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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.263-2020

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

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Foreword

GB 9706 "Medical Electrical Equipment" is divided into 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.Specific requirements for 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 short-wave treatment equipment;

---Part 2-4.Special requirements for the basic safety and basic performance of cardiac defibrillators;

---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 basic safety and basic performance of anesthesia workstations;

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

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

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

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

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

---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.Specific 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.Specific 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.Special requirements for the basic safety and basic performance of mammography equipment and mammography stereotaxic devices;

---Part 2-54.Specific 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 intraoral imaging dental X-ray machines;

---Part 2-66.Special requirements for basic safety and basic performance of hearing equipment and hearing equipment system.

This part is part 2-63 of GB 9706.

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

This part uses the redrafting law to amend and adopt IEC 60601-2-63.2017 ``Medical

Electrical Equipment Part 2-63.Extraoral Imaging Dental

Special requirements for the basic safety and basic performance of X-ray machines.

The technical differences between this part and IEC 60601-2-63.2017 and the reasons are as follows.

---Regarding normative reference documents, this section 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 60601-1.2012 (see.201.2 and related provisions) with GB 9706.1-2020 which is modified to adopt international standards;

* Replace IEC 60601-1-2 with YY0505 which is equivalent to adopting international standards (see.201.1.3 and related provisions);

* Replace IEC 60336 (see.201.7.9.3) with YY/T 0063 equivalent to the international standard;

* Replace IEC 60601-1-3.2008/AMD1.2013 with GB 9706.12 equivalent to the international standard (see.201.2 and related provisions);

--- Deleted the content of "IEC 60601-1-3" and "AnnexB" in 203.6.3.1, and added the description of "priority number system", which is in harmony with the current domestic standards.

This section has made the following editorial changes.

---The foreword and introduction of international standards have been deleted;

--- The note in 203.4.101.1 has been deleted, which is in harmony with the current domestic standards;

--- Deleted the words "replacement" and "addition" in the normative references;

---All terms are represented in bold;

---The term index is deleted.

Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents.

This part is proposed and managed by the State Drug Administration.

Medical electrical equipment-Part 2-63.Extraoral imaging dentistry

X-ray machine basic safety and basic performance special requirements