



Designation: F 1464 – 93 (Reapproved 1999)

Standard Specification for Oxygen Concentrators for Domiciliary Use¹

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 Plane²

ISO 8359 Oxygen Concentrators for Medical Use—Safety Requirements²

ISO 9703 Anaesthesia and Respiratory Care Alarm Signals—Part 1: Visual Alarm Signals²

2.2 IEC Standards:

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

IEC Publication 651 Sound Level Meters³

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		

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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)
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	
	(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:

