Designation: F 1464 – 93 (Reapproved 2005)

Standard Specification for Oxygen Concentrators for Domiciliary Use[1]

This standard is issued under the fixed designation F 1464; 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

Oxygen concentrators provide a safe source of oxygen-enriched air for patients in need. They are devices that raise the level of inspired oxygen by separating nitrogen or oxygen from ambient air.

Oxygen concentrators fall into two main classes according to the means whereby gas separation is effected, namely: oxygen concentrators in which oxygen selectively permeates or transports through a membrane or lattice, and pressure swing adsorbers (PSA) in which air is exposed at a certain pressure to molecular sieve material that selectively retains nitrogen and other components until they are subsequently released when the pressure is reduced.

The scope of this specification is not restricted to these two classes as alternative methods of concentrating oxygen may become available and it is not intended that this specification should restrict future developments.

This particular specification is one of a series of standards based on IEC 601-1 second edition and it amends and supplements IEC 601-1 second edition, hereinafter called the "general standard." As stated in 1.3 of the general standard, the requirements of this particular specification take precedence over those of the general standard.

As in the general standard the requirements are followed by compliance tests. The numbers of the sections and clauses in this specification refer to the related sections and clauses in the general standard. Clauses, sub-clauses or figures that are additional to those of the general standard are numbered starting after the last numbered clause in the general standard; additional annexes are lettered AA, BB, etc. and additional items (aa), (bb), etc. The changes from the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause, sub-clause or specified paragraph of the general standard is replaced by the text of this specification.

"Amendment" means that the clause, sub-clause or specified paragraph of the general standard is amended as indicated by the text of this specification.

"Addition" means that the text of this specification is additional to the requirements of the general standard.

Details of the arrangement of test apparatus for carrying out a number of the tests to check compliance with certain requirements are given in Annex A1.

A rationale for the most important requirements is given in Annex A2. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This annex does not form part of the specification.

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

The format of this specification is similar to that of IEC "particular standards"; but differs in the following respects: Sections 1, 2, and 3 will appear in the format as recommended in *Form and Style for ASTM Standards Manual*. Section 4 includes a chart listing all of the clauses of IEC 601-1 and indicates whether that clause applies (A), does not apply (NA), or applies with an amendment or replacement (AM/R). For the text of clauses that either apply or do not apply, consult IEC 601-1 Second Edition, 1988. Section 5 includes, in numerical order, the text of all amendments, additions or replacements to the general standard, and includes tests for compliance.

1. Scope

1.1 This clause of the general standard applies except as follows (replacement): This particular specification specifies safety requirements for oxygen concentrators as defined in 3.1. This specification does not apply to oxygen concentrators intended to supply gas to several patients via a piped medical gas installation or to those intended for use in the presence of flammable anaesthetic or cleaning agents, or both.

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

2. Referenced Documents

2.1 *ISO Standards:*

ISO 3744 Acoustics—Determination of Sound Power Levels of Noise Sources—Engineering Method for Free-Field Conditions Over a Reflecting Plane[2]

ISO 8359 Oxygen Concentrators for Medical Use—Safety Requirements[2]

ISO 9703 Anaesthesia and Respiratory Care Alarm Signals—Part 1: Visual Alarm Signals[2]

2.2 *IEC Standards:*

IEC Publication 601-1 Medical Electrical Equipment Part I, General Requirements for Safety (Second Edition)

IEC Publication 651 Sound Level Meters[3]

3. Terminology

3.1 *Definitions:* For the purposes of this specification, the definitions given in Clause 2 of IEC 601-1:1988 apply, with the following replacements and additions.

3.1.1 *applied part*—the oxygen concentrator outlet.

3.1.2 *administration accessories*—all accessories for conducting the product gas from the oxygen concentrator outlet to the patient for example, tubing, humidifier, breathing system, mask or nasal cannulae, but excluding any fixed tubing extensions.

3.1.3 *flow adjuster*—a device that controls the flow of the product gas.

3.1.4 *flow indicator*—a device that shows the volume of gas passing through the oxygen concentrator in a unit of time.

3.1.5 *operator control*—a control to enable the user, without the need for tools, to cause the oxygen concentrator to perform its intended function.

3.1.6 *outlet pressure*—the gage pressure at the oxygen concentrator outlet under the test flow conditions.

3.1.7 *oxygen analyzer*—a device that measures and quantitatively indicates the concentration of oxygen present in a gaseous mixture.

3.1.8 *oxygen concentration status indicator*— a device that by measuring the proportion of oxygen in the product gas, indicates when that proportion is at an abnormal level.

3.1.9 *oxygen concentrator*—a device that, by separating out nitrogen or oxygen from ambient air, provides oxygen enriched air.

3.1.10 *oxygen concentrator outlet*—the port of the oxygen concentrator from which the product gas flows.

3.1.11 *product gas*—the output from the oxygen concentrator consisting of respirable oxygen-enriched air.

4. Relationship of This Specification to IEC 601-1, Second Edition:

	(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 documents			X
7. Power input	X		
Section Two - Environmental Conditions			
8. Basic safety categories		X	
9. (Not used in IEC-601-1 Second Edition)			
10. Environmental conditions	X		
11. (Not used in IEC-601-1 Second Edition)			
12. (Not used in IEC-601-1 Second Edition)			
Section Three - Protection Against Electric Shock Hazards			
13. General	X		
14. Requirements related to classification	X		
15. Limitation of voltage and/or energy	X		
	(A)	(NA)	(AM/R)
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 in normal use	X		
25. Expelled parts	X		
26. (Not used in IEC-601-1 Second Edition)			
27. Pneumatic and hydraulic power (Under Consideration in IEC-601-1, 2nd Ed.)		X	
28. Suspended masses	X		
Section Five - Protection Against Hazards from Unwanted or Excessive Radiation			
29. X-radiation	X		
30. Alpha, beta, gamma, neutron radiation and other particle radiation (Under Consideration in IEC-601-1, 2nd Ed.)		X	
31. Microwave radiation (Under Consideration in IEC-601-1, 2nd Ed.)		X	
32. Light radiation (including lasers) (Under Consideration in IEC-601-1, 2nd Ed.)		X	
33. Infra-red radiation (Under Consideration in IEC-601-1, 2nd Ed.)		X	
34. Ultraviolet radiation (Under Consideration in IEC-601-1, 2nd Ed.)		X	

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.14 on Ventilators.

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

	(A)	(NA)	(AM/R)
35. Acoustical energy (Under Consideration in IEC-601-1, 2nd Ed.)		X	
36. Electromagnetic compatibility (Under Consideration in IEC-601-1, 2nd Ed.)			X
Section Six - Protection Against Hazards of Ignitions of Flammable Anaesthetic Mixtures			
37. Locations and basic requirements		X	
38. Marking, ACCOMPANYING DOCUMENTS		X	
39. Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT		X	
40. Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof		X	
41. Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof		X	
Section Seven - Protection Against Excessive Temperatures and Other Safety Hazards			
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. (Not used in IEC-601-1 Second Edition)			
47. (Not used in IEC-601-1 Second Edition)			
48. (Not used in IEC-601-1 Second Edition)			
49. Interruption of the power supply	X		
Section Eight - Accuracy of Operating Data and Protection Against Hazardous Output			
50. Accuracy of operating data			X
51. Protection against hazardous output			X

	(A)	(NA)	(AM/R)
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. (Not used in IEC-601-1 Second Edition)			
56. Components and general assembly			X
57. MAINS PARTS, components and layout	X		
58. Protective earthing - TERMINALS AND CONNECTORS	X		
59. Construction and layout	X		
Additional Clauses			
60. Auditory indicators	X		
61. Malfunction indicator	X		
62. Noise	X		

5. CLAUSES CONTAINING AMENDMENTS, ADDITIONS, OR REPLACEMENTS TO TEXT IN IEC 601-1 SECOND EDITION

6. Identification, Markings and Documents

Additional Item—(aa) All markings pertaining to the operation of the oxygen concentrator shall be legible to an operator having visual acuity, corrected if necessary, of 1.0 when seated or standing 1 m from the oxygen concentrator, at an illuminance of 215 lx.

NOTE 1—All markings should have a luminance contrast of at least 50 %, when compared with the surrounding background material.

6.1 *Marking on the Outside of Equipment or Equipment Parts:*

5.2.1 *(Item e) Indication of Origin*—The oxygen concentrator shall be marked with its country of origin.

6.1 *Additional Item*—(aa) The marking on the outside shall additionally include the following:

1 A warning against removal of the covers by unauthorized persons
2 A warning stating “No Smoking or Open Flames.”
3 The nominal concentration of oxygen in the product gas expressed in % oxygen v/v at a flow of 2 L/min, and at recommended maximum flow.
4 The statement “Use No Oil or Grease.”
5 The flow indicator shall be marked so as to indicate output for example; output, gas flow, or the like.
6 If the operator adjustable controls are capable of setting the flow in excess of the maximum recommended rate or; if the flow indicator is marked above the maximum flow, or both, then markings in excess of the recommended maximum flow shall be uniquely marked on the flow indicator in red and a warning shall be marked on the device.

6.7 *Indicator Lights and Push Buttons:*

(a) *Colors of Indicator Lights*—Table 1, Recommended colors of indicator lights and their meaning for equipment (refer also to ISO 9703 for guidance) (replacement).

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

5.3.3 Compliance shall be checked by functional test and inspection.

6.8 *Accompanying Documents:*

6.8.2 *Instructions for Use*—(Item a) General information

The instructions for use shall additionally include the following information:

The intended use of the oxygen concentrator.

At least one type of humidifier which is suitable for use with the oxygen concentrator.

The statement “Use of certain humidifiers not specified for use with this oxygen concentrator may impair the performance.”

The preferred location of any humidifier in the administration accessories.

A statement that in certain circumstances oxygen therapy can be hazardous and that seeking medical advice before using this machine is advisable.

A statement of the time taken from switching on the concentrator to reach a stated performance.

A statement that the air intake of the oxygen concentrator should be located in a well-ventilated space so as to avoid airborne pollutants or fumes.

Intervals at which cleaning procedures need to be performed and the items required for such cleaning.

A statement that no lubricants are to be used other than those recommended by the manufacturer.

TABLE 1 Recommended Colors of Indicator Lights and Their Meaning for Equipment

Color	Meaning
Red, non-flashing	Denotes oxygen concentrator has failed.
Red, flashing	Immediate response required to deal with a condition. High priority.
Yellow, non-flashing	Awareness of condition. Low priority.
Yellow, flashing	Prompt response to deal with a condition. Medium priority.
Green	Ready for action.
Any other color	None allowed.

A statement that advises operator to call for service when the oxygen concentration status indicator indicates an abnormal oxygen concentration level.

d Cleaning, disinfection and sterilization of parts in contact with the patient.

The instructions for use shall additionally include the following information:

1 A specification for at least one complete set of administration accessories that are suitable for use with the oxygen concentrator and, except for administration accessories intended for single-use, recommendations for their cleaning, sterilization, and disinfection.

2 The statement" Use of some administration accessories not specified for use with this oxygen concentrator may impair the performance."

6.8.3 *Technical Description:*

a *General*—The technical description shall additionally include the following information:

1 A table or graph showing values of oxygen concentration as a function of flow at specified operator settings at an outlet pressure of nominal zero.

2 The maximum recommended flow, expressed in L/min.

3 The flow values in liters per minute at a specified control setting for outlet pressures of nominal zero and 7 kPa.

4 The maximum outlet pressure when the oxygen concentrator is operated according to the method given to check compliance with Clause 50.8.

5 The maximum A-weighted sound pressure level in dB(A) when the oxygen concentrator is operated under the test conditions specified in Clause 62.

6 If a pressure relief mechanism is provided, the range of pressure in kPa at which the mechanism operates.

7 The nominal concentration of oxygen in the product gas expressed in percent oxygen v/v at a flow of 2 L/min.

8 A statement of the concentration of oxygen in the product gas expressed in % v/v at the maximum recommended flow.

9 d Restricted environmental condition for transport and storage.

1 The temperature range in which the concentrator is intended to be used must be specified (addition).

2 Any degradation of performance over the altitude range of from 0 to 4000 m above sea level must be specified (addition).

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36 *Electromagnetic Compatibility:*

36.1 *Protection from Electrostatic Discharge* (addition)—The oxygen concentrator shall continue to function and meet the requirements of this specification or shall fail without causing a safety hazard when tested in accordance with IEC-801-2. The discharge shall have a potential of 3 kv ± 5 % direct current for a contact discharge and 8 kilovolts ± 5 % direct current for an air discharge. A minimum of eight discharges shall be applied only to accessible parts and coupling planes (as defined in IEC 801-2). If an anomaly occurs, such as, display interrupt, alarm activation, etc., it should be possible to restore normal operation within 30 s after the electrostatic discharge has been applied. (Silencing of an activated alarm shall not be considered a failure.)

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES, AND OTHER SAFETY HAZARDS

42 *Excessive Temperature*—

42.1 Amendment: Amend the last entry of Table Xa as follows:

Equipment parts that may in normal use have unintentional contact with a patient shall not attain temperatures exceeding 50°C, if made from metal, or 60°C, if made from non-metal.

42.3 Replace 42.3 with the following:

42.3.1 The gas temperature at the oxygen concentrator outlet shall not exceed 6°C above ambient temperature when the oxygen concentrator is operated in accordance with the manufacturer's instructions (replacement).

7.3 Compliance shall be checked by the following test:

7.3.1 Use the test apparatus described in Annex A1. With the variable restrictor fully open, set the flow adjuster to give approximately the maximum flow recommended by the manufacturer in the technical description. Operate the oxygen concentrator for 0.5 h and readjust the flow so that exactly the maximum flow recommended by the manufacturer is indicated on the flowmeter of the test apparatus. Operate the oxygen concentrator for a further 9 h and take readings of the product gas temperature at intervals not exceeding 0.5 h, the first reading being taken after 1 h.

The temperature of the product gas shall not exceed the specified value.

43.3.1 The gas temperature at the oxygen concentrator outlet shall not exceed 41°C when operated in accordance with the manufacturer's instructions over the range of ambient temperature recommended by the manufacturer.

Compliance shall be checked by repeating the test given in 42.3.1 with the oxygen concentrator in an atmosphere maintained at the maximum temperature at which the manufacturer recommends it should be used.

43 *Fire Prevention*—Additional subsections:

43.1 In order to minimize the risk of fire in normal use or in single fault conditions at least one of the following requirements shall be satisfied.

a) Electrical components shall be separated from compartments in which accumulations of oxygen 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 of 43.3.

c) Electrical components which, in normal use or single fault conditions can be a source of ignition, shall comply with the requirements given in 43.4.

43.2 Any barrier separating electrical components from compartments where accumulations of oxygen can occur shall be sealed at all joints and holes for cables or for other purposes.

Compliance shall be checked by inspection and, if applicable, by the compliance test for sealed enclosures given in 40.5 of the General Standard (IEC 601-1 1988).

If, in normal use, a pressure difference of 0.4 kPa or greater exists between the spaces separated by the barrier, the compliance test described in 7.4.3 shall be used.

43.3 The ventilation required under the provision of 43.1(b) shall be such that the oxygen concentration in the compartment containing electrical components shall not exceed 25 % v/v.

Compliance shall be checked by the following test:

Measure the oxygen concentration under the following conditions and for such a period that the highest possible concentration of oxygen occurs and is maintained for 0.5 h.

a) Rupture or leakage of any component which carries oxygen-enriched air in close proximity to the test compartment.

b) Selection of the least favorable control settings for example, highest oxygen concentration or maximum flow.

c) Supply mains voltage variation of + 10 to – 15 %.

The oxygen concentration measured shall not exceed the specified value.

43.9 Electrical circuits that can produce sparks or generate increased surface temperatures and which can be a source of ignition shall be so designed that in normal use and single fault conditions no ignition occurs. The following requirements shall be satisfied:

a) The surface temperature of components shall not exceed 300°C, unless it can be shown that no ignition occurs when the component(s) is (are) exposed to 99.5 % oxygen at temperatures above 300°C.

7.5.2 Compliance shall be checked by measuring the surface temperatures of the components under normal and single fault conditions. If the surface temperature of the component(s) exceeds 300°C, inspect for ignition when the component(s) is (are) exposed to 99.5 % oxygen at the measured temperature.

SECTION EIGHT—ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 *Accuracy of Operating Data*—A flow indicator shall be provided on the oxygen concentrator and shall indicate total product gas flow. It shall be graduated in L/min and be accurate to ±10 % of the indicated flow or ±0.5 L/min, whichever is the greater (addition).

Compliance shall be checked by the following test:

Use the test apparatus described in Annex AA. With the variable restrictor completely open set the flow adjuster on the oxygen concentrator so that the flow indicator shows 20 % of the maximum flow stated by the manufacturer. Operate the oxygen concentrator for 15 min and measure the flow of the product gas using the flowmeter of the test apparatus. Repeat the procedure at the 100 % flow indicated and at a 50 % flow. If a fixed orifice device is used to regulate flow, each orifice shall be tested.

The flow shown on the flow indicator shall be within the tolerance specified.

50.4 The concentration of oxygen in the product gas, at a flow of 2 L/min, shall be within ±3 % v/v oxygen of the value stated by the manufacturer in the accompanying documents.

Compliance shall be checked by the following test:

Use the test apparatus described in Annex AA and set the mains voltage 10 % above the rated supply voltage. With the variable restrictor completely open, set the flow adjuster to give an output of approximately 2 L/min. Operate the oxygen concentrator for 0.5 h and then adjust the flow to exactly 2 L/min, as indicated on the flow meter of the test apparatus. Operate the oxygen concentrator for a further 1 h and take five consecutive readings of the concentration of oxygen in the product gas, as displayed on the oxygen analyzer, at intervals of 1 min. Repeat the test with the mains voltage set 15 % below the rated supply voltage.

The concentration of oxygen in the product gas shall be within the tolerance specified.

50.5 When the oxygen concentrator is operated at the maximum flow recommended by the manufacturer in the technical description, the mean concentration of oxygen in the product gas over an 8 h period shall be within ± 3 % v/v oxygen of the value stated by the manufacturer in the accompanying documents and no individual reading shall vary by more than ±3 % v/v oxygen of the mean.

Compliance shall be checked by the following test:

Use the test apparatus described in Annex AA and set the mains voltage 10 % above the rated supply voltage. With the variable restrictor completely open, set the flow adjuster to give approximately the maximum flow recommended by the manufacturer in the technical description. Operate the oxygen concentrator for 0.5 h and re-adjust the flow so that exactly the maximum flow recommended by the manufacturer is indicated on the flow meter of the test apparatus. Operate the oxygen concentrator for a further 9 h and take readings of the concentration of oxygen in the product gas, as indicated on the oxygen analyzer, averaged over 1 min, at intervals of 0.5 h, the first reading being taken after 1 h. Calculate the arithmetic mean of the readings obtained. Repeat the test with the mains voltage set 15 % below the rated supply voltage.

The mean concentration of oxygen in the product gas and the individual readings shall be within the tolerances specified.

50.6 When the oxygen concentrator is set to the maximum flow recommended by the manufacturer in the technical description and operated for 8 h, the mean of the flows recorded at intervals of 0.5 h over the period shall be within ± 10 % of the stated value or ±0.5 L/min, whichever is the greater, and no individual reading shall vary by more than ±10 % of the mean value.

Compliance shall be checked by the following test:

During the test for compliance with 50.5, note the flow from the oxygen concentrator, as indicated on the flowmeter of the test apparatus, at the same time as taking readings of the concentration of oxygen in the product gas. Calculate the arithmetic mean of the flow readings obtained.

The mean of the flows recorded and the individual flows shall be within the tolerances specified.

50.7 The change in the maximum recommended flow when a back pressure of 7 kPa is applied shall be within ±10 % of the figure stated by the manufacturer in the technical description.

Compliance shall be checked by the following test:

Use the test apparatus described in Annex A1. Set the flow from the oxygen concentrator so that its flow indicator shows the maximum flow recommended by the manufacturer in the technical description. Adjust the variable restrictor in the test apparatus to give a back pressure of 7 kPa. Operate the oxygen concentrator for 15 min and record the flow indicated on the

flowmeter of the test apparatus. Subtract this figure from the manufacturer's recommended flow to give the change in flow when a back pressure of 7 kPa is applied.

The change in flow shall be within the tolerance specified.

50.8 The maximum outlet pressure shall be within ±10 % of the value stated by the manufacturer in the technical description.

Compliance shall be checked by the following test:

Use the test apparatus described in Annex AA. Operate the oxygen concentrator at the maximum flow recommended by the manufacturer in the technical description and adjust the variable restrictor to stop the flow. Record the pressure indicated. The pressure indicated shall be within the tolerance specified.

51 *Protection Against Hazardous Output*—

51.1 Flow adjuster—Replace 51.1 with the following:

The oxygen concentrator shall be fitted with a flow adjuster. Compliance shall be checked by inspection.

The flow adjuster should be provided with a means to prevent adjustments by the user.

51.2 *Filter*: Replace 51.2 with the following:

A filter capable of retaining particles of 10 µm or greater shall be provided between the oxygen concentrating elements and the oxygen concentrator outlet.

Compliance shall be checked by inspection.

Oxygen Concentration Status Indicator—Replace 51.3 with the following:

An oxygen concentration status indicator shall be included to warn the operator of abnormality in the product gas.

Compliance shall be checked by operating the oxygen concentrator and inducing an oxygen concentration below the manufacturer's stated normal level.

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

56 Components and General Assembly—at 56.8 Indicators (addition):

An indicator(s) of continued mechanical and electrical function or of malfunction shall be provided on the oxygen concentrator.

Compliance shall be checked by operating the oxygen concentrator and inducing the following faults individually:

a) Compressor failure,

b) Pump failure,

c) Cycle failure,

d) Pressure failure,

e) Vacuum failure, and

f) Oxygen concentration failure.

A non-resetable elapsed time indicator showing the total operating time in hours shall be provided on the oxygen concentrator.

Compliance shall be checked by inspection.

56.9 *Pre-Set Controls*: (addition)

Pre-set controls shall either be inside the casing or shall require the use of a tool for adjustment.

Compliance shall be checked by inspection.

60 *Additional Clauses:*

Auditory Indicators—Any auditory indicator provided with the oxygen concentrator shall annunciate in a tone distinctly different from the sounds generated by the oxygen concentrator during normal operation in order to avoid masking. If an oxygen concentrator of the domiciliary type is to be used in a hospital, auditory indicators should meet ASTM guidelines or standards for such auditory indicators.

61 *Loss of Mains Power Indicator*—An auditory alarm shall be provided to indicate when mains power has been interrupted.

62 *Noise:*

62.1 In normal use the maximum A-weighted sound pressure level (steady or peak value) of the oxygen concentrator shall not exceed 60 dB(A).

Compliance shall be checked by the following test:

a) Place the microphone on a sound level meter complying with the requirements for Type 1 specified in IEC 651 at the position of maximum sound pressure level in the horizontal plane passing through the geometric center of the oxygen concentrator at a radius of 1 m. The measured sound pressure level shall not exceed the specified value.

b) For this test, operate the oxygen concentrator over its normal working range of flow including the maximum flow recommended by the manufacturer. Use the sound level meter with the "A" weighted network and the "fast" meter characteristics selected. Carry out the measurements in a free field over a reflecting plane as specified in ISO 3744.

c) The background level of extraneous noise shall be at least 10 dB(A) below that measured during the test.

ANNEXES

(Mandatory Information)

A1. (AA) TEST APPARATUS

A1.1 *Components:*

A1.1.1 (AA.1.1) *Flowmeter,* accurate to within ± 2 % of the flow to be measured.

A1.1.2 (AA.1.2) *Oxygen analyzer,* accurate to within ± 1 % of the oxygen concentration to be measured and which gives a reading equal to at least 90 % of the actual oxygen concentration within 10 s of the sensing element being exposed to the gas flow. If a pump is required to aspirate the gas sample, it shall neither reduce the pressure at the outlet of the flowmeter to below atmospheric pressure nor draw air back through the open end of the tube.

A1.1.3 (AA.1.3) *Pressure Indicator,* accurate to within ± 2 % of the pressure to be measured.

A1.1.4 (AA.1.4) *Thermometer,* accurate to within ± 0.5° of the temperature to be measured.

A1.2 (AA.21) *Component Assembly*—Assemble the components as shown in Fig. A1.1 (AA.1) using tubing of 6 ± 1 mm internal diameter to connect between the components.

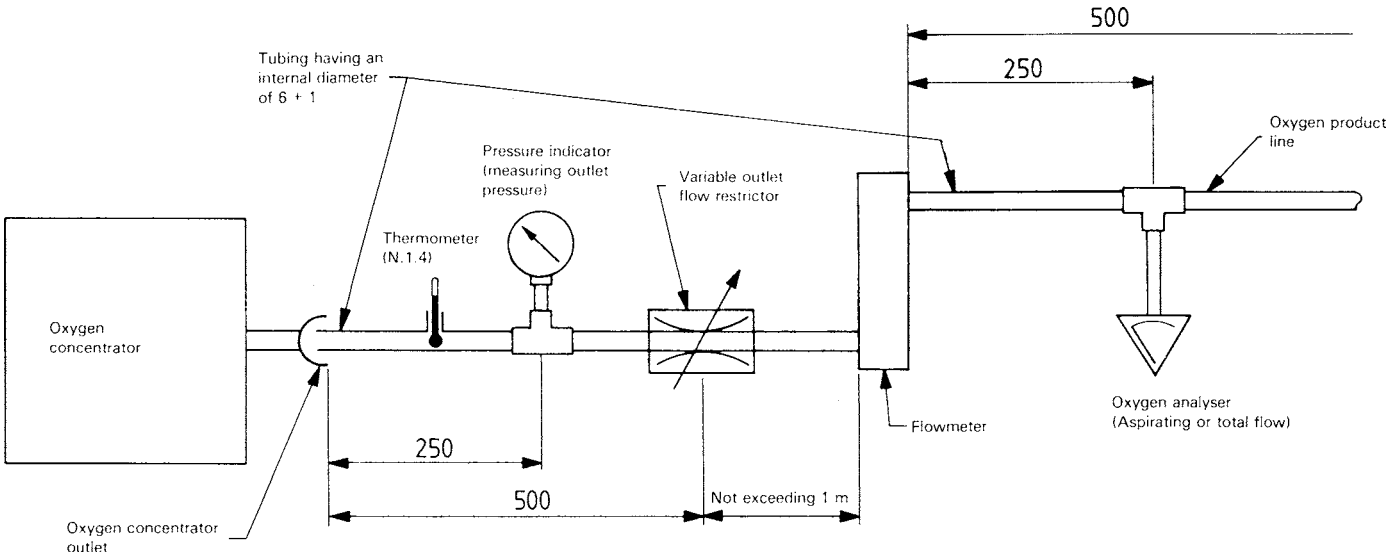

FIG. A1.1 Test Apparatus

A2. (BB) RATIONALE

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 the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by those developments.

A2.1 (BB) *Scope and Field of Application:*

A2.1.1 This international standard does not apply to institutional pressure swing adsorber devices (molecular sieve devices) which use the separation principle to deliver oxygen of a specified minimum concentration to a hospital or like distribution system at a minimum pressure of 400 kPa. The performance and safety requirements for this type of device vary considerably from the portable oxygen concentrators addressed in this specification.

A2.1.2 (6.1) *Marking on the Outside of Equipment or Equipment Parts*—(aa) To ensure the safety of the patients, it is important to visibly warn the operator whenever the manufacturers recommend maximum flow is exceeded. Flows in excess of those recommended can result in reduced oxygen concentration.

A2.1.3 (6.7a) *Colors of Indicator Lights*—(a), The use of the existing standardized color system for visible indicators decreases the likelihood of patient and operator error.

A2.1.4 (6.8.2) *Instructions for Use*—(Item a) General Information:

A2.1.4.1 (2) The need for humidification is a matter for clinical judgment and its assessment should take into consideration the method of delivery, the volume of entrained air and total flow.

A2.1.4.2 (3) It was recognized that the supplier cannot be required to test or approve all types of humidifiers that might be used with the oxygen concentrator. Such equipment which requires a high pressure might seriously degrade the performance of the oxygen concentrator.

A2.1.5 (d) *Parts in Contact with the Patient—*

(1) The supplier is required to recommend oxygen administration accessories that are suitable for use with the oxygen concentrator because administration accessories suitable for use with medical gas pipelines or cylinder regulators may not be satisfactory.

A2.1.6 (6.8.3) *Technical Description*:

A2.1.6.1 This performance data is important information concerning the functioning of oxygen concentrators. It is necessary that the operator should understand this data for safe and effective prescription.

A2.1.6.2 (42.1) Temperatures outside the specified range may constitute a thermal hazard.

A2.2 (43) *Fire Prevention:*

A2.2.1 It is important that particular care be taken to reduce the fire hazard of oxygen concentrators because they may contain high oxygen concentrations. Oxygen concentrators do not contain a large volume of stored oxygen and are therefore not capable of sustaining a fire. Potential hazards relating to fire prevention have been dealt with by separating electrical components into closures, by ventilating or by limiting the specification of electrical components, where appropriate.

A2.2.2 Oxygen concentrators are used in homes, extended care facilities, and nursing homes where the mains voltage variation may be higher than the +10 % specified in the general standard.

A2.3 (50) *Accuracy of Operating Data:*

A2.3.1 (50.3) A medical need was expressed for these accuracies. The design of a molecular sieve oxygen concentrator is such that oxygen concentration decreases with increasing flow whilst the total volume of oxygen delivered generally increases with flow. Oxygen administration by flow adjustment should be accurate and related to the device used for administration, the patient minute ventilation and the desired arterial blood oxygen concentration.

A2.3.2 (50.4) There is a medical need for accurate oxygen concentrations. Deviations within ±3 % v/v oxygen concentration were considered to be achievable by the manufacturer and were acceptable medically.

A2.3.3 (50.5) Measurement of stability of oxygen concentration over a long period is necessary to give a meaningful result.

A2.3.4 (50.6) A medical need was expressed for flow stability without attention on the part of the patient for this period of time. The maintenance of a stable flow with its resultant oxygen concentration is, therefore, important to the patient.

A2.4 (51.1) *Flow Adjuster*—A flow adjuster was considered necessary to match the output of the oxygen concentrator to variations in the needs of the patient. It was considered that in some clinical circumstances a deterrent to operator adjustment of flow was important. The presence of this deterrent might remind the patient to consult the physician before making any flow changes.

A2.5 (51.5) *Oxygen Concentration Status Indicator*—An oxygen concentration status indicator was considered necessary to indicate to the operator when the concentrator was not delivering adequate levels of oxygen concentration. It was determined the adequate levels should be those specified by the manufacturer, but typically not less than 85 %.

A2.6 (56.8) *Indicators:*

A2.6.1 *Function Indicator*—It was considered advisable that some mechanism be available to inform the operator whether or not the oxygen concentrator is performing adequately during continued operation.

A2.6.2 *Elapsed-Time Indicator*—An elapsed-time indicator is essential for maintenance procedures.

A2.7 (62) *Noise*—It is essential that the noise level be related to patient acceptability and comfort. It is desirable to reduce the noise level as far as possible for devices that might interfere with sleeping. It is recognized that oxygen concentrators (pressure swing adsorbers) may have both a steady sound level and a peak sound level. The peak sound pressure level was considered to be the more likely to be obtrusive to the patient during continuous machine performance.