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Medical electrical equipment —

Part 2-67:
Particular requirements for basic safety and essential performance of oxygen conserving equipment

Appareils électromédicaux —

Partie 2-67: Exigences particulières pour la sécurité de base et les performances essentielles des économiseurs 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

ISO/IEC 80601-2-67 was prepared jointly by 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*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-67 cancels and replaces the first edition of ISO 18779:2005. This edition of ISO 80601-2-67 constitutes a major technical revision of ISO 18779:2005 and includes an alignment with the third edition of IEC 60601-1, including its Amendment 1, and IEC 60601-1-11.

The most significant changes are the following modifications:

– extending the scope to include not only the CONSERVING EQUIPMENT but also its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CONSERVING EQUIPMENT;

– identification of ESSENTIAL PERFORMANCE for a CONSERVING EQUIPMENT and its ACCESSORIES;

and the following additions:

– tests for oxygen delivery performance;

– new symbols;

– tests for cleaning and disinfection procedures; and

– consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 201 includes subclauses 201.1, 201.2);
– "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 committees 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

Long term oxygen therapy has been demonstrated in randomized, controlled clinical trials to prolong survival in PATIENTS with chronic respiratory disease and documented hypoxemia. Typical sources of therapeutic long term oxygen therapy include gaseous oxygen from cylinders or from liquid oxygen and oxygen from an oxygen concentrator.

Most clinicians prescribe low flow oxygen therapy as continuous flow oxygen (CFO) delivery in l/min. CFO systems deliver the flow of oxygen without regard for the PATIENT'S breathing rate or pattern. Outside of the institutional care setting, the provision of CFO therapy is often a significant expense and can limit the mobility of a PATIENT to the immediate vicinity of a stationary or fixed oxygen delivery system. To support mobility, PATIENTS use CFO from portable liquid or compressed oxygen systems with a limited storage capacity that can limit a PATIENT'S time and activities while away from a stationary oxygen supply.

CONSERVING EQUIPMENT that delivers supplemental oxygen as a bolus conserves usage while allowing satisfactory PATIENT arterial oxygen saturation (SaO_2) to be maintained during daily activities. CONSERVING EQUIPMENT delivers supplemental oxygen unlike CFO in that the therapy gas flow is delivered only during the inspiratory phase of the breath cycle, when it is most likely to reach the alveoli. During both the expiratory and pause phase of the breath cycle, the flow of supplemental oxygen is stopped, minimizing waste. Because flow over time produces a volume, the bolus delivered by the CONSERVING EQUIPMENT is typically represented as a volume of gas. Therapy using CONSERVING EQUIPMENT versus CFO results in lower operating costs and longer ambulatory times for PATIENTS using the same CFO storage capacity.

Operation of CONSERVING EQUIPMENT from various MANUFACTURERS might differ in the dose delivery mechanism resulting in variations in oxygen therapy to the PATIENT. The use of CFO numerical markings for dose settings on CONSERVING EQUIPMENT might not directly correlate to CFO settings and might lead to misinterpretation of gas delivery rates and volumes for a particular PATIENT. This might result in incorrect PATIENT setup and therapy delivery over all breathing rates and patterns versus CFO. Because of the differences in delivery, settings, and markings versus CFO therapy, CONSERVING EQUIPMENT use requires PATIENT titration to determine the proper setting(s) needed to provide adequate SaO_2 levels for the PATIENT breathing patterns.

This standard is intended to reduce ambiguity between operation of various CONSERVING EQUIPMENT models and CFO by requiring standardized performance testing and labelling.