ICS 11.040.55
CCS B05

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.249-2023

Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

医用电气设备 第2-49部分：多参数患者监护仪的基本安全和基本性能专用要求

Issued on: January 13, 2023 **Implemented on: January 15, 2026**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 13 January 2023 by the National Medical Products Administration and takes effect on 15 January 2026.

It is a YY standard without the /T suffix: compliance is mandatory in China.

It is classified under ICS 11.040.55, Chinese classification B05.

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting. The "Medical Electrical Equipment" series of standards are divided into two parts.

--- Part 1: General and parallel requirements;

--- Part 2: Special requirements. This document is part 2-49. This document replaces YY 0668-2008 "Medical Electrical Equipment Part 2-49: Special Requirements for the Safety of Multi-parameter Patient Monitors" and is in line with Compared with YY 0668-2008, except for editorial changes, the main technical changes are as follows.

--- Rearranged according to the structure of GB 9706.1-2020;

--- Added basic performance requirements (see.201.4.3.101);

--- Add requirements for protection against electrosurgery interference (see 202.6.2.1.102);

--- Added requirements for usability (see 206);

--- Added requirements for alarm system logs (see 208.6.12). This document uses the redrafted method to revise and adopt IEC 80601-2-49.2018 "Medical Electrical Equipment Part 2-49: Multi-parameter patients Particular requirements for basic safety and essential performance of monitors". The main technical differences between this document and IEC 80601-2-49.2018 and their reasons are as follows.

--- Regarding the normative reference documents, this document has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustments The situation is reflected in Chapter.201.2 "Normative References", and the specific adjustments are as follows. * IEC 60601-1.2012 is replaced by GB 9706.1-2020, which adopts international standards; * Replace IEC 60601-1-2.2007 with YY 9706.102-2021, which adopts the international standard; * Replace IEC 60601-1-6.2010 with YY/T 9706.106-2021, which adopts the international standard AMD1.2013; * Replace IEC 60601-1-8.2006 AMD1.2016 with YY 9706.108-2021, which adopts international standards; * Replace IEC 60601-2-2.2017 with GB 9706.202-2021, which adopts international standards; * Replace IEC 60601-2-27.2011 with GB 9706.227-2021, which adopts international standards; * Replace IEC 60601-2-34.2011 with YY 9706.234-2021, which adopts the international standard; * Deleted from normative references because IEC 60601-1-11.2015 is not referenced; * Because IEC 60601-1-12.2014 is not referenced, it is deleted from the normative references. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the Medical Electronic Instrument Sub-Technical Committee (SAC/TC10/SC5) of the National Standardization Technical Committee for Medical Electrical Appliances. The previous versions of the documents replaced by this document are as follows.

---First published as YY 0668-2008 in 2008;

---This is the first revision, and the file number is changed to YY 9706.249-2023.

Introduction

Safety standards for medical electrical equipment, also known as the 9706 series of standards, are proposed to be composed of general standards, collateral standards, specific standards, guidelines and interpretations constitute.

---General standard. The safety standard generally applicable to medical electrical equipment, that is, the equipment that meets the definition of medical electrical equipment meets this basis standard requirement.

--- Parallel standard. generally applicable safety standards for medical electrical equipment, but in most cases limited to certain specific functions or characteristics The equipment needs to meet the requirements of these standards.

---Specific standards. Safety standards applicable to a certain type of medical electrical equipment, and not all medical electrical equipment have specific standards.

---Guidelines and interpretations. explanations for the application guidelines and clauses of the relevant requirements in the standards involved. This document addresses the basic safety and essential performance of multiparameter patient monitors. This document modifies and supplements GB 9706.1-2020 (hereinafter referred to as the general standard). This revision brings this document up to date with the latest editions of relevant general standards and collateral standards. The requirements of this specific standard have priority over the general standard. An asterisk (*) used as the first character of a title or the beginning of a paragraph or table title in this document indicates that there is a relevant item in Appendix AA. Project-specific guidelines and rationale. The relevant content of Appendix AA is not only helpful to the correct use of this document, but also when used in clinical practice. After changes or technological developments, the process of revising standards can be accelerated in a timely manner. However, Appendix AA is not part of the requirements of this document. Medical Electrical Equipment Part 2-49. The basics of multiparameter patient monitors Specific requirements for safety and essential performance 201.1 Scope, purpose and relevant standards Except as described below, Chapter 1 of the general standard applies. 201.1.1 *Scope replace. This document specifies the basic safety and essential performance requirements for multi-parameter patient monitors (hereinafter referred to as ME EQUIPMENT or ME SYSTEM). This document applies to multi-parameter patient monitors intended to be connected to a single patient, with two or more physiological monitoring units, which are expected to For use in professional healthcare settings and in emergency medical services settings or home care settings. NOTE. In this document, a pregnant woman and her fetus are considered a single patient. This document does not apply to the implantable part of a multiparameter patient monitor. This document does not specify requirements for individual physiological monitoring units, such as electrocardiography (ECG), invasive pressure and pulse oximetry, which are specified in the relevant dedicated It is stipulated in the standard from the standpoint of stand-alone

medical electrical equipment. When multiparameter patient monitors are integrated into other medical electrical equipment or medical When using electrical systems, other relevant standards also apply. Example. A multi-parameter patient monitor incorporated into an intensive care ventilator is also applicable to GB 9706.212. 201.1.2 Purpose replace. The purpose of this document is to establish basic safety and basic performance requirements for multi-parameter patient monitors defined in.201.3.201. 201.1.3 Collateral Standards Supplement. This document refers to Chapter 2 of the General Standard as well as applicable collateral standards listed in Clause.201.2 of this document. YY 9706.102, YY/T 9706.106 and YY 9706.108 should be modified according to Chapter 202, Chapter 206 and Chapter 208 respectively use. GB 9706.103 and IEC 60601-1-9 are not applicable. All other published collateral standards in the 9706 series apply. 201.1.4 Particular standards replace. A particular standard may modify, replace or delete requirements contained in a general standard or a collateral standard as applicable to the multiparameter patient monitoring under consideration. Protective devices, other basic safety and basic performance requirements may also be added. The requirements of a particular standard take precedence over those of a general standard. In this document, GB 9706.1 is referred to as a general standard. Collateral standards are indicated by their standard number. The numbers of chapters and clauses in this document correspond to general standards by adding the prefix "201" (for example,.201.1 in this document corresponds to general standard No. 1 chapter), or by prefixing "20x" to the applicable collateral standard, where x is the end of the International Standard number corresponding to the collateral standard digits (for example, 202.4 in this document corresponds to the parallel standard YY 9706.102, which corresponds to Chapter 4 of the international standard IEC 60601-1-2

1 Scope

YY 9706.249 is the mandatory Chinese standard for multiparameter patient monitors, the bedside units that display ECG, blood pressure, oxygen saturation, respiration and temperature together. It sets the particular requirements for basic safety and essential performance of such equipment on top of the general medical electrical safety standard, and its distinctive concern is the combination itself: how the monitor prioritises and presents alarms from several sources at once, how a failure in one measurement is prevented from corrupting the others, and what the device does when it can no longer measure. Alarm fatigue and missed alarms are recognised hazards in intensive care. Being a YY standard without the /T suffix, compliance is compulsory in China. It takes effect in January 2026.