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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.

Medical electrical equipment —

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

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows.

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a HUMIDIFIER, also hereafter referred to as ME EQUIPMENT, in combination with its ACCESSORIES, the combination also hereafter referred to as ME SYSTEM.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a HUMIDIFIER where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER.

EXAMPLE 1 Heated BREATHING TUBES (heated-wire BREATHING TUBES) or ME EQUIPMENT intended to control these heated BREATHING TUBES (heated BREATHING TUBE controllers).

NOTE 1 Heated BREATHING TUBES and their controllers are ME EQUIPMENT and are subject to the requirements of IEC 60601-1.

NOTE 2 ISO 5367 specifies other safety and performance requirements for BREATHING TUBES.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy PATIENTS.

NOTE 3 A HUMIDIFIER can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the HUMIDIFIER.

EXAMPLE 2 Heated HUMIDIFIER incorporated into a critical care ventilator where ISO 80601-2-12[12] also applies.

EXAMPLE 3 Heated HUMIDIFIER incorporated into a homecare ventilator for dependent PATIENTS where ISO 80601-2-72[14] also applies.

EXAMPLE 4 Heated HUMIDIFIER incorporated into sleep apnoea therapy equipment where ISO 80601-2-70[13] also applies.

This document also includes requirements for an ACTIVE HME (HEAT AND MOISTURE EXCHANGER), ME EQUIPMENT which actively adds heat and moisture to increase the humidity level of the gas delivered from the HME to the PATIENT. This document is not applicable to a passive HME, which returns a portion of the expired moisture and heat of the PATIENT to the respiratory tract during inspiration without adding heat or moisture.

NOTE 4 ISO 9360-1[5] and ISO 9360-2[6] specify the safety and performance requirements for a passive HME.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for cold pass-over or cold bubble-through humidification devices, the requirements for which are given in ISO 20789:—.[8]

This document is not applicable to equipment commonly referred to as "room humidifiers" or humidifiers used in heating, ventilation and air conditioning systems, or HUMIDIFIERS incorporated into infant incubators.

This document is not applicable to nebulizers used for the delivery of drugs to PATIENTS.

NOTE 6 ISO 27427[10] specifies the safety and performance requirements for nebulizers.

This document is a particular standard in the IEC 60601-1 and the ISO/IEC 80601 series.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a HUMIDIFIER, as defined in 201.3.209, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the HUMIDIFIER and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of a HUMIDIFIER.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard[1] and Clause 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-11 apply as modified in Clauses 202, 206, 208 and 211, respectively. IEC 60601-1-3[15] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

[1] The general standard is IEC 60601-1:2005+AMD1:2012.

ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.6 in this document addresses the content of Clause 6 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 6060-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+AMD1:2012, Clause 2 applies, except as follows.

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 18562-1:—[2], *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-2-19:2009, *Medical electrical equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*

[2] To be published.

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*