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Medical Electrical Equipment – Part 2-90: Particular Requirements for Basic Safety and Essential Performance of Respiratory High Flow Therapy Equipment

(ISO 80601-2-90:2021, MOD)

医用电气设备 第 2-90 部分：高流量呼吸治疗设备的基本安全和基本性能专用要求

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Table of Contents

Foreword

This Document was drafted in accordance with the rules in GB/T 1.1-2020 *Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents*.

This Document is Part 2-90 of GB 9706 *Medical Electrical Equipment*. GB 9706 has published the following parts:

--- Part 1: General requirements for basic safety and essential performance;

--- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment;

--- Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators;

--- Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;

--- Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers;

--- Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs;

--- Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs;

--- Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment;

--- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis;

--- Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators;

--- Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy;

--- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment;

--- Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment;

--- Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures;

--- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography;

--- Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices;

--- Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy;

--- Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment;

--- Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment;

--- Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment;

--- Part 2-90: Particular requirements for basic safety and essential performance of respiratory high flow therapy equipment.

This Document modified and adopted ISO 80601-2-90:2021 Medical Electrical Equipment – Part 2-90: *Particular Requirements for Basic Safety and Essential Performance of Respiratory High-Flow Therapy Equipment*.

The technical differences and causes between this Document and ISO 80601-2-90:2021 are as follows:

--- Regarding normative reference documents, the following adjustments have been made to this document to adapt to my country's technical conditions:

- Replace IEC 60601-1:2005+AMD1:2012+AMD2:2020 with GB 9706.1-2020, which is a modified and adopted international standard (see Clause 201);
- Replace IEC 60601-2-12:2020 with GB 9706.212, which is modified to adopt international standards (see 201.1.1);
- Replace IEC60601-2-13:2011 with GB 9706.213, which is modified to adopt international standards (see 201.1.1);
- Replace ISO 4871:1996 with GB/T 14574-2000, which is equivalent to the international standard (see 201.9.6.2.1.101);
- Replace ISO 32:1997 with GB 50751 [see 201.7.2.18 dd)];

Medical Electrical Equipment – Part 2-90: Particular Requirements for Basic Safety and Essential Performance of Respiratory High Flow Therapy Equipment

201.1 Scope, Object and Related Standards

Clause 1 of the general standard applies, except as follows:

201.1.1 *Scope

Replacement:

This document applies to the basic safety and essential performance of respiratory high-flow therapy equipment, as defined in 201.3.220, hereafter also referred to as ME equipment or ME system, in combination with its accessories:

Respiratory high-flow therapy equipment:

— intended for use with patients who can breathe spontaneously; and

— intended for patients who would benefit from improved alveolar gas exchange; and who would benefit from receiving high-flow humidified respiratory gases, which can include a patient whose upper airway is bypassed.

EXAMPLE 1: Patients with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation.

EXAMPLE 2: Patients who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial carbon dioxide is high.

EXAMPLE 3: Patients requiring humidification to improve mucociliary clearance.

Respiratory high-flow therapy equipment can be intended for use in the home healthcare environment or intended for use in professional healthcare facilities.

NOTE 1: In the home healthcare environment, the supply mains is often not reliable.

Respiratory high-flow therapy equipment can be:

— fully integrated ME equipment; or

degradation of the health of the patient."

d) * If applicable, a warning statement to the effect that "WARNING: Do not connect the equipment to the battery of a battery-powered wheelchair unless the connection is listed in the instructions for use of the equipment or wheelchair as this can compromise the equipment performance which consequently can result in degradation of the health of the patient."

e) A warning statement to the effect that "WARNING: To reduce the likelihood of disconnection and to prevent adverse equipment performance use only accessories compatible with the equipment. Compatibility is determined by reviewing the instructions for use of either the equipment or the accessories".

f) A warning statement to the effect that "WARNING: The high-flow mode of this equipment is only suitable for a spontaneously breathing patient."

g) If applicable, a warning statement to the effect that "WARNING: The therapy supplied to the patient can be adversely affected by the gas added by the use of a pneumatic nebuliser."

h) * A warning statement to the effect that "WARNING: It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the equipment and indicated in the instructions for use as this can affect the performance of the equipment or pipeline system that can consequently result in serious deterioration of health."

i) A warning statement to the effect that "WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only use tubes with a retention force in conformance with YY 0461-2003 or ISO 80601-2-74:2021".

j) A warning statement to the effect that "WARNING: Do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma".

NOTE: Full face masks, ET tubes and helmets are examples of sealed patient interfaces.

k) A warning statement to the effect that "WARNING: There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near sparks or open flames."

l) A warning statement to the effect that "WARNING: Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns".

m) A warning statement to the effect that "WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns."

n) A warning statement to the effect that "WARNING: Use only spare parts recommended

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