



Specification for Oxygen Analyzers¹

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 One¹ through Three³ of this specification are in keeping with the *Form and Style for ASTM Standards* manual. Section Four⁴ 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 Five⁵ 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 X1 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 problems, 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 Care²

F 1054 Standard Specification for Conical Settings of 15 mm and 22 mm Sizes²

2.3 *IEC Standard:*

IEC 601-1:1988, Medical Electrical Equipment—Part 1—General Requirements for Safety³

2.4 *ANSI Standard:*

ANSI Z79.10 Requirements for Oxygen Analyzers for Monitoring Patient Breathing Mixtures⁴

2.5 *ISO Standards:*

ISO 7767 Oxygen Analyzers for Monitoring Patient Breathing Mixtures—Safety Requirements⁴

¹ This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.03.04 on Harmonization of Alarms.

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

³ Available from International Electrochemical Commission, 3 rue de Varembe, 1211 Geneva 20, Switzerland.

⁴ Available from American National Standards Institute, 11 West 42nd Street, 13th Floor, NY, NY 10036.

ISO 8158 Evaluation of the Performance Characteristics of Gas Analyzers

2.6 Military Standard:

MIL-STD-810C Environmental Test Methods for Engineering Guidelines⁵

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 to 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

Section One—General	(A)	(NA)	(AM/R)
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

Section Six—Protection Against Hazards of Ignition of Flammable Anesthetic Mixtures

	(A)	(NA)	(AM/R)
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 61.1)

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) $70 \pm 1^{\circ}\text{C}$; 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) $-40 \pm 1^{\circ}\text{C}$; 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*:

10.2.1.1.1 *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 $40 \pm 1^{\circ}\text{C}$ 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 $40 \pm 2^{\circ}\text{C}$ during both tests.

Repeat the procedure at the test temperature of $15 \pm 1^{\circ}\text{C}$.

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 $300 \text{ m/s}^2 (30 \times \text{gravity})$ 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.

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 volumes

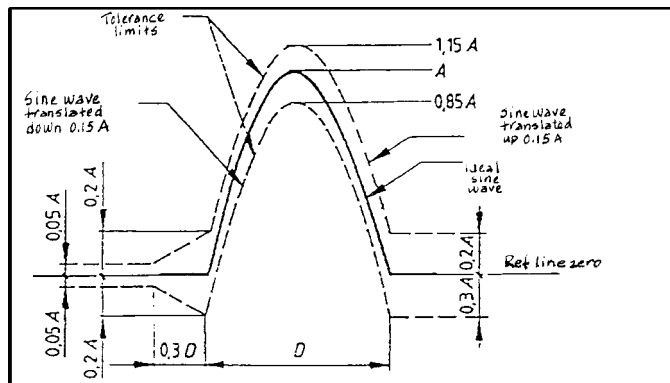


FIG. 1 Half-Sine Shock Pulse Configuration and Its Tolerance Limits