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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.208-2021

Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

Issued on: August 10, 2021 **Implemented on: May 1, 2023**

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

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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.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 2-4.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 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 2-22.Special requirements for basic safety and basic performance of laser equipment for surgery, plastic surgery, treatment and diagnosis;

---Part 2-24.Specific requirements for the 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.Special 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 2-8 of GB 9706.

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

This part replaces GB 9706.10-1997 "Medical Electrical Equipment Part 2.Special Requirements for the Safety of Therapeutic X-ray Generating Devices",

Compared with GB 9706.10-1997, the main technical changes are as follows.

---Added field test information that should be included in the technical description (see.201.5.4);

---Added the requirements for the external marking of X-ray tubes (see.201.7.2.2);

---Added the requirements for the treatment console outside the treatment room [see.201.10.1.2.105.1];

---Added the signal requirements for the console [see.201.10.1.2.105.6];

---Added the requirements for the transition time interval [see.201.10.1.2.105.7];

---Added the requirements for X-ray tube replacement [see.201.10.1.2.105.8];

--- Increased the limit of absorbed dose (see.201.10.1.2.109.1), the choice of irradiation time or MU (see.201.10.1.2.109.2),

Display of preset irradiation time or MU (see.201.10.1.2.109.3), system design (see.201.10.1.2.109.4), irradiation time

Or MU display (see.201.10.1.2.109.5), irradiation control (see.201.10.1.2.109.6), moving beam radiotherapy

Irradiation control (see.201.10.1.2.109.7).

This part uses the redrafting law to amend and adopt IEC 60601-2-8.2015 "Medical Electrical Equipment Part 2-8.Energy is 10kV

Specific requirements for the basic safety and basic performance of 1MV therapeutic X-ray equipment".

The technical differences between this part and IEC 60601-2-8.2015 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 the chapter "Normative Reference Documents", and the specific adjustments are as follows.

* Replace IEC 60601-2-1.2009 with GB 9706.201-2020, which is modified to adopt international standards.