ICS 11.040.55
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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.271-2022

Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy(NIRS) equipment

Issued on: December 29, 2022 **Implemented on: January 1, 2026**

Issued by: State Administration for Market Regulation, China National Standardization Administration

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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 2-71 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;

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

--- Part 2-19.Particular requirements for basic safety and basic performance of infant incubators;

--- Part 2-22.Special requirements for basic safety and essential performance of laser equipment for surgery, plastic surgery, therapy and diagnosis;

--- 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;

--- Part 2-27.Special requirements for basic safety and basic performance of ECG monitoring equipment;

--- 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;

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

--- 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.Particular requirements for basic safety and basic performance of mammography equipment and mammography stereotaxic devices;

--- Part 2-54.Special requirements for basic safety and basic 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 IEC 80601-2-71.2015 "Medical Electrical Equipment Part 2-71.Functional Near Infrared Spectroscopy (NIRS)

Particular Requirements for Basic Safety and Essential Performance of Equipment".

The technical differences between this document and IEC 80601-2-71.2015 and their reasons are as follows.

--- Replaced IEC 60825-1.2014 with the normative reference GB 7247.1-2012 (see.201.2,.201.3,.201.7.2.101,

--- Replaced IEC 60601-1-6 (see.201.2,.201.3) with the normative referenced YY/T 9706.106 to adapt to my country's national conditions;

--- Replaced IEC 60601-1 (see.201.2,.201.3) with the normatively quoted GB 9706.1 to adapt to my country's national conditions;

--- Replaced ISO 80601-2-61 (see.201.1.1,.201.2) with normatively quoted YY0784 to adapt to my country's national conditions;

--- Increased the normative reference document YY9706.257-2021 (see.201.2) to adapt to the national conditions of our country;

---Added the classification information specified in.201.6 of YY9706.257-2021 (see.201.7.2.101, Table.201.C.101) to apply

Functional near-infrared spectroscopy equipment for incoherent light sources;

--- It is clear that the filter for data processing in signal stability is a low-pass filter (see.201.12.1.101.6) to avoid ambiguity;

---Changed the calculation formula of the standard deviation deltaS in the signal-to-noise ratio (see.201.12.1.101.8), the international standard formula was edited incorrectly, and it was modified

make corrections;

--- Increased the test method of average optical power in the pulse output mode (see.201.12.1.101.2), so as to be applicable to all

In the case of pulse modulation;

--- Increase the shutter switching time requirements (see.201.12.1.107) to ensure the test accuracy of the response time.

The following editorial changes have been made to this document.

--- Deleted "References";

--- Deleted the "index of term definitions".

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

Safety standards for medical electrical equipment, also known as the 9706 series of standards, consist of general standards, collateral standards, specific standards, guidelines and interpretations.

---General standard. The safety standard that medical electrical equipment should be generally applicable, that is, the equipment that meets the definition of medical electrical equipment should meet this

Basic standard requirements.

--- Parallel standards. safety standards that should be generally applicable to medical electrical equipment, but in most cases are limited to certain specific functions or special

It is only the equipment that needs to meet the requirements of such standards.