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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0671.1-2009

Sleep apnoea breathing therapy –

Part 1: Sleep apnoea breathing therapy devices

(ISO 17510-1:2002, MOD)

睡眠呼吸暂停治疗 第 1 部分：睡眠呼吸暂停治疗设备

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Foreword

YY 0671 *Sleep apnoea breathing therapy* consists of the following parts:

-- Part 1: Sleep apnoea breathing therapy devices;

-- Part 2: Masks and application accessories.

This Part is the first part of YY 0671.

The modification of this Part uses the International Standard ISO 17510-1:2002 Sleep apnoea breathing therapy -- Part 1: Sleep apnoea breathing therapy devices.

The main difference between this Part and ISO 17510-1:2002 is as follows:

This Part modified Clause 2 “Normative references” of ISO 17510-1:2002 to sub-clause 1.101, Clause 3 “Terms and definitions” to Clause 2, so as to be consistent with the common standard number.

This Part is a special standard based on GB 9706.1-2007 *Medical electrical equipment - Part 1: General requirements for safety* (a general standard). It shall be used together with GB 9706.1-2007.

Clause 36 Electromagnetic compatibility of this Part shall be implemented concurrently with YY 0505-2005 (IEC 60601-1-2:2001, IDT) *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standards: Electromagnetic compatibility - Requirements and tests*.

Clause 56 of this Part referred to EN 556 *Sterilization of medical devices. Requirements for medical devices to be designated "STERILE"*, PrEN 737-6:1998 *Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum*, EN 739 *Low-pressure hose assemblies for use with medical gases*, EN ISO 8185 *Humidifiers for medical use - General requirements for humidification systems*, EN ISO 9360-1 *Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 1: HMEs for use with minimum tidal volumes of 250 ml*. It shall be implemented concurrently with these standards after they are converted to national or industry standards. It shall be explained in the preparation instructions.

Annex AA and Annex BB of this Part are informative.

This Part was proposed by and shall be under the jurisdiction of National Technical Committee on Anesthesia and Breathing Apparatus of Standardization Administration of China.

Introduction

This Part of YY 0671 is a special standard based on GB 9706.1-2007 *Medical electrical equipment - Part 1: General requirements for safety*. GB 9706.1-2007 is referred to herein as a "general standard". A general standard is the basic standard for the safety of medical electrical equipment used or monitored by qualified personnel in general medical and patient environments. It also includes some requirements for reliable operation to ensure safety.

General standards are used in conjunction with parallel standards and specialized standards. The parallel standards include special technical and/or hazardous requirements and are applicable to all application equipment such as medical systems, EMC, ray protection for diagnostic X-ray equipment, software, etc. Specialized standards apply to special equipment types, such as medical electronic accelerators, high frequency electric knife, beds, etc.

NOTE See 1.5 and A.2 of GB 9706.1-2007 for descriptions of parallel standards and specialized standards, respectively.

The numbers of chapter, clause and sub-clause of this Part of YY 0671 are consistent with general standard.

The changes to general standard text and additions to parallel standard shall be specified by the use of the following words:

-- “replacement” means that the chapter or clause of the general standard is completely replaced by the text of this Part;

-- "addition" means that the relevant text in this Part is new to the general standard (e.g., sub-clause, column, note, table, figure);

-- “modification” means that the existing content of the general standard is partially modified.

In order to avoid confusion with the modified version of the general standard itself, the chapter, sub-clause, table and figure of this Part of YY 0671 are numbered from 101; supplementary column items are numbered by letters aa), bb); supplementary annexes shall be numbered as AA, BB, etc.

The terms of this Part marked by the asterisk (*) have descriptions for basic principles in Annex AA.

Sleep apnoea breathing therapy –

Part 1: Sleep apnoea breathing therapy devices

1 Scope*

The scope given in Clause 1 of GB 9706.1-2007 is applicable but it made the following additions:

this Part of YY 0671 specifies the specific requirements for sleep apnoea breathing therapy for the home and health care department;

this Part of YY 0671 is not applicable to a variety of equipment involved in GB 9706.28;

this Part of YY 0671 does not consider high-frequency jet ventilator, high-frequency oscillation ventilator;

Part 2 of YY 0671 sets out requirements for masks and application accessories;

this Part of YY 0671 is not applicable to vitro breathing apparatus described in GB/T 4999-2003.

1.101 Normative references

The provisions in following documents become the provisions of this Part of YY 0671 through reference in this Part. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Part, however, parties who reach an agreement based on this Part are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 3767-1996, *Acoustics - Determination of Sound Power Levels of Noise Sources Using Sound Pressure - Engineering Method in an Essentially Free Field over a Reflecting Plane* (eqv ISO 3744-94)

GB/T 3785-1983, *Electric，sonic properties and measuring methods for sound level meters*

GB/T 4999-2003, *Anaesthetic and respiratory equipment - Vocabulary* (ISO 4135:2001, IDT)

GB/T 5332-2007, *Method of test for ignition temperature of flammable liquids*

and gases (IEC 60079-4:1975, IDT)

GB 7144-1999, *Coloured cylinder mark for gases*

GB 9706.1-2007, *Medical electrical equipment - Part 1: General requirements for safety* (IEC 60601-1:1988, IDT)

GB 18278-2000, *Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization* (idt ISO 11134:1994)

GB 18279-2000, *Medical devices--Validation and routine control of ethylene oxide sterilization* (idt ISO 11135:1994)

GB 18280-2000, *Sterilization of health care products - Requirement for validation and routine control - Radiation sterilization* (idt ISO 11137:1995)

YY 1040.1-2003, *Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets* (ISO 5356-1:1996)

YY 1040.2-2008, *Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors* (ISO 5356-2:2006, IDT)

YY 0505-2005, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standards: Electromagnetic compatibility - Requirements and tests* (IEC 60601-1-2:2001, IDT)

YY 0466-2003, *Medical devices -- Symbols to be used with medical device labels labelling and information to be supplied* (ISO 15223:2000, IDT)

EN 556, *Sterilization of medical devices - Requirements for medical devices to be designated “STERILE”*

PrEN 737-6:1998, *Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum*

EN 739, *Low-pressure hose assemblies for use with medical gases*

EN ISO 8185, *Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems*

EN ISO 9360-1, *Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 1: HMEs for use with minimum tidal volumes of 250 ml*

2 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB

Annex B

(Informative)

Glossary

BB.1 Apnoea index

Number of apnoea per hour of sleep

BB.2 Low breathing

There are two explanations:

a) Reduction of the number of chest ups and downs and reduction of nose and mouth flow:

- at least 50%;

- duration time ≥ 10 s;

- stable ventilation cycle 10 s;

- the period may be in the sleep segment before and/or after the apnoea, or a "awakening" record before sound sleep; or

b) perceptible reduction of nose and mouth flow while no significant decrease in oxygen saturation.

NOTE As is often mentioned in the literature, BB.2 b) is controversial because it defines low ventilation with oxygen saturation and many hypopnea is not associated with reduced oxygen saturation.

BB.3 Obstructive sleep apnoea syndrome (OSAS)

Multiple episodes of upper respiratory tract occlusion occurred during sleep shall result in a disruption or a significant reduction in ventilation. Usually it is based on oxygen saturation, special clinical manifestations and polysomnography change to determine.

NOTE Apnoea index ≥5, (apnea + hypopnea) index ≥10.

BB.4 Sleep apnoea

Mouth and nose flow is greater than or equal to 10 s.

Bibliography

[1] GB 9706.28-2006, *Medical electrical equipment - Part 2: Particular requirements for the safety of lung ventilators - Critical care ventilators*

[2] YY 0600.1-2006, *Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 1: Home-care ventilatory support devices*

[3] YY 0600.2-2006, *Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients*

[4] YY 0600.3-2006, *Lung ventilators for medical use- Particular requirements for basic safety and essential performance - Part 3：emergency and transport ventilators*

[5] GB/T 17626.2-1998, *Electromagnetic compatibility--Testing and measurement techniques--Electrostatic discharge immunity test*

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