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Australian Standard™

Humidifiers for medical use—General requirements for humidification systems

Standards Australia

This Australian Standard was prepared by Committee HE-019, Anaesthetic and breathing equipment. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

The following are represented on Committee HE-019:

Australasian Society of Anaesthesia Technicians
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Industry Group
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Australian and New Zealand Intensive Care Society
College of Biomedical Engineering Institution of Engineers Australia
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PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-019 on Anaesthetic and breathing equipment.

This Standard is identical with and has been reproduced from ISO 8185:1997, *Humidifiers for medical use — General requirements for humidification systems.*

The objective of this Standard is to specify requirements for the safety and performance of humidifiers suitable for inclusion in breathing systems.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the International Standards referenced herein:

Reference to International Standard or other publication		*Equivalent Australian/New Zealand Standard*	
IEC		AS/NZS	
60079-4	Electrical apparatus for explosive gas atmospheres. Part 4: Method of test for ignition temperature	60079.4	Electrical apparatus for explosive gas atmospheres - Part 4: Method of test for ignition temperature
60601-1	Medical electrical equipment: Part 1: General requirements for safety	3200.1.0	Medical electrical equipment — Part 1.0: General requirements for safety — Parent Standard
60601-1-2	Medical Electrical Equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and test methods	3200.1.2	Approval and test specification - Medical electrical equipment — Part 1.2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests
60601-2-19	Medical electrical equipment. Part 2: Particular requirements for the safety of baby incubators	3200.2.19	Approval and test specification - Medical electrical equipment - Part 2.19 Particular requirements for safety - Baby incubators (nursing)

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this International Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

INTRODUCTION

Humidifiers are used to raise the water content of gases delivered to patients. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract or dessicate secretions of patients whose supraglottic airways have been by-passed. Heat may be employed to increase the water output of the humidifier.

In addition, many humidifiers utilize heated delivery tubes in order to increase operating efficiency and reduce excessive water and heat loss. Ventilator and anaesthesia delivery tubes in common use may not withstand the heat generated by humidifiers and heated delivery tubes mechanisms.

Many humidifier manufacturers use off-the-shelf electrical connectors for their electrically heated delivery tubes. However, since different manufacturers have used the same electrical connector for different power outputs, electrically heated delivery tubes may be physically, but not electrically, interchangeable. Improper electrically heated delivery tubes use has caused overheating, circuit melting, patient and care-giver burns, and fires. Reduction of the relative humidity at the patient connection port may cause dessication of tracheo-bronchial secretions (see reference [20], annex T). It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between humidifiers and delivery tubes produced by different manufacturers.

Since the safe use of a humidifier is dependent on the interaction of the humidifier with its many accessories, this International Standard sets total-system performance requirements, including accessories such as delivery tubes (both heated and nonheated), temperature sensors, and devices intended to control the environment within these delivery tubes.

A rationale for the most important requirements is given in annex S. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revision.

NOTES

AUSTRALIAN STANDARD

Humidifiers for medical use—General requirements for humidification systems

Section 1: General

1.1 Scope

Clause 1 of IEC 60601-1:1988 applies with the following amendment:

ISO 8185 is one of a series of International Standards based on IEC 60601-1; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 60601-1:1988, the requirements of this International Standard take precedence over those of IEC 60601-1.

Humidifiers may be gas-powered, electrically powered, or both. However, this International Standard has been prepared as a Particular Standard based on IEC 60601-1, which gives general requirements for all aspects of safety, not only electrical safety, and many of the requirements are therefore applicable to humidifiers not powered by electricity. Where this International Standard specifies that a clause of IEC 60601-1 applies, it means that the clause applies only if the requirement is relevant to the humidifier system under consideration.

This International Standard includes requirements for the safety and performance of humidifiers, as defined in 1.3.107, suitable for inclusion in breathing systems.

This International Standard also includes some requirements for delivery tubes, including heated delivery tubes (heated-wire delivery tubes), and devices intended to control these heated delivery tubes, heated delivery tube controllers.

This International Standard is not applicable to heat and moisture exchangers (HMEs).

This International Standard is not applicable to devices commonly referred to as "room humidifiers" and humidifiers used in heating, ventilation and air conditioning systems, and humidifiers incorporated into infant incubators.

This International Standard is not applicable to nebulizers used for the delivery of drugs to patients

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*