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

GB 9706.227-2021

**Medical electrical equipment-Part 2-27: Particular requirements
for the basic safety and essential performance of
electrocardiographic monitoring equipment**

医用电气设备 第2-27部分：心电监护设备的基本安全和基本性能专用要求
(English Translation)

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 2-27 of GB 9706 Medical Electrical Equipment. GB 9706 has published

the following parts.

- Part 1.General requirements for basic safety and essential performance;
- Part 1-3.General requirements for basic safety and essential performance-Collateral Standard. Radiation protection in diagnostic X-ray equipment;
- Part 2-1.Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV;
- Part 2-2.Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories;
- Part 2-3.Particular requirements for the basic safety and essential performance of short-wave therapy equipment;
- Part 2-4.Particular requirements for the basic safety and essential performance of cardiac

defibrillators;

--- Part 2-5.Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment;

--- Part 2-6.Particular requirements for the basic safety and essential performance of microwave therapy 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;

--- Part 2-11.Particular requirements for the basic safety and essential performance of gamma beam therapy equipment;

--- Part 2-12.Particular requirements for basic safety and essential performance of critical care ventilators;

--- Part 2-13.Particular requirements for the basic safety and essential performance of an anaesthetic workstation;

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

--- Part 2-17.Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy after-loading equipment;

--- Part 2-18.Particular requirements for the basic safety and essential performance of endoscopic equipment;

--- Part 2-19.Particular requirements for the basic safety and essential performance of infant incubators;

--- Part 2-22.Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;

--- Part 2-24.Particular requirements for the basic safety and essential performance of infusion pumps and controllers;

--- Part 2-25.Particular requirements for the basic safety and essential performance of electrocardiographs;

--- Part 2-26.Particular requirements for the basic safety and essential performance of

electroencephalographs;

--- Part 2-27.Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment;

--- Part 2-28.Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis;

--- Part 2-29.Particular requirements for the basic safety and essential performance of radiotherapy simulators;

--- Part 2-36.Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy;

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

--- Part 2-39.Particular requirements for basic safety and essential performance of peritoneal dialysis equipment;

--- Part 2-43.Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures;

--- Part 2-44.Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography;

--- Part 2-45.Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices;

--- Part 2-54.Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy;

--- Part 2-60.Particular requirements for the basic safety and essential performance of dental equipment;

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

--- Part 2-65.Particular requirements for the basic safety and essential performance of dental

intra-oral X-ray equipment;

--- Part 2-66.Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems.

This Document replaced GB 9706.25-2005 Medical Electrical Equipment - Part 2.Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment. Compared with GB 9706.25-2005, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications.

--- Integrate all the contents of YY 1079-2008;

--- Add energy reduction test (see 201.8.5.5.2);

--- Add performance requirements (see 201.12.1), and specify basic performance (see Table

201.101);

--- Add EMC requirements (see 202);

--- Add alarm requirements (see 208);

--- Change the experimental circuit diagram of the defibrillation protection effect (see Figure 201.102, Figure 201.103 of this Edition; Figure 104, Figure 105 of the 2005 Edition);

--- Delete the requirement for electrode polarization recovery time after defibrillation (see

51.102 of the 2005 Edition).

This Document used the redrafting method to modify and adopt IEC 60601-2-27.2011 Medical

Electrical Equipment - Part 2-27.Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment.

The technical differences and causes between this Document and IEC 60601-2-27.2011 are as follows.

--- Regarding normative references, this Document has been adjusted with technical differences to adapt to China's technical conditions. The adjustments are reflected in