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

GB 9706.255-2022

**Medical electrical equipment - Part 2-55: Particular
requirements for the basic safety and essential performance of
respiratory gas monitors**

医用电气设备 第2-55部分：呼吸气体监护仪的基本安全和基本性能专用要求
(English Translation)

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Introduction

foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1. Structure and Drafting Rules for Standardization Documents" drafting.

This document is part 2-55 of GB 9706 "Medical Electrical Equipment". GB 9706 has released the following parts.

- Part 1. General requirements for basic safety and essential performance;
- Part 1-3. General requirements for basic safety and essential performance Collateral standard. Radiation protection of diagnostic X-ray equipment;
- Part 2-1. Particular requirements for the basic safety and essential performance of electron accelerators with energies ranging from 1 MeV to 50 MeV;
- Part 2-2. Special requirements for basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;
- Part 2-3. Special requirements for basic safety and basic performance of short-wave therapy equipment;
- Part 2-4. Particular requirements for basic safety and basic performance of cardiac defibrillators;
- Part 2-5. Particular requirements for basic safety and basic performance of ultrasonic physiotherapy equipment;
- Part 2-6. Particular requirements for basic safety and basic performance of microwave therapy equipment;
- Part 2-8. Particular requirements for basic safety and essential performance of therapeutic X-ray equipment with energy from 10kV to 1MV;
- Part 2-11. Particular requirements for basic safety and essential performance of gamma beam therapy equipment;
- Part 2-12. Particular requirements for basic safety and basic performance of critical care ventilators;

- Part 2-13.Special requirements for basic safety and basic performance of anesthesia workstations;
- Part 2-16.Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment;
- Part 2-17.Particular requirements for basic safety and basic performance of automatically controlled brachytherapy afterloading equipment;
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- Part 2-24.Particular requirements for basic safety and essential performance of infusion pumps and infusion controllers;
- Part 2-25.Specific requirements for basic safety and basic performance of electrocardiographs;
- Part 2-26.Special requirements for basic safety and basic performance of EEG machines;
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- Part 2-28.Particular requirements for basic safety and essential performance of medical diagnostic X-ray tube assemblies;
- Part 2-29.Particular requirements for basic safety and basic performance of radiotherapy simulators;
- Part 2-36.Particular requirements for the basic safety and essential performance of in vitro induced lithotripsy equipment;
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- Part 2-39.Particular requirements for basic safety and basic performance of peritoneal dialysis equipment;
- Part 2-43.Particular requirements for basic safety and essential performance of X-ray equipment for interventional operation;
- Part 2-44.Particular requirements for basic safety and essential performance of X-ray computed tomography equipment;

--- Part 2-45. Basic safety and basic performance of mammography equipment and mammography stereotaxic devices

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--- Part 2-54. Particular requirements for basic safety and essential performance of X-ray photography and fluoroscopy equipment;

--- Part 2-55. Particular requirements for basic safety and basic performance of respiratory gas monitors;

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

--- Part 2-63. Particular requirements for basic safety and basic performance of dental X-ray machines for extraoral imaging;

--- Part 2-65. Particular requirements for basic safety and basic performance of dental X-ray machines for intraoral imaging;

--- Part 2-71. Particular requirements for basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment;

--- Part 2-75. Particular requirements for basic safety and essential performance of photodynamic therapy and photodynamic diagnostic equipment;

--- Part 2-83. Particular requirements for the basic safety and essential performance of household phototherapy equipment;

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

This document is modified to adopt ISO 80601-2-55:2018 "Medical Electrical Equipment Part 2-55. Basic Safety of Respiratory Gas Monitors

and Basic Performance Specific Requirements".

The technical differences between this document and ISO 80601-2-55:2018 and their reasons are as follows.

--- Replaced IEC 60601-1:2005 Amd1:2012 (see.201) with the normative reference GB 9706.1-2020, two documents

The degree of consistency between the documents is modified to suit the national conditions of our country;

--- Replaced ISO 80601-2-13:2011 Amd1:2015 Amd2 with the normative reference GB 9706.213-2021 (see

201.3), the degree of consistency between the two documents is modified to suit my

country's national conditions;

--- Replaced IEC 60601-1-2:2014 (see.201.3, 202) with the normatively referenced YY9706.102, one between the two documents

The degree of consistency is modified to suit the national conditions of our country;

--- Replaced IEC 60601-1-6:2010 Amd1:2013 with normatively referenced YY/T 9706.106 (see.201.3,

206), the degree of consistency between the two documents is modified to suit my country's national conditions;

--- Replaced IEC 60601-1-8:2006 Amd1:2012 with normative reference YY9706.108-2021 (see.201.3,

208), the degree of consistency between the two documents is modified to suit my country's national conditions.

--- Replaced IEC 60601-1-11:2015 with normative reference YY9706.111-2021 (see.201.3,.201.15.3.5.

101.1, 211), the degree of consistency between the two documents is modified to suit my country's national conditions;

--- Replaced IEC 60601-1-12:2014 with normative reference YY9706.112-2021 (see.201.3,.201.15.3.5.

101.1, 212), the degree of consistency between the two documents is modified to suit my country's national conditions;

--- Replaced ISO 7010:2011 (see.201.7.2.3) with the normative reference GB/T 31523.1-2015, between the two documents

The degree of consistency is modified to suit my country's national conditions;

--- Replaced IEC 60529:2013 (see.201.11.6.5) with the normatively quoted GB/T 4208 to adapt to my country's national conditions;

--- Replaced ISO 14937:2009 (see.201.11.6.6) with the normatively quoted GB/T 19974 to adapt to my country's national conditions;

--- Replaced ISO 15223-1:2017 (see.201.7.2.13.101) with normatively referenced YY/T 0466.1-2016 to accommodate

The national conditions of our country;

--- Replaced ISO 17664:2004 (see.201.11.6.6) with the normative referenced YY/T 0802 to adapt to my country's national conditions.

The following editorial changes have been made to this document.