CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.234-2021

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

医用电气设备 第2-34部分：有创血压监护设备的基本安全和基本性能专用要求

Issued on: September 6, 2021 **Implemented on: May 1, 2024**

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Foreword

This document was issued on 6 September 2021 by the National Medical Products Administration and takes effect on 1 May 2024.

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

It is classified under Chinese classification C39.

All technical content in this section is mandatory. The "Medical Electrical Equipment" series of standards is divided into two parts.

--- Part 1: General and side-by-side requirements;

--- Part 2: Specific requirements. This part is part 2-34. This section is drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0783-2010 "Medical Electrical Equipment Part 2-34: Safety and Basic Performance of Invasive Blood Pressure Monitoring Equipment" Special Requirements". The main technical differences between this part and YY 0783-2010 are as follows.

--- Increased the requirements for basic performance (see.201.4.3.101);

--- Added the requirement for alarm reset (see 208.6.9);

--- Modified some test methods and test circuits (see.201, 208). This part uses the redrafted method to modify and adopt IEC 60601-2-34.2011 "Medical Electrical Equipment Part 2-34: Invasive Blood Pressure Monitoring Particular requirements for basic safety and basic performance of protective equipment. The technical differences between this part and IEC 60601-2-34.2011 and their reasons are as follows.

--- Regarding normative reference documents, this part has made adjustments with technical differences to adapt to the technical conditions of our country and the circumstances of the adjustment. The situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows. * Replacing IEC 60601-1-2.2007 with YY 9706.102-2021 which has been modified to adopt the international standard; * Replacing IEC 60601-1-8.2006 with YY 9706.108-2021 which has been modified to adopt

the international standard; * Replace IEC 60601-2-2.2009 with GB 9706.4 which is equivalent to adopting international standards; * Deleted IEC 60601-2-27; * Deleted IEC 60601-2-49; * Replace IEC 60529 with GB/T 4208-2017 which is equivalent to adopting international standards. The following editorial changes have been made to this section.

--- Removed the index to IEC 60601-2-34.2011. Please note that some content of this document may be patented. The issuing authority of this document assumes no responsibility for identifying these patents. This part is proposed by the State Drug Administration. This part is approved by the National Medical Electrical Equipment Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) focal point. This section is drafted by: Shenzhen Mindray Biomedical Electronics Co., Ltd., Shanghai Medical Device Testing Institute. The main drafters of this section. Cen Jian, Tao Hua, Zhang Jun, Feng Guangzhou, Jia Zhiyu, Han Fei. The previous versions of the standards replaced by this part are as follows.

---YY 0783-2010.

Introduction

This section deals with the basic safety and basic performance of invasive blood pressure monitoring equipment. This part 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). The purpose of this third edition is to update this part with reference to the third edition of the Common Standard through format modifications and technical changes. The requirements of this section take precedence over the general standard. A "General Guidance and Rationale" for the more important requirements of this part is contained in Appendix AA. Chapters with an asterisk (*) in this section And the relevant principles are explained in Appendix AA. We believe that an understanding of these requirements not only facilitates the correct application of this standard, but also The process of revising the standard due to changes in clinical practice or technological development is accelerated from time to time, however, Annex AA is not a requirement of this standard. part. Medical Electrical Equipment Part 2-34: Invasive Blood Pressure Particular requirements for basic safety and basic performance of monitoring equipment 201.1 Scope, Purpose and Related Standards Clause 1 of the general standard 1) applies, except for the following. 1) The general standard is GB 9706.1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Basic Performance". 201.1.1 *Scope replace. This part specifies the basic safety and basic performance of invasive blood pressure monitoring equipment (hereinafter referred to as ME equipment). This section applies to invasive blood pressure monitoring equipment including related sensors for internal measurement or monitoring of circulatory system pressure. This section does not apply to puncture catheters, puncture needles, Luer

connectors, stopcocks, and stopcock tables for connecting pressure-transmitting diaphragms. This section does not apply to non-invasive blood pressure monitoring devices. 201.1.2 Purpose replace. The purpose of this section is to develop requirements for the essential safety and essential performance of invasive blood pressure monitoring devices as defined in.201.3.63. 201.1.3 Tied standards Replenish. This section refers to Chapter 2 of the General Standard and the applicable collateral standards listed in.201.2 of this section. YY 9706.102-2021 and YY 9706.108-2021 apply after amendments in Chapter 202 and Chapter 208 respectively. GB 9706.103- 2020 does not apply. 201.1.4 Particular standards replace. Particular standards may modify, replace or delete requirements contained in general or collateral standards to apply to the ME EQUIPMENT under consideration, and also Additional essential safety and essential performance requirements may be added. Requirements of specific standards take precedence over general standards. GB 9706.1 is referred to as the general standard in this part. Collateral standards are indicated by their standard numbers. The numbering of chapters and articles in this part corresponds to the general standard by prefixing "201" (for example,.201.1 in this part corresponds to the general standard Chapter 1), or by prefixing "20x" with the applicable collateral standard, where x is the corresponding International Standard number of the collateral standard (for example, 202.4 in this section corresponds to the international standard IEC 60601-1-2 corresponding to the collateral standard YY 9706.102-2021. The content of Chapter 4 in 2007, 203.4 in this part corresponds to the international standard IEC 60601-1-3 corresponding to the parallel standard GB 9706.103. Chapter 4, etc.). For changes to the general standard text, the following terms are specified. "Replacement" means that the chapters and clauses of the General Standard or applicable Concurrent Standard are completely replaced by the provisions of this Part. "Supplement" means that the provisions of this part supplement the requirements of the General Standard or the applicable Concurrent Standard. "Modification" means the modification of the general standard or the chapters and clauses of the applicable collateral standard in accordance with the description of the provisions of this part.

1 Scope

YY 9706.234 is the mandatory Chinese standard for invasive blood pressure monitoring equipment, the systems that measure pressure continuously through a catheter placed in an artery or a central vein. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the accuracy and frequency response of the pressure measurement, the zeroing and calibration, the alarms, and the electrical isolation that matters enormously here because a conductive path runs directly into a vessel and, in a central line, close to the heart. Invasive monitoring is standard in Chinese cardiac and intensive care. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in May 2024.