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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.290-2022

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

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
(English Translation)

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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