RATIFIED EUROPEAN TEXT

EN12598:1999

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This ratified text was approved by CEN/CENELEC in its three official languages on the date given below. Under CEN/CENELEC rules, BSI is obliged to publish its national transposition within six months of this date.

This ratified text was approved on

1998-12-17

EUROPEAN STANDARD
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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.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN 12598:1999 E

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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.

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

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.

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;

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

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)

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

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:

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

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.

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.

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.

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.

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:

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.

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)

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.

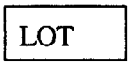
- The name or trademark and address of the manufacturer. For devices imported into the European Union the following applies: the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the European Community shall be provided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

- A device identification and content information.

- Where appropriate, the symbol

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



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

- Where appropriate, an indication of the date by which the device can be used safely, expressed as the year and month.

- Where appropriate, an indication that the device is for single use.

- Any special storage and/or handling conditions.

- Any warning or precautions to take.

- For active medical devices the year of manufacture except for those covered by dd) 6th dash;

- Where appropriate, the recommended method(s) of cleaning, disinfection and sterilisation.

- Device packaging and/or labelling shall differentiate between the same or similar products placed on the market both sterile and non-sterile by the same manufacturer.

- The necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of re-sterilization.

In 6.3 add the following item:

aa) **R** Oxygen level displays shall be expressed in % (V/V) or kPa.

In 6.8.2 add the following items:

aa) EN 1041 shall apply.

bb) A description of the purpose and intended use.

cc) A description of the principles of operation of the oxygen monitor, the relationship between gas concentration and its partial pressure, including the effects of humidity.

dd) A detailed specification, including the following:

- The oxygen level measurement range and the accuracy of measurement (see clause 51.101)

- The stability of measurement accuracy (see clause 51.102)

- Any interference with other gases as specified in clause 101.1 exceeding 1% (V/V) oxygen.

- The rise time (see clause105.1);

- The oxygen level alarm range and its accuracy (see clause 51.104);

- For diverting oxygen monitors, the gas diversion rate (see clause 103.2);

- Time from switching on to achieving specified operating performance.

- A statement of the operating period after which recalibration is recommended.

ee) Details of any effect on stated function due to the following:

- Humidity or condensation including, for example, any adverse effects if an adaptor is provided to improve the function of the sensor in the presence of condensation or particulate water (see clause 51.101.3.2);

- Interfering gases or vapours (see clause 101.1);

- Cyclic pressure (see clause 51.103);

- Barometric pressure or pressure at the site of use of the oxygen monitor.

ff) The expected service life of the oxygen sensor, if it is intended to be replaced, shall be stated as the number of hours times oxygen concentration (% (V/V)) of continuous use in dry or water-saturated gas as specified by the manufacturer with 100 % (V/V) oxygen at (23 +/- 2) °C for dry gas or (37 +/- 2) °C for water-saturated gas respectively during which the oxygen monitor meets the requirements given in clause 51.101 of this European Standard.

NOTE: Additional information at, e.g. 50 % (V/V) oxygen, balance nitrogen, can be provided.

gg) The expected service life of other expendable components of the oxygen monitor (eg. batteries).

hh) Instructions for pre-use checking and calibration.

1.7 Power input

Clause 7 of the General Standard applies.

2 Environmental conditions

2.1 Basic Safety Categories

Not used.

2.2 Removable protective means

Clause 9 of the General Standard does not apply.

2.3 R Environmental conditions

Clause 10 of the General Standard applies.

2.4 Clause 11 of the General Standard does not apply.

2.5 Clause 12 of the General Standard does not apply.

3 Protection against electric shock hazards

3.1 General

Clause 13 of the General Standard applies.

3.2 Requirements related to classification

Clause 14 of the General Standard applies.

3.3 Limitation of voltage and/or energy

Clause 15 of the General Standard applies.

3.4 Enclosures and protective covers

Clause 16 of the General Standard applies.

3.5 R Separation

Clause 17 of the General Standard applies.

3.6 Protective earthing, functional earthing and potential equalization

Clause 18 of the General Standard applies.

3.7 R Continuous leakage currents and patient auxiliary currents

Clause 19 of the General Standard applies with the following additions.

In item 19.1 e), add the following:

The patient leakage current shall be measured at the following positions:

- for non-diverting oxygen monitors, at the oxygen sensor;
- for diverting oxygen monitors, at the connection port of the sampling tube.

3.8 Dielectric strength

Clause 20 of the General Standard applies.

4 Protection against mechanical hazards

4.1 Mechanical strength

Clause 21 of the General Standard applies.

4.2 Moving parts

Clause 22 of the General Standard applies.

4.3 Surfaces, corners and edges

Clause 23 of EN the General Standard applies.

4.4 Stability in normal use

Clause 24 of the General Standard applies.

4.5 Expelled parts

Clause 25 of the General Standard applies.

4.6 Vibration and noise

Clause 26 of the General Standard does not apply.

4.7 Pneumatic and hydraulic power

Clause 27 of the General Standard applies.

4.8 Suspended masses

Clause 28 of the General Standard applies.

5 Protection against hazards from unwanted or excessive radiation

5.1 X-Radiation

Clause 29 of the General Standard applies.

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

Clause 30 of the General Standard is under consideration.

5.3 Microwave radiation

Clause 31 of the General Standard is under consideration.

5.4 Light radiation (including lasers)

Clause 32 of the General Standard is under consideration

5.5 Infra-red radiation

Clause 33 of the General Standard is under consideration

5.6 Ultraviolet radiation

Clause 34 of the General Standard is under consideration

5.7 Acoustical energy (including ultra-sonics)

Clause 35 of the General Standard is under consideration

5.8 Electromagnetic compatibility

Clause 36 of the General Standard applies with the following addition:

36.101 The oxygen monitor 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 :1993.
Discharges shall be applied only to accessible parts and coupling planes (as defined in EN 60801-2 :1993). If an anomaly occurs, such as display interrupt, alarm activation, etc., it shall be possible to restore normal operation within 30 s after the electrostatic discharges have been applied.

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

6. Protection against hazards of ignition of flammable anaesthetic mixtures

6.1 Locations and basic requirements

Clause 37 of the General Standard applies with the following additions:

37.101 **R** Anaesthetic agents which are ignited by the test in annex CC of this European Standard shall be regarded as flammable anaesthetic agents.

Oxygen monitors specified for use with such agents shall be classified and marked as category APG equipment and shall comply with the requirements for APG equipment in the General Standard.

NOTE: Diethyl-ether and cyclopropane are such agents in use.

37.102 **R** Anaesthetic agents which are not ignited by the test in annex CC of this European Standard shall be regarded as non flammable anaesthetic agents.

Oxygen monitors specified for use only with such agents shall comply with clause 37.103 of this European Standard.

NOTE: Such an agent in use is, e.g. halothane (2-bromo 2 chloro 1,1,1-trifluoro ethane).

37.103 **R** Requirements for oxygen monitors not specified and marked as category APG equipment:

In an oxygen monitor not classified as category APG equipment electrical circuits which may be a source of ignition under normal condition and single fault condition in enclosed compartments within which anaesthetic mixtures with oxygen and/or nitrous oxide are produced or used, shall comply with the requirements of 7.2 of this European Standard.

6.2 Marking, accompanying documents

Clause 38 of the General Standard applies.

6.3 R Common requirements for category AP and category APG equipment

Clause 39 of the General Standard applies..

6.4 Requirements and tests for Category AP equipment, parts and components thereof

Clause 40 of the General Standard applies.

Clause 41 of the General Standard applies.

7. Protection against excessive temperatures and other safety hazards

7.1 Excessive temperatures

Clause 42 of the General Standard applies.

7.2 R Fire prevention

Clause 43 of the General Standard applies with the following addition:

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable materials, 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.

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

Compliance is checked 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 oxidising conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

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

Clause 44 of the General Standard applies with the following additions:

In 44.3, add the following:

The oxygen monitor shall be so constructed that spillage does not wet components which, when wetted can cause a safety hazard.

Compliance shall be checked by the test given in 44.3 of the General Standard.

In 44.7, add the following:

In order to minimize the risk of infection to the patient from respiratory gas-conducting components, all components specified as reusable by the manufacturer which come into contact with the inspiratory gas shall be sterile or disinfected, or sterilizable or disinfectable, or be provided with a microbial filter.

If a claim is made in the labelling that a device is sterile it shall have been sterilized using an appropriate, validated method.

Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

7.4 Pressure vessels and parts subject to pressure

Clause 45 of the General Standard applies.

7.5 Human errors

Clause 46 of the General Standard does not apply.

7.6 Electrostatic charges

Clause 47 of the General Standard does not apply.

7.7 Biocompatibility

Clause 48 of the General Standard applies.

7.8 Interruption of the power supply

Clause 49 of the General Standard applies with the following additions:

49.101 R Means shall be provided to prevent inadvertent operation of the off switch.

Compliance shall be checked by inspection.

8. Accuracy of operating data and protection against hazardous output

8.1 Accuracy of operating data

Clause 50 of EN 60601-1: 1990 applies.

8.2 Protection against hazardous output

Clause 51 of the General Standard applies with the following additions:

51.101 R Measurement accuracy

51.101.1 *General*

The difference between the mean oxygen reading and the oxygen level shall be within +/-3 % (V/V) over the range specified by the manufacturer.

Compliance shall be checked by the tests given in clauses 51.101.3, 51.101.3.1 and 51.101.3.2.

51.101.2 *Out-of-range indication*

If the oxygen reading is outside the specified oxygen level measurement range this shall be indicated.

Compliance shall be checked by simulation of out-of-range conditions.

51.101.3 *Oxygen level test method*

Oxygen readings are determined at a number of oxygen levels spanning the oxygen monitor measurement range.

Test gases of an accuracy equal to or better than 1/5 of the tolerance of the requirement stated in clause 51.101 as determined by gravimetric methods shall be used for these tests. Alternative methods of certifying gas composition accuracy may be substituted for the gravimetric method if the alternative method can be shown to be equivalent to or better than the gravimetric method.

51.101.3.1 *Dry gas testing*

The oxygen monitor shall be set up and calibrated in accordance with the accompanying

documents and tested using dry test gas mixtures, given in table 101, at an ambient temperature of (23 +/- 2) °C, a relative humidity within the range of 45 % RH to 75 % RH, and atmospheric pressure within the range of 860 hPa to 1060 hPa (645 mmHg to 795 mmHg). Verify that the accuracy requirements of clause 51.101 are met at 95 % confidence level.

Table 101: Dry gas test mixtures

% (V/V) Oxygen (Balance Nitrogen)
15
21
40
60
100

51.101.3.2 *Water saturated gas testing*

This requirements does not apply to oxygen monitors intended solely for use with dry gas mixtures.

The oxygen monitor shall be set up in accordance with the accompanying documents and using ambient conditions described in clause 51.101.3.1

Operate the monitor in accordance with the manufacturer's instructions for a minimum of 1h using gas saturated at (37+3) °C.

At this time, perform an accuracy test using the gas mixtures given in table 102 (with a dry gas accuracy specified in clause 51.101.3) saturated at(37 +/- 3) °C:

Table 102 : Water saturated gas test mixtures

% (V/V) Oxygen (Balance Nitrogen)
15
21
40
60
100

Oxygen monitors shall maintain the accuracy required in clause 51.101 after readings are corrected for humidity (if required) as specified in the accompanying documents.

51.102 R Drift of measurement accuracy

51.102.1 *General*

The oxygen monitor shall meet the requirements specified in clause 51.101 for a minimum of 8 h when used in accordance with the accompanying documents.

Compliance shall be checked by the test given in clause 51.102.2.

51.102.2 *Test method (water saturated)*

This requirement does not apply to oxygen monitors intended solely for use with dry gas mixtures.

Continue to operate the oxygen monitor as specified in clause 51.101.3.2, sampling the gas test mixtures in table 102 every 2 h for a minimum of 8 h.

51.102.3 *Test method (dry gas)*

If the oxygen monitor is tested by the method in clause 51.102.2 this clause does not apply.

The oxygen monitor shall be set up in accordance with the accompanying documents and using ambient conditions described in clause 51.101.3.1 connect the oxygen monitor to a supply of dry

air at (23 +/- 2) °C.

Operate the monitor for a minimum of 1 h.

At this time, perform an accuracy test using the dry gas method as described in clause 51.101.3.1, and using the test gas mixtures given in table 101.
Continue to operate for a minimum of 8 h repeating the accuracy test every 2 h.

51.103 R Pressure effects

51.103.1 *General*

Oxygen monitors shall either:

a) meet the requirements given in clause 51.101 following exposure of the sampling site to a nominal positive pressure of 10 kPa (100 cm H_2O) and a nominal negative pressure of 1,5 kPa (15 cm H_2O) for 5 s each for 20 cycles;

or

b) shall be marked with a warning "NOT FOR USE WITH BREATHING SYSTEMS" and a similar warning shall appear in the accompanying documents. (See clause 6).

Compliance shall be checked by the test given in clause 51.103.2.

NOTE: The rate at which a diverting oxygen monitor withdraws gas flow from a breathing system should not exceed 1,15 times the maximum value stated in the accompanying documents.

51.103.2 *Test method for pressure effects*

51.103.2.1 *Principle*

The accuracy of the oxygen monitor is determined after exposure of the sensor to pressure cycling.

51.103.2.2 *Procedure*

Cycle the pressure at the sampling site between a positive pressure with respect to ambient of (10 +/- 1) kPa ((100 +/- 10)cm H_2O) and a negative pressure with respect to ambient of (1,5 +/- 0,2) kPa ((15 +/- 2) cm H_2O) for not less than 5 s each. Repeat this procedure 20 times, then carry out the test for measurement accuracy using the dry method as described in clause 51.101.3.1 using the gases listed in table 101.

51.104 Alarm characteristics

51.104.1 The low oxygen and (if provided) high oxygen concentration visual and auditory signals shall conform to the requirements of EN 475 for high priority alarms.

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

51.104.3 If a means of temporarily silencing the auditory alarm(s) is provided, this silencing shall not exceed 120 s.

51.104.4 If provided, a remote alarm extension shall be arranged so that a failure in the remote circuit will not affect the correct functioning of the local alarm.

51.104.5 R The oxygen monitor shall have a low oxygen alarm set point. The low oxygen alarm set point shall not have a default setting lower than 18 % (V/V). If the low oxygen alarm set point is operator adjustable it shall not be possible to adjust it to below 18 % (V/V).

51.104.6 The low and high oxygen alarms shall activate as follows:

- The low oxygen alarm: Oxygen readings less than or equal to the low oxygen alarm set point.

- The high oxygen alarm (if provided):Oxygen readings greater than or equal to the high oxygen alarm set point.

51.104.7 If alarm parameters are adjustable by the operator, means shall be provided to prevent unintentional change of such adjustable settings.

NOTE: Prevention of unintentional change may be achieved by a deliberate sequence of operator actions, a recess or guard over the control.

51.104.8 Compliance shall be checked by inspection and by simulation of the alarm conditions in accordance with the accompanying documents.

51.105 R *Function and position of controls*

Check or test controls for battery condition or signal operation and signal override shall automatically return from the check or test position.

Calibration controls shall include means to prevent an inadvertent change from the intended position.

9. Fault conditions causing overheating and/or mechanical damage; Environmental tests

9.1 Abnormal operation and fault conditions

Clause 52 of the General Standard applies.

9.2 Environmental tests

Clause 53 of the General Standard applies.

10. Constructional requirements

10.1 General

Clause 54 of the General Standard applies.

10.2 Enclosures and covers

Clause 55 of the General Standard applies. (See clauses 16, 21 and 24 of the General Standard).

10.3 Components and general assembly

Clause 56 of the General Standard applies.

10.4 Mains parts, components and layout

Clause 57 of the General Standard applies.

10.5 Protective earthing - Terminals and connections

Clause 58 of the General Standard applies.

10.6 Construction and layout

Clause 59 of the General Standard applies.

11. Additional requirements

11.1 R Interfering gas and vapour effects

101.1 General

Oxygen monitors shall either:

a) have not more than 2 % (V/V) oxygen interference with measurement accuracy in the presence of any of the gases or vapours at the levels listed in table 103;

or

b) if the body of the oxygen monitor is marked "Not for use with inhalation agents" or equivalent, the oxygen monitor shall not have more than 2 % (V/V) oxygen interference

with measurement accuracy in the presence of helium or carbon dioxide at the levels listed in table 103.

If the oxygen interference is greater than 1 % (V/V) this shall be stated in the accompanying documents. (see clause 6.8.2dd, 3rd indent)

Compliance shall be checked by the test given in clause 101.2.

Table 103 : Inhalation anaesthetics and other interfering gases and vapours

Gas or vapour level (Balance: mixture of 30 % (V/V) oxygen/70 % (V/V) nitrous oxide except where stated)	
Helium	50 % (V/V) balance O_2
Carbon dioxide	5 % (V/V)
Nitrous oxide	80 % (V/V) balance O_2
Halothane	4 % (V/V)
Enflurane	5 % (V/V)
Isoflurane	5 % (V/V)
Sevoflurane	5 % (V/V)
Desflurane	15 % (V/V)
Nitric oxide	100 ppm (10^{-6}) in N_2 70% (V/V) balance O_2 *
Diethyl ether	20 % (V/V) (APG only)

* NOTE: The NO and O_2 components of the mixture should be introduced in such a manner as to minimize the formation of NO_2 at the measuring point.

101.2 Test method for interfering gas and vapour effects

101.2.1 *Principle*

Determination of the accuracy of the oxygen reading in the presence of interfering gases and vapours given in table 103.

101.2.2 *Test gases*

Dry pre-mixtures of 30 % (V/V) oxygen and 70 % (V/V) nitrous oxide and the interfering gas or vapour at the level given in table 103, the oxygen levels being known to within +/- 0.6 % (V/V), shall be used.

101.2.3 *Procedure*

Carry out the test described in clause 51.102.1 with the following modification:

Expose the sensing area to the test gas for a continuous period of 2 h, ensuring that both the oxygen monitor and the oxygen sensor are maintained in the same condition during the whole period. Repeat the procedure for each applicable mixture given in table 103.

101.2.4 *Expression of results*

Correct the oxygen readings for changes in barometric pressure, if the errors due to this effect equal or exceed +/- 0,1 % (V/V) oxygen, and report the corrected readings to demonstrate that no more than 2% (V/V) oxygen interference with the measurement accuracy as defined in 51.101.1 exists.

11.2 Contamination of breathing systems

It shall not be possible to reverse the direction of flow through the sampling tube in a diverting oxygen monitor.

11.3 R Gas leakage and sampling loss

103.1 Gas leakage

103.1.1 *General*

The rate of leakage of a non-sampling oxygen monitor shall not be greater than 20 ml/min.

> NOTE: This requirement ensures that when fitted to a breathing system, the rate of leakage of the breathing system at a continuous pressure of 3 kPa (30 cm H_2O) does not increase by more than 20 ml/min.

Compliance shall be checked by the test given in clause 103.1.2.

103.1.2 *Test method for gas leakage*

103.1.2.1 *Apparatus*

A pressure gauge having an accuracy within +/- 0,3 kPa and a flowmeter having an accuracy within

+/- 2 ml/min shall be used.

103.1.2.2 *Procedure*

Assemble the oxygen analyzer so that the oxygen sensor is installed in a dimensionally suitable port of test apparatus containing an inlet fitting to which a test gas and air flow meter are attached. Connect the pressure gauge to a third port of the test apparatus. Slowly open the flowmeter to raise the pressure in the test apparatus to 3 kPa. Determine the flow necessary to maintain this pressure.

103.2 Sampling loss (gas diversion rate)

103.2.1 *General*

The rate at which a sampling oxygen monitor withdraws gas from a breathing system (the gas diversion rate) shall not exceed 1.15 times the value stated in the accompanying documents.

Compliance shall be checked by the tests given in clause 103.2.2.

103.2.2 *Test method for sampling loss (gas diversion rate)*

103.2.2.1 *Principle*

Measurement of the rate at which a sampling (intermittent) oxygen monitor withdraws gas from a simulated breathing system.

103.2.2.2 *Test gas*
Pressurized air at room temperature shall be used.

103.2.2.3 *Apparatus*

A pressure gauge having an accuracy within +/- 0,3 kPa and a flowmeter having an accuracy within +/- 2 % of the rate at which the oxygen monitor withdraws gas from the breathing system as stated in the accompanying documents shall be used.

103.2.2.4 *Procedure*

Assemble the apparatus as described in clause 103.1.2.2 but using the flow meter specified in clause 103.2.2.3. Adjust the pressurized air source to a pressure of 3 kPa and monitor the flowmeter reading for 1 min.

11.4 Connections

If an oxygen sensor is intended to be connected to the breathing system through a T-piece, the breathing system connection ports of the T-piece shall be 15 mm and/or 22 mm conical connectors in accordance with EN 1281-1 or EN 1281-2.

If the oxygen sensor is mounted directly into the T-piece, the oxygen sensor connection port of the T-piece shall not be interchangeable with the breathing system connection ports of the T-piece.

The gas sample inlet port and the gas sample return port of a diverting oxygen monitor shall comply with prEN 13014.

11.5 Rise time

105.1 General

The rise time shall not be greater than 1,15 times the value stated in the accompanying documents, when tested in accordance with clause 105.2

105.2 Test method

105.2.1 *Principle*

Measurement of the time taken for the oxygen monitor to follow a step change in oxygen level at the sensing area.

105.2.2 *Test gases*

Two mixtures of oxygen and nitrogen that contain levels of oxygen equal to 95 % to 100 % of the full scale oxygen reading and between 20 % and 25 % of the full scale oxygen reading indicated on the oxygen monitor shall be used.

NOTE: If a reading of 21 % (V/V) oxygen lies within the required range, room air or compressed air may be used as the test gas mixture

105.2.3 *Procedure*

Hold the ambient temperature of the oxygen monitor and the temperature of the test gas mixtures delivered to the sensing area constant to within +/- 1 °C of a nominal value within the operating temperature range specified in the accompanying documents

NOTE: The test gas mixture need not be at ambient temperature.

Calibrate the oxygen monitor at its full scale reading as described in the accompanying documents.

Deliver the test gas mixture to the sensing area at ambient barometric pressure. Ensure that the oxygen sensor is in equilibrium with the test gas mixture and that the oxygen monitor is at ambient temperature.

Expose the sensing area to a test gas mixture with an oxygen level equivalent to 95 % to 100 % of the full-scale oxygen reading. After a period of at least three times the rise time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen monitor (R_1). Expose the sensing area to a test gas mixture with an oxygen level equivalent to 20 % to 25 % of the full-scale oxygen reading. After a period of at least three times the rise time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen monitor (R_2). With the oxygen monitor measuring R_2, re-expose the sensing area to the 95 % to 100 % full-scale oxygen reading test gas mixture. Measure the interval from the time at which the oxygen reading is at 10 % of the change above the initial reading (R_3) to the time at which the oxygen reading is 90 % of the change above the initial oxygen reading, that is, when the oxygen reading (R_4) is:

$$R_4 = R_2 + (0{,}9 \times [R_1 - R_2])$$

$$R_3 = R_2 + (0{,}1 \times [R_1 - R_2]).$$

Finally, with the oxygen monitor measuring R_1, re-expose the sensing area to the 20 % to 25 % full-scale oxygen reading test gas mixture. Measure the interval from the time at which the oxygen reading is 10 % of the change below the initial reading, (R_6) to the time at which the oxygen reading is 90 % of the change below the initial oxygen reading, that is, when the oxygen reading (R_5) is:

$$R_5 = R_1 - (0{,}9 \times [R_1 - R_2])$$

$$R_6 = R_1 - (0{,}1 \times [R_1 - R_2]).$$

Rise time is the time between R_4 and R_3 or R_5 and R_6 for decreasing and increasing

concentrations respectively.

NOTES: 1) See also the requirements of clauses 2.3, 4.1 and 7.3 of this standard.

2) The stated rise time is the slowest that occurs when any one of the above referenced conditions is varied over its full range.

Annexes

Appendices A to K of the General Standard apply.

Annex AA (informative) Rationale

General

This annex provides a concise rationale for the important requirements of this European Standard and is intended for those who are familiar with the subject of the European Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the specification necessitated by those developments. The numbering of the following rationale corresponds to the numbering of this European Standard. The numbering is, therefore, not consecutive.

Introduction

This annex presents the rationale on which the requirements, and, where necessary, the test methods are based. To the extent possible, it summarizes the discussions which were carried on by the participants in the meetings of the committee that developed this European Document.

AA.1.1 Scope and object

There exists a great variety of devices for the measurement of oxygen level. The scope excludes devices used in laboratory research applications. Devices used in these applications are often experimental or intended primarily for non-medical uses.

Imposition of the requirements of this draft standard on devices used for research might unduly limit development of beneficial new techniques or devices.

It is expected that some devices that are not intended for clinical applications may eventually become used in the clinical environment. They would then be subject to the provisions of this standard if, for instance, the manufacturer suggested (for example, through advertising) applications that fall within the scope of this European Standard.

AA.1.3 Definitions

AA.1.3.1 *Alarm*

The distinction between the terms "alarm", "alarm system" and "alarm set-point" are important because the terms tend to be used imprecisely and somewhat interchangeably. "Alarm" is used in this European Standard only to refer to the high priority signal that occurs when the oxygen reading crosses the alarm set-point. The alarm set-point value is the oxygen reading at which the alarm limit control or display indicates the alarm will activate. The alarm system comprises all of the preceding elements. The alarm set-point definition implies that the alarm set-point value need not be continuously displayed, but is capable of being readily displayed.

AA.1.3.6 *Display*

The term "display" is used to denote any device which visually conveys information to the operator. The term "visual indicator" is used to denote only those displays which present an indication of a condition, such as "on" (lamp illuminated) or "off" (lamp not illuminated).

AA.1.3.13 *Oxygen level*

The term "oxygen level" was deliberately chosen and defined to allow oxygen readings in any accepted units, such as partial pressure or percent by volume. Oxygen level refers to the actual concentration of oxygen in a gas mixture.

> NOTE: Most oxygen monitors operate according to the partial pressure of oxygen present. Since, in medical applications, the gases measured are mixed by known volumes, it is normal practice to graduate monitor scales in percent oxygen.

AA.1.3.14 *Oxygen monitor*

Devices that do not "measure and indicate" are not intended to be covered by this European Standard. For instance, a device that has no function other than to signal an alarm at a specific oxygen level would not be considered to be an oxygen monitor for use in direct patient monitoring applications.

The term "in a gaseous mixture" implies that devices that measure or monitor oxygen in a liquid phase (for example, blood gas analyzer or indwelling catheters) are not covered by this European Standard.

AA.1.3.15 ***Oxygen reading***

The term "oxygen reading" refers to the measured concentration of oxygen in the gas mixture. The oxygen reading will, in general, be different from the oxygen level. The magnitude of this difference will be the sum of the error (that is, the accuracy) of the monitor and the error (again, the accuracy) of the reference method by which the gas mixture oxygen level was analyzed (for example, gas chromatography).

AA.1.3.20 ***Sensing area***

The term "sensing area" is not intended to be a synonym for "oxygen sensor". It is that location at which oxygen is detected. The actual oxygen sensor may be remote, as in the case of a diverting oxygen monitor.

AA.1.4.1 /3.6 bb ***Oxidant leaks***

A fault which is not detected can exist for a long time. Under those circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded. Such a first fault must be regarded as a normal condition.

AA.1.6 Identification, marking and documents

Clause 6.1 of the General Standard addition:

For monitor markings, it is essential that users be able to identify the manufacturer, catalogue number and serial number of any medical device in order that problems, questions or complaints regarding the device can be communicated expeditiously. The absence of such information can, under some circumstances, render the instrument useless.

Since it is common for oxygen monitors to be operated in areas where the personnel using them change frequently, it is likely that full instructions will not be given in the use of an individual manufacturer's unit.

Thus, it was generally agreed that some instructions and precautions needed to be placed on the monitor itself, in addition to the detailed information contained in the accompanying documents. The requirement for instructions is intended to specify, in general, the minimum level of information that an unfamiliar user would need to operate the monitor correctly and safely. It is recognized that there are limitations to the amount of information that can be placed on the monitor without creating clutter or confusion. Thus, for this requirement, as well as throughout this entire clause, manufacturers are required to warn only of the more serious potential hazards on the monitor itself, referring the user to the accompanying documents for details and cautions.

Clause 6.3 of the General Standard addition:

AA.6.3 *Marking of controls and instruments*

Because oxygen level may be stated in a number of different units of measure, such as % (V/V) oxygen, kPa or mm Hg, it is necessary that the oxygen display be marked with the appropriate units of measure.

Clause 6.8.2 cc) of the General Standard addition:

It has been noted by some users that some oxygen monitors have cables or sample tubing that are of insufficient length to be safely and conveniently mounted on apparatus such as an anaesthetic machine. It is difficult to specify universal lengths for all monitors, since the required lengths may vary depending on the application. This requirement asks only that manufacturers recognize this problem and adequately inform users of the procedure for correct use.

AA.2.3 Environmental conditions - temperature limitations

Temperatures as high as 40 °C are often encountered in incubators. Temperatures as low as -40 °C may be encountered during transport.

AA.3.5 Deterioration of materials

Deterioration of components due to anaesthetic agents and gases should be taken into account by the manufacturer.

AA.3.6 Protection against hazards of explosion in medically used rooms

Since the worldwide use of flammable anaesthetics is becoming rare, a monitor that has a restricted use is considered acceptable.
Two levels of safety for explosion hazards are set. The first, less stringent, level is for the monitor body and oxygen sensor in a flammable environment not in direct communication with a patient (ambient atmosphere in an operating room). If there are no sparks possible, only thermal energy could ignite a flammable gas mixture and thus the temperature maximum has been specified. If there could be sparks, the maximum level of energy in the electrical circuit is additionally specified. This level is based on the ignition energy of the most flammable mixtures of diethyl ether and air.
The second, more stringent, level is for oxygen sensors that are placed in a breathing system in direct communication with breathing gas mixtures and the patient's airway. In this case, the supply voltage is restricted and, if sparks are possible, the maximum level of electrical circuit energy is specified in addition. This level is based on the ignition energy level of the most flammable mixture of diethyl ether and oxygen.

AA.3.7 Continuous leakage currents and patient auxiliary currents

It is essential that the leakage current is limited because the monitor may come into contact with pacemaker leads or other conduction paths to the patient.

AA.7.2 Fire prevention

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);

- Temperatures 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 the General Standard , the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidising 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 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 60079-4.

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 minimise fire risk are based on limitation of temperature, electrical energy and oxidant concentrations to absolute values.

The temperature value is based on the minimum hot plate 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 temperatures, 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 may 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 of a pure oxygen environment, even under single fault condition.

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

AA.51.101 ***Measurement accuracy***

The accuracy of the oxygen reading is of major importance due to the critical applications of oxygen monitors.
In this European Standard, accuracy takes into account all errors in the measurement system introduced between the sensing area and the displayed oxygen reading as perceived by the operator. This includes sampling system errors, oxygen sensor errors, electrical circuit errors,

calibration errors and play errors, among others.

The maximum error allowance of +/- 3 % (V/V) oxygen satisfies the criterion of effective function for all three primary areas of medical use: anaesthesia, paediatrics and respiratory therapy. For anaesthesia, the requirement is particularly critical, because a patient being maintained on an indicated 21 % (V/V) oxygen reading would, in most cases, suffer no ill effects if the oxygen level were between 18 % (V/V) and 24 % ((21 +/- 3) % (V/V)) oxygen. Below an oxygen level of 18 % (V/V) oxygen, primary organ function could begin to be compromised. The maximum error allowance of +/- 3 % (V/V) oxygen is considered by paediatric anaesthesiologists to be the maximum acceptable error in the normal range of their applications between 40 % (V/V) and 60 % (V/V) oxygen. The requirements of respiratory therapy are also satisfied. For diagnostic measurements where 90 % (V/V) to 100 % (V/V) oxygen is delivered (the most rigid need), an error of +/- 3 % (V/V) oxygen is the maximum permissible. Therefore, a maximum error allowance of +/- 3 % (V/V) oxygen has been chosen for the entire range of 0 % (V/V) to 100 % (V/V) oxygen.

A simple, effective calibration method would be:

a) place the sensing area in 100 % (V/V) oxygen;

b) adjust the calibration control so that the oxygen reading is 100 % (V/V) oxygen;

c) place the sensing area in room air and verify that the oxygen reading is (21 % +/- 3) % (V/V) oxygen.

The use of single point calibration methods (for example, only air) is discouraged, because anomalies such as non-linearities and zero offsets would not be detected.

Pre-mixed gas standards of better than +/- 0,5 % (V/V) oxygen accuracy are not so readily available. Thus, this accuracy value was chosen.

NOTE: For further information, see bibliography in annex BB.

The requirement for digital displays was included to avoid unsafe situations such as display that indicates 99 % (V/V) oxygen when the actual electrical signal to the display is well over 100 % (V/V) oxygen. Such a display with a maximum reading of 99 would hide an otherwise clear device error or out-of-calibration state. Solutions to this problem include:

a) a three-digit display;
b) an indicator for oxygen levels above the specified range of the display.

AA.51.102 ***Drift of measurement accuracy***

It is reasonable that users should expect that a monitor will not drift beyond its stated accuracy for a period of at least 8 h after it has been calibrated according to the accompanying documents.

This requirement implies that the stability will be within the specified limits at any constant temperature within the operating temperature range.

AA.51.103 ***Pressure effects***

This requirement does not deal with the "problem" of oxygen level changes due to breathing circuit pressure changes based on the fundamental physical principle of operation of oxygen monitors - that is, that they measure the partial pressure of oxygen which is a function of ambient pressure. Instead, this requirement deals with permanent mechanical changes to oxygen sensors due to imposed cyclical pressure changes.

The pressure extremes of +10 kPa and -1,5 kPa are considered clinically relevant pressures that are occasionally attained.

AA.51.104.5 A low alarm limit that can be adjusted or is pre-set to a set-point value below 18 % (V/V) oxygen is considered unsafe. It is important to recognize that due to the cumulative nature of the permissible measurement and alarm accuracy errors, a monitor with a low alarm limit that is adjusted to a set-point value of 18 % (V/V) oxygen may begin to alarm at an oxygen level as low as 15 % (V/V) oxygen (with a corresponding alarm limit of 18 % (V/V) oxygen) or at an oxygen level as high as 21 % (V/V) oxygen (with a corresponding alarm limit of 18 % (V/V) oxygen).

AA.51.105 ***Function and position of controls***

An operator unaware that checking of test controls can cause a control to be permanently left in one position can lead to the mistaken assumption that oxygen levels are being measured when, in fact, they are not. An example would be a battery check that indicated good battery condition when the display indicates 20 % (V/V) to 22 % (V/V) oxygen. Distinguishable control positions are necessary to determine what is being displayed on multi-function displays.

Inadvertent changes in the calibration control position will result in the display of erroneous measurements.

Controls should operate according to stereotyped expectations to discourage inappropriate control settings.

AA.11.1/101 Interfering gas and vapour effects

One of the principal applications of oxygen monitors is in anaesthesia. It is essential that operators are informed of any additional errors in the oxygen reading that may be introduced as a result of cross-sensitivity of the oxygen sensor to any of the gases or vapours likely to be encountered during anaesthesia. An interference greater than +/- 2 % (V/V) oxygen is not permitted because, even though stated in the accompanying documents, it could produce an

unsafe condition in the hands of the user unaware of this type of interference. An interference of less than +/- 1 % (V/V) oxygen is considered insignificant and, therefore, the value need not be stated.

The use of oxygen for the balance of the mixture allows the test to identify interference errors that may only occur in the presence of oxygen.

The operator should be aware that in some monitors the combination of low battery and interfering gases or vapours can be especially misleading.

AA.11.3/103 Gas leakage and sampling loss

Sensors mounted in T-pieces have contributed to leakage in breathing systems due to both poor seals at the sensor and incorrect 22 mm connectors on the T-piece. As the breathing system normally contains a number of various components, it is essential that the maximum leakage rate from the oxygen monitor be as low as possible. Otherwise, it will be impossible to achieve an acceptably low maximum leakage rate for the breathing system.

When sampling monitors withdraw gas from the breathing system, it may have a significant effect on the gas volume delivered to the patient. The requirement to provide information on the sampling gas flow provides the user with the information necessary to assess the significance of the sampling gas flow for various clinical situations. In closed circuit systems, high gas withdrawal flows are not acceptable with regard to patient safety and pollution effects. Because oxygen monitor manufacturers usually do not manufacture the fittings with which their T-pieces must mate, testing is performed with standard 22 mm fittings.

AA.11.5/105 Rise time

Operators (especially those unfamiliar with the characteristics of a specific monitor) should be given some indication of the period of time required for a reading to reach steady state after a change in oxygen level has been introduced. It is felt that the rise time represents a reasonable approximation to steady state conditions and would thus indicate to the operator how long he or she should wait in order to ensure that a stable reading has been reached. The rise time gives an indication for the maximum breathing frequency to be monitored. The inspiratory or expiratory time should not be less than the rise time. The rise time is measured with both increasing and decreasing oxygen levels, since rise time can be a function of the direction of the change in oxygen level.

Annex BB (informative) Bibliography

EN 739 : 1998	Low-pressure hose assemblies for use with medical gases
ISO 32 : 1977	Gas cylinders for medical use - Marking for identification of content
ISO 7250	Basic list of anthropometric measurements
ISO 8158 : 1985	Evaluation of the performance characteristics of gas analyzers
NFPA publication 53M	Fire hazards in oxygen -enriched atmospheres [1)]

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

Annex CC (normative) Test method for anaesthetic agents for non-flammability

CC.1 General

This annex gives test methods of anaesthetic agents which, according to clause 6.1 of this European Standard, shall be regarded as non-flammable anaesthetic agents and to which the requirements of Section six of the General Standard do not apply.

CC.2 Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent mixed with the gases oxygen and/or nitrous oxide in which the anaesthetic agent is most ignitable using the test apparatus described in appendix F of EN 60601-1:1990 and in IEC 60079-3.

With an ignition probability of less than 10^{-3}, ignition shall not occur:

- in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0A and at a d.c. voltage of 100 V with a current of 0,15A.

- in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1000 mH.

- in a capacitive circuit at a d.c. voltage of 100 V with a capacitance of 1 μF and at a d.c. voltage of 20 V with a capacitance of 20 μF.

The measuring circuits are illustrated in EN 60601-1:1990 figures 29 and 31.

CC.3 Surface temperature ignition tests

Determination of the ignition temperature shall be carried out with apparatus and procedures based on IEC 60079-4, with the following additional requirements:

- fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests and;

- cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

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 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 following clauses of this standard are likely to support requirements of Directives.

Compliance with these clauses of 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
1.1	Not applicable	
1.2	Not applicable	
1.3	Not applicable	
1.4	1, 2, 3	
1.4 (3.6.aa))	9.3	
1.4 (3.6.bb))	7.5, 9.3	
1.5	1, 2, 3	
1.6 (6.1)	1, 2, 3, 8.7, 13.1, 13.3, 13.4, 13.5, 13.6	
1.6 (6.3)	1, 2, 3, 10.3, 12.9	
1.6 (6.8.2)	1, 2, 3, 9.1, 10.1, 13.4, 13.6	
1.7	1, 2, 3	
2.1	Not applicable	
2.2	Not applicable	
2.3	1, 2, 3, 4, 5	
2.4	Not applicable	
2.5	Not applicable	
3 (all subclauses)	1, 2, 3, 12.6	
4.1	1, 2, 3, 4, 5, 9.2	
4.2	1, 2, 3, 9.2	

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4.3	1, 2, 3, 9.2	
4.4	1, 2, 3, 9.2	
4.5	1, 2, 3, 9.2	
4.6	Not applicable	
4.7	Not applicable	Clause 27 'No general requirement' in EN 60601-1
4.8	1, 2, 3, 9.2	
5.1	1, 2, 3, 11.1, 11.3	
5.2 to 5.7	Not applicable	
5.8	1, 2, 3, 9.2, 12.5	
6.1	1, 2, 3, 7.3, 9.3	
6.2	1, 2, 3, 13.2, 13.3, 13.6	
6.3 and 6.4	1, 2, 3, 7.3, 9.3	
7.1	1, 2, 3, 12.7.5	
7.2	1, 2, 3, 7.1, 7.3, 9.3	
7.3	1, 2, 3, 7.6, 8.1, 8.3, 8.4, 8.6	
7.4	1, 2, 3, 9.2	
7.5	Not applicable	
7.6	Not applicable	
7.7	1, 2, 3, 7.1	
7.8	1, 2, 3, 4	
8.1	Not applicable	Clause 50 not used in EN 60601-1
8.2 (all subclauses)	1, 2, 3	

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
8.2 (51.101)	10.1	
8.2 (51.102)	10.1	
8.2 (51.104)	12.4	
9.1	1, 2, 3	
9.2	Not applicable	Clause 53 not used in EN 60601-1
10.1	1, 2, 3	
10.2	Not applicable	Clause 55 not used in EN 60601-1
10.3	1, 2, 3	
10.4	1, 2, 3, 12.6, 12.7.4	
10.5	1, 2, 3, 12.6	
10.6	1, 2, 3, 12.6	
11.1	1, 2, 3, 7.3	
11.2	1, 2, 3	
11.3	1, 2, 3, 7.5	
11.4	1, 2, 3, 9.1, 12.7.4	
11.5	1, 2, 3	