulse oximeter probes** is close matching of emitter wavelength (and wavelength distribution) to the calibration code in the **pulse oximeter probe**. Currently available **functional testers** cannot verify the correctness of the value of the centre wavelength.



Key

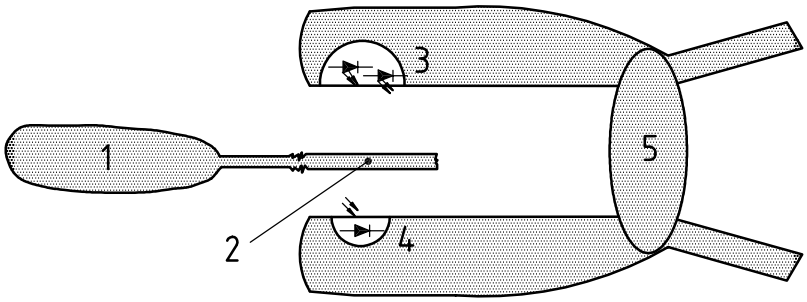
1	test finger	4	photodiode
2	sensor	5	LED
3	2 LEDs	6	photodiode

Figure FF.2 — Interface of a functional tester that uses a photodiode and LED to interact with a pulse oximeter probe

— Some **functional testers** provide comprehensive tests for all possible shorts and opens in the **pulse oximeter probe**. While this is a valuable test, electrical integrity is a necessary, but not sufficient, condition for **accuracy**.

— In a **pulse oximeter probe**, the colour of the plastic cushion or bandage that touches the **patient's** skin has an important effect on the calibration of the **pulse oximeter equipment**. If a bandage were badly stained, this could affect the **SpO_2 accuracy** of the **pulse oximeter probe** in actual use. The types of **functional tester** described above would be insensitive to the presence of the stain. This "bandage colour" issue actually symbolizes a larger sphere of concern. The **SpO_2 accuracy** of **pulse oximeter equipment** is affected strongly by the interacting optical properties of both the **patient's** tissue and every part of the surrounding optical environment. **Functional testers** are insensitive to such effects. A true pulse oximetry calibrator, when it appears, will need to reproduce faithfully this complex interaction. An implication is that the documentation accompanying any POC that eventually comes to market should include a discussion as to which physical and physiological aspects of **pulse oximeter equipment** performance are replicated, and which are not.

One class of **functional testers** has inherent sensitivity to the wavelength distributions of **pulse oximeter equipment's** emitter. Such testers work by modulating optically the light emitted by the **pulse oximeter probe's** own emitter, and conducting the modulated light to the **pulse oximeter probe's** detector. One such tester family works by modulating the amount of a dye solution that is forced between the **pulse oximeter probe's** emitter and detector (see Figure FF.3). Another such family uses a liquid crystal device to modulate the light en route from emitter to detector (see Figure FF.4). Such testers can be designed to cause wavelength-dependent modulation approximating the dependence of haemoglobin's optical absorption on wavelength. In principle they could also be designed to approximate the important effects of tissue scattering on oximeter calibration (although we know of no published evidence that this has yet been done). For such testers to approach the status of true POCs, they would also need to reproduce the optical interactions of human tissue with the coloured materials that surround emitter and detector. At the present state of the art, we believe that this class of **functional tester** should be not be assumed to come any closer to being true **SpO_2 accuracy** testers than the other classes of **functional tester**. They can be compared to other testers on the usual basis of comparing test **equipment** — trade-off among cost, convenience, durability, versatility and reproducibility of results.

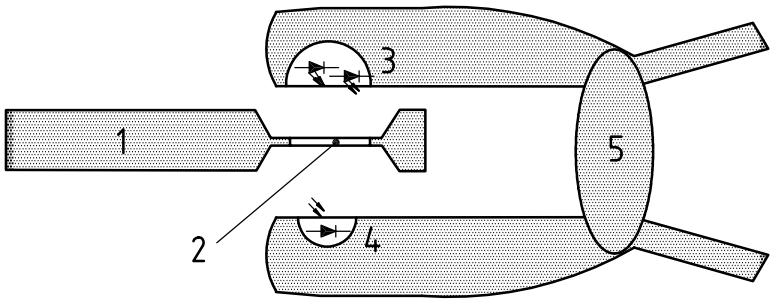


Key

1 bladder with dye mixture
2 variable-gap optical cell
3 2 LEDs
4 photodiode
5 sensor

NOTE By squeezing the bladder, the amount of dye that is forced between the plates of the optical cell is varied.

Figure FF.3 — Interface of a functional tester that uses a dye mixture



Key

1 test finger
2 liquid crystal modulator
3 2 LEDs
4 photodiode
5 sensor

Figure FF.4 — Interface of a functional tester that uses a liquid crystal modulator

Some vendors of new or **reprocessed pulse oximeter probes** have claimed that their **pulse oximeter probes** are routinely shown to be accurate by testing with **functional testers**. Such evidence has so far been insufficient to reflect the true performance of **pulse oximeter equipment**, given the limitations of **functional testers**.

FF.6 Beyond functional testers

How will we know when a true **pulse oximeter equipment** calibrator has been developed? Such a device would be recognized by the way it is used and by the nature of the published experimental results that validate its capabilities. Its properties would be as follows.

— The **pulse oximeter probe** of **pulse oximeter equipment** is applied to a part of the POC that approximates the dynamic optical behaviour of a body part for which the **pulse oximeter probe** is designed. The optical simulation should include the interaction that occurs between the **pulse oximeter probe's** materials and human tissue, in which light repeatedly leaves and re-enters the tissue, reflecting from the materials of the **pulse oximeter probe**.

— The POC can be set to simulate the optical behaviour of the simulated body part for a **patient** having selected oxygen saturation, $\mathbf{SaO_2}$, causing the **pulse oximeter equipment** to display an $\mathbf{SpO_2}$ reading.

— Validation experiments will have established that the reading induced in the **pulse oximeter equipment** by the POC matches within stated simulation $\mathbf{SpO_2}$ **accuracy** the reading that the same **pulse oximeter monitor** and **pulse oximeter probe** would give on a **patient**. The basic validation experiment that should be done, many times and under many conditions, is as follows.

1) Apply an oximeter **pulse oximeter probe** to a human being whose $\mathbf{SaO_2}$ is determined by measuring arterial blood samples in a multi-wavelength oximeter (e.g. **CO-oximeter**).

2) Observe the $\mathbf{SpO_2}$ value displayed by the **pulse oximeter equipment**. It doesn't matter whether this number is accurate or not.

3) Apply the same oximeter and **pulse oximeter probe** to the POC, with the POC set to simulate the same $\mathbf{SaO_2}$ that was seen on the human subject.

4) Observe the $\mathbf{SpO_2}$ value displayed by the **pulse oximeter equipment**.

5) Calculate the error of the POC as the difference between the two $\mathbf{SpO_2}$ values.

— The validation of POC performance should include testing over the following ranges of conditions:

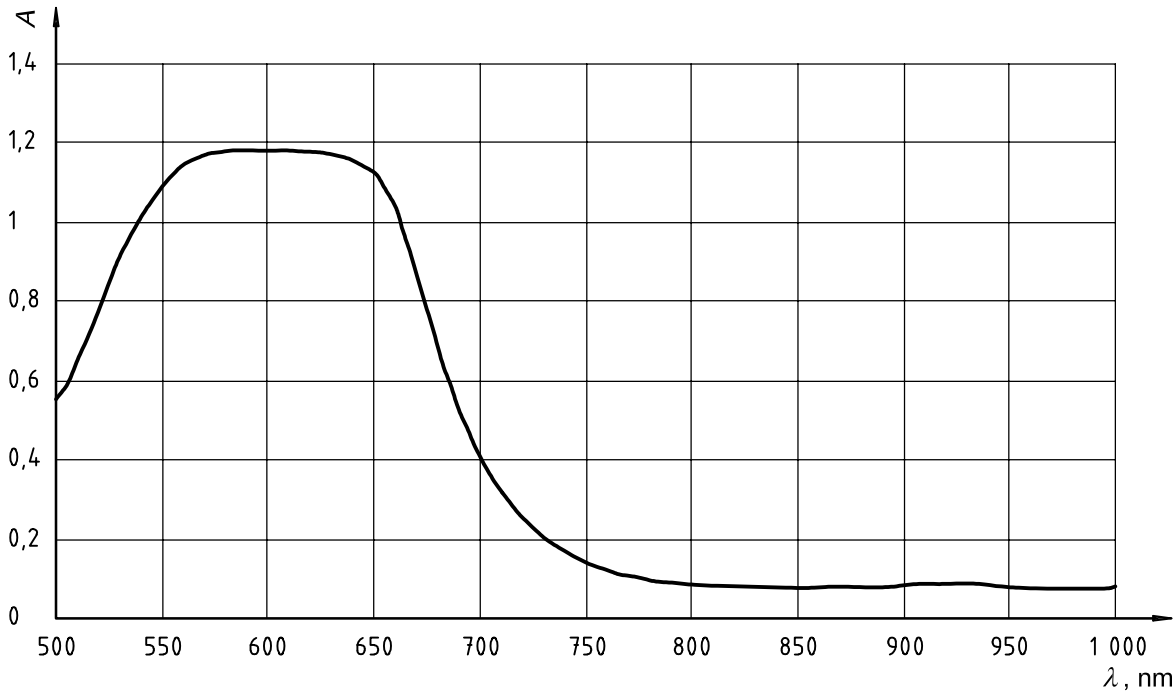
1) many different brands of **pulse oximeter equipment**, having emitters of the widest available variety of wavelength distributions;

2) many different **pulse oximeter probes** designed for use with the chosen body part, including the widest available variety of shapes and material colours. Testing should preferably include use of "challenge" **pulse oximeter probes** that are known to be very inaccurate in use on **patient**s. The POC is required to cause the oximeter to exhibit exactly the same inaccuracy that the real **patient** does;

3) testing should preferably include use of a particular class of challenge **pulse oximeter probes** that are known to produce very different $\mathbf{SpO_2}$ readings when tested on different human volunteers having the same value of $\mathbf{SaO_2}$. As an example of such a **pulse oximeter probe**, Figure FF.5 shows the reflectance spectrum of a particular blue bandage material which has been shown to give extremely variable performance from one **patient** to another. This is not a material that would be used in any commercial **pulse oximeter probe**; it was specifically selected to demonstrate the variable calibration that would result when compared to a standard **pulse oximeter probe**. Figure FF.6 displays this extremely variable calibration, compared to a standard **pulse oximeter probe**. This **pulse oximeter probe** could not be accurate on all **patients**, no matter what calibration curve was used in the oximeter. If a POC has not been validated in testing with such **pulse oximeter probes** (which implies that a particular **pulse oximeter probe/oximeter equipment** combination could appear accurate when tested on the POC but be inaccurate on many **patients**), this limitation should be disclosed clearly in the documentation accompanying the POC, and the POC **user** should be advised of the importance of testing **pulse oximeter equipment** on a variety of human volunteers. In order to test meaningfully the behaviour of these variable-calibration challenge **pulse oximeter probes**, the POC would presumably have to be adjustable to simulate one of several different human subjects.

Many **patients** or volunteer test subjects, tested at each $\mathbf{SaO_2}$ level where the POC is specified for use. Special emphasis should be given to testing at the lowest values of $\mathbf{SaO_2}$ at which the POC is specified for use, because **pulse oximeter equipment** errors tend to be larger at low saturation.

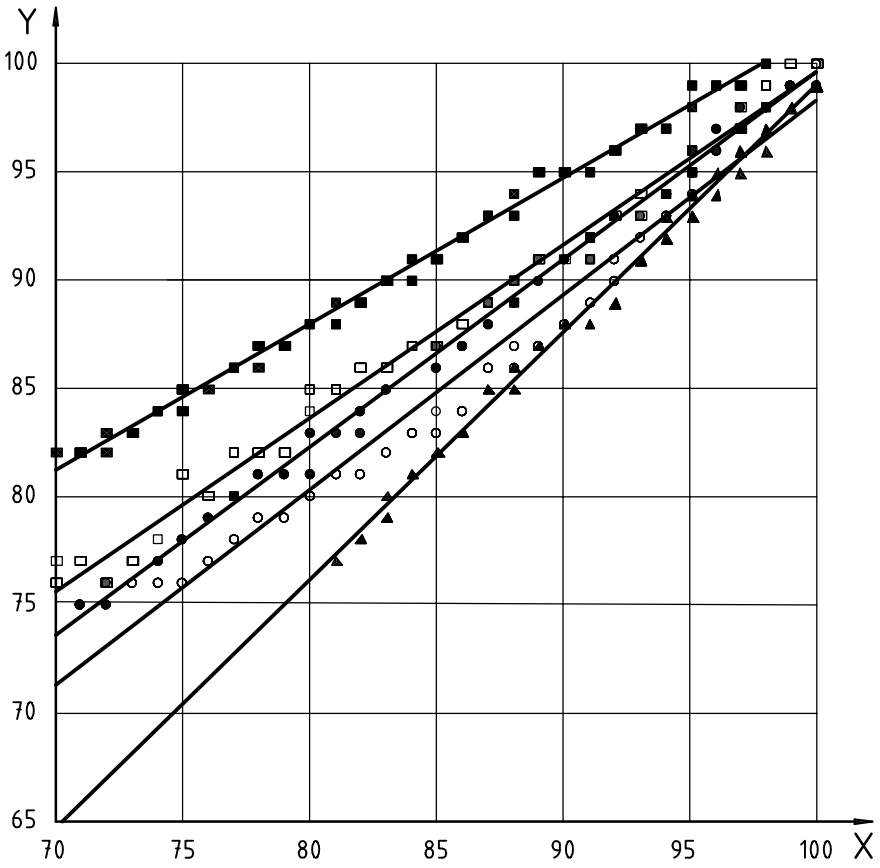
The **accuracy** specification of the POC does not include any component for inaccuracy of the **pulse oximeter equipment** under test (compare this to the typical **functional tester** specification, such as ± 1 $\mathbf{SpO_2}$ point $\pm$ stated oximeter $\mathbf{SpO_2}$ **accuracy**). It is the purpose of the POC to determine the $\mathbf{SpO_2}$ **accuracy** of the **pulse oximeter equipment**, without direct human testing. In this sense, the POC will be a secondary-standard, with **controlled desaturation study** testing on humans retaining the role of "gold standard." See also EE.3.



A absorbance, measured in reflection

λ optical wavelength

Figure FF.5 — Absorbency of blue bandage material (measured in reflection) used in a special test pulse oximeter probe with great patient-to-patient variability of calibration



Key

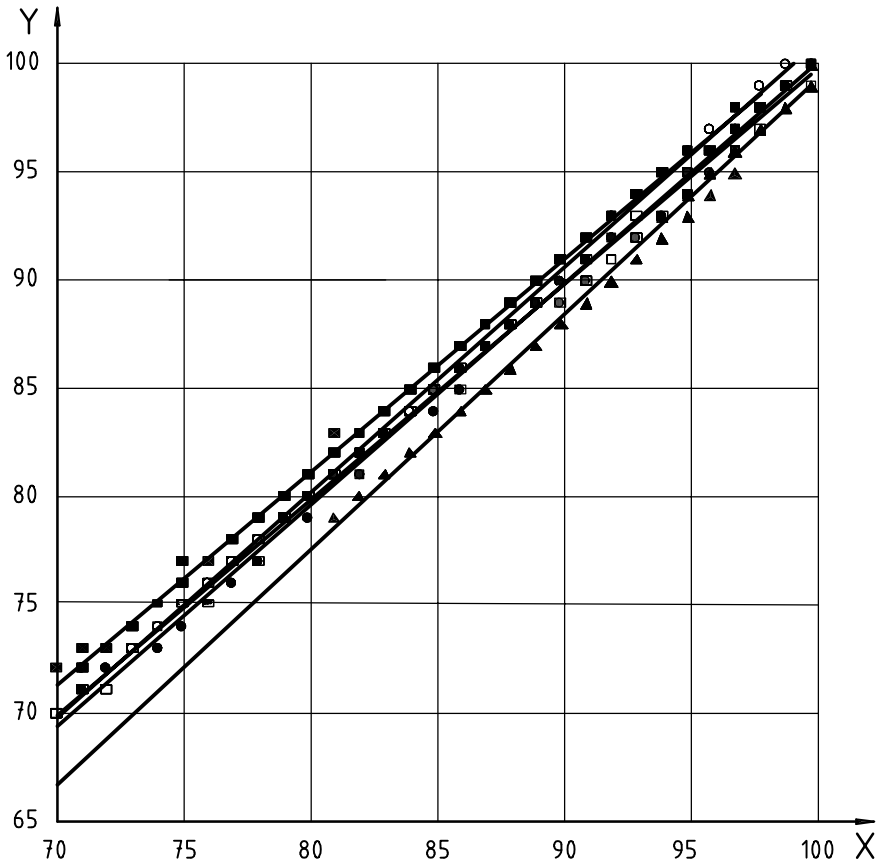
X reference SpO_2, %

Y blue test sensor SpO_2, %

a) Comparison of blue test sensor to standard production sensor

Blue test **sensor SpO_2** (left index finger) as a function of reference **sensor SpO_2** (left little finger). Separate regression line is shown for each of five test subjects.

Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects



Key

X reference SpO_2, %

Y test SpO_2, %

b) Comparison of one standard production sensor to another

Test **sensor SpO_2** (left middle finger) as a function of reference **sensor SpO_2** (left little finger). Separate regression line is shown for each of five test subjects.

Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects (*continued*)

Annex GG
(informative)

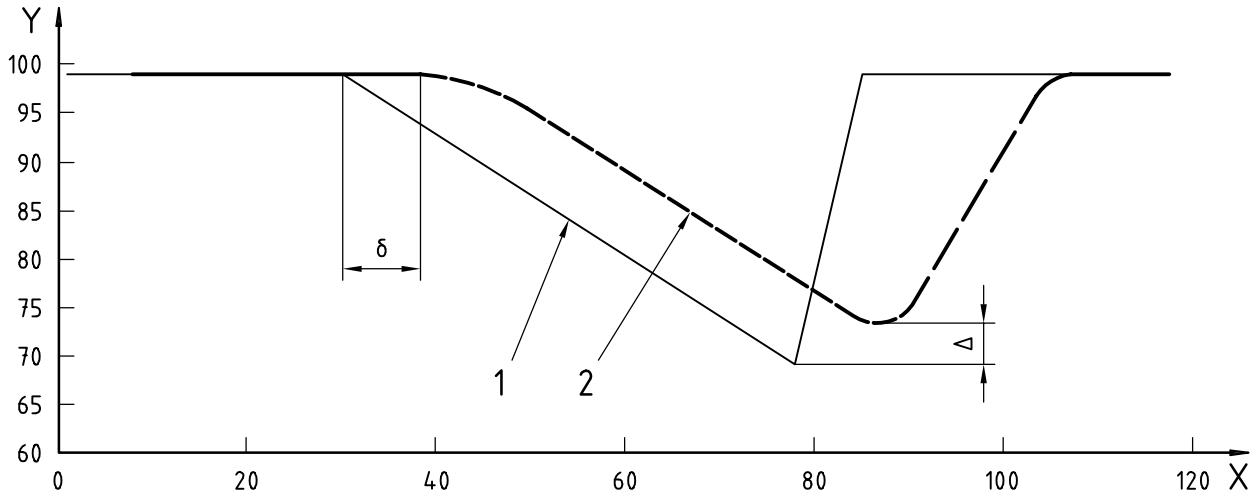
Concepts of equipment response time

GG.1 General

There can be tradeoffs between accurately tracking the magnitude of changes in saturation and minimizing the effects of noise. In general, faster response times can cause **pulse oximeter equipment** to be more vulnerable to noise, but can allow them to follow the actual saturation more closely. The response of some devices can be optimized for particular clinical situations. There are two important concepts in describing **pulse oximeter equipment** response. One is the *fidelity* in tracking saturation changes. The other is the *delay* from the time that an event occurs until the display or the generation of **alarm signals** indicates the event. “Fidelity” and “delay” are influenced by **pulse oximeter equipment** design and **operator settings**. **Pulse oximeter equipment** design can include signal processing and conditioning times and data transmission delays. Adjustable controls can set, for example, averaging time and **alarm signal generation delay**.

GG.2 Fidelity

Fidelity can be described graphically by showing the range of responses of the **pulse oximeter equipment** to a change in saturation. Figure GG.1 illustrates a simulated response of **pulse oximeter equipment** to a change in saturation. Figure GG.2 illustrates the simulated effect of different averaging times on the response of the **pulse oximeter equipment**.



Key

1 **SaO_2**

2 displayed **SpO_2**

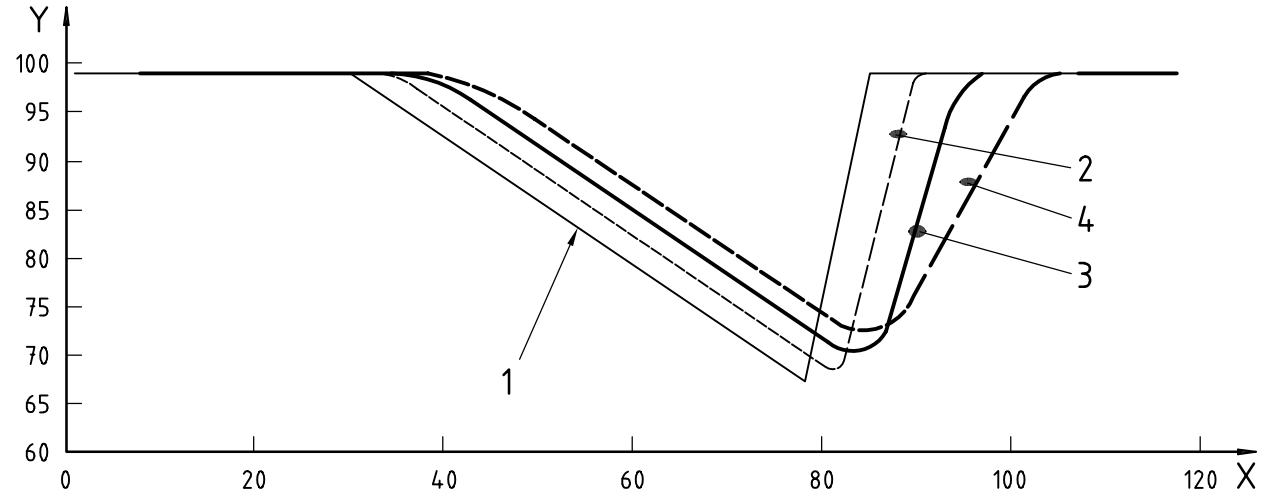
Δ saturation deviation

δ time delay

X time, in seconds

Y saturation, %

Figure GG.1 — Illustration of fidelity of pulse oximeter equipment performance in tracking saturation changes



Key

1 **SaO_2**

2 displayed **SpO_2**, faster averaging

3 displayed **SpO_2**, normal averaging

4 displayed **SpO_2**, slower averaging

X time, in seconds

Y saturation, %

Figure GG.2 — Illustration of effect of different averaging times on fidelity

The symbols δ and Δ in Figure GG.1 do not refer to any particular requirement in this International Standard. They are illustrated here as possible points of interest, in that these are the likely areas of **SpO_2 accuracy** that can be affected by different averaging or filtering techniques response curves. The span depicted by the symbol δ represents a time lag before changes in saturation become reflected in the processed **SpO_2** value. This lag can be caused by, for example, the time required for data acquisition, signal conditioning, and algorithm processing. The deviation denoted by Δ illustrates a lack of fidelity in reproducing the degree of change in a transient desaturation. Δ is generally affected by, for example, signal averaging and/or the **data update period**.

The importance of the errors (δ and Δ) introduced by the processing of the **SpO_2** parameter as well as the generation of **alarm signals** that the purchasers of **pulse oximeter equipment** need to consider for the applications in their clinical practice (see 6.8.2 5) are well illustrated in reference [40].

GG.3 Effects of delays

Delays can be described graphically, for example, by showing the response of the **pulse oximeter equipment** using the Figure GG.3. The time from t_1 to t_2 is the **alarm condition delay** and the time from t_2 to t_3 is the **alarm signal generation delay**.

A possible procedure to measure the sum of the **alarm condition delay** and **alarm signal generation delay** of **pulse oximeter equipment** is described below.

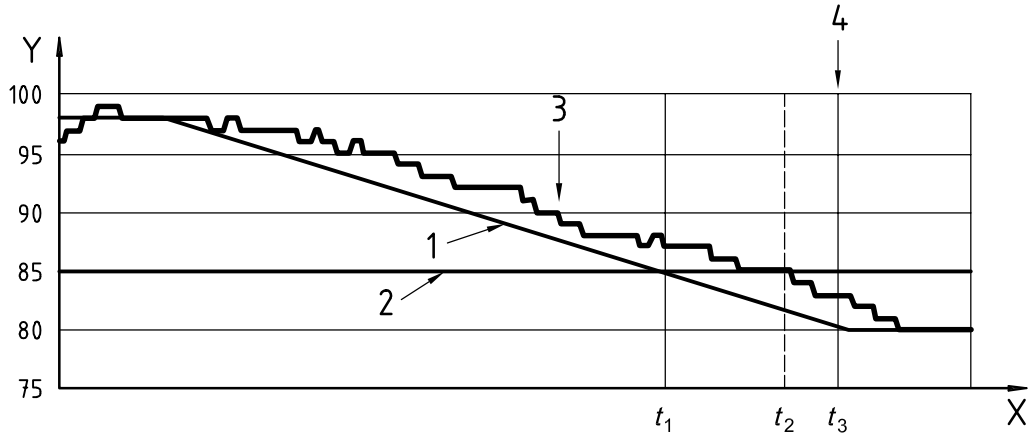
— A simulator is set to a start saturation level of e.g. 98 %.

— This level should be simulated for a period of time that is sufficient to allow stabilization of the **pulse oximeter equipment** under test (DUT).

— The simulator then changes the saturation level in a linear ramp function with a predefined slope (or any other predefined function) down to a given end-value (e.g. 5 % below the **alarm limit**).

— The sum of the **alarm condition delay** and **alarm signal generation delay** is defined as the time from having the simulated saturation passing the **alarm limit** threshold (e.g. 85 % or the default low saturation **alarm limit**) to the time the **alarm system** generates the appropriate **alarm signal**.

Figure GG.3 illustrates the components of **alarm signal generation delay**.



Key

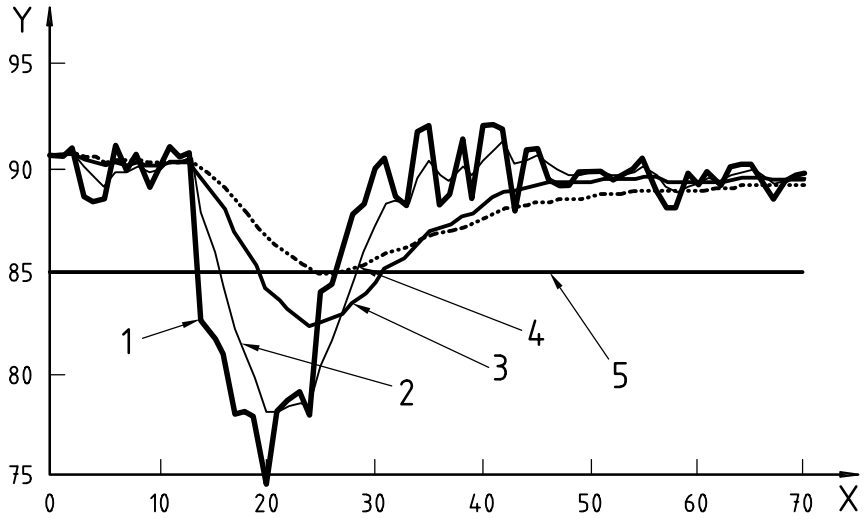
1 **SaO_2**
2 **alarm limit**
3 displayed **SpO_2**
4 **alarm signal** generation

X time, in seconds
Y saturation, %

Figure GG.3 — Graphic representation of components of alarm system delay

The delay due to the **pulse oximeter equipment** processing and averaging is $t_2 - t_1$, the **alarm condition delay**. The interval $t_3 - t_2$, the **alarm signal generation delay,** is attributed to the **alarm system** strategy and the communication time to the **alarm signal** generation device or **distributed alarm system** (e.g. **patient** monitor or central station). Thus, the overall **alarm system** delay time is $t_3 - t_1$.

Figure GG.4 represents a faster desaturation slope and a more realistic, noisier saturation signal. Curves A and B underestimate the depth of the fall in saturation. Curve C, faster averaging, can cross a low saturation **alarm limit** sooner than curve B, normal averaging, or curve A, slower averaging, which might not cause an **alarm condition** at all. The benefit of normal and slower averaging is to smooth out the otherwise noisy signal and reduce the number of **false positive alarm conditions**.



Key

1 unprocessed $\mathbf{SpO_2}$
2 displayed $\mathbf{SpO_2}$, faster averaging
3 displayed $\mathbf{SpO_2}$, normal averaging
4 displayed $\mathbf{SpO_2}$, slower averaging
5 **alarm limit**

X time, in seconds
Y saturation, %

Figure GG.4 — Illustration of the effects of different averaging times on a more rapid and noisier desaturation signal

Annex HH
(informative)

Reference to the Essential Principles

This International Standard has been prepared to support the essential principles of safety and performance of **pulse oximeter equipment** as medical devices according to ISO/TR 16142. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

Table HH.1 — Correspondence between this International Standard and the Essential Principles

Clause/subclause of this International Standard	Corresponding Essential Principle	Comments
all	1	
all, 6.1, 102.1, 201	2	
all, 4.101, 4.102, 102.1	3	
21, 49, 102.1	4	
21, 102.1	5	
4, 6.8.2, 42.3, 50, 51, 101, 102.1, 201	6	
43.101, 102.1	7.1	
48	7.2	
43.101	7.3	
—	7.4	Not applicable
48	7.5	
44.6, 102.1	7.6	
44.7	8.1	
—	8.1.1	Not applicable
—	8.1.2	Not applicable
48	8.2	
10.1.1, 102.1	8.3	
44.7	8.4	
—	8.5	Not applicable
44.7	8.6	
4.103, 6.1, 6.1 f), 51.101, 102.1, 102.2, 201	9.1	
21, 36, 102.1	9.2	
43.101	9.3	
50, 51.101, 101, 102.1	10.1	
46, 51.101, 101, 103, 201	10.2	
6.1 aa)	10.3	
32, 102.1	11.1.1	

Table HH.1 (*continued*)

Clause/subclause of this International Standard	Corresponding Essential Principle	Comments
29, 30, 31, 32, 33, 34, 35	11.2.1	
32, 102.1	11.2.2	
36	11.3.1	
6.8.2 aa) 2)	11.4.1	
—	11.5.1	Not applicable
—	11.5.2	Not applicable
—	11.5.3	Not applicable
52	12.1	
49, 201	12.2	
49, 201	12.3	
6.1 d) 4th dash, 101, 201	12.4	
36, 102.1	12.5	
19.4, 20.4, 102.1	12.6	
21, 102.1	12.7.1	
—	12.7.2	Not applicable
—	12.7.3	Not applicable
57	12.7.4	
42, 102.1	12.7.5	
—	12.8.1	Not applicable
42	12.8.2	
6	12.8.3	
6.1, 6.1 d) 1st dash, 6.1 f), 102.2	13.1	
50, 102.1	14.1	

Annex II
(informative)

Environmental aspects

The environmental impact generated by a **pulse oximeter equipment** measuring **SpO_2** is mainly restricted to the following occurrences:

a) impact on local environment during **normal use**;

b) disposal of biologic fluids during **controlled desaturation studies**;

c) use, cleaning and disposal of consumables during testing and **normal use**;

d) scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the **pulse oximeter equipment**.

See Table II.1 for a mapping of the life cycle of **pulse oximeter equipment** to aspects of the environment.

Table II.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause/subclause	Addressed in clause/subclause	Addressed in clause/subclause	Addressed in clause/subclause
1	Resource use	54	54	6.8.1, 54	54
2	Energy consumption	54	54	54 42	—
3	Emission to air	54	54	54 29 36 42 43 44 45 56.7 57 59 201	54
4	Emission to water	54	54	54 44	54
5	Waste	54	54 10.1	54 6.1 6.8.2 44 56.7	54 6.1 6.8.2
6	Noise	—	—	54 35 201	—
7	Migration of hazardous substances	54	—	54 6.1 6.8.2 25 44 45 48 56.7	54
8	Impacts on soil	—	—	—	54 6.8.2
9	Risks to the environment from accidents or misuse	54	—	54 6.8.2 44 45 56 57 201	54

Annex JJ
(informative)

Index of defined terms

Bibliography

[1] IEC/TR 60825-9, *Safety of laser products — Part 9: Compilation of maximum permissible exposure to incoherent optical radiation*

[2] ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

[3] ASTM E 456-96: *Standard terminology relating to quality and statistics. American Society for Testing and Materials*, 1996

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