ICS 11.040.10
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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.261-2023

Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment

医用电气设备 第2-61部分：脉搏血氧设备的基本安全和基本性能专用要求

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

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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 11.040.10, Chinese classification J04.

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 requirements and parallel requirements;

--- Part 2: Special requirements. This document is Part 2-61. This document replaces YY 0784-2010 "Special Requirements for Basic Safety and Main Performance of Medical Electrical Equipment and Medical Pulse Oximeter Equipment" "Seeking", compared with YY 0784-2010, except for structural adjustment and editorial changes, the main technical changes are as follows.

--- Added basic performance requirements (see.201.4.102);

--- Increased availability requirements (see 206);

--- Added requirements for household equipment (see 211);

--- Increased requirements for first aid equipment (see 212). This document uses the redrafted method to revise and adopt ISO 80601-2-61.2017 "Medical Electrical Equipment Part 2-61: Pulse Oxygen Device Particular Requirements for Basic Safety and Essential Performance of Equipment". The technical differences between this document and ISO 80601-2-61.2017 and their 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 Centrally reflected in.201.2 "Normative Reference Documents", the specific adjustments are as follows. * Replace IEC 60601-1-2.2007 with YY 9706.102-2021, which adopts the international standard; * Replace IEC 60601-1-6.2010 AMD1.2013 with YY/T 9706.106-2021, which adopts international standards; * Replace IEC 60601-1-8.2006 AMD1.2012 with YY 9706.108-2021, which adopts international standards; * Replace IEC 60825-1.2014 with GB 7247.1, which is equivalent to the international standard; * Replaced ISO 7000 with GB/T 16273.1-2008, which is not equivalent to the international standard; * Replaced ISO 7010.2011 with GB/T 31523.1-2015, which adopts international standards; * Replace IEC 60601-1-11.2010 with YY 9706.111-2021, which adopts the international standard; * Replace IEC 60601-1-12.2014 with YY 9706.112-2021, which adopts the international standard; * Replaced IEC 60825-2.2004 amd1.2006 with GB/T 7247.2-2018,

which is equivalent to the international standard; * Replaced IEC 62366-1.2015 with YY/T 1474-2016 which was adopted equally; * IEC 60068-2-31.2008 was deleted due to non-standard reference; * IEC 60417 was deleted due to non-standard reference; * Deleted ISO 14937.2009; * Deleted ISO 14155.2011;

--- In.201.11.6.5.101, the description of the scope of application has been added regarding the protection level;

--- The requirements for confirmation of clinical accuracy in international documents are revised to be carried out in accordance with the relevant regulations of clinical evaluation in my country (see 201.12.1.101.2, EE.1). 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 sponsored by the National Medical Electrical Appliance Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) Focus on. The release status of previous versions of this document and the documents it replaces are as follows.

---First published as YY 0784 in 2010;

---This is the first revision, and the document number is YY 9706.261-2023.

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 standards. generally applicable safety standards for medical electrical equipment, that is, equipment that meets the definition of medical electrical equipment should meet this basic basic standard requirements.

--- 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 such 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. application guidelines and explanations for the relevant requirements of the standards involved. In many medical fields, pulse oximetry is widely used to estimate arterial oxygen saturation and pulse rate. This document covers the prior art The basic safety and basic performance requirements that can be achieved within the scope. This document modifies and supplements GB 9706.1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance (hereinafter referred to as the General Standard). Appendix AA contains a rationale for

some of the requirements, which includes the background and reasons for certain requirements, and the identification of related issues that need to be addressed. danger. An asterisk (*) used in this document as the first character of a heading or at the beginning of a paragraph or table heading indicates that there is a Specific guides and rationale for this project. Appendix BB is a literature survey regarding the determination of the maximum safe temperature between the pulse oximetry probe and patient tissue interface. Appendix CC discusses the formulas for evaluating the blood oxygen accuracy of pulse oximetry devices and the nomenclature of these formulas. Appendix DD presents guidance on when blood gas calibration of pulse oximetry equipment is required. Appendix EE presents guidelines for the calibration of pulse oximetry devices through controlled desaturation studies. Appendix FF is a tutorial describing the tester used with various pulse oximeters. Appendix GG describes the concept of pulse oximetry device response time. Appendix HH describes the data interface requirements. Appendix II is not adopted. Medical Electrical Equipment Part 2-61: Pulse Oxygen Particular requirements for basic safety and essential performance of equipment 201.1 Scope, Purpose and Related 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 of pulse oximetry equipment (hereinafter referred to as ME equipment). This document applies to pulse oximetry devices for human use and reprocessed pulse oximetry devices. ME EQUIPMENT including pulse oximetry monitoring meter, pulse oximeter probe, and probe cable extension. This document is intended for use in, but not limited to, the estimation of arterial Pulse oximetry device for oxygen saturation and pulse rate. This document also applies to pulse oximetry devices for the compensation or mitigation of illness, injury, or disability, and those For use of pulse oximetry equipment outdoors in extreme environments or in uncontrolled environments, such as ambulances and air transport, supplementary standards apply where pulse oximeters for use in these environments. This document does not apply to pulse oximetry equipment used in laboratory research, nor does it apply to oximeters that require the collection of blood samples from patients. This document does not apply to fetal pulse oximeters. This document does not apply to remote or slave (secondary) devices placed outside the patient's environment that display SpO2 values. Note 1 to entry. If a clause or clause clearly states that it applies only to me equipment or me systems, the title and text of the clause or clause will indicate that. If this is not the case, The relevant clause or subclause applies to both me equipment and me systems. Note 2 to entry. ME EQUIPMENT providing a selection of diagnostic and monitoring functions is expected to meet the requirements of the corresponding documentation when this function is configured. Intrinsic hazards arising from the intended physiological effects of me equipment or me systems within the scope of this document are not covered by the requirements specified in this document. In addition to.201.11 and general standards 7.2.13 and 8.4.1.

Note 3: See 4.2 of the general standard, "general standard" refers to GB 9706.1-2020.