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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.236-2021

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

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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 of Standardization Documents"

Drafting.

This document is part 2-36 of GB 9706 "Medical Electrical Equipment". GB 9706 has released the following parts.

---Part 1.General requirements for basic safety and basic performance;

---Part 1-3.General requirements for basic safety and basic performance Parallel standard. Radiation protection of diagnostic X-ray equipment;

---Part 2-1.Special requirements for the basic safety and basic performance of electron accelerators with energy from 1MeV to 50MeV;

---Part 2-2.Special requirements for the 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 shortwave treatment equipment;

---Part 2-5.Special requirements for the basic safety and basic performance of ultrasonic physical therapy equipment;

---Part 2-6.Special requirements for the basic safety and basic performance of microwave therapy equipment;

---Part 2-8.Special requirements for the basic safety and basic performance of therapeutic X-ray equipment with an energy of 10kV to 1MV;

---Part 2-11.Special requirements for the basic safety and basic performance of gamma beam therapy equipment;

---Part 2-12.Special requirements for the basic safety and basic performance of intensive care ventilators;

---Part 2-13.Special requirements for the basic safety and basic performance of the anesthesia workstation;

---Part 2-16.Specific requirements for the basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;

---Part 2-17.Special requirements for the basic safety and basic performance of automatic control brachytherapy after-installation equipment;

---Part 2-18.Specific requirements for the basic safety and basic performance of endoscopic equipment;

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

---Part 2-24.Special requirements for basic safety and basic performance of infusion pumps and infusion controllers;

---Part 2-25.Special requirements for basic safety and basic performance of electrocardiograph;

---Part 2-26.Special requirements for the 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.Special requirements for the basic safety and basic performance of medical diagnostic X-ray tube components;

---Part 2-29.Specific requirements for the basic safety and basic performance of radiotherapy simulators;

---Part 2-36.Special requirements for the basic safety and basic performance of in vitro lithotripsy equipment;

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

---Part 2-39.Special requirements for the basic safety and basic performance of peritoneal dialysis equipment;

---Part 2-43.Special requirements for the basic safety and basic performance of interventional X-ray equipment;

---Part 2-44.Special requirements for the basic safety and basic performance of X-ray computed tomography equipment;

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

Require;

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

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

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

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

This document replaces GB 9706.22-2003 "Medical Electrical Equipment Part 2.Special Requirements for the Safety of In Vitro Induced Lithotripsy Equipment", and

Compared with GB 9706.22-2003, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

--- Added the term "energy flow density", "single pulse energy", "stone crushing equipment" (see.201.3.201,.201.32,.201.3.206);

---Added basic performance requirements (see.201.4.3.11);

---Added the minimum, typical and maximum output energy settings of the energy flow density, including the technical parameters of the time integration limit [see

201.7.9.3.101d)].

This document uses the redrafting method to modify and adopt IEC 60601-2-36.2014 "Medical Electrical Equipment Part 2-36.In Vitro Induced Fragmentation

Special requirements for basic safety and basic performance of stone equipment.

The technical differences between this document and IEC 60601-2-36.2014 and the reasons are as follows.

---Regarding normative reference documents, this document has made adjustments with technical differences to adapt to my country's technical conditions and adjustments.

The situation is collectively reflected in.201.2 "Normative Reference Documents", and the specific adjustments are as follows.

* Replace IEC 60601-1.2005 with GB 9706.1-2020, which is modified to adopt international standards;

* Replace IEC 60601-1-2.2007 with YY9706.102-2021 which is modified to adopt international standards;

* The IEC 60601-2-5.2009, which is not normatively cited in the text, is transferred to the reference.

The following editorial changes have been made to this document.

---The term index is deleted.

Introduction

Medical electrical equipment safety standards are also known as the 9706 series of standards, which consist of general standards, parallel standards, special standards, guidelines and interpretations.

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

Basic standard requirements.

---Parallel standards. Medical electrical equipment should be generally applicable to safety standards, but in most cases it is limited to certain specific functions or features.

Sexual equipment only needs to meet the requirements of such standards.