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Medical electrical equipment —

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Appareils électromédicaux —

Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire

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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 (see 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 (see 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.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

This first edition of ISO 80601-2-74 cancels and replaces the third edition of ISO 8185:2007[1], which has been technically revised. It also incorporates the third edition of IEC 60601-1, including amendment 1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, including amendment 1, the second edition of IEC 60601-1-8, including amendment 1, and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

— extending the scope to include the HUMIDIFIER and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the HUMIDIFIER, and thus not only the HUMIDIFIER itself;

— identification of ESSENTIAL PERFORMANCE for a HUMIDIFIER and its ACCESSORIES;

— modification of the humidification test PROCEDURE and the disclosure of humidification performance;

— more fully dimensioning the removable temperature sensor port and sensor;

— removal of requirements for so-called “bubble” HUMIDIFIERS as a separate document is being prepared for them[8];

and the following additions:

— requirements for mechanical strength (via IEC 60601-1-11);

— new symbols;

— requirements for a HUMIDIFIER as a component of an ME SYSTEM;

— requirements for ENCLOSURE integrity (water ingress via IEC 60601-1-11);

— requirements for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);

— requirements for BIOCOMPATIBILITY;

— requirements for USABILITY.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on PATIENTS in HOME HEALTHCARE ENVIRONMENT and in healthcare facilities. HUMIDIFIERS are used to raise the water content of gases delivered to PATIENTS. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of PATIENTS whose upper airways have been bypassed. Inadequate humidity at the PATIENT-CONNECTION PORT can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway[19][20]. Heat is employed to increase the water output of the HUMIDIFIER.

In addition, many HUMIDIFIERS utilize heated BREATHING TUBES in order to increase operating efficiency and reduce water loss (condensate) as well as heat loss in the BREATHING TUBE. Ventilator and anaesthesia BREATHING TUBES in common use might not withstand the heat generated by HUMIDIFIERS and BREATHING TUBE heating mechanisms.

Many HUMIDIFIER MANUFACTURERS use off-the-shelf electrical connectors for their electrically heated BREATHING TUBES. However, since different MANUFACTURERS have used the same electrical connector for different power outputs, electrically heated BREATHING TUBES can be physically, but not electrically, interchangeable. Use of improper electrically heated BREATHING TUBES has caused overheating, circuit melting, PATIENT and OPERATOR burns and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between HUMIDIFIERS and BREATHING TUBES produced by different MANUFACTURERS.

Since the safe use of a HUMIDIFIER depends on the interaction of the HUMIDIFIER with its many ACCESSORIES, this document sets total system performance requirements up to the PATIENT-CONNECTION PORT. These requirements are applicable to ACCESSORIES such as BREATHING TUBES (both heated and non-heated), temperature sensors and equipment intended to control the environment within these BREATHING TUBES.

Humidification can also be used by respiratory support ME EQUIPMENT to increase PATIENT comfort and compliance with the therapy. Examples are obstructive sleep apnoea and nasal high flow therapy equipment. The HUMIDIFICATION OUTPUT requirements of such ME EQUIPMENT is less demanding as the PATIENT'S upper airway is not bypassed.

HUMIDIFIERS are commonly used with air and air-oxygen mixtures and any HUMIDIFIER should be able to operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures, as the different physical and thermal properties of these gases may disturb the operation of the HUMIDIFIER.

In this document, 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 document or as noted: small capitals;

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

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

— "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 AA.

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 be adopted for implementation nationally not 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.