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

GB 9706.226-2021

**Medical electrical equipment - Part 2-26: Particular
requirements for the basic safety and essential performance of
electroencephalographs**

医用电气设备 第2-26部分：脑电图机的基本安全和基本性能专用要求
(English Translation)

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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 2-26 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. 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 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 document replaces GB 9706.26-2005 "Medical Electrical Equipment Part 2-26.Special Requirements for the Safety of EEG Machines". This document and

Compared with GB 9706.26-2005, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

--- Changed the scope of application and deleted the brain function monitor (see.201.1.1.,2005 edition 1.1);

--- Increased performance requirements (see.201.12.1), and stipulated the basic performance (see.201.4.3.).

This document uses the redrafting method to modify and adopt IEC 60601-2-26.2012 "Medical Electrical Equipment Part 2-26.EEG Machine

Special requirements for basic safety and basic performance.

The technical differences between this document and IEC 60601-2-26.2012 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;

- Added GB/T 4208-2017;

- Removed IEC 60601-2-27.2011 and adjusted to references.

The following editorial changes have been made to this document.

---The term index of the international standard has been deleted.