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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements

Analyseurs d'oxygène pour le contrôle des mélanges gazeux respirés par un malade — Prescriptions de sécurité

Reference number
ISO 7767 : 1988 (E)

Foreword

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

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7767 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Annexes N and P of this International Standard are given for information only.

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Introduction

The measurement and monitoring of the level of oxygen present in a gaseous mixture has become a common practice in many areas of clinical medicine. These include anaesthesia, respiratory therapy, paediatrics, and intensive care. A variety of devices are currently available which are intended for these applications. This International Standard establishes minimum safety requirements based on parameters that are believed to be achievable within the limitations of existing technology.

Annex N 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 into this International Standard. Annex P contains a bibliography of other pertinent literature.

Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements

Section 1 : General

1 Scope

ISO 7767 is one of a series of International Standards based on IEC 601-1 : 1977; in IEC 601-1 : 1977 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1 : 1977, the requirements of this International Standard take precedence over those of IEC 601-1 : 1977.

The scope and object given in clause 1 of IEC 601-1 : 1977 applies except that 1.1 shall be replaced by the following.

> This International Standard specifies safety requirements for oxygen analyzers, as defined in 3.8 (in this International Standard) intended for use in determining the oxygen level in breathing gas mixtures administered to patients. Both sampling and non-sampling oxygen analyzers are covered.

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

a) anaesthetic machines and breathing systems;

b) ventilators;

c) baby incubators;

d) oxygen concentrators (domiciliary or clinical).

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5356-1 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1 : Cones and sockets.*

ISO 5356-2 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2 : Screw-threaded weight-bearing connectors.*

IEC 79-3 : 1972, *Electrical apparatus for explosive gas atmospheres — Part 3 : Spark test apparatus for intrinsically-safe circuits.*

IEC 79-4 : 1975, *Electrical apparatus for explosive gas atmospheres — Part 4 : Method of test for ignition temperature.*

IEC 601-1 : 1977, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1 : 1977 apply together with the following additional definitions.

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

3.2 alarm limit: Oxygen reading at which the alarm is first activated.

NOTE — This occurs either when

a) a decreasing oxygen level reaches the low alarm limit;

b) an increasing oxygen level reaches the high alarm limit.

3.3 alarm set-point: Alarm limit adjustment control or display value which indicates the oxygen reading at which the alarm will be activated (the indicated alarm limit).

NOTE — Depending on the construction and design of the equipment, the alarm limit and alarm set-point may differ from each other.

3.4 alarm system: Those parts of the oxygen analyzer which

a) establish the alarm limit(s);

b) detect when the indicated oxygen level exceeds the alarm limit(s);

c) provide a warning signal when the alarm limit(s) is (are) exceeded.

3.5 caution signal: Indication meaning that caution or prompt action is required.

NOTE — Examples of such a condition are a change from mains to battery power in a mains-operated device, or the battery test mode activated.

3.6 display: Device that visually indicates quantitative or qualitative information.

3.7 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 has been replaced by nitrogen.

3.8 oxygen analyzer: Device that measures and indicates the oxygen level in a gaseous mixture.

3.9 oxygen level: Concentration of oxygen in a gaseous mixture.

NOTE — This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mmHg).

3.10 oxygen reading: Measured oxygen level as indicated by the oxygen analyzer.

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

3.12 percent (V/V) oxygen (or other gases): Level of oxygen (or other gas) in a mixture, expressed as a percentage volume fraction.

3.13 response time: Time required for the oxygen analyzer to achieve a 10 % to 90 % response to a step change in oxygen level.

3.14 sensing area: Part of the oxygen analyzer that is in direct contact with the gas mixture of which the oxygen level is to be measured.

NOTE — An example of such a part is the membrane surface of an oxygen-sensing electrode.

3.15 shelf life: Period during which the oxygen analyzer or any of its components are stored in its original container according to the accompanying documents.

3.16 useful life: Period of time during which the performance of an oxygen analyzer or any of its components meets the requirements of this International Standard, when used and maintained according to the accompanying documents.

3.17 expected useful life: Period during which the performance of an oxygen analyzer or any of its components is expected to meet the requirements of this International Standard, when used and maintained according to the accompanying documents.

3.18 warning signal: Indication of danger, meaning that urgent action is required.

4 General requirements and general requirements for tests

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

The requirements given in clauses 3 and 4 of IEC 601-1 : 1977 apply except for the following addition:

In 4.5, add the following:

— at 20 °C if the tests are to be carried out at any nominal temperature within the operating temperature range of the oxygen analyzer;

— unless otherwise specified in individual test methods, with dry test gas mixtures that have a relative humidity below 2 %;

— at ambient atmospheric pressure.

NOTES

1 Room air is considered to be 20,9 % oxygen.

2 Care should be taken to ensure that room air used for testing is not contaminated, e.g. from exhaust ducts, etc., and has a relative humidity below 95 %.

5 Classification

The requirements given in clause 5 of IEC 601-1 : 1977 apply.

NOTE — Oxygen analyzers used in the home (for example, to monitor oxygen concentrators) should be designated as Class II equipment due to the fact that the protective earthing in many homes may be inadequate or nonexistent.

6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1 : 1977 apply except for the following additions and modifications:

a) In 6.1, replace item d) by the following:

If the size of the oxygen analyzer does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the oxygen analyzer: the name of the manufacturer; a serial number or lot or batch-identifying number; and symbol number 14 in table D.1 of IEC 601-1 : 1977.

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

Oxygen analyzers shall be marked with a serial number or other lot or batch-identifying number.

c) In 6.1, add the following to item q):

Oxygen analyzers shall be marked with the words "Not for use in breathing systems", if applicable (see clause 62.1).

d) In 6.1, add additional items as follows:

y) marking on the outside of the oxygen analyzer shall additionally include the following:

— for oxygen analyzers not intended for use with inhalation anaesthetic agents, the phrase "Not for use with inhalation anaesthetic agents", if applicable (see clause 60.1).

— a statement that the operator should see the accompanying documents for the effect of moisture on accuracy, if applicable.

— symbol number 14 in table D.1.

— the words "Will not withstand mechanical shock", if applicable (see clause 21.1), and symbol number 14 in table D.1.

— the alarm set-point of the oxygen level, if the oxygen analyzer is provided with a non-adjustable oxygen level alarm.

z) the following shall either be marked on the body of the oxygen analyzer or be permanently attached to the oxygen analyzer:

— abridged operating instructions which shall include an indication of the period of time necessary, following a change in oxygen level, for the oxygen reading to stabilize.

NOTE — Markings related to controls should be visible and/or legible to an operator having a visual acuity (corrected if necessary) of at least 1 when the operator is 1 m in front of the oxygen analyzer at an illuminance of 215 lux. Markings should be clearly identified with their associated displays or visual indicators.

e) In 6.7, replace item a) by the following:

If visual indicators are used on the oxygen analyzer, with the exception of alphanumeric displays, their colouring shall conform to the following requirements:

1) Red shall be used to indicate to the operator that the oxygen analyzer or a portion of it has failed.

2) Flashing red shall be used to denote an emergency condition requiring an immediate response by the operator.

3) Yellow shall be used to denote a condition in which there is need for caution or re-check, or in which an unexpected delay is experienced.

4) Green shall be used to indicate that the oxygen analyzer is ready for use or in normal operation.

5) Blue shall be used only as an advisory indicator.

The function of all lights and displays shall be marked.

Compliance shall be checked by functional test and inspection.

NOTE — Visual indicators and their associated markings should be visible and/or legible to an operator having visual acuity (corrected if necessary) of at least 1 when the operator is located 1 m in front of the oxygen analyzer at an illuminance of 215 lux.

f) In 6.8.2, add the following to item a):

The instructions for use shall additionally include the following information:

1) A description of the purpose and intended use of the oxygen analyzer.

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

3) A detailed specification, including the following:

— the oxygen level measurement range and the accuracy of measurement (see clauses 50.3, 50.4 and 50.5);

— the stability of measurement accuracy (see clauses 50.6 and 50.7);

— the response time (see clauses 50.8 and 50.9);

— the oxygen level alarm range and its accuracy (see clauses 50.10, 50.11 and 50.12);

— the operating and non-operating temperature ranges (see clause 61);

— for sampling-type oxygen analyzers, the gas diversion rate (see clause 63.3);

— power requirements;

— time from switching on to obtaining specified operating performance.

4) 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 44.5);

— interfering gases or vapours (see clause 60);

— mechanical shock (see clauses 21.1 and 21.2);

— cyclic pressure (see clause 62);

— barometric pressure or pressure at the site of use of the oxygen analyzer;

— fluctuations in line or battery voltage;

— ageing of the oxygen sensor or of the oxygen analyzer itself (see clause 64).

NOTE — If the oxygen level is displayed in units of oxygen concentration, the accompanying documents should contain an explanation that readings in concentration units are correct only under the pressure at which the oxygen analyzer is calibrated.

5) The expected useful life of the oxygen sensors, if they are intended to be replaced during the useful lifetime of the oxygen analyzer. The useful life shall be stated as the number of hours, days, or months of continuous use in dry, 100 % (V/V) oxygen at 23 °C during which the oxygen analyzer meets the requirements given in 50.3, 50.5, 50.6 and 50.8 of this International Standard (see clause 64).

NOTES

1 Other operating conditions may also be used as a basis for useful life.

2 The shelf life of oxygen sensors should be stated.

3 The expected useful life of other expendable components of the oxygen analyzer, for example batteries, should be stated under specified conditions of use.

6) An illustration of the features of the oxygen analyzer indicating the location of all operating controls, adjustments and system components (e.g., the battery compartment) necessary for correct operation and on-site servicing by the user.

7) Instructions for operation of the oxygen analyzer, including the following:

— pre-use checking and calibration;

— routine inspection and testing;

— recommended methods for cleaning and disinfection or sterilization.

8) A description of an in-service test using room air as the calibration gas.

9) Illustrated service information, including:

Instructions for preventive maintenance and service calibration, and those adjustments that are necessary to maintain the oxygen analyzer in correct operating conditions, as well as a description of those adjustments and replacements that can be performed by the operator.

10) A description of the correct installation of the oxygen analyzer and the connection of the oxygen sensor or sampling tubing. The maximum permissible distance of separation between the oxygen analyzer and the sensing area shall be stated.

NOTE — If the oxygen analyzer requires a sensor cable or sampling tubing for connection from the oxygen analyzer to the sensing area, the cable or tubing should be of sufficient length to reduce the likelihood of its being elongated beyond its elastic limit and being stressed at the connection points. In the event that the sensor cable becomes disconnected, this should be indicated by an alarm.

11) Unless it can be demonstrated that the oxygen analyzer is not susceptible to electromagnetic interference, a warning statement in the instructions for use to the effect that the function of the oxygen analyzer may be adversely affected by the operation of such equipment as high frequency apparatus, short-wave or micro-wave equipment in the vicinity.

12) If the lowest temperature that the oxygen analyzer can withstand during transport is higher than − 40 °C and/or if the highest temperature the oxygen analyzer can withstand during transport is lower than 70 °C, the recommended temperature shall be stated in the accompanying documents and the transport package shall be printed with a notice indicating the restrictions on temperature during transport.

NOTE — Attention is drawn to the bibliography given in annex P.

7 Power input

The requirements given in clause 7 of IEC 601-1 : 1977 apply.

Section 2 : Safety requirements

8 Basic safety categories

The requirements given in clause 8 of IEC 601-1 : 1977 apply.

9 Removable protective means

The requirements given in clause 9 of IEC 601-1 : 1977 apply.

10 Special environmental conditions

The requirements given in clause 10 of IEC 601-1 : 1977 apply.

11 Special measures with respect to safety

The requirements given in clause 11 of IEC 601-1 : 1977 apply.

12 Single fault condition

The requirements given in clause 12 of IEC 601-1 : 1977 apply with the following addition:

Applicable single fault conditions are short and open circuits of the sensor and associated circuitry which

— cause sparks to occur, or

— increase the energy of sparks, or

— increase temperatures.

Section 3 : Protection against electric shock hazards

13 General

The requirements given in clause 13 of IEC 601-1 : 1977 apply.

14 Requirements related to classification

The requirements given in clause 14 of IEC 601-1 : 1977 apply.

15 Limitation of voltage and/or current

The requirements given in clause 15 of IEC 601-1 : 1977 apply.

16 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1 : 1977 apply.

17 Insulation and protective impedances

The requirements given in clause 17 of IEC 601-1 : 1977 apply together with the following additional item:

g) Deterioration of parts due to anaesthetic agents and oxygen should be taken into account.

18 Earthing and potential equalization

The requirements given in clause 18 of IEC 601-1 : 1977 apply. See also clauses 19 and 39.3.

19 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1 : 1977 apply except as follows:

In item e), add the following:

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

— for non-sampling (continuous monitoring) oxygen analyzers, at the oxygen sensor;

— for sampling (intermittent) oxygen analyzers, at the junction of the sampling tubing and the body of the oxygen analyzer.

20 Dielectric strength

The requirements given in clause 20 of IEC 601-1 : 1977 apply.

Section 4 : Protection against mechanical hazards

21 Mechanical strength

The requirements given in clause 21 of IEC 601-1 : 1977 are replaced by the following:

21.1 Free-standing oxygen analyzers

Such oxygen analyzers (that is, those not manufactured as an integral, inseparable component of a larger system) and all separable components, such as oxygen sensors shall either:

a) meet the requirements given in 50.3 and 50.8 and, if applicable 50.10, 50.12 and 50.13; electrically live parts shall not be accessible, compliance being checked by the test given in 21.2; or

b) be marked with the warning to the effect that it does not meet this requirement (see 6.1), with a similar warning appearing in the accompanying documents.

21.2 Test method

21.2.1 Principle

Determination of the accuracy of the oxygen reading, the response time and, if applicable, the alarm accuracy after the oxygen analyzer and all separable components have been subjected to a mechanical shock.

21.2.2 Procedure

Attach the unpackaged items to be tested rigidly to a shock machine table. Apply three shocks in both directions along three mutually perpendicular axes of each test item (a total of 18 shocks to each item), taking care to ensure the following:

— that the shape of the shock pulse is in accordance with figure 1;

— that the oscillogram of the shock pulse includes a time approximately 33 ms (3 D) long;

— that the acceleration amplitude (A) of the ideal half-sine pulse is 300 m/s^2 (30 × gravity) and its duration (D) is 11 ms;

— that the measured acceleration pulse is contained between the broken line boundaries shown in figure 1;

— that the measured velocity change (which may be obtained by integration of the acceleration pulse) is within the limits $V_i \pm 0{,}1\ V_i$, where the velocity change associated with the ideal pulse is:

$$V_i = 2 \times \frac{A \times D}{\pi} = 2 \times \frac{300 \times 0{,}011}{3{,}141\ 6} = 2{,}1 \text{ m/s};$$

— that the integration to determine velocity change extends from 4,4 ms (0,4 D) before the pulse to 1,1 ms (0,1 D) after the pulse.

Inspect the oxygen analyzer to check that the appearance and condition of the oxygen analyzer, including the enclosure and warning or display indications or markings, have not been damaged or have not deteriorated in such a way as to prevent normal operation of the oxygen analyzer and that no electrically live parts have become accessible.

Reattach any separable components to the oxygen analyzer and carry out the test for measurement accuracy as described in clause 50.4 and the test for response time as described in clause 50.9 and, if the oxygen analyzer is fitted with an oxygen level alarm, a test for oxygen level alarm limit as described in clause 50.11.

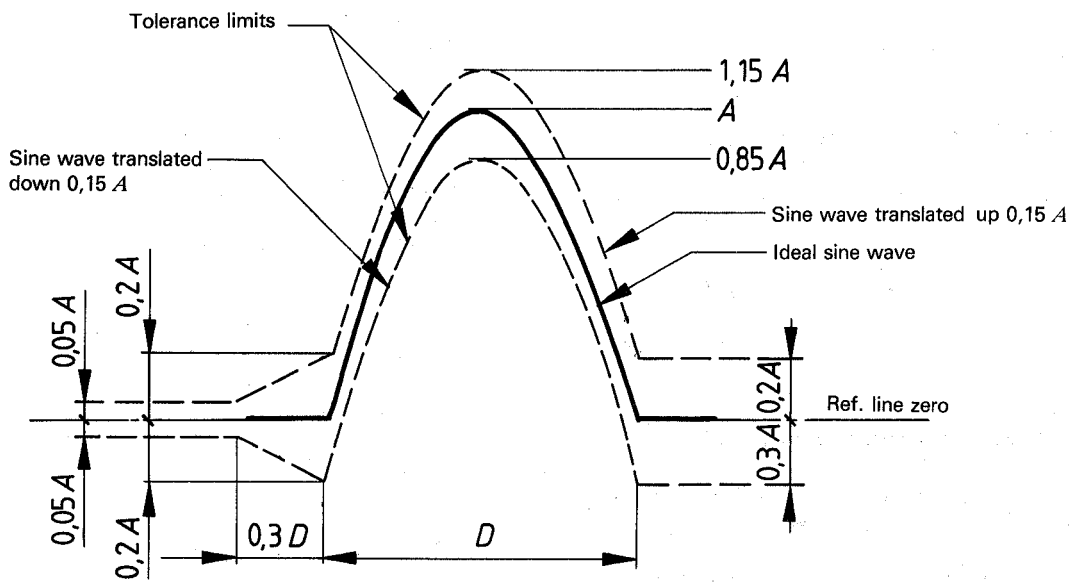

Figure 1 — Half-sine shock pulse configuration and its tolerance limits

21.2.3 Expression of results

Express the results as described in relevant subclauses of clause 50 and report any damage or accessibility of electrically live parts.

22 Moving parts

The requirements given in clause 22 of IEC 601-1 : 1977 apply.

23 Surfaces, corners and edges

The requirements given in clause 23 of IEC 601-1 : 1977 apply.

24 Stability and transportability

The requirements given in clause 24 of IEC 601-1 : 1977 apply.

25 Expelled parts

The requirements given in clause 25 of IEC 601-1 : 1977 apply.

26 Vibration and noise

The requirements given in clause 26 of IEC 601-1 : 1977 apply.

27 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1 : 1977 apply.

28 Suspended masses

The requirements given in clause 28 of IEC 601-1 : 1977 apply.

Section 5 : Protection against hazards from unwanted or excessive radiation

29 X-radiation

The requirements given in clause 29 of IEC 601-1 : 1977 apply.

30 Beta, gamma, neutron radiation and other particle radiation

The requirements given in clause 30 of IEC 601-1 : 1977 apply.

31 Microwave radiation

The requirements given in clause 31 of IEC 601-1 : 1977 apply.

32 Light radiation (including visual radiation and lasers)

The requirements given in clause 32 of IEC 601-1 : 1977 apply.

33 Infra-red radiation

The requirements given in clause 33 of IEC 601-1 : 1977 apply.

34 Ultra-violet radiation

The requirements given in clause 34 of IEC 601-1 : 1977 apply.

35 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC 601-1 : 1977 apply, together with the following additional requirement:

If an oxygen analyzer is included as a part of, or is integral to, another item of equipment, the relevant standards for the equipment shall apply.

36 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1 : 1977 apply.

NOTE — Attention is drawn to the bibliography in annex P.

Section 6 : Protection against hazards of explosion in medically used rooms

37 General

The requirements given in clause 37 of IEC 601-1 : 1977 are replaced by the following:

Oxygen analyzers not designed for use with flammable anaesthetic agents shall comply with the requirements given in 37.1 to 37.4.4.

37.1 Oxygen analyzers not intended for use in the presence of flammable anaesthetics, and which contain electrical circuits which may be a source of ignition in enclosed compartments within which anaesthetic mixtures are produced, guided or used shall meet the requirements given in clause 43 of this International Standard.

37.2 Oxygen analyzers designed for use with flammable anaesthetic agents (see 37.3) shall comply with the requirements for anaesthetic proof category G equipment (APG) given in clauses 38, 39, 40, and 41 of IEC 601-1 : 1977.

37.3 Anaesthetic agents shall be considered as flammable unless, when tested according to the method described in 37.4, the following criteria are met.

a) In the spark ignition test with an ignition probability of less than 10^{-3}, ignition does not occur with any of the following circuits:

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

ii) an inductive circuit with a d.c. current of 0,2 A with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1 000 mH,

iii) 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.

b) In the surface ignition test, ignition does not occur at a temperature below 300 °C.

37.4 Flammability of anaesthetic agents shall be tested as follows.

37.4.1 Principle

Two methods are used. In the first, the most ignitable concentration of an anaesthetic agent mixed with oxygen and/or nitrous oxide is exposed to a spark, and in the second, the surface ignition temperature of mixtures is determined.

37.4.2 Test gases

Two test gases are used:

a) for the spark ignition test, the most ignitable concentration of the anaesthetic agent mixed with oxygen and/or nitrous oxide;

b) for the surface ignition test, the anaesthetic agent mixed with oxygen and nitrous oxide in varying proportions in successive tests.

37.4.3 Apparatus

The following apparatus is needed:

a) for the spark ignition test

— the test apparatus for explosive mixtures or atmospheres described in IEC 601-1 : 1977 or in IEC 79-3,

— the measuring circuits illustrated in figures 29 and 31 in IEC 601-1 : 1977;

b) for the surface ignition test, the test apparatus described in IEC 79-4, but with the modification that the vessel is covered with a lid which prevents diffusion, but lifts easily if there is an explosion.

37.4.4 Procedure

Proceed as follows:

a) for the spark ignition test, carry out the test described in IEC 79-3;

b) for the surface ignition test, carry out the test described in IEC 79-4 but with the modification that the anaesthetic agent is mixed with oxygen and nitrous oxide in varying proportions in successive tests.

38 Classification, marking and accompanying documents of anesthetic-proof equipment

The requirements given in clause 38 of IEC 601-1 : 1977 apply.

39 Common requirements for "AP" and "APG" equipment

The requirements given in clause 39 of IEC 601-1 : 1977 apply except as follows:

In 39.3, add an additional item as follows:

k) Any oxygen analyzer classified and marked APG shall provide a continuous current path for electrostatic charges from the sensing area to earth and the resistance shall be no greater than 1 MΩ (see also clauses 19 and 41).

Compliance shall be checked by the test given in 39.4.

39.4 Test method

39.4.1 Principle

Measurement of the electrical resistance between the sensing area of the oxygen analyzer and earth.