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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.243-2021

**Medical electrical equipment - Part 2-43: Particular
requirements for the basic safety and essential performance of
X-ray equipment for interventional procedures**

医用电气设备 第2-43部分：介入操作X射线设备的基本安全和基本性能专用要求
(English Translation)

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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 the basic safety and basic performance of electron accelerators with an energy of 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. Special 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

Claim;

---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 2-43 of GB 9706.

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

This Part replaces GB 9706.23-2005 "Medical Electrical Equipment Part 2-43.Special Requirements for the Safety of Interventional X-ray Equipment

Compared with GB 9706.23-2005, the main technical changes are as follows.

---Modified the scope and purpose of the standard application (see.201.1, see Chapter 1 of the.2005 edition);

---Added the definition of the terms "image display delay" and "emergency perspective" (see.201.3);

---Added basic performance requirements (see.201.4);

---Added requirements for quality control procedures, anti-liquid and emergency instructions (see.201.7);

---Added requirements for dust and other particle source protection and enclosure protection levels (see.201.11);

---Added the image display delay, the recording of the image direction, the usability of perspective in network activities, and the appropriate mask of the subtraction image

Location, image measurement function and emergency power supply requirements (see.201.12);

---Added the requirements for loading status indication, last frame image storage and limiting radiation output (see 203.6);

--- Deleted the terms "perspective guided intrusion operation", "intervention reference point", "dose area product", "reference air kerma" and "operation model"

The definition of "style" (see Chapter 2 of the.2005 edition);

--- Deleted the additional requirements of environmental conditions for temperature (see Chapter 10 of the.2005 edition);

---The half price requirement for X-ray equipment has been deleted, which has been covered by GB 9706.103-2020.Informative appendix deleted

Intervention reference point (see 29.201.2 in the.2005 edition).

This part uses the redrafting law to modify and adopt IEC 60601-2-43.2017 ``Medical Electrical Equipment Part 2-43.Interventional Operations X

Specific requirements for basic safety and basic performance of radiographic equipment.

The technical differences between this part and IEC 60601-2-43.2017 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.