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# NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# GB 9706.283-2022

## Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

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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 2-83 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.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 IEC 60601-2-83.2019 "Medical Electrical Equipment Part 2-83.Basic Safety of Household Light Therapy Equipment

and Basic Performance Specific Requirements".

Compared with IEC 60601-2-83.2019, this document has made the following structural adjustments.

---202.6.2.1.10 corresponds to 202.8 in IEC 60601-2-83.2019.

The technical differences between this document and IEC 60601-2-83.2019 and their reasons are as follows.

--- Replaced ISO 15223-1.2016 with the normatively referenced YY/T 0466.1-2016 (see.201.2,.201.7.2.13,

211.8.3.1, Appendix D), to adapt to my country's national conditions;

--- Replaced ISO 3864-1.2011 with the normative reference GB/T 2893.1-2013 (see.201.2, Appendix D), between the two documents

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

--- Replaced IEC 60601-1.2012 with the normative reference GB 9706.1-2020 (see.201.1.4,.201.2,.201.7.2.3,

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

--- Replaced IEC 60601-1-2.2014 with normative reference YY9706.102-2021 (see.201.1.3,.201.1.4,.201.2,

201.3, 202), in order to adapt to my country's national conditions;

--- Replaced IEC 60601-1-6.2013 with the normatively referenced YY/T 9706.106-2021 (see.201.1.3,.201.2,.201.3,

206), 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.201.1.3,.201.2,.201.3,

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

--- Replaced IEC 62471-1.2016 with the normative reference GB/T 20145-2006 (see.201.2,.201.6,.201.10.105,

"Clause.201.3.201 Acceptance Angle gamma/Clause.201.3.202 Opposite Angle alpha" of Appendix AA, "Clause.201.6.101 of Appendix AA

Optical Radiation Protection") to adapt to the national conditions of our country.

The following editorial changes have been made to this document.

--- Add "201.7.9.2.2.101 warning and

Note that the content of the statement may be replaced by other statements expressing the same meaning";

--- Changed "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