BRITISH STANDARD

BS EN 865 : 1997
BS 5724 : Section 2.201 : 1997

Pulse oximeters — Particular requirements

The European Standard EN 865 : 1997 has the status of a British Standard

ICS 11.040.50

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/46, Lung ventilators and related equipment, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
Association of Paediatric Anaesthetists
British Anaesthetic and Respiratory Equipment Manufacturers' Association
Department of Health
Electro Medical Trade Association Limited
Institution of Mechanical Engineers
Institution of Physics and Engineering in Medicine and Biology
Intensive Care Society
Royal College of Paediatrics and Child Health
Safety Equipment Association

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on
15 July 1997

The following BSI references relate to the work on this standard:
Committee reference CH/46
Draft for comment 92/57781 DC

ISBN 0 580 27907 3

Amendments issued since publication

Amd. No.	Date	Text affected

Contents

National foreword

This British Standard has been prepared by Technical Committee CH/46 and is the English language version of EN 865 *Pulse oximeters — Particular requirements* published by the European Committee for Standardization (CEN).

Cross-references

Publication referred to	Corresponding British Standard
EN 475	BS EN 475 : 1995 *Medical devices. Electrically-generated alarm signals*
EN 60601-1 : 1990	BS 5724 *Medical electrical equipment* Part 1 : 1989 *General requirements for safety* BS EN 60601 *Medical electrical equipment*
EN 60601-1-2	Part 1 *General requirements for safety* Section 1.2 : 1993 *Collateral standard. Electromagnetic compatibility — Requirements and tests*
IEC 801-2	BS EN 60801 *Electromagnetic compatibility for industrial-process measurement and control equipment* Part 2 : 1993 *Electrostatic discharge requirements*

The Technical Committee has reviewed the provisions of IEC 79-4, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 16, an inside back cover and a back cover.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 865

April 1997

ICS 11.040.50

Descriptors: Electromedical equipment, pulse oximeters, safety requirements, accident prevention, detail specifications, protection against electric shocks, protection against mechanical hazards, radiation protection, explosion protection, fire protection, performance evaluation, tests, markings

English version

Pulse oximeters — Particular requirements

Oxymètres de pouls —
Prescriptions particulières

Pulsoximeter —
Besondere Anforderungen

This European Standard was approved by CEN on 1997-01-17. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Section eight. Accuracy of operating data and protection against hazardous output

50 Accuracy of operating data

Clause **50** of EN 60601-1 : 1990 applies with the following addition:

50.101 For SpO_2, calibration ranges shall not extend beyond measured values (but interpolation is permitted) and the basis for calibration shall be stated (see **6.8.2**aa of this standard).

NOTE. Ranges in which displayed SpO_2 values have been reached by extrapolation of data from *in vivo* or *in vitro* methods are not considered to be calibrated ranges.

51 Protection against hazardous output

Clause **51** of EN 60601-1 : 1990 applies with the following additions:

51.101 If the pulse oximeter is provided with user-adjustable controls to compensate for dysfunctional haemoglobin, there shall be a clear indication that these controls have been adjusted.

51.102 The display value shall be updated at intervals of no more than 30 s and not hold the previous value for longer than the update time (see **6.8.2**aa, third dash, of this standard).

51.103 Control function and position

If the intended test control function is not clearly distinguishable when displayed on the pulse oximeter, the corresponding control(s) shall automatically return from such control function position(s). The position of measurement and test control shall be clearly distinguishable. Any calibration control shall include a means to prevent inadvertent change from the intended position.

Operator-operable function checks other than 'power on' for test controls such as battery condition or signal operation should automatically return from the check, test, or override position.

All other controls should also include means to prevent inadvertent changes from the intended position and should have clearly distinguishable positions.

NOTE 1. Attention is drawn to the fact that the ISO convention for adjustment of rotary controls in pneumatic and fluidic systems is contrary to the IEC convention for electronic controls.

Manufacturers should ensure consistency and visibility of rotary controls on a modular basis.

NOTE 2. The separation between control knobs, switches, toggles, pinwheels, or push buttons should conform to the recommendations given in ISO 7250.

Controls and their associated markings shall be visible and/or legible to a user having a visual acuity (corrected if necessary) of at least 1,0 when the user is located 1 m in front of the pulse oximeter and the illuminance level is 215 lx. Markings shall be clearly identified with their associated controls.

51.104 Alarms

51.104.1 Alarm prioritization

The alarms of the pulse oximeter are grouped in three categories: high priority, medium priority or low priority and the corresponding signal shall have the characteristics specified in EN 475.

51.104.1.1 The auditory components of these alarms should allow silencing by the operator until the pulse oximeter is placed in use (i.e. connected to the patient) in order to reduce nuisance alarms.

51.104.1.2 The set points of adjustable alarms shall be indicated continuously or on operator demand.

51.104.2 High priority signal

When a high priority signal is activated and when the condition causing the alarm has cleared, the auditory component shall reset automatically. The duration of the auditory signal shall not be less than one complete burst.

51.104.3 Medium priority signal

When a medium priority signal is activated and when the condition causing the alarm has cleared the auditory component shall reset automatically. The duration of the auditory signal shall not be less than one complete burst.

51.105R Alarm characteristics

51.105.1 If intended for continuous monitoring, the pulse oximeter shall have an operation adjustable low SpO_2 alarm (see also **51.104.1** of this standard).

Adjustment of alarm setpoints or default parameters shall require a deliberate sequence of actions.

NOTE. In certain clinical applications, such as neonatal monitoring, a high saturation alarm may provide an additional safety feature.

51.105.2 The difference between the alarm set point and the SpO_2 activating the alarm shall not exceed 2 % SpO_2.

Compliance shall be checked by the test given in **51.105.3** of this standard.

51.105.3 Method of test for SpO_2 alarm set point accuracy

Generate at least four stable SpO_2 readings that span the range of the alarm system in approximately equal steps by varying the input to the pulse oximeter, or by adjusting the calibration control (if provided).

For each SpO_2 reading, adjust the alarm set point so that the alarm is deactivated. Incrementally adjust the alarm set point until the alarm is activated. The difference between the alarm set point and the corresponding SpO_2 reading shall not exceed 2 % SpO_2.

NOTE. An alarm can be of a type that is activated at a SpO_2 reading above (high alarm) or below (low alarm) the alarm set point.

51.106 The default limit on the low SpO_2 alarm shall be 80 % SpO_2 or greater.

51.107 Temporary silencing of audible alarms, if provided, shall not exceed 2 min. The visual signal shall remain until the condition is corrected. If permanent disabling of the audible alarm is provided, it shall require deliberate action on the part of the operator if the disabling is performed after the pulse oximeter is ready for use. The visual signal shall remain until the condition is corrected.

51.108 If intended for continuous monitoring, a probe fault alarm shall be provided and the corresponding signal shall not be a high priority one and its function shall be checked by the test given in **51.109**.

51.109 Disconnect the probe from the pulse oximeter and replace it with a circuit whereby each signal wire can be opened or shortened to any other probe wire. Verify that the alarm is activated.

Section nine. Abnormal operation and fault conditions; environmental tests

52 Abnormal operation and fault conditions

Clause **52** of EN 60601-1 : 1990 applies.

53 Environmental tests

Clause **53** of EN 60601-1 : 1990 applies.

Section ten. Constructional requirements

54 General

Clause **54** of EN 60601-1 : 1990 applies.

55 Enclosures and covers

Clause **55** of EN 60601-1 : 1990 applies.

56 Components and general assembly

Clause **56** of EN 60601-1 : 1990 applies.

57 Mains parts, components and layout

Clause **57** of EN 60601-1 : 1990 applies.

58 Protective earthing - Terminals and connections

Clause **58** of EN 60601-1 : 1990 applies.

59 Construction and layout

Clause **59** of EN 60601-1 : 1990 applies.

Section eleven. Additional requirements specific to pulse oximeters

101 Pulse amplitude

A visual display of signal amplitude shall be provided (see also annex BB of this standard).

Annexes

Appendices A to K of EN 60601-1 : 1990 apply.

Annex AA (informative) Rationale

AA.1 General and scope

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

The present technology requires an adequate concentration of haemoglobin, a volume 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 oximeters may not function effectively during cardiopulmonary bypass or extreme low-flow states, and are not at present intended as a means for the measurement of blood flow or volume.

Within the limitations of the present technology, pulse oximetry is not a precision measurement technique. The presently marketed *in vivo* pulse oximeters are not a replacement for measurement of blood samples by bench-type oximeters utilizing more than two wavelengths of light. Development of pulse oximeters that utilize more than two wavelengths of light for measurement and determination may improve their precision.

The values derived from pulse oximetry are not a measurement of blood or tissue oxygen tension, and therefore pulse oximetry provides no direct indication of oxygen delivery to, or consumption by, tissues.

There is no reproducible or comparative method available whereby a user or a test-house can verify the accuracy of calibration of any pulse oximeter. Recently published work by Reynolds et al shows that pulse oximeter readings can be made on a model finger in an *in vitro*, oxygenated blood circuit. Comparisons have been published of the results from 10 different makes of pulse oximeter with those from a multi-wavelength oximeter over a wide range of SpO_2 values using the *in vitro* system. These results showed that the pulse oximeters varied widely in their reproducibility and linearity and that in four cases there appeared to be non-linearity between the calibrated range and the uncalibrated range obtained by extrapolation. The authors of the paper stress that this *in vitro* system is currently a research method and is not yet suitable for the calibration of pulse oximeters.

Although work is progressing on the development of direct *in vitro* calibration methods, present techniques still require the use of human subjects. To include test methods in standards that require the use of human subjects, has, through past experience, been found to be unacceptable, and therefore *in vivo* test methods are not included in this standard.

The known complications of pulse oximetry are pressure injuries from improper probe application, burns from the light source and from improper grounding of electrosurgical units, and chemical burns from electrolysis as a result of current leakage from the probe.

Pulse oximeters are increasingly being used by personnel who are not necessarily familiar with the pitfalls of their operation. There is an ongoing need for education of users in which manufacturers could play a part. Although there is a limit to the scope for a standard to ensure aspects of safety which are associated with the competence and training of the users of any equipment, the provision of appropriate warnings is considered to be within the remit of the standard.

AA4.1 (3.6aa) A fault which is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded. It is essential that such a first fault is regarded as a normal condition.

AA6.8.2 (6th dash) Other artefacts have been reported to interfere with measurements:

- 'flooding' when a loose probe detects high intensity light from, for example theatre lights or treatment lights, and typically gives a fixed reading 85 % SpO_2;
- movement of the limb to which the probe is attached;
- inappropriate positioning of the probe.

AA.42 Due to the thermal energy present, there can be increased temperature in the tissue, and this can cause burns.

AA.43 Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which 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;
- an oxidant.

Therefore, following the basic safety concepts of EN 60601-1 : 1990, the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may 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 may occur provided it is self limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of 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 79-4.

In considering the ignitable materials particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, e.g. ignition tests, may be necessary to assume safety under these conditions.

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 the American NFPA publication 53M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. However, 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 may be dissipated and the proximity and type of any 'fuel' present.

It is 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. 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 may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. 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 add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a 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.51.9 80 % SpO_2 is a generally accepted lower limit for most clinical situations; however lower alarm limits may be desirable in particular clinical conditions. Lower limits can be set by the user after power up.

Annex BB (informative)
Guidance on pulse signals

Visual indication of the signal adequacy should be provided.

If a variable pitch auditory annunciation is provided for the pulse signal, a pitch or amplitude change in the sound indicator should be provided parallel to the reading, for example as the SpO_2 reading lowers, the sound pitch should also be lowered.

Annex CC (informative)
Bibliography

1 NFPA Publication 53 M *Fire hazards in oxygen-enriched atmospheres*[1)]

2 Reynolds et al : 1992. British Journal of Anaesthesia, Vol 68; pp 365-369.

3 ISO 7250 *Basic human body measurements for technical design.*

[1)] Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy MA 02269-9101, USA.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard, as listed in table ZA.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All	1, 2	
4 (3.1)	8.3, 8.6	
4 (3.6aa)	1, 12.1	
6	13.1	
6.1	9.1, 13.2, 13.3 a) to m), 13.4, 13.5	
6.1a	10.3	
6.1bb	8.7	
6.1cc	8.7	
6.1dd	8.7	
6.4	13.2	
6.8	13.4, 13.6 a) to p)	
6.8.2	3, 9.1, 9.2	
6.8.2aa 1st dash	7.3	
6.8.2aa 2nd dash	8.1	
6.8.2aa 6th dash	4, 6	
6.8.2aa 13th dash	9.1	
6.8.2*aa 15th dash*	10.1	
6.8.2aa 16th dash	7.1, 7.2	
6.8.2aa 19th dash	12.1	
6.8.3d	7.2	
17	12.6	
18	12.6	

Table ZA.1 Correspondence between this European Standard and EU Directives *(continued)*

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
19	12.6	
19.4h 9)	7.6	
20	12.6	
21	9.2, 12.7.1, 12.7.2, 12.7.3	
22	9.2, 12.7.1, 12.7.2, 12.7.3	
23	9.2, 12.7.1, 12.7.2, 12.7.3	
24	9.2, 12.7.1, 12.7.2, 12.7.3	
25	9.2, 12.7.1, 12.7.2, 12.7.3	
26	9.2, 12.7.1, 12.7.2, 12.7.3	
27	9.2, 12.7.1, 12.7.2, 12.7.3	
28	9.2, 12.7.1, 12.7.2, 12.7.3	
29	9.2, 11.1, 11.3	
30	9.2, 11.1, 11.3	
31	9.2, 11.1, 11.3	
32	9.1, 11.1, 11.2.1, 11.2.2, 11.3, 11.4	
33	9.2, 11.1, 11.2.1, 11.2.2, 11.3, 11.4	
34	9.2, 11.1, 11.3	
35	9.2, 11.1, 11.3	
36	9.2, 11.1, 11.3, 12.5	
37	7.3	
38	7.3	
39	7.3	
40	7.3	
41	7.3	
42	9.2, 12.7.5	
43	7.1, 7.3, 9.2, 9.3	

Table ZA.1 Correspondence between this European Standard and EU Directives *(continued)*		
Clause/subclause of this European Standard	**Corresponding Essential Requirement of Directive 93/42/EEC**	**Comments**
44	7.5, 7.6, 9.2	
45	9.2	
46	9.2	
47	9.2	
48	9.2	
49	9.2, 12.2, 12.3	
50	10.1	
51	6, 12.8.1	
51.101	10.2, 12.9	
51.102	12.9	
51.103	10.2, 12.9	
51.104	12.8.2	
51.105	12.4, 12.8.2	
52	12.6	
54	1	
55	1	
56	1, 9.1	
57	1, 9.1, 12.7.4	
58	1, 12.6	
59	1	

N/A = not applicable

Foreword

This European Standard has been prepared by Technical Committee TC 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

Annexes AA, BB, CC and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

Introduction

This European Standard is one of a series based on European Standard EN 60601-1 : 1990.

In EN 60601-1 this type of European Standard is referred to as a 'Particular Standard'. As stated in **1.3** of EN 60601-1 : 1990, the requirements of this European Standard take precedence over those of EN 60601-1 : 1990. Clauses and subclauses additional to those in EN 60601-1 : 1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional items in lettered lists are lettered beginning 'aa)'.

The approximate measurement of haemoglobin saturation through the use of pulse oximetry has become an increasingly common practice in many areas of clinical medicine, such as anaesthesia, respiratory therapy, paediatrics, and intensive care. The minimum safety requirements given in this European Standard are based on parameters that are achievable within the limits of existing technology.

Annex AA contains a rationale for the most important requirements. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this standard. Clauses and subclauses marked with R after their number have corresponding rationales contained in annex AA.

Section one. General

1 Scope

Clause 1 of EN 60601-1 : 1990 applies except that **1.1** is replaced by the following:

1.1 This European Standard specifies requirements for the safety of pulse oximeters, as defined in **3.12** of this standard, intended for use in the approximate measurement of the saturation of human arterial haemoglobin, non-invasively.

The field of application includes, but is not limited to:

a) perioperative use;

b) adult critical care application;

c) paediatric and neonatal applications;

d) general determination of saturation on hospitalized and non-hospitalized patients.

Pulse oximeters intended for use in laboratory research applications and 'bench' type oximeters that require a blood sample from the patient are outside the scope of this standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies:

Annex L of EN 60601 : 1990 applies with the following additions:

EN 475	*Medical devices — Electrically-generated alarm signals*
EN 60601-1 : 1990	*Medical electrical equipment* Part 1: *General requirements for safety* (IEC 601-1:1988)
EN 60601-1-2	*Medical electrical equipment* Part 1: *General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests* (IEC 601-1-2:1993)
IEC 79-4	*Electrical apparatus for explosive gas atmospheres —* Part 4: *Method of test for ignition temperature*
IEC 801-2	*Electromagnetic compatibility for industrial-process measurement and control equipment —* Part 2: *Electrostatic discharge requirements*

3 Terminology and definitions

For the purposes of this standard, clause 2 of EN 60601-1 : 1990 applies with the following additions.

3.1 alarm

Signal that is activated when a monitored variable equals or crosses the alarm limit.

3.2 alarm set point

Setting of the adjustment control or display value which indicates the SpO_2 reading, at or beyond which the alarm is intended to be activated.

NOTE. Terms such as 'alarm limits' or 'alarm threshold' are frequently used to describe the same function.

3.3 alarm system

Those parts of the pulse oximeter which:

a) establish the alarm set point(s);

b) activate an alarm when the SpO_2 is less than or equal to the low alarm set point or is equal to or greater than the high alarm set point.

3.4 calibration range

Range over which SpO_2 values have been calibrated and validated by appropriate *in vivo* or *in vitro* methods.

3.5 default setting; default limits

Parameters first active on power up of the device.

3.6 display range

Range of SpO_2 values indicated by the pulse oximeter.

3.7 display update period

Intervals between updates of the displayed values.

3.8 fractional saturation

That saturation given by the oxyhaemoglobin (O_2Hb) divided by the total haemoglobin (Hb_{total}), represented mathematically as:

$$\frac{O_2Hb}{Hb_{total}}$$

3.9 functional saturation

That saturation given by the oxyhaemoglobin divided by the sum of the oxyhaemoglobin and the deoxyhaemoglobin (HH_b), represented mathematically as:

$$\frac{O_2Hb}{(O_2Hb + HHb)}$$

3.10 probe

Part of the pulse oximeter intended to sense the signal from the patient from which the SpO_2 is derived.

3.11 probe fault

Condition including, but not limited to a probe component failure or the disconnection of the probe from either the pulse oximeter, or from the patient.

3.12 pulse oximeter

Device for determination of saturation of haemoglobin non-invasively from light signals of at least two wavelengths transmitted through or reflected from tissues.

NOTE. The measurement principle depends on a changing signal caused by the pulsatile nature of blood flow.

3.13 $Sa0_2$

Percent haemoglobin saturation with oxygen in systemic arteries.

3.14 SpO_2

Percent haemoglobin saturation with oxygen, either fractional or functional, as measured by a pulse oximeter and displayed as a percentage.

3.15 Total haemoglobin; Hb_{total}

Sum of all haemoglobin species including, but not limited to, oxyhaemoglobin, methaemoglobin (Met Hb), deoxyhaemoglobin and carboxyhaemoglobin (COHb).

4 General requirements and general requirements for test

4.1 Modifications to clause 3 of EN 60601-1 : 1990

Clause **3** of EN 60601-1 : 1990 applies with the following additions.

3.1 Add the following to **3.1**:

Packaging of equipment shall be of sufficient strength to ensure integrity of the equipment during storage and transport of the device.

For sterile equipment, packaging shall ensure sterile conditions until opened, damaged or its expiration date is reached or exceeded.

3.6 Add the following items:

3.6aa) Incorrect output resulting from software errors is an applicable single fault condition.

3.6bb) R An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

4.2 Modification to clause 4 of EN 60601-1 : 1990

Clause **4** of EN 60601-1 : 1990 applies with the following addition.

4.101 Test methods other than those specified in this European Standard but of equal or greater accuracy and severity may be used to verify compliance with the requirements of this standard. However, in the event of dispute, the methods specified in this European Standard shall be used as the reference methods.

5 Classification

Clause **5** of EN 60601-1 : 1990 applies.

6 Identification marking and documents

Clause **6** of EN 60601-1: 1990 applies with the following additions and modifications.

In **6.1**, replace item b) by the following:

If the size of the pulse oximeter does not permit the complete marking as specified throughout this clause in EN 60601-1 : 1990, at least the following shall be marked on the pulse oximeter:

- the name of the manufacturer;
- a serial number or lot or batch identifying number;*
- symbol number 14 in table D.1 of EN 60601-1 : 1990;
- if not provided with a low SpO_2 alarm, the words 'NOT FOR CONTINUOUS MONITORING'.

In **6.1**, add the following to item f):

- a serial number or other lot or batch identifying number;
- detachable applied parts shall be marked with type number and a batch or serial number on them or on the packaging as appropriate.

In **6.1**, add the following additional items:

- aa) Displays of percent saturation shall be marked as % SpO_2. All other displayed measured values shall be marked in appropriate units.
- bb) Appropriate marking shall be provided on the package or on the probe itself if the probe is for single patient use or for single use as applicable.
- cc) Packages shall be marked with the word 'STERILE' where appropriate.
- dd) Where appropriate an indication of the time limit for completely safe use, expressed as the year and month.

In **6.7** add the following to item a)

Colours of indicator lights shall comply with EN 475.

Compliance shall be checked by visual inspection.

In **6.8.2** add the following item:

- aa) The instructions for use shall additionally include the following information:
- If the pulse oximeter is provided with adjustable alarm limits, the range of adjustment of the alarm limits.
- Appropriate methods of disinfection and/or sterilization of both the probe and the body of the pulse oximeter, where applicable.

If probes are delivered in sterile packaging, the instructions for use shall contain the necessary information regarding how to re-sterilize or dispose of the probe in the event of damage to the sterile packaging and/or the probe.

– The display update period of the pulse oximeter in various operating conditions. (See **51.102** of this standard).

– The calibration range of the pulse oximeter.

– The display range of the pulse oximeter.

– R any types of interference known to influence the function of the pulse oximeter at the time that the instructions for use were prepared.

NOTE. Typical causes of interference include, but are not limited to, ambient light, movement, electromagnetic interference, artifacts, dysfunctional haemoglobin, and certain dyes.

– If the pulse oximeter requires in-service calibration, a suitable calibration procedure.

– The means to accomplish alarm silencing, for example, during probe disconnection, probe off the finger etc. and method for manual self-testing of the alarm circuitry if an automatic self-test is not provided.

– If applicable, the default limits for the alarm(s) or any other user-adjustable controls which are set when the pulse oximeter is switched on.

– Whether the pulse oximeter is calibrated to display functional or fractional saturation.

– If the pulse oximeter displays a visual indication of the patient's pulse, (e.g. by waveform or straight bar graph) a statement of whether or not that display is proportional to the pulse volume.

– If no low SpO_2 alarm is provided, directions not to use the pulse oximeter for continuous monitoring.

– The accompanying documents shall specify probes which can be used with the pulse oximeter.

– The manufacturer shall also state in the accompanying documents the recommended application time for each probe at a single site.

– The accuracy and the range of haemoglobin saturation with oxygen over which the accuracy of the pulse oximeter is claimed shall be disclosed. The manufacturer shall also disclose whether the calibration was to functional or fractional saturation. Test methods shall be available from the manufacturer upon request.

If measurement of pulse rate is provided, the manufacturer shall disclose in the accompanying documents the accuracy of the pulse rate measurement, and the range over which accuracy is claimed. The test methods shall be available from the manufacturer on request.

– The instructions for use shall include all necessary information about materials which the patient or user may come into contact with, as regards toxicity and/or action on tissues. The wavelength range and the energies of the light emitted by the probe shall be stated.

– The characteristics of alarms provided.

– If unusual risks are related to the disposal of the equipment or parts thereof including batteries and/or rechargeable batteries, the manufacturer shall specify those items in the instructions for use, and state whether the manufacturer is able to dispose of the listed items.

– Manufacturers of software-controlled devices shall disclose by which means the possibility of hazards arising from errors in the software programme is minimized.

7 Power input

Clause **7** of EN 60601-1 : 1990 applies.

Section two. Environmental conditions

8 Basic safety categories

Not used.

9 Removable protective means

Not used.

10 Environmental conditions

Clause **10** of EN 60601-1 : 1990 applies.

11 Not used.

12 Not used.

Section three. Protection against electric shock hazards

13 General

Clause **13** of EN 60601-1 : 1990 applies.

14 Requirements related to classification

Clause **14** of EN 60601-1 : 1990 applies.

15 Limitation of voltage and/or energy

Clause **15** of EN 60601-1 : 1990 applies.

16 Enclosures and protective covers

Clause **16** of EN 60601-1 : 1990 applies.

17 Separation

Clause **17** of EN 60601-1 : 1990 applies.

18 Protective earthing, functional earthing and potential equalization

Clause **18** of EN 60601-1 : 1990 applies.

19 Continuous leakage currents and patient auxiliary currents

Clause **19** of EN 60601-1 : 1990 applies except for the following modification:

In **19.4**h 9) Delete the second sentence in the first paragraph ('Alternatively ..... immersed') and substitute the following:

Probes marked as watertight (using symbol 13 in table D.1 of EN 60601-1 : 1990 shall comply with the following test: Immerse the probe for 1 min in a saline solution containing 0,9 % *m/V* sodium chloride which is maintained at a temperature between 20 °C and 25 °C. While the probe is still immersed, perform the tests for patient leakage current as specified in clause **19.4**g 5) of EN 60601-1 : 1990.

20 Dielectric strength

Clause **20** of EN 60601-1 : 1990 applies except for the following addition:

20.4 aa) Probes marked as watertight (using symbol 13 in table D.1 of EN 60601-1 : 1990 shall comply with the following test: Immerse the probe for 1 min in a saline solution containing 0,9 % *m/V* sodium chloride which is maintained at a temperature between 20 °C and 25 °C. While the probe is still immersed, perform the tests for dielectric strength as specified in clause **20.4**a of EN 60601-1 : 1990.

Section four. Protection against mechanical hazards

21 Mechanical strength

Clause **21** of EN 60601-1 : 1990 applies except as follows:

Replace **21.5** by the following:

21.5 Patient probes and pulse oximeters which are hand held during normal use and cord-connected control switches shall not present a safety hazard as a result of a free fall from a height of 1 m onto a hard surface.

Compliance shall be checked by the following test:

Allow the test sample to be tested to fall freely once from each of three different starting orientations from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood having a density of greater than 700 kg/m^3) which lies flat on a rigid base (concrete block). After this test no live parts shall have become accessible. Cracks not visible to the naked eye and surface cracks in fibre-reinforced mouldings and the like shall be ignored. If the test sample appears operational after the fall, a dielectric strength test, according to clause **20** of EN 60601-1 : 1990, shall be carried out.

22 Moving parts

Clause **22** of EN 60601-1 : 1990 applies.

23 Surfaces, corners and edges

Clause **23** of EN 60601-1 : 1990 applies.

24 Stability in normal use

Clause **24** of EN 60601-1 : 1990 applies.

25 Expelled parts

Clause **25** of EN 60601-1 : 1990 applies.

26 Vibration

Not used.

27 Pneumatic and hydraulic power

Clause **27** of EN 60601-1 : 1990 applies.

28 Suspended masses

Clause **28** of EN 60601-1 : 1990 does not apply.

Section five. Protection against hazards from unwanted or excessive radiation

29 X-radiation

Clause **29** of EN 60601-1 : 1990 does not apply.

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

Clause **30** of EN 60601-1 : 1990 does not apply.

31 Microwave radiation

Clause **31** of EN 60601-1 : 1990 applies.

32 Light radiation (including lasers)

Clause **32** of EN 60601-1 : 1990 applies.

33 Infra-red radiation

Clause **33** of EN 60601-1 : 1990 applies.

34 Ultra-violet radiation

Clause **34** of EN 60601-1 : 1990 applies.

35 Acoustical energy (including ultrasonics)

Clause **35** of EN 60601-1 : 1990 does not apply.

36 Electromagnetic compatibility

Clause **36** of EN 60601-1 : 1990 applies with the following additions:

36.101 Electromagnetic compatibility

The pulse oximeter shall continue to function and meet the requirements of this European Standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2.

If an anomaly occurs, such as display interruption, alarm activation etc., it shall be possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.

NOTE. Silencing of an activated alarm should not be considered as a failure.

36.102 Electrostatic discharge

Discharges shall be applied only to accessible parts and coupling planes as defined in IEC 801-2.

Section six. Protection against hazards of ignition of flammable *anaesthetic mixtures*

37 Locations and basic requirements

Clause **37** of EN 60601-1 : 1990 applies.

38 Marking, accompanying documents

Clause **38** of EN 60601-1 : 1990 applies.

39 Common requirements for category AP and category APG equipment

Clause **39** of EN 60601-1 : 1990 applies.

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

Clause **40** of EN 60601-1 : 1990 applies.

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

Clause **41** of EN 60601-1 : 1990 applies.

Section seven. Protection against excessive temperatures and other safety hazards

42 R Excessive temperatures

Clause **42** of EN 60601-1 : 1990 applies.

43 R Fire prevention

Clause **43** of EN 60601-1 : 1990 applies with the following addition:

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, 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 is present.

Determine the minimum ignition temperature in accordance with IEC 79-4 using the oxidizing conditions present under the normal and single fault conditions.

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

If sparking can occur under normal or single fault conditions 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

Clause **44** of EN 60601-1 : 1990 applies with the following modifications:

Replace the first paragraph of **44.3** by the following:

During and after the test as described in clause **44.3** of EN 60601-1 : 1990:

- the pulse oximeter shall be so constructed that the spillage does not wet parts which can cause a safety hazard;
- the pulse oximeter shall continue to function within the tolerances specified by the manufacturer for normal use.

45 Pressure vessels and parts subject to pressure

Clause **45** of EN 60601-1 : 1990 applies.

46 Human errors

Not used.

47 Electrostatic charges

Not used.

48 Biocompatibility

Clause **48** of EN 60601-1 : 1990 applies.

49 Interruption of the power supply

Clause **49** of EN 60601-1 : 1990 applies.