SLOVENSKI STANDARD
SIST EN 865:2000

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Pulzni oksimetri - Posebne zahteve

Pulse oximeters - Particular requirements

Pulsoximeter - Besondere Anforderungen

Oxymetres de pouls - Prescriptions particulieres

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English version

Pulse oximeters - Particular requirements

Oxymètres de pouls - Prescriptions particulières

Pulsoxymeter - Besondere Anforderungen

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CEN

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

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Foreword

This European Standard has been prepared by the 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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.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.

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 hospitalised and non-hospitalised 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:

Appendix 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 $Sp0_2$ 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 $Sp0_2$ 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 $Sp0_2$ 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 $Sp0_2$ 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:

$$\frac{O_2Hb}{(0_2Hb + HHb)}$$

3.10 probe: Part of the pulse oximeter intended to sense the signal from the patient from which the $Sp0_2$ 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 wave lengths 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 $Sp0_2$: 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;