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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

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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 document 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 or www.iec.ch/members_experts/refdocs).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-74:2021), which has been technically revised.

The main changes compared to the previous edition are as follows:

— updated normative references;

— added requirements for the fill *connector*; and

— clarified *system recovery* requirements.

A list of all parts in the ISO 80601 and IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on *patients* in *home healthcare environment* and in professional healthcare environment. *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 in the inspired gas 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[27] [37]. 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*. Some *ventilator* and anaesthesia *breathing tubes* in common use cannot 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;

— t*est specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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;

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.

For the purposes of this document, the auxiliary verb:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" is used to describe a possibility or capability; and;

— "must" is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.