ICS 11.40.60
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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.205-2020

Replacing GB 9706.7-2008

Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

Issued on: July 23, 2020 **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.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 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;

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

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---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

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---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 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 2-5 of GB 9706.

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

This part replaces GB 9706.7-2008 "Medical Electrical Equipment Part 2-5.Special Requirements for the Safety of Ultrasonic Physical Therapy Equipment", and

Compared with GB 9706.7-2008, the main technical changes are as follows.

---Added "Basic safety and basic performance special requirements" (see.201.1.1);

---Added "Special requirements for basic safety and basic performance" (see.201.1.2);

---Modified the "normative references" (see.201.2, 1.5 of the.2008 edition);

---Added the "increased basic performance requirements" (see.201.4.3.11);

--- Added "Patient Auxiliary Current Measurement" (see.201.8.7.4.8);

---Added "dielectric strength" (see.201.8.8.3);

--- Added "ultrasonic energy" (see.201.10.101);

---Added the "application part that does not provide heat to the patient" (see.201.11.1.2.2);

---Modified "measurement" (see.2011.11.1.3, 42.3 of the.2008 edition);

--- Added "Accuracy of Controllers and Instruments" (see.201.12.1);

--- Added "Programmable Medical Electrical System (PEMS)" (see.201.14);

--- Added "ME system" (see.201.16);

--- Added "Examples of surface temperature measurement arrangements for external transducer components" (see Appendix BB).

This part uses the redrafting law to amend and adopt IEC 60601-2-5.2009 "Medical Electrical Equipment Part 2-5.Ultrasonic Physical Therapy Equipment

Specific requirements for basic safety and basic performance.

The technical differences between this part and IEC 60601-2-5.2009 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.

* Removed IEC 60601-1-2.2007 (see.201.2).

This section also made the following editorial changes.

--- Deleted the "index of defined terms".

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