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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.

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