YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.274-2022

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

医用电气设备 第2-74部分：呼吸湿化设备的基本安全和基本性能专用要求

Issued on: January 13, 2022 **Implemented on: May 1, 2025**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document was issued on 13 January 2022 by the National Medical Products Administration and takes effect on 1 May 2025.

It is a YY standard without the /T suffix: compliance is mandatory in China.

All technical content of this Part is mandatory. The "Medical electrical equipment" series of standards consist of two parts. - Part 1: General and collateral requirements; - Part 2: Particular requirements. This Part is Part 2-74. This Part was drafted in accordance with the rules given in GB/T 1.1-2009. This Part replaces YY 0786-2010 "Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source". Compared with YY 0786-2010, the main technical changes, except for editorial modifications, are as follows. - EXTEND 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 requirements for the HUMIDIFIER itself (see 201.1.1 of this Part, Clause 1 of YY 0786-2010); - ADD the ESSENTIAL PERFORMANCE of respiratory humidifying equipment and its accessories (see 201.4.3); - MODIFY the humidification test procedure and the disclosure of humidification performance (see 201.12.1.101 and Annex CC of this Part, 101 and Annex EE of YY 0786-2010); - MODIFY the requirements for removable temperature sensor ports and sensor marking (see 201.101.8 and Annex EE of this Part, 56.102 and Annex DD of YY 0786-2010); - DELETE the requirements for "bubble" humidifiers (see Clause 1 of YY 0786-2010), which will be given in a separate standard[8]; - ADD cleaning and disinfection PROCEDURES (see 201.7.9.2.12 and 201.11.6.6); - ADD the test of protection provided by ENCLOSURE (see 201.11.6.6); - ADD the requirements for BIOCOMPATIBILITY (see 201.11.7); - ADD the requirements when a HUMIDIFIER is used as a component of the ME SYSTEM (see 201.1.1 and 201.16.1.101); - ADD the electromagnetic compatibility (see 202); - ADD special requirements for respiratory humidifying equipment in the collateral standard of usability (see 206); - ADD special requirements for respiratory humidifying equipment in the collateral standard of alarm systems (see 208); - ADD special requirements for respiratory humidifying equipment in the collateral standard of home healthcare environment (see 211); - ADD the test of mechanical strength (see 211.10.1.1); - ADD new symbols (see Annex D).c This Part modified and adopted ISO 80601-2-74.2017 "Medical Electrical Equipment Part 2-74: Special Requirements for Basic Safety and Basic Performance of Respiratory Humidification Equipment" using the redrafting method. The technical differences between this Part and ISO 80601-2-74.2017 and their reasons are as follows. - Regarding normative references, this Part has made adjustments with technical differences to adapt to the technical conditions of China. The adjustments are reflected in Clause 2 "Normative references". The specific adjustments are as follows. * REPLACE IEC 61672-1.2013 with GB/T 3785.1, which is identical to the international standard; * REPLACE IEC 60601-1.2005 + AMD1.2012 with GB 9706.1-2020, which modified and

adopted the international standard; * REPLACE IEC 60601-2-19.2009 with GB 9706.219-2021, which modified and adopted the international standard; * REPLACE ISO 14937.2009 with GB/T 19974, which modified and adopted the international standard; * REPLACE ISO 5356-1.2015 with YY/T 1040.1, which is identical to the international standard; * REPLACE IEC 60601-1-2.2014 with YY 9706.102-2021, which modified and adopted the international standard; * REPLACE ISO 9360-1.2000 with YY/T 0735.1, which is identical to the international standard (see 201.1.1, 201.2, 201.3, 201.7.9.2.9.101.2); * REPLACE ISO 9360-2.2001 with YY/T 0735.2, which is identical to the international standard (see 201.1.1, 201.2, 201.3, 201.7.9.2.9.101.2); 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 General standard, Clause 1 applies, except as follows. 201.1.1 * Scope Replacement. This Part 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 Part 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 GB 9706.1. NOTE 2: YY 0461 specifies other safety and performance requirements for BREATHING TUBES. This Part 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 GB 9706.212[12] also applies. EXAMPLE 3: Heated HUMIDIFIER incorporated into a homecare ventilator for dependent PATIENTS where ISO 80601-2-72[14] also applies. of NORMAL USE and is moved over a threshold as described in GB 9706.1- 2020, 9.4.2.4.3.

f) Return the HUMIDIFIER to normal orientation and subsequently refill the LIQUID CONTAINER to the maximum level then add a further quantity equal to 15 % of the capacity of the LIQUID CONTAINER, poured in steadily over a period of 1 min.

g) After these PROCEDURES, the HUMIDIFIER is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

h) In addition, confirm that there is no more liquid than is specified in 201.13.1.101 exits the HUMIDIFICATION CHAMBER outlet. 201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM Amendment (add additional requirement as new first paragraph). aa) GAS PATHWAYS through the HUMIDIFIER and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION that are not single use. 1) shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in GB 9706.1-2020, 11.6.7 and YY 9706.111-2021, Clause 8). 2) Dismantling may be used. Amendment (add additional requirement and replace the compliance test). bb) HUMIDIFIER ENCLOSURES shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the RISK of cross infection of the OPERATOR, other persons or next PATIENT. cc) Instructions for processing and reprocessing the HUMIDIFIER and its ACCESSORIES shall 100) comply with YY/T 0802 and GB/T 19974, and 101) be disclosed in the instructions for use. NOTE 1: GB/T 19891 provides guidance for the design of ENCLOSURES. .....

1 Scope

YY 9706.274 is the mandatory Chinese standard for respiratory humidifying equipment, the heated humidifiers that condition gas delivered to a ventilated or oxygen-therapy patient. Dry gas delivered past the upper airway dries secretions, blocks tubes and damages the mucosa; too much heat burns it. The standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the temperature delivered at the patient connection, the humidity output, the control and its failure behaviour, the alarms, and the protection against condensate reaching the patient or the electronics. High-flow humidified oxygen became routine in Chinese critical care during the pandemic years. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in May 2025.