Designation: F 1462 – 93

Specification for Oxygen Analyzers[1]

This standard is issued under the fixed designation F 1462; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Subcommittee F29.03.08 met in Boston in January of 1989 and August of 1990 and agreed to consider ISO 7767 as a possible replacement for the existing oxygen analyzer standard, ANSI Z-79.10. ISO 7767 is one of a series of standards developed for specific medical electrical equipment (a "particular standard") based on IEC 601-1 (the "general standard"). The text that follows has been taken from ISO 7767 and modified editorially. ISO 7767 references the first edition of IEC-601-1, published in 1977, and this specification references the second edition, published late in 1988.

Sections 1-3 of this specification are in keeping with the *Form and Style for ASTM Standards* manual. Section 4 is a compilation of all the clauses in IEC 601-1:1988 with an indication as to whether the clause applies, does not apply, or applies with an amendment or addition.

Section 5 lists in numerical order all of the clauses in IEC 601-1:1988 that have amendments or additions in this specification. Additional requirements specific to oxygen analyzers begin with Clause 60.

Annex A1 provides a rationale for specific requirements.

1. Scope

1.1 The scope given in Clause 1 of IEC 601-1 1988 applies except that 1.1 shall be replaced by the following:

1.2 This specification covers safety requirements for oxygen analyzers, as defined in 3.11 (in this specification 3.1.11) intended for use in determining the oxygen level in breathing gas mixtures administered to patients. Both sampling and non-sampling oxygen analyzers are covered.

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

1.3.1 Anesthetic machines and breathing systems,

1.3.2 Ventilators,

1.3.3 Baby incubators, and

1.3.4 Oxygen concentrators (domiciliary or clinical).

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

1.5 The values stated in SI units are to be regarded as the standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 The following standards contain provisions that, through reference in the test, constitute provisions of this specification. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this draft specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed below:

2.2 *ASTM Standards:*

F 1463 Specifications for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care[2]

F 1054 Standard Specification for Conical Settings[2]

2.3 *IEC Standard:*

IEC 601-1:1988 Medical Electrical Equipment—Part 1—General Requirements for Safety[3]

2.4 *ANSI Standard:*

ANSI Z79.10 Requirements for Oxygen Analyzers for Monitoring Patient Breathing Mixtures[4]

2.5 *ISO Standards:*

ISO 7767 Oxygen Analyzers for Monitoring Patient Breathing Mixtures—Safety Requirements[4]

ISO 8158 Evaluation of the Performance Characteristics of Gas Analyzers

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.11 on Gas Monitors.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from International Electrochemical Commission, 3 rue de Varembé, 1211 Geneva 20, Switzerland.

[4] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, NY, NY 10036.

2.6 *Military Standard:*

MIL-STD-810C Environmental Test Methods for Engineering Guidelines[5]

3. Terminology

3.1 *Definitions*—For the purposes of this specification, the definitions given in Clause 2 of IEC 601-1: 1988 apply together with the following additional definitions:

3.1.1 *alarm*—a warning signal that is activated when the oxygen reading reaches or exceeds the alarm limit.

3.1.2 *alarm set-point*—the setting of the adjustment control or display value that indicates the oxygen level at or beyond which the alarm is intended to be activated (the indicated alarm limit).

3.1.3 *alarm system*—those parts of the oxygen analyzer that establish the alarm set-point(s); activate an alarm when the 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.

3.1.4 *delay time*—the 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 analyzer.

3.1.5 *display*—a device that visually indicates quantitative or qualitative information.

3.1.6 *expected useful life*—the period during which the performance of an oxygen analyzer or any of its components is expected to meet the requirements of this specification, when used and maintained according to the accompanying documents.

3.1.7 *high priority alarm*—a combination of audible and visual signals indicating that immediate operator response is required.

3.1.8 *interference with measurement accuracy*— the 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 vapor fraction has been replaced by nitrogen.

3.1.9 *low priority alarm*—a visual signal, or a combination of audible and visual signals indicating that operator awareness is required.

3.1.10 *medium priority alarm*—a combination of audible and visual signals indicating that prompt operator response is required.

3.1.11 *oxygen analyzer*—a device that measures and indicates the oxygen level in a gaseous mixture.

3.1.12 *oxygen level*—the concentration of oxygen in a gaseous mixture.

3.1.12.1 *Discussion*—This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mm Hg).

3.1.13 *oxygen reading*—the measured oxygen level as indicated by the oxygen analyzer.

3.1.14 *partial pressure*—the pressure that each gas in a gas mixture could exert if it alone occupied the volume of the mixture at the same temperature.

3.1.15 *percent (V/V) oxygen (or other gases)*— the level of oxygen (or other gas) in a mixture, expressed as a percentage volume fraction.

3.1.16 *response time*—the time required for the oxygen analyzer to achieve a 90 % response to a step change in oxygen level.

3.1.17 *sensing area*—the part of the oxygen analyzer that is in direct contact with the gas mixture of which the oxygen level is to be measured.

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

3.1.18 *shelf life*—the period during which the oxygen analyzer or any of its components are stored in its original container according the the accompanying documents.

3.1.19 *useful life*—the period of time during which the performance of an oxygen analyzer or any of its components meets the requirements of this specification, when used and maintained according to the accompanying documents.

4. Relationship of This Specification to the General Standard

	(A)	(NA)	(AM/R)
Section One—General			
1. Scope and object			X
2. Terminology and definitions			X
3. General requirements			X
4. General requirements for tests			X
5. Classification			X
6. Identification, marking, and document			X
7. Power input			X
Section Two—Environmental Conditions			
8. Basic safety requirements	X		
9. Removable protective means	X		
10. Environmental conditions			X
11. Not used			
12. SINGLE FAULT CONDITION—Not used			
Section Three—Protection Against Electric Shock Hazards			
13. General	X		
14. Requirements related to classification	X		
15. Limitation of voltage and/or current	X		
16. Enclosures and PROTECTIVE COVERS	X		
17. Separation			X
18. Protective earthing, functional earthing, and potential equalization	X		
19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS			X
20. Dielectric strength	X		
Section Four—Protection Against Mechanical Hazards			
21. Mechanical strength			X
22. Moving parts	X		
23. Surfaces, corners, and edges	X		
24. Stability and transportability	X		
25. Expelled parts	X		
26. Not used			
27. Pneumatic and hydraulic power	X		
28. Suspended masses	X		
29. X-radiation	X		
30. Alpha, beta, gamma, neutron radiation and other particle radiation	X		
31. Microwave radiation	X		
32. Light radiation (including visual radiation and lasers)	X		
33. Infra-red radiation	X		
34. Ultra-violet radiation	X		
35. Acoustical energy (including ultra-sonics)			X
36. Electromagnetic compatibility			X

[5] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094. Attn: NPODS.

	(A)	(NA)	(AM/R)
Section Six—Protection Against Hazards of Ignition of Flammable Anesthetic Mixtures			
37. Locations and basic requirements	X		
38. Marking ACCOMPANYING DOCUMENTS	X		
39. Common requirements for "AP" and "APG" EQUIPMENT	X		
40. Requirements and tests for Category AP equipment, and components thereof	X		
41. Requirements and tests for Category APG equipment, parts and components thereof	X		
42. Excessive temperatures			X
43. Fire prevention			X
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection			X
45. Pressure vessels and parts subject to PRESSURE	X		
46. Human errors—Not used			
47. Electrostatic charges—Not used			
NOTE: WG 13 of IEC 62A is currently preparing a draft standard for electrostatic discharges for medical equipment.			
48. Materials in APPLIED PARTS in contact with the body of the PATIENT—Not used			
49. Interruption of the power supply	X		
Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output			
50. Accuracy of operating data—Not used			
51. Protection against incorrect output			X
Section Nine—Abnormal Operation and Fault Conditions; Environmental Tests			
52. Abnormal operation and fault conditions	X		
53. Environmental tests	X		
Section Ten—Constructional Requirements			
54. General	X		
55. Enclosures and covers—Not used			
56. Components and general assembly	X		
57. MAIN PARTS, components, and layout	X		
58. Protective earthing—terminals and connections	X		
59. Construction and layout	X		
Additional Clauses			
60. Interfering gas and vapor effects other than water vapor	X		
61. Cyclic pressure	X		
62. Gas leakage and sampling loss	X		
63. Replacement of oxygen sensor	X		
64. Alarms	X		
65. Connectors	X		
66. Measurement accuracy	X		

A = applies, NA = Not Applicable, AM/R = applies with an amendment, addition, or revision to the requirements in the General Standard.

"Not used" means that material in this (these) sections of IEC 601-1:1977 has been deleted from the 1988 edition, but the section number is reserved for future use.

5. Clauses Containing Amendments, Additions, or Replacements to the Text in IEC 601-1:1988, and Additional Clauses 60–67

NOTE 1—The clause numbers used reference the specific section in the general standard.

4. *General Requirements and General Requirements for Tests:*

Clauses 3 and 4 of the general standard apply together with the following additions:

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

In 3.6 (i) add the following: additional single fault conditions include short and open circuits of the sensor and associated circuitry that cause sparks to occur, or increase the energy of sparks, or increase temperatures.

In 4.5, add the following:

At 20°C if the tests are to be carried out at any nominal temperatures 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 %, and

At ambient atmospheric pressure.

NOTE 2—Room air is considered to be 20.9 % oxygen.

NOTE 3—Care should be taken to ensure that room air used for testing is not contaminated, for example, from exhaust ducts, etc., and has a relative humidity below 95 %.

6. Classification

NOTE 4—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.

7. Identification, Marking, and Documents

The requirements given in Clause 6 of IEC 601-1 1988 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.I. of IEC 601-1 1988.

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:

(zz) 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 level to stabilize.

NOTE 5—Markings related to controls should be visible or legible, or both, to an operator having a visual acuity (corrected if necessary) of at least" one" when the operator is 1 m in front of the oxygen analyzer at an illuminance of 215 lx. Markings should be clearly identified with their associated displays or visual indicators.

a) Marking on the outside of the oxygen analyzer shall additionally include the following:

b) For oxygen analyzers not intended for use with inhalation anesthetic agents, the phrase "Note for use with inhalation anesthetic agents", if applicable (see Clause 60.1).

c) A statement that the operator should see the accompanying documents for the effect of moisture on accuracy, if applicable.

6.1.5.3 Symbol number 14 in Table D.I. of the general standard.

6.1.5.4 The words "Will not withstand mechanical shock", if applicable (see Clause 21.1), and symbol Number 14 in Table D.I.

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

6.1.6 In 6.3, add the following:

6.1.6.1 Oxygen Level Displays—Oxygen level displays shall be marked with the appropriate units of measurement.

NOTE 6—Displays should not be obscured by the hand normally adjusting the control(s) associated with the display.

6.1.7 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 coloring shall conform to the following requirements:

6.1.7.1 Red, with a flashing frequency of 1.4 to 2.8 Hz, shall be used as a high priority alarm.

6.1.7.2 Yellow, with a flashing frequency of 0.4 to 0.8 Hz, shall be used to indicate a medium priority alarm.

6.1.7.3 Yellow, with a constant signal, shall be used to indicate a low priority alarm.

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

6.1.7.5 Blue shall be used only as an advisory indicator.

6.1.8 The function of all lights and displays shall be marked.

6.1.9 Compliance shall be checked by functional test and inspection.

NOTE 7—Visual indicators and their associated markings should be visible or legible, or both, to an operator having visual acuity (corrected if necessary) of at least "one" when the operator is located 1 m in front of the oxygen analyzer at an illuminance of 215 lux.

g) 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:

a) The oxygen level measurement range and the accuracy of measurement (see Clauses 66.1, 66.2 and 66.3),

b) The stability of measurement accuracy (see Clauses 66.4 and 66.5),

c) The response time (see Clauses 66.6 and 66.7),

d) The oxygen level alarm range and its accuracy (see Clauses 64.3, 64.4 and 64.5),

e) The operating and non-operating temperature ranges (see Clause 10),

f) For sampling-type oxygen analyzers, the gas diversion rate (see Clause 62.3),

g) Power requirements, and

h) Time from switching on to obtaining specific operating performance.

4. Details of any effect on stated function due to the following:

a) 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),

b) Interfering gases or vapours (see Clause 60),

c) Mechanical shock (see Clauses 21.1 and 21.2),

d) Cyclic pressure (see Clause 61),

e) Barometric pressure or pressure at the site of use of the oxygen analyzer,

f) Fluctuations in line or battery voltages, and

g) Aging of the oxygen sensor or of the oxygen analyzer itself (see Clause 63).

NOTE 8—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 60.3, 60.5, 60.6 and 60.8 of this specification (see Clause 63).

NOTE 9—Other operating conditions may also be used as a basis for useful life.

NOTE 10—The shelf life of oxygen sensors should be stated.

NOTE 11—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 (for example, 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:

a) Pre-use checking and calibration,

b) Routine inspection and testing, and

c) 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 12—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, microwave or magnetic resonance imaging equipment in the vicinity.

12. If the lowest temperature that the oxygen analyzer can withstand during transport is higher than − 40°C or if the highest temperature the oxygen analyzer can withstand during transport is lower than 70°C, or both, 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.

SECTION TWO—ENVIRONMENTAL CONDITIONS

10. *Environmental Conditions*—Replace 10.1 and 10.2.1 with the following:

10.1 *Nonoperating Temperature Range:*

The oxygen analyzer shall meet the requirements given in 66.1 and 66.6, after it has been subjected to the extremes of the specified non-operating temperature range as detailed in the accompanying documents.

Compliance shall be checked by the test given in 10.1.1

10.1.1 *Test Method:*

10.1.1.1 *Principle*Determination of the accuracy of the oxygen reading and the response time at normal operating temperature after the oxygen analyzer, as packaged for transport, has been subjected to the extremes of the specified non-operating temperature range.

10.1.1.2 *Procedure*

Place the oxygen analyzer, as packaged for transport, in an atmosphere of room air having a relative humidity of less than 95 %, at the lower of the following temperatures until it has reached equilibrium: a) 70 ± 1°C; or, b) the highest temperature recommended during transport, as marked on the transport package.

NOTE 13—Equilibrium can be verified by a suitable means, such as placing a thermistor inside the oxygen analyzer.

Maintain the oxygen analyzer at this temperature for 4 h after equilibrium is attained.

Return the packaged oxygen analyzer to room temperature, unpack it and install it so that it is ready for use, as described in the accompanying documents.

Carry out the test for measurement accuracy as described in 66.2 and the test for response time as described in 66.7.

Repeat the procedure equilibrating the packaged oxygen analyzer at the higher of the following temperatures: a) − 40 ± 1°C; or b) the lowest temperature recommended during transport, as marked on the transport package.

10.1.1.3 *Expression of Results*—Express the results as described in 66.2 and 66.7 at both test temperatures.

10.2.1 *Operating Temperature Range:*

Oxygen analyzers shall meet the requirements given in 66.1 and 66.6 over a sample gas and ambient temperature range of 15 to 40°C.

Compliance shall be checked by the test given in 10.2.1.1.

10.2.1.1 *Test Method:*

10.2.1.1. *Principle*—Determination of the accuracy of the oxygen reading and the response time after equilibrating the oxygen analyzer at the extremes of the specified operating temperature range.

10.2.1.1.2. *Procedure:*

Place the oxygen analyzer in an atmosphere of room air at 40 ± 1°C having a relative humidity of less than 95 % until it has reached equilibrium.

NOTE 14—Equilibrium can be verified by a suitable means, such as placing a thermistor inside the oxygen analyzer.

Carry out the test for measurement accuracy as described in 66.2 and the test for response time as described in 66.7 except that both the oxygen analyzer and the test gases are to be maintained at 40 ± 2°C during both tests.

Repeat the procedure at the test temperature of 15 ± 1°C.

10.2.1.1.3 *Expression of Results*Express the results as described in 50.4 and 50.9 at both test temperatures.

17. *Separation*—The requirements given in Clause 17 of IEC 601-1:1988 apply together with the following additional item:

h) Deterioration of parts due to anesthetic agents and oxygen should be taken into account.

18. *Earthing and Potential Equalization*—See also Clauses 19 and 39.3.

19. *Continuous Leakage Currents and Patient Auxiliary Currents*—The requirements given in Clause 19 of IEC 601-1:1988 apply except in Item 19.1e), 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, and

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

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

21. *Mechanical Strength*—The requirements given in Clause 21 of IEC 601-1:1988 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 66.1 and 66.6 and, if applicable, 6.3, 60.12, and 64.3; 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 section 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:

8.2.2.1 That the shape of the shock pulse is in accordance with Fig. 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 Fig. 1,

That the measured velocity change (that 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:

$$V_i = 2 \times \frac{A \times D}{\pi} = 2 \times \frac{300 \times 0.011}{3.1416} = 2.1 \text{ m/s} \quad (1)$$

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 66.2 and the test for response time as described in Clause 66.7 and, if the oxygen analyzer is fitted with an oxygen level alarm, a test for oxygen level alarm limit as described in Clause 64.4.

21.2.3 *Expression of Results*—Express the results as described in relevant subclauses of Clause 66 and report any damage or accessibility of electrically live parts.

35. *Acoustical Energy (Including Ultrasonics)*—The requirements given in Clause 35 of IEC 601-1:1988 apply, together with the following additional requirement:

Unless the analyzer is an integral inseparable component of a larger system, the relevant standards of the equipment shall apply.

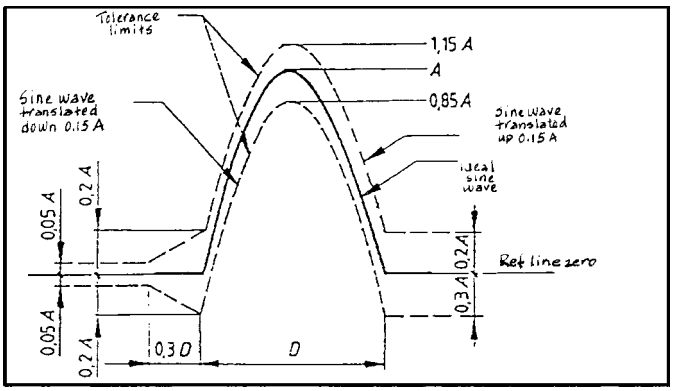

FIG. 1 Half-Sine Shock Pulse Configuration and Its Tolerance Limits

36. *Electromagnetic Compatibility*—The requirements given in Clause 36 of the general standard apply.

SECTION 6—PROTECTION AGAINST HAZARDS OF EXPLOSION IN MEDICALLY USED ROOMS

9.1 *Locations and Basic Requirements*—The requirements given in Clause 37 of IEC 601-1:1988 apply.

9.2 *Common Requirements for Category AP and Category APG Equipment*—The requirements given in Clause 39 of IEC 601-1:1988 apply.

SECTION 7—PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE, AND OTHER HAZARDS, SUCH AS HUMAN ERRORS

42. *Excessive Temperatures*—The requirements given in Clause 42 of IEC 601-1:1988 apply except as follows: Replace 42.3 with the following:

42.3 Applied parts with intentionally come in contact with the patient and that are not intended to supply heat to the patient shall not have surface temperatures exceeding 41°C.

43. *Fire Prevention*—The requirements given in Clause 43 of IEC 601-1:1988 apply together with the following additional requirements:

43.1 In order to eliminate the risk of fires caused by electrical components that may be a source of ignition in oxygen or nitrous oxide enriched atmospheres (or mixtures of gases containing anesthetic agents referred to in Clause 37), at least one of the following requirements shall be met:

a) Electrical components shall be separated from compartments in which accumulations of such gases can occur by a barrier complying with the requirements given in 43.2.

b) Compartments containing electrical components shall be ventilated according to the requirements given in 43.5.

c) Electrical components that in normal use and single fault condition can be source of ignition shall comply with the requirements given in 43.7.

43.2 Any barrier required under the provisions of 43.1 (a) shall be sealed at all joints and at any holes for cables, shafts, or other purposes. Compliance shall be checked by the following methods, as appropriate:

Inspection,

By compliance test for enclosures with restricted breathing given in 40.5 of IEC 601-1:1988, and

If under normal use conditions a pressure difference exists between the spaces separated by the barrier, the test method given in 43.4.

43.3 The ventilation required in 43.1 (b) shall be such that when tested by the method described in 43.2, the oxygen level in the enclosed compartment containing electrical components shall not exceed 4 % above the ambient oxygen level; if this requirement is met by forced ventilation, an alarm shall be provided to warn of failure of the ventilation.

43.4 Oxygen levels in enclosed compartments shall be tested as follows:

43.4.1 *Principle*—Measurement of the oxygen level in the enclosed compartment is measured after the oxygen analyzer is operated for 18 h under single fault conditions.

43.4.2 *Procedure*—Place the oxygen analyzer in a room in which the air exchange is between three and ten room volumes

per hour. Set the oxygen flow through the oxygen analyzer so that it equals the maximum flows of oxygen and nitrous oxide under normal conditions. Switch off the mains supply and measure the oxygen level in the enclosed compartment; operate the oxygen analyzer under single fault conditions with the least favorable control setting selected and with the mains voltage deviating by ±10 %, if applicable. After 18 h, switch off the supply mains and measure the oxygen level in the enclosed compartment.

43.4.3 *Expression of Results*—Record the oxygen levels measured at the beginning and the end of the 18 h period.

43.5 Electrical circuits that can produce sparks or generate increased surface temperatures and that can be a source of ignition shall be so designed that no ignition occurs. At least the following requirements shall be satisfied in normal condition and single fault condition:

The product of the R.M.S. value of the no load voltage and the R.M.S. value of the short circuit current shall not exceed 10 VA.

The surface temperature of components shall not exceed 300°C. Short- and open-circuiting of resistors, capacitors, and inductances complying with the requirements given in Clause 14 of IEC 65:1985 are not considered to be single fault conditions.

Compliance shall be checked by the test given in 43.6.

43.6 Measure or calculate the voltages and currents in steady state condition and measure the surface temperatures in normal condition and single fault condition.

43.5 Electrical circuits that can produce sparks or generate a high surface temperature and can be a source of ignition shall be so designed that in normal use and single fault condition, no ignition occurs; under these conditions, the product of the effective open circuit voltage and effective short circuit current shall not exceed 10 VA in each circuit.

43.6 The surface temperature of components that may constitute a source of ignition shall not exceed 300°C.

44. *Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization, and Disinfection:*

The requirements given in Clause 44 of IEC 601-1:1988 apply except (a) replace 44.3 by the following:

44.3 *Spillage*—Oxygen analyzers shall be so constructed that spillage does not wet parts which, if wetted, may cause a safety hazard.

44.3.1 Compliance shall be checked by the test given in 44.3.2.

44.3.2 Position the oxygen analyzer as in normal use. Pour 200 mL of water steadily on an arbitrarily chosen point on the top surface of the oxygen analyzer. After this the oxygen analyzer shall comply with the requirements of this specification; (b) replace 44.5 by the following:

44.5 *Humidity and Condensation Effects:*

44.5.1 *Humidity Effects*—When operated in accordance with the instructions for use, oxygen analyzers shall maintain ±5 % (V/V) measurement accuracy when used with air or comparable gas mixtures having any relative humidity between 0 % and 100 %.

NOTE 15—These requirements may be met with the addition of an adaptor if required.

Compliance shall be checked by the test given in 44.5.2.

44.5.2 *Test Method:*

44.5.2.1 *Principle*—Determination of the accuracy of the oxygen reading over a 2-h period of exposure of the oxygen sensor to a high relative humidity (non-condensing) after calibration in dry air.

44.5.2.2 *Test Gases*—Dry room or compressed air as the calibration gas mixture and humidified room or compressed air having a relative humidity between 95 and 100 % (non-condensing) shall be used as the test gas mixture.

44.5.2.3 *Procedure:*

Hold the ambient temperature of the oxygen analyzer constant to within ±1°C of a nominal value within the operating rate of the oxygen analyzer (see 10.2.1). Hold the temperature and calibration of the test gas mixtures delivered to the sensing area constant at ±2°C. Deliver the calibration and test gas mixtures to the sensing area at ambient barometric pressure. Set up the oxygen analyzer for the measurement of humidified gases as described in the accompanying documents (for example, by attachment of an adaptor or orientation of the oxygen sensor). Maintain the oxygen analyzer and oxygen sensor in the same position throughout the test.

Ensure that the oxygen sensor is at a temperature of 35 ± 2°C and that the oxygen analyzer is at ambient temperature. Calibrate the oxygen analyzer according to the accompanying documents using the calibration gas mixture. Do not recalibrate the oxygen analyzer during the test period. Expose the sensing area to the test gas mixture for a continuous period of 2 h. For continuous monitoring oxygen analyzers, record the oxygen reading at least once every 15 min. For intermittent sampling oxygen analyzers, sample the test gas mixture at least once every 15 min and record the oxygen reading. In either case, record the temperature to an accuracy of ±0.2°C and the barometric pressure to an accuracy of ±0.2 % of the reading every time an oxygen reading is recorded.

44.5.2.4 *Expression of Results:*

If the oxygen readings are not already in partial pressure use, convert each oxygen reading to partial pressure, P, for example in kilopascals using the equation:

$$P = (R/100) \times B \tag{2}$$

where:

R = the oxygen reading in percent (V/V) oxygen, and
B = the barometric pressure, for example, in kilopascals.

Correct each oxygen reading for the dilution effect of 100 % water vapor at the temperature and barometric pressure of each reading, using the following equation:

$$A = \frac{\frac{B}{B - V_t} \times P}{B} \times 100 \tag{3}$$

where:

A = the corrected oxygen reading in percent (V/V) oxygen,
B = the barometric pressure, for example in kilopascals,
V_t = the vapor pressure of water, for example, in kilopascals at temperature t,
t = the temperature of the humidified test gas in degrees Celsius, and

P = the oxygen partial pressure, for example in kilopascals.

Table 1 lists the vapor pressure of water at selected temperatures.

44.5.3 *Condensation Effects*—Oxygen analyzers intended for use in a breathing system shall meet the following requirements, either:

a) Oxygen analyzers shall maintain the oxygen measurement accuracy specified in 66.1 and 66.3 and the response time specified in 66.6. If the manufacturer recommends or supplies an attachment for use when measuring gases of high humidity, these requirements shall be met with the attachment in place.

b) Compliance shall be checked by the test given in 44.5.4, or

If the oxygen analyzer does not meet these requirements, a cautionary notice shall be included in the accompanying documents.

44.5.4 *Test Method:*

44.5.4.1 *Principle*—Determination of the accuracy of the oxygen reading and the response time over a 2-h period of exposure of the oxygen sensor to a relative humidity of 100 % (condensing) after calibration in dry air.

44.5.4.2 *Test Gases*—Dry room or compressed air as the calibration gas mixture and humidified room or compressed air having a relative humidity of 100 % (condensing) shall be used as the test gas mixture.

44.5.4.3 *Procedure*—Carry out the procedure described in 44.5.2 ensuring that the test gas is delivered to the sensing area in a fully saturated condensing state and that condensate forms at the sensing area. In addition, measure the response time by the method described in 50.9 after recording each oxygen reading.

44.5.4.4 *Expression of Results*—Express the results as described in 44.5.2.4.

47. *Electrostatic Charges*—This clause of the general standard applies.

SECTION 8—ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

51. *Protection Against Hazardous Output*—The requirements given in Clause 51 of IEC 601-1:1988 apply together with the following additional requirements:

51.5 *Function and Position of Controls:*

Check or test controls for battery condition or signal operation and signal override shall automatically return from the check, test or override position, unless these functions are carried out automatically when switching to the operating mode.

The positions of measurement and test controls shall be clearly distinguishable.

TABLE 1 Vapor Pressure Over Water

Temperature, °C	Pressure, kPa	Pressure, mmHg
33	4.90	37.7
34	5.19	39.9
35	5.48	42.2
36	5.79	44.6
37	6.12	47.1

Calibration controls shall include means to prevent an inadvertent change from the intended position (for example, by recessing the control or by providing a locking mechanism).

NOTE 16—All other controls should also include means to prevent inadvertent changes from the intended positions and should have clearly distinguishable positions.

SECTION 9—FAULT CONDITIONS CAUSING OVERHEATING OR MECHANICAL DAMAGE, OR BOTH; ENVIRONMENTAL TESTS

56. *Components and General Assembly*—The requirements given in Clause 56 of IEC 601-1:1988 apply except as follows:

In 56.8, add the following:

High priority signals provided with the oxygen analyzer for monitoring oxygen levels shall be both visual and auditory.

Medium priority signals provided with the oxygen analyzer shall be visual.

NOTE 17—Visual and auditory indicators may be accompanied by a display. Medium priority signals may be accompanied by an auditory signal.

In 56.10, add an additional item as follows:

d) *Movement of controls*—for controls that consist of a movable part and a non-movable part, movement upwards, to the right, or clockwise shall increase the control function.

Rotary gas flow controls are exempt from this requirement.

NOTE 18—The separation between control knobs, switches, toggles, pinwheels, or push buttons should conform to the recommendations given in DOD Handbook 743A.

NOTE 19—Controls and their associated markings should be visible or legible, or both, to an operator having visual acuity (corrected if necessary) of at least "one" when the operator is located at least 1 m in front of the oxygen analyzer at an illuminance of 215 lux. Markings should be clearly identified with their associated controls.

SECTION 11—ADDITIONAL REQUIREMENTS

60. *Interfering Gas and Vapor Effects:*

60.1 Oxygen analyzers shall either:

a) Have not more than 5 % (V/V) oxygen interference with measurement accuracy in the presence of any of the gases or vapors at the levels listed in Table 2; or

b) If the body of the oxygen analyzer is marked "Not for use with inhalation agents" or equivalent, the oxygen analyzer shall not have more than 5 % (V/V) oxygen interference with measurement accuracy in the presence of helium or carbon dioxide at the levels listed in Table 2. If the oxygen interference is greater than 1 % (V/V) this shall be stated in the accompanying documents.

Compliance shall be checked by the test given in 60.2.

60.2 Compliance shall be tested as follows:

TABLE 2 Inhalation Anesthetics and Other Interfering Gases and Vapors

Gas or Vapor (In 30 % Oxygen, 70 % Nitrous Oxide)	Level Volume %
Nitrous Oxide[A]	80
Carbon Dioxide	5
Halothane[A]	4
Enflurane[A]	5
Isoflurane[A]	5

[A] Inhalation anesthetic agent.

60.2.1 *Principle*Determination of the accuracy of the oxygen reading in the presence of interfering gases and vapors given in Table 2.

60.2.2 *Test Gases*—Dry pre-mixtures of 30 % oxygen and 70 % nitrous oxide and the interfering gas or vapor at the level given in Table 2, the oxygen levels being known to within ± 5 % (V/V), shall be used.

60.2.3 *Procedure*—Carry out the test described in 66.2 with the following modification:

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

60.2.4 *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.

61. *Cyclic Pressure:*

61.1 Oxygen analyzers shall either meet the requirements given in 66.1 and 66.6 following exposure to cyclic positive pressure of 10 kPa (100 cm H_2O) and negative pressure of 1.5 kPa (15 cm H_2O) in the breathing system, or be marked with the warning "Not for use in breathing systems" and a similar warning shall appear in accompanying documents.

Compliance shall be checked by the test given in 61.2.

61.2 Accuracy shall be tested as follows:

61.2.1 *Principle*—Determination of the accuracy of the oxygen reading and the response time after exposure of the sensing area to cyclic pressure.

61.2.2 *Procedure*—Expose the sensing area to a cyclic pressure waveform such that 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) are each maintained, in turn, for not less than 2 s each. Cycle the pressures at a rate of 0.167 ± 0.017 Hz (10 ± 1 cycle/minute) for 10 min.

Carry out the test for measurement accuracy as described in 50.4 and the test for response time as described in 50.9.

61.2.3 *Expression of Results*—Express the results as described in 66.2 and 66.7.

62. *Gas Leakage and Sampling Loss:*

62.1 The rate of leakage of a non-sampling oxygen analyzer shall not be greater than 20 mL/min.

NOTE 20—This requirement ensures that when fitted to a breathing system its rate of leakage 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 62.2. The accuracy shall be tested as follows:

62.2.1 *Apparatus*—A pressure gage having an accuracy within ± 0.3 kPa and a flowmeter having an accuracy within ± 2 mL/min shall be used.

62.2.2 *Procedure*—Assemble the oxygen analyzer so that the oxygen sensor is installed in a dimensionally suitable port of a test apparatus containing an inlet fitting to which a test gas and air flow meter are attached. Connect the pressure gage 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. This leakage flow shall be as specified in Clause 62.1.

62.3 The rate at which a sampling oxygen analyzer 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 62.4.

62.4 The rate of gas withdrawal shall be tested as follows:

62.4.1 *Principle*—Measurement of the rate at which a sampling (intermittent) oxygen analyzer withdraws gas from a simulated breathing system.

62.4.2 *Test Gas*—Pressurized air at room temperature shall be used.

62.4.3 *Apparatus*—A pressure gage having an accuracy within ±0.3 kPa, and a flowmeter having an accuracy to within ±10 % of the rate at which the oxygen analyzer withdraws gas from the breathing system as stated in the accompanying documents shall be used.

62.4.4 *Procedure*—Assemble the apparatus as described in 62.2.2 but using the flow meter specified in 62.4.3. Adjust the pressurized air source to 3 kPa and monitor the flowmeter reading for 1 min.

62.5 A means shall be provided to collect the gas from the oxygen analyzer.

63. *Replacement of Oxygen Sensor*

63.1 The accuracy of the oxygen reading and stability of measurement accuracy in response time shall meet the requirements given in 66.1, 66.3, 6.4, and 66.6, respectively, over a period of time, as described by the manufacturer in the accompanying documents.

Compliance shall be checked by the test given in 63.2.

63.2 The accuracy shall be tested as follows:

63.2.1 *Principle*—Determination of the accuracy of the oxygen reading, the stability of measurement accuracy and the response time over a period of time.

63.2.2 *Test gas*—A dry gas mixture containing oxygen at a level greater than 98 % (V/V) shall be used.

63.2.3 *Procedure:*

Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture 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 21—The test gas mixture need not be at ambient temperature.

Deliver the test gas to the sensing area at ambient barometric pressure. Verify that the requirements given in 66.1, 66.3, 66.4, and 66.6 have been met.

13.5.3.3 Expose the sensing area to the test gas for at least 31 days.

NOTE 22—The ambient and test gas temperatures may vary over the full operating temperature range specified in accompanying documents during this period.

At the end of the period, carry out the test for measurement accuracy as described in 66.2, stability of measurement accuracy as described in 66.5, and response time as described in 66.7.

63.2.4 *Expression of Results*—Express the results as described in 66.2, 66.5, and 66.7, before and after the exposure period.

64. *Alarms:*

64.1 *Manual High Priority Signal Override*—If a manual control is provided to override the low oxygen level alarm, it shall only override the auditory high priority signal and shall automatically cancel after not more than 120 s following its most recent activation.

64.2.1 *Auditory Signal Frequency:*

Sound Quality—The fundamental frequency of auditory signals should lie between 150 and 1000 Hz, that shall be based on standard musical pitches, that is, the A440 system ±1 %. There shall be at least four frequency components ranging from 300 to 4000 Hz. These frequency components shall be related so that they form a distinct sound. These alarms should be non-startling. Rise times should exceed 15 mg.

64.2.2 *Sound Intensity*—Alarms that have an adjustable volume shall not be totally silenced by the adjustment, and shall have a minimum setting of 45 dB(A) or greater and a maximum setting of 85 dB(A) or less (peak output at 1 m) from the source in an anechoic chamber. Alarms with fixed intensity shall be between 70 and 85 dB(A) peak output at 1 m. If operator adjustment is provided, the control and its associated indicator shall be marked to indicate an increase or decrease in volume.

64.3 *Oxygen Level Alarms*—If an oxygen level alarm system is provided, is shall meet the following requirements:

a) The alarm shall be both visual and auditory.

b) The alarm limit shall lie within ±2 % (V/V) oxygen of the alarm set-point in the range of 15 % (V/V) to 60 % (V/V) oxygen and within ±5 % (V/V) oxygen of the alarm set-point elsewhere throughout the range.

Compliance shall be checked by the test given in 64.4.

64.4 *Test Method for Oxygen Level Alarm Limit*

64.4.1 *Principle*—Determination of the alarm limit values and the alarm set-point values at a number of oxygen readings across the range of the alarm system.

64.4.2 *Procedure:*

Hold the ambient temperature of the oxygen analyzer constant to within ±1°C of a nominal value within the operating temperature range specified in the accompanying documents. Generate at least four stable oxygen readings that span the range of the alarm system in approximately equal steps, by varying the oxygen level delivered to the sensor, or by electrically stimulating the oxygen sensor, or by adjusting the calibration control.

For each oxygen reading, adjust the alarm limit control so that the alarm is deactivated. Slowly adjust the alarm limit control until the alarm is activated. For each oxygen reading, record the alarm limit value, that is, the indicated oxygen reading, and the corresponding alarm set-point value, that is, the most precise set-point indication at the point of first activation of the alarm.

NOTE 23—An alarm may be of a type that is activated at an oxygen reading above (high alarm) or below (low alarm) the alarm limit. An oxygen analyzer may have either or both types of alarm.

64.5 *Low Alarm Limit Requirements*—If an adjustable low alarm limit is provided, it shall not be adjustable below an alarm set-point point value of 15 % (V/V) oxygen. If a non-adjustable low alarm limit is provided, the alarm set-point value shall not be below 15 % (V/V) oxygen. There shall be a visual indication to the user when a low alarm limit is adjusted to an alarm set-point value below 21 % (V/V) oxygen.

NOTE 24—This requirement may be met by methods such as red markings on the low alarm limit control in the range below 21 % (V/V) oxygen, or a caution signal that is activated when the low alarm limit control is set below 21 % (V/V) oxygen, or markings on the oxygen analyzer itself.

65. *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- or 22-mm conical connectors, or both, in accordance with ISO 5356-1:1987 or ISO 5356-2:1987.

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 sampling gas and outlet ports of a sampling oxygen analyzer shall not be interchangeable with the breathing system connection port or with the oxygen sensor connection port.

66. *Measurement Accuracy:*

66.1 Oxygen readings shall be within ±3 % (V/V) oxygen of the actual oxygen level.

NOTE 25—This tolerance includes errors from all sources associated with the oxygen analyzer, such as its electrical circuits, calibration method, display resolution, and oxygen sensor, excluding the effects of interfering gases as listed in Table 2.

Compliance shall be checked by the method given in 66.2.

66.2 *Determination of Measurement Accuracy:*

66.2.1 *Principle*—Determination of the accuracy of the oxygen reading at a number of oxygen levels across the full range of the oxygen analyzer.

66.2.2 *Test gases*—At least the following four mixtures of oxygen and nitrogen shall be used: 15, 21, 40, and 60 % (V/V) oxygen. Ensure that the gas mixtures are dry, are pre-mixed, and that the oxygen level is known to within ±0.5 % (V/V) oxygen.

66.2.3 *Procedure:*

Operate the oxygen analyzer as described in the accompanying documents. Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture delivered to the oxygen sensor constant to within ±1°C of a nominal value within the operating range specified for the oxygen analyzer.

NOTE 26—The test gas mixtures need not be at ambient temperature.

Calibrate the oxygen analyzer as described in the accompanying documents. Deliver one of the test gas mixtures to the sensing area at ambient barometric pressure. Ensure that the oxygen analyzer is in equilibrium with the test gas mixture and that the oxygen analyzer is at ambient temperature. After a period of at least three times the response time in the accompanying documents, record the oxygen reading indicated by the oxygen analyzer. Repeat the procedure with the other gas mixtures.

66.2.4 *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.

66.3 *Digital Readings*—If an oxygen analyzer displays the oxygen reading digitally, there shall be: a) at least two digits, and b) a means for indicating that the oxygen reading is above the specified range of the display.

NOTE 27—This requirement may be met, for example, by a two-digit display that flashes or by a three-digit display that reads greater than 100 % (V/V) oxygen when the reading exceeds 100 % (V/V) oxygen, for instance, during calibration.

66.4 *Stability of Measurement Accuracy:*

Oxygen analyzers shall maintain the measurement accuracy specified in 66.1, 66.2, and 66.3 for a period of at least 8 h continuous use.

Compliance shall be checked by the test given in 66.5.

66.5 *Test Method:*

66.5.1 *Principle*—Determination of the accuracy of the oxygen reading in the central part of the oxygen measurement range of the oxygen analyzer during an eight-hour period after calibration.

66.5.2 *Test Gas*—A dry pre-mixture of oxygen and nitrogen containing oxygen at a level between 20 and 80 % of the full scale oxygen reading indicated on the oxygen analyzer shall be used, the oxygen level being known to within ±0.5 % (V/V) oxygen.

NOTE 28—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.

66.5.3 *Procedure:*

Operate the oxygen analyzer as described in the accompanying documents. Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture delivered to the sensing area constant to within ±1°C of a nominal value within the operating temperature range as specified in the accompanying documents.

NOTE 29—The test gas mixture need not be at ambient temperature.

Calibrate the oxygen analyzer 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 analyzer is at ambient temperature. Expose the sensing area to the test gas for a continuous period of 8 h, ensuring that the oxygen analyzer is maintained in the same position during the whole period. For continuous monitoring oxygen analyzers, record the oxygen reading at least once every 15 min. For intermittent sampling oxygen analyzers, sample the test gas mixture at least once every 15 min and record the oxygen reading.

66.5.4 *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.

66.5 *Response Time*—The response time shall not be greater than 1.15 times the value stated in the accompanying documents.

Compliance shall be checked by the test given in 66.6.

66.6 *Test Method:*

66.6.1 *Principle*—Measurement of the time taken for the oxygen analyzer to respond to changes in oxygen level at the sensing area.

66.6.2 *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 analyzer shall be used.

NOTE 30—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.

66.6.3 *Procedure:*

Hold the ambient temperature of the oxygen analyzer 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 31—The test gas mixture need not be at ambient temperature.

Calibrate the oxygen analyzer 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 analyzer 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 response time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen analyzer (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 response time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen analyzer (R_2). With the oxygen analyzer measuring R_2, re-expose the sensing area to the 95 to 100 % full-scale oxygen reading test gas mixture. Measure the interval, to the nearest second, 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:

$$R_4 = R_2 + (0.9 \times [R_1 - R_2]) \quad (4)$$

$$R_3 = R_2 + (0.1 \times [R_1 - R_2]). \quad (5)$$

Finally, with the oxygen analyzer measuring R_1, re-expose the sensing area to the 20 to 25 % full-scale oxygen reading test gas mixture. Measure the interval, to the nearest second, from the time at which the oxygen reading is 10 % of the change above 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:

$$R_5 = R_1 + (0.9 \times [R_1 - R_2]) \quad (6)$$

$$R_6 = R_1 + (0.1 \times [R_1 - R_2]). \quad (7)$$

66.6.4 *Expression of Results*—Report the times taken to reach the R_4 and R_6 readings.

NOTE 32—See also the requirements of Clauses 10.1, 21, 44.5.1, 61, and 63.1.

NOTE 33—The stated response time is the slowest that occurs when any one of the above referenced conditions is varied over its full range.

ANNEXES

(Mandatory Information)

A1. RATIONALE

INTRODUCTION

This annex provides a concise rationale for the important requirements of this specification and is intended for those who are familiar with the subject of this specification 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 clauses in this annex have been so numbered to correspond to the clauses in this specification to which they refer. The numbering is, therefore, not consecutive.

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 that were carried on by the participants in the meetings of the subcommittee that developed this specification.

NOTE A1.1—Annexes A to M given in IEC 601-1:1988 together with Annex A1 and Annex A2 in this specification apply.

A1.1 (X1.1) Scope

A1.1.1 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.

A1.1.2 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 draft standard if, for instance, the manufacturer suggested (for example, through advertising) applications that fall within the scope of this specification.

A1.2 (X1.3) Definitions

A1.2.1 (X1.3.1) *Alarm*—The distinction between the terms “alarm,” “alarm system,” and “alarm set-point” are important because they tend to be used imprecisely and somewhat interchangeably. Alarm is used in this specification only to refer to the high priority signal that occurs when the oxygen reading exceeds 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.

A1.2.2 (X1.3.6) *Display*—The term “display” is used to denote any device that 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).

A1.2.3 (X1.3.8) *Oxygen Analyzer*—Devices that do not “measure and indicate” are not intended to be covered by this specification. 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 analyzer for use in direct patient monitoring applications.

A1.2.3.1 The term “in a gaseous mixture” implies that devices that measure or monitor oxygen in a liquid phase (for example, blood gas analyzers or indwelling catheters) are not covered by this draft specification.

A1.2.4 (X1.3.9) *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 A1.2—Most oxygen analyzers 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 analyzer scales in percent oxygen.

A1.2.5 (X1.3.10) *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 analyzer and the error (again, the accuracy) of the reference method by which the gas mixture oxygen level was analyzed (for example, gas chromatography).

A1.2.6 (X1.3.14) *Sensing Area*—The term “sensing area” is not intended to be a synonym for “oxygen sensor”. It is, rather, intended to define that location in the gaseous environment being measured at which oxygen molecules are considered to pass into the oxygen analyzer system. The actual oxygen sensor may be remote, as in the case of a sampling type analyzer.

A1.3 (X1.6.1) Identification, Marking, and Documents

A1.3.1 *Analyzer Markings*—(a) and (b) 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.

A1.3.2 (d) *Instructions*—Since it is common for oxygen analyzers to be operated in areas where the personnel using these change frequently, it is likely that full instructions will not be given in the use of an individual manufacturer's unit.

A1.3.2.1 Thus, it was generally agreed that some instructions and precautions needed to be placed on the analyzer itself, in addition to the detailed information contained in the accompanying documents. The requirement for instructions is intended to specify, in general, the minimal level of information that an unfamiliar user would need to operate the analyzer correctly and safely. It is recognized that there are limitations to the amount of information that can be placed on the analyzer 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 analyzer itself, referring the user to the accompanying documents for details and cautions.

A1.3.3 (X1.6.3) *Marking of Controls and Instruments*—Since oxygen level may be stated in a number of different units of measure, such as % (V/V) oxygen, kPa or mmHg, it is necessary that the oxygen display be marked with the appropriate units of measure.

A1.3.4 (X1.6.7) If visual indicators are used on the oxygen analyzer, with the exception of alphanumeric displays, their color shall conform to the following requirements:

A1.3.4.1 (1) Red, with a flashing frequency of 1.4 to 2.8 Hz, shall be used as a high priority alarm.

A1.3.4.2 (2) Yellow, with a flashing frequency of 0.4 to 0.8 Hz, shall be used to indicate a medium priority alarm.

A1.3.4.3 (3) Yellow, with a constant signal, shall be used to indicate a low priority alarm.

A1.3.4.4 (4) Green shall be used to indicate that the oxygen analyzer is ready for use or in normal operation.

A1.3.4.5 (5) Blue shall be used only as an advisory indicator. Green indicators are reserved for indications of satisfactory function. Green is not intended to be used as a power-on indicator, unless the analyzer is ready for use and operating within tolerance without any warm-up delay. For example, it is not acceptable to have a green power-on indicator that illuminates simultaneously with a yellow warm-up delay indicator. In a case such as this, the green indicator illuminates only after the yellow indicator extinguishes.

A1.3.5 Blue indicators may not be used for any of the applications reserved for red, flashing red, yellow or green, in order to avoid confusion. Blue may only indicate information that has no connotation of good, marginal or poor performance of the analyzer or the monitored function(s).

A1.3.6 There are no color restrictions on displays, such as dot matrix displays or cathode ray tubes. Displays are generally monochromatic and are usually used to convey detailed information. The implication of the requirements of this draft specification is that if a monochromatic display is used, separate colored indicators are to be used to alert the operator to warning or caution conditions. A single indicator of each required color may be used, however, with the display providing the information on the nature of the problem.

A1.3.7 (X1.6.8.2) (f10) *Accompanying Documents*—It has been noted by some users that some oxygen analyzers have cables or sample tubing that are of insufficient length to be safely and conveniently mounted on apparatus, such as an anesthetic machine. It is difficult to specify universal lengths for all analyzers, 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.

A1.3.8 (f11) *Electromagnetic Interference*—Electromagnetic susceptibility is considered to be an important, but difficult to solve, medical device problem. Electrosurgery devices are the best-known primary offenders in terms of electromagnetic emissions. For these reasons, it was decided to compromise on a warning in the accompanying documents to educate the device user.

A1.3.8.1 There are no generally accepted specifications for minimum levels of electromagnetic interference to which medical devices should not be susceptible. When a recognized standard exists, this will be taken into account in the revision of this specification.

A1.3.8.2 (f) (12) An oxygen analyzer may be exposed to temperatures in the range of −40 to +70°C during transport. The extremes are those that might reasonably be expected to be met in transport by air, land, or sea. The objective of this requirement is to ensure that an analyzer will still be operable after exposure to these temperature extremes during transport.

A1.3.8.3 It is recognized that some types of oxygen sensor probably cannot withstand extremely low temperatures and that their response time or expected useful life, or both, are likely to be adversely affected. To account for this and to allow such oxygen sensors to be used because of their other desirable benefits, a narrower non-operating temperature range is permitted, provided that a notice to that effect is printed on the transport package and the actual range is disclosed in the accompanying documents. It is left to the manufacturer's discretion to determine the details of such precautionary instructions.

A1.4 (X1.10) Environmental Temperature Limitations

A1.4.1 Operating temperature range-temperatures as high as 40°C are often encountered in incubators. Temperatures as low as 15°C may be encountered during transport.

A1.5 (X1.19) Continuous Leakage Currents and Patient Auxiliary Currents

A1.5.1 It is essential that the leakage current is limited because the analyzer may come into contact with pacemaker leads or other conduction paths to the patient.

A1.6 (X1.21) Mechanical Strength

A1.6.1 Both line and battery powered oxygen analyzers, if easily portable or rack-mounted, will be subjected to frequent shock in the course of normal use. This requirement and test

method is adapted from US MIL-STD-810C (Method 516.2). The intent of this requirement is not to require that severe shocks or drops (for example, from tabletops to floor) be withstood. Rather it is an attempt to set a baseline, minimum suggested standard for the moderate shocks or drops frequently encountered in portable or rack-mounted medical equipment. It appears that no data exist on average or extreme shock conditions in medical environments. However, it is generally agreed that medical equipment is typically subjected to abuse. A300 m/s_2, 11 ms, half-sine wave shock pulse has an energy content of 0.23 g/s, which is about equivalent to the 30 cm free fall of an object. A shock pulse time of 11 ms is reasonable for a fall to a typical hospital surface such as wood or tile. In summary, the test requires portable analyzers to have enough strength to withstand roughly the equivalent of a 30-cm free fall to a table.

A1.7 (X1.37.1) Protection Against Hazards of Explosion in Medically Used Rooms

A1.7.1 Since the worldwide use of flammable anesthetics is becoming rare, an analyzer that has a restricted use is considered acceptable.

A1.7.2 Two levels of safety for explosion hazards are set. The first, less stringent, level is for the analyzer 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.

A1.7.3 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 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.

A1.7.4 This level is based on the ignition energy level of the most flammable mixture of diethyl ether and oxygen.

A1.8 (X1.44.5) Humidity and Condensation Effects

A1.8.1 Analyzers are routinely used in humid environments or in environments where condensate could form on the oxygen sensor. It is essential that users are informed of any adverse effects of such conditions. There are four potential effects to be considered:

A1.8.1.1 (1) The addition of water vapor to a dry gas mixture under isothermal, isobaric conditions changes the partial pressure of gases in that mixture. This physical principle is not construed as an adverse effect of humidity and, therefore, needs no precautionary warning. Clause 6 requires that this physical principle be explained in the accompanying documents.

A1.8.1.2 (2) Water vapor may interfere with the measurement of oxygen, as may other gases or vapors listed in Table 1. For water vapor, this effect is covered by the test described.

A1.8.1.3 (3) The accuracy, stability, or response time of the analyzer may be affected under less than saturation conditions by mechanisms other than interference that would not be detected by the test described in 44.5.2. This effect is not examined separately in this draft specification; rather, it is assumed that such an effect would also be encountered under saturation conditions and is thus covered by the test described in 44.5.4.

A1.8.1.4 (4) The formation of condensate in breathing mixtures can have significant effects on oxygen measurement systems. It is probably the most serious humidity effect and is frequently encountered in clinical practice. This problem is checked by the test described in 44.5.4. This test requires, as does the test described in 44.5.2, that temperature equilibrium be attained to separate humidity effects from those of transient temperature effects.

A1.9 (X1.51.5) Function and Position of Controls

A1.9.1 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 to 22 % (V/V) oxygen. Distinguishable control positions are necessary to determine what is being displayed on multi-function displays.

A1.9.2 Inadvertent changes in the calibration control position will result in the display of erroneous measurements.

A1.9.3 Controls should operate according to stereotyped expectations to discourage inappropriate control settings.

A1.10 (X1.56.8) Indicators

A1.10.1 Operator attention is required when a condition occurs that results in the activation of a high, medium, or low priority signal. In the case of a high priority signal, immediate attention is required. The requirement for an auditory signal ensures that the operator will be made aware of a serious problem immediately, even if he or she is not looking at the analyzer. Since medium priority signals indicate conditions that do not require immediate action, an auditory component is not required. In either case, the visual indicator is intended primarily to identify which piece of equipment requires attention. The specific nature of the problem which resulted in the signal being activated can be identified by the use of multiple visual indicators or by a display such as a dot matrix display, a cathode ray tube, or a liquid crystal display.

A1.11 (X1.60) Interfering Gas and Vapor Effects

A1.11.1 One of the principal applications of oxygen analyzers is in anesthesia. 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 vapors likely to be encountered during anesthesia. An interference greater than ± 2 % (V/V) oxygen is not permitted since, 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.

A1.11.2 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.

A1.11.3 The operator should be aware that in some analyzers the combination of low battery and interfering gases or vapors can be especially misleading.

A1.12 Cyclic Pressure

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 analyzers—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.

A1.12.1 The pressure extremes of +10 and −1.5 kPa are considered clinically relevant pressures that are occasionally attained.

A1.13 (X1.62) 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 analyzer be as low as possible. Otherwise, it will be impossible to achieve an acceptably low maximum leakage rate for the breathing system.

When sampling analyzers 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 use with the information necessary to assess its significance for various clinical situations. In closed circuit systems, high gas withdrawal flows are not acceptable with regard to patient safety and pollution effects.

Since oxygen analyzer manufacturers usually do not manufacture the fittings with which their T-pieces must mate, testing is performed with standard 22 mm fittings.

A1.14 (X1.63) Replacement of Oxygen Sensor

While it is recognized that the expected life may vary considerably as a function of test conditions, it is important that the operator is given some indication of the expected life of the analyzer's expendable components. Manufacturers are required to express expected life by the same conventions so that the user has a consistent set of information on which to base clinical and financial decisions.

The conditions for determining expected useful life were chosen somewhat arbitrarily to represent routine environments in which oxygen analyzers will be operated in anesthesia and respiratory therapy applications. The conditions will yield a conservative estimate of expected useful life, since they are a combination of that which tends to be a "worse case" environment for all sensing techniques employed at the time that this draft specification was developed.

In the test method, oxygen analyzer function is evaluated at 85 % of expected useful life rather than at 100 % of expected useful life. This allows the stated useful life to be at or closer to the nominal value rather than at the worst case value, allowing for variations between individual sensors. A tolerance of plus or minus one day is included to allow the test to begin and conclude when personnel are available.

A1.15 (X1.64) Alarms

Auditory signals with very low or very high fundamental frequencies may be difficult for some operators to hear. At such frequencies, it can be more difficult to locate the position in the room from which the signal is emanating. Also, more sound energy is required at low or high frequencies to achieve the same perceived sound intensity, since human hearing is less sensitive in those ranges.

Frequencies between 150 and 1000 Hz provide a reasonable combination of perceived loudness and directionality.

Warning signals are more effective in attracting the attention of the user when they are cyclic rather than continuous. A relatively slow cycle rate is recommended, in order to convey a sense of urgency without startling the people in the room.

A1.16 (X1.64.1) Manual High Priority Signal Override

Continuous signals may be used for the auditory component of high priority signals, yet they can be a significant distraction during the time that the operator is attempting to correct such a condition. Thus, a temporary silencing mechanism is desirable. In the case of a low oxygen level alarm, a prolonged deactivation of the auditory components of the high priority signal is allowed. It was considered that 120 s was the maximum time that would be required to correct any condition that results in the activation of a low oxygen level alarm.

This requirement implies that all high priority signals may have their auditory component overridden but only low oxygen level alarms are required to cancel automatically.

A1.17 (X1.64.3, X1.64.4, X1.64.5) Oxygen Level Alarms

Alarm systems, although a desirable feature, should be optional. Not all applications require alarms. The operator makes the final decision on whether an alarm system is required. An auditory warning signal is required, since the exceeding of an oxygen level alarm limit requires immediate attention by the user. A visual indicator is required, since there may be many instruments in the same room with similar sounding auditory warning signals. The visual indicator serves to identify which device is to be attended to. The requirements for alarm accuracy are based primarily on the minimum necessary for patient safety, although technical and financial constraints are also a consideration. An alarm accuracy of ±2 % (V/V) oxygen should be sufficient in the lower range of clinical applications where the concern is the accidental delivery of an hypoxic breathing mixture. The additive error of ±3 % (V/V) oxygen reading accuracy and ±2 % (V/V) oxygen alarm accuracy implies that a combined error of ±5 % (V/V) oxygen could occur in the worst case. It is believed that such an error could be tolerated for warning by the alarm of an unsafe condition. The individual and combined errors are believed to be achieved by reasonable means within the limitations of existing technology and the financial constraints of the marketplace. A lesser degree of accuracy can be tolerated over the balance of the alarm range, since the combined error of ±8 % (V/V) oxygen is within the range of any established,

clinically significant effects on the patient (see 64.3).

A1.15.3 A low alarm limit that can be adjusted or is pre-set to a set-point value below 15 % (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, an analyzer with a low alarm limit that is adjusted to a set-point value of 15 % (V/V) oxygen may begin to alarm at an oxygen level as low as 10 % (V/V) oxygen (with a corresponding alarm limit of 13 % (V/V) oxygen) or at an oxygen level as high as 20 % (V/V) oxygen (with a corresponding alarm limit of 17 % (V/V) oxygen).

A1.16 (X1.66) Measurement Accuracy

X1.16.1 (X1.66.1, X1.66.2, X1.66.3) *Measurement Accuracy*—The accuracy of the oxygen reading is of major importance due to the critical applications of oxygen analyzers.

In this specification, 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 criteria of effective function for all three primary areas of medical use: anesthesia, pediatrics and respiratory therapy. For anesthesia, 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 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 pediatric anesthesiologists to be the maximum acceptable error in the normal range of their applications between 40 and 60 % (V/V) oxygen. The requirements of respiratory therapy are also satisfied. For diagnostic measurements where 90 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 to 100 % (V/V) oxygen.

(a) A simple, effective calibration method would be:

(b) Place the sensing area in 100 % (V/V) oxygen,

(c) Adjust the calibration control so that the oxygen reading is 100 % (V/V) oxygen,

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, since anomalies such as non-linearities and zero offsets would not be detected.

The four points specified in the test method (66.2.2) have been chosen to allow a reasonably simple procedure for checking accuracy. For instance, an oxygen analyzer with a span of 0 to 100 % (V/V) oxygen might be tested at 0 and 100 % (V/V) oxygen. One of the two other points could be room air. The fourth point could then be a pre-mixed calibration standard of ±0.5 % (V/V) oxygen accuracy and containing between 40 and 80 % (V/V) oxygen. High purity mixtures of 0 and 100 % (V/V) oxygen are easily and inexpensively obtainable, as is dry room air. 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 A1.3—For further information, see Annex A2.

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 and

(b) An indicator for oxygen levels above the specified range of the display.

A1.17 (A1.66.4, X1.66.5) Stability of Measurement Accuracy

It is reasonable that users should expect that an analyzer 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. It is felt reasonable to require that the analyzer's calibration be confirmed at the change of each eight-hour working shift when in continuous use.

A1.17.2 This requirement implies that the stability will be within the specified limits at any constant temperature within the operating temperature range.

A1.18 (X1.66.6, X1.66.7) Response Time

Operators (especially those unfamiliar with the characteristics of a specific analyzer) 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 90 % response 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. With such information, calibration errors are less likely to occur. In the test method, the measured response time is allowed to be as much as 1.15 times slower than the value stated by the manufacturer. This allows the stated response time to be at or closer to the nominal value rather than at the worst case value, allowing for variations between individual sensors. The response time is measured with both increasing and decreasing oxygen levels, since response time can be a function of the direction of the change in oxygen level.[6]

[6] DOD Handbook 743 A: *Anthropometry of U.S. Military Personnel (Metric)*, February 13, 1991.

A2. INFORMATIVE

A2.1 For documents containing further information see ISO 8158, DOD Handbook 7434[6], and MIL-STD-810.