SLOVENSKI STANDARD
SIST EN 12598:2000

01-januar-2000

Monitorji za kisik pri vdihavanju dihalne zmesi - Posebne zahteve

Oxygen monitors for patient breathing mixtures - Particular requirements

Überwachungsgeräte für Sauerstoff in Atemgasgemischen von Patienten - Besondere Festlegungen

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Moniteurs d'oxygene pour les mélanges gazeux respiratoires - Prescriptions particulieres

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Ta slovenski standard je istoveten z: **EN 12598:1999**

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 12598:2000 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12598

January 1999

ICS 11.040.10

Descriptors: medical equipment, anaesthetic equipment, artificial breathing apparatus, oxygen monitor, medical gases, gas mixtures, oxygen, definitions, classifications, marking, safety requirements, accident prevention, protection against electrical shocks, protection against mechanical hazards, radiation protection, fire protection

English version

Oxygen monitors for patient breathing mixtures - Particular requirements

Moniteurs d'oxygène pour les mélanges gazeux respiratoires - Prescriptions particulières

Überwachungsgeräte für Sauerstoff in Atemgasgemischen von Patienten - Besondere Festlegungen

This European Standard was approved by CEN on 17 December 1998.

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.

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This European Standard exists in one official version in accordance with Resolution BT 74/1997, the one language experiment. 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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Foreword

This European Standard has been prepared by Technical Committee CEN/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 July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

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.

This European Standard specifies particular requirements for oxygen monitors for patient breathing mixtures.

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Annex CC of this European Standard is normative. Annexes AA, BB and ZA are given for information.

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Annex AA contains rationale statements for this European Standard. The clauses which have corresponding rationale statements are marked with R after their number.

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

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1 General

1.1 R Scope and object

This European Standard refers to IEC 60601-1:1988: Medical electrical equipment - Part 1 : General requirements for safety, as amended by its amendments 1 (1991) and 2 (1995).
For brevity Part 1 is referred to in this European standard either as the General Standard or as the General requirements.

The scope given in clause 1 of the General Standard applies except that 1.1 is replaced by the following:

This European Standard provides particular requirements for oxygen monitors, as defined in clause 1.3.14 (in this specification) intended for use in determining the oxygen level in gas mixtures. Both diverting and non-diverting oxygen monitors are covered.

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

a) anaesthetic workstations and breathing systems;

b) ventilators;

c) infant incubators;

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Oxygen monitors intended for use in laboratory research applications are outside the scope of this Standard.

The requirements of clause 1.3 of the General Standard apply with the following addition:

The numbering of clauses and subclauses of this European Standard corresponds to that of the General Standard, thereby, sections have become major clause numbers. The changes to the text of the General Standard are specified by the use of the following words.

´Replacement´ means that the clause or subclause of the General Standard is replaced completely by the text of this European Standard.

´Addition´ means that the text of this European Standard is additional to the requirements of the General Standard.

´Amendment´ means that the clause or subclause of the General Standard is amended as indicated by the text of this European Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA. BB. Etc. and additional items aa), bb), etc.

The term ´this Standard´ is used to make reference to the General Standard and this European

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Standard taken together.

Where there is no corresponding section, clause or subclause in this European Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification, where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this European Standard.

1.2 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 60601-1:1990 applies with the following additions:

EN 475:1995	Medical devices - Electrically-generated alarm signals
EN 980:1996	Graphical symbols for use in the labeling of medical devices
EN 1041:1998	Information supplied by the manufacturer with medical devices
EN 1281-1:1997	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN 1281-2:1995	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)
EN ISO 4135:1996	Anaesthesiology - Vocabulary (ISO 4135:1995)
EN 60601-1:1990+A1:1993+A2:1995	Medical electrical equipment - Part 1: General requirements for safety[1)] (IEC 60601-1:1988+A1:1991+A2:1995)
EN 60601-1-2:1993	Medical electrical equipment - Part 1: General requirements for safety - Part 2: Collateral standard: Electromagnetic compatibility - Requirements and test (IEC 60601-1-2:1993)

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[1)] called ´General Standard´ throughout the document.

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EN 60801-2:1993	Electromagnetic compatibility for industrial-process measurement and control equipment - Part 2: Electrostatic discharge requirements (IEC 60801-1:1991)
prEN 13014	Connections for gas sampling tubes to anaesthetic and respiratory equipment
IEC 60079-3:1990	Electrical apparatus for explosive gas atmosphere - Part 3: Spark test apparatus for intrinsically-safe circuits.
IEC 60079-4:1975	Electrical apparatus for explosive gas atmospheres - Part 4: Methods of test for ignition temperature

1.3 Definitions and terminology

Clause 2 of the General Standard applies together with EN ISO 4135 and the following additions:

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1.3.1 R alarm: Warning signal that is activated when the oxygen reading reaches or exceeds the alarm limit.

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1.3.2 alarm set-point: Setting of the adjustment control or display value which indicates the oxygen level at or beyond which the alarm is intended to be activated (the indicated alarm limit).

1.3.3 alarm system: Those parts of the oxygen monitor which a) establish the alarm set-point(s); b) activate an alarm when oxygen level is less than or equal to the low alarm set-point, or is equal to or greater than the high alarm set-point.

1.3.4 default (alarm or setting): Those operating parameters within the system, which are pre-set at the factory or by the operator and which the system itself sets, without further intervention, when it is turned on.

1.3.5 delay time: Time from a step function change in oxygen concentration or partial pressure at the sampling site to the achievement of 10% of final oxygen value in the oxygen monitor.

1.3.6 R display: Device that visually indicates quantitative or qualitative information.

1.3.7 diverting oxygen monitor: Oxygen monitor which transports the gas mixture from the sampling site to the sensing area.

1.3.8 expected service life: Period during which the performance of an oxygen monitor or any of its components is expected to meet the requirements of this standard when used and maintained according to the accompanying documents.

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1.3.9 high priority alarm: Combination of audible and visual signals indicating that immediate operator response is required.

1.3.10 interference with measurement accuracy: Difference between the oxygen reading in the presence of an interfering gas mixture and the oxygen reading in a corresponding mixture in which the interfering gas or vapour fraction have been replaced by nitrogen.

1.3.11 low priority alarm: Visual signal, or a combination of audible and visual signals indicating that operator awareness is required.

1.3.12 medium priority alarm: Combination of audible and visual signals indicating that prompt operator response is required.

1.3.13 R oxygen level: Concentration of oxygen in a gaseous mixture expressed in percent by volume (V/V) or partial pressure in kPa.

1.3.14 R oxygen monitor: Device that measures and indicates the oxygen level in a gaseous mixture.

1.3.15 R oxygen reading: Measured oxygen level as indicated by the oxygen monitor.

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1.3.16 oxygen (or other gases) % (V/V) : The level of oxygen (or other gas) in a mixture, as volume fraction expressed as a percentage.

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1.3.17 partial pressure: Pressure that each gas in a gas mixture could exert if it alone occupied the volume of the mixture at the same temperature.

1.3.18 response time: Time required for the oxygen monitor to achieve a 90 % change to a step function (delay in response to a step change in oxygen level plus rise time).

1.3.19 rise time : Time required for an oxygen monitor to change from 10% to 90% of a step function.

1.3.20 R sensing area: That part of the sensor at which oxygen is detected.

1.3.21 sensor: That part of the oxygen monitor which is sensitive to the presence of oxygen.

1.3.22 shelf life: Period during which the oxygen monitor or any of its components can be stored in its original container according to the accompanying documents.

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1.4 General requirements and requirements for test

1.4.1 Modifications to clause 3 of the General Standard

Clause 3 of the General Standard applies with the following additions:

3.6 Add the following items:

3.6.aa) Additional single fault conditions include:

- short and open circuits of the sensor and associated circuitry which increase temperatures

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

1.4.2 Modification to clause 4 of the General Standard

Clause 4 of the General Standard applies with the following addition:

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4.101 Test methods other than those specified in this European Standard, but of equal or greater accuracy may be used to verify compliance with requirements.

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1.5 Classification

Clause 5 of the General Standard applies.

1.6 Identification, marking and documents

Clause 6 of the General Standard applies together with the following additions and modifications:

In 6.1 **R** replace item d) by the following:

If the size of the oxygen monitor does not permit the complete marking as specified in this clause, at least the following shall be marked on the oxygen monitor:

- the name of the manufacturer;

- the serial number;

- symbol number 14 in table D1 of appendix D of the General Standard.

In 6.1 **R** add the following item to q)

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Oxygen monitors not meeting the requirements of clause 51.103.1 of this European Standard shall be marked with the words "Not for use with breathing systems".

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

aa) Oxygen monitors not meeting the requirements of clause 101.1a) of this European Standard shall be marked with the words "Not for use with inhalation anaesthetic agents".

bb) Oxygen monitors intended solely for use with dry gas mixtures shall be so marked (see clause 51.101.3.2 of this European Standard).

cc) The alarm set-point of the oxygen level, if the oxygen monitor is provided with a non-adjustable oxygen level alarm.

dd) The device, labels and/or packaging shall include the following information as applicable:

- If the intended purpose of the device is not obvious to the operator, the device shall be provided with instructions for use.

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- The name or trademark and address of the manufacturer. For devices imported into the European Union the following applies: the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the European Community shall be provided with the device or with the accompanying documents.

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- A device identification and content information.

- Where appropriate, the symbol

STERILE

together with the method of sterilisation. The symbol shall be in accordance with 4.6 to 4.7.3 in EN 980:1996.

- Where appropriate, the batch code, preceded by the symbol

LOT

or serial number. The symbol shall be in accordance with 4.3 and 4.4 in EN 980:1996.