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Medical electrical equipment —

Part 2-69:
Particular requirements for basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 80601-2-69 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment.*

This first edition of ISO 80601-2-69 cancels and replaces the first edition of ISO 8359:1996. This edition of ISO 80601-2-69 constitutes a major technical revision of ISO 8359:1996 and includes an alignment with the third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

– extending the scope to include not only the OXYGEN CONCENTRATOR but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR;
– identification of ESSENTIAL PERFORMANCE for an OXYGEN CONCENTRATOR and its ACCESSORIES;
– and the following additions:
  — tests for oxygen delivery performance;
  — new symbols;
  — new requirement for a means to prevent the propagation of fire into the OXYGEN CONCENTRATOR and its ACCESSORIES;
  — tests for cleaning and disinfection PROCEDURES; and
  — consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Oxygen supplementation can be part of management of PATIENTS with chronic, acute–on-chronic and acute respiratory disorders. The amount of supplemental oxygen depends on the individual PATIENT'S needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate.

The goal of long term oxygen therapy is to keep the oxygen saturation above 90 % in PATIENTS that require supplemental oxygen. The flowrate should be adjusted for rest, exertion, and sleep to meet the individual PATIENT'S needs under these various conditions. Ideally, the resting flowrate is adjusted to maintain SpO_2 > 90 % as indicated by pulse oximetry.

Supplemental oxygen is supplied by various sources: MEDICAL GAS PIPELINE SYSTEMS, OXYGEN CONCENTRATORS, compressed gas cylinders, and liquid oxygen reservoirs. This standard covers the particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of OXYGEN CONCENTRATORS. OXYGEN CONCENTRATORS produce oxygen enriched air from room air for delivery to a PATIENT requiring oxygen therapy. The most common OXYGEN CONCENTRATOR uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air, generating oxygen concentrations of typically 82 % to 96 %. The main component of this type of OXYGEN CONCENTRATOR is the molecular sieve, which adsorbs nitrogen from air to produce a product gas which is a mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption process.