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Standard Specification for Humidifiers for Medical Use—Part 1: General Requirements for Active Humidification Systems[1]

This standard is issued under the fixed designation F 1690; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

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 of patients. Heat may be 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 excessive water and heat loss. Ventilator and anesthesia breathing tubes in common use may not withstand the heat generated by humidifiers and heated breathing tube 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 may be physically, but not electrically, interchangeable. Improper electrically heated breathing tube use has caused overheating, circuit melting, patient and care-giver 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 manufactures.

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

A rationale for the most important requirements is given in Appendix X1. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this specification, but will expedite any subsequent revision.

This specification along with IEC (International Electrotechnical Committee) 601-1, henceforth known as the "General Standard," specify the minimum safety and performance requirements for humidification systems. This specification indicates which clauses of the General Standard apply and amends certain clauses with additions or modifications.

SECTION ONE—GENERAL

1. Scope

1.1 The requirements given in Clause 1 of the General Standard apply with the following additions and modifications:

1.1.1 Replace 1.1 with the following:

1.1.1.1 This specification includes requirements for the safety and performance of active vaporizing and nebulizing humidification systems, as defined in 3.63.1.6, suitable for inclusion in breathing systems (both intubated and non-intubated patients).

1.1.1.2 This specification also includes requirements for breathing tubes, including heated breathing tubes (heated-wire breathing circuits), and devices intended to control these heated breathing tubes, heated breathing tube controllers.

1.1.1.3 Heat and moisture exchangers (HMEs) are outside the scope of this specification. However, it is recognized that their safety and performance may affect that of humidification systems. Numerous studies have been published citing the benefits and risks of HMEs used in conjunction with humidification systems. It is advisable to review the instructions for

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