ICS 11.040.01
CCS B60

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.230-2023

Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

医用电气设备 第2-30部分：自动无创血压计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

Table of Contents

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 11.040.01, Chinese classification B60.

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. This document is Part 2-30 of Medical Electrical Equipment. The "Medical Electrical Equipment" series of standards have published the following parts.

--- Part 1: General requirements and parallel requirements;

--- Part 2: Special requirements. This document replaces YY 0667-2008 "Medical Electrical Equipment Part 2-30: Safety and Safety of Automatic Circulating Non-invasive Blood Pressure Monitoring Equipment Special Requirements for Basic Performance" and YY 0670-2008 "Non-invasive Automatic Measuring Sphygmomanometer". This document is based on YY 0667-2008, integrating The content of YY 0670-2008 has been updated. Compared with YY 0667-2008, except for structural adjustment and editorial changes, the main technical changes as follows.

--- Added basic performance requirements (see.201.4.3);

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

--- Added requirements for physiological closed-loop controllers (see 210);

--- Increased the requirements for equipment used in the home care environment (see 211);

--- Added requirements for equipment used in emergency medical service environments (see 212). This document uses the redrafted method to revise and adopt IEC 80601-2-30.2018 "Medical Electrical Equipment Part 2-30: Automatic Non-invasive Hemorrhage Particular requirements for basic safety and essential performance of pressure gauges". The main differences between this document and IEC 80601-2-30.2018 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. * IEC 60601-1.2012 is replaced by GB 9706.1-2020, which adopts international standards; * Replace IEC 60601-1-2.2014 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 60601-1-10.2007 with YY/T 9706.110-2021, which adopts international standards; * Replace IEC 60601-1-11.2015 with YY 9706.111-2021, which adopts international standards; * Replace IEC 60601-1-12.2014 with YY 9706.112-2021, which adopts the international standard; * Replace IEC 60601-2-2.2017 with GB 9706.202-2021, which adopts international standards; * Replaced ISO 80369-1 with YY/T 0916.1, which is equivalent to the international standard; * Added normative reference document YY 9706.108-2021; * The normative reference document GB/T 31523.1-2015 has been added.

---The normative reference document ISO 81060-2 uses ISO 81060-2.2018 AMD1.2020.

---.201.3.201 and.201.3.208 add "non-invasive" to the English counterparts, and "non-invasive" in Chinese, which is consistent with the standard name.

--- Regarding EMC related content, since the domestic YY 9706.102-2021 adopts IEC 60601-1-2.2007, this document Chapter 202 adjusted the number of chapters, and the content corresponds to YY 9706.102-2021.

--- Deleted Appendix BB and Appendix CC. 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 0667-2008 in 2008;

---First published as YY 0670-2008 in 2008;

--- This is the first revision.

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 that medical electrical equipment should be generally applicable, that is, the equipment that meets the definition of medical electrical equipment should meet this Basic standard requirements.

--- Parallel standards. safety standards that should be generally applicable to medical electrical equipment, but in most cases are limited to certain specific functions or special It is only the equipment that needs to meet the requirements of such standards.

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

---Guidelines and interpretations. application guidelines and explanations for the relevant requirements of the standards involved. This document specifies the practical minimum safety requirements for the operational safety of automatic non-invasive sphygmomanometers. The requirements are followed by a description of the relevant test. A "Special Guidance and Rationale" regarding the requirements of this document is contained in Appendix AA. We believe that understanding these requirements will not only help It is essential for the correct application of this document, and it can speed up the

process of revising the standards due to changes in clinical practice or technological developments in a timely manner. but, Appendix AA is not part of the requirements of this document. Medical electrical equipment part 2-30.automatic non-invasive Particular requirements for basic safety and essential performance of sphygmomanometers 201.1 Scope, Purpose and Related Standards Except for the following, Chapter 1 of GB 9706.1-2020 applies. 201.1.1 Scope replace. This document specifies the basic safety and essential performance requirements for automatic non-invasive blood pressure monitors and their accessories. Include measurement accuracy requirements. This document applies to automatic non-invasive blood pressure monitors (hereinafter referred to as ME equipment). It is through an inflatable cuff, without arterial puncture, non-continuous Blood pressure is measured sequentially.

Note 1: The device does not require arterial puncture to perform indirect determination of blood pressure and does not measure blood pressure directly. It simply measures blood pressure. Note 2 to entry. This document covers automated electronic ME equipment, which does not require arterial puncture, for the intermittent indirect measurement of blood pressure, including blood pressure for use in home care settings Monitor. This document does not apply to the use of electronic pressure transducers and/or displays in combination with a stethoscope or other manual methods for the determination of blood pressure (non-automated non-invasive sphygmomanometer) equipment. The requirements for it are specified in ISO 81060-1.

Note 3: If the provisions of the chapter or subclause apply only to me equipment or me system, the title and content of the chapter or subclause will state. If not stated, the chapter or article Applies to both me equipment and me systems. Hazards inherent in 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. Except.201.11,.201.105.3.3 and 7.2.13 and 8.4.1 of GB 9706.1-2020. 201.1.2 Purpose replace. The purpose of this document is to establish specific basic safety and essential performance requirements for automatic non-invasive blood pressure 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.201.2 of this document. YY 9706.102, YY/T 9706.106, YY/T 9706.110, YY 9706.111 and YY 9706.112 respectively in Chapter 202, Adopted with modification in Chapters 206, 210, 211, and 212: GB 9706.103-2020 is not applicable. In the 9706 series All other published collateral standards apply. 201.1.4 Particular standards replace. In the 9706 series, Particular Standards may modify, replace or delete General Standards and Collateral Standards, depending on the particular ME EQUIPMENT considered. Included requirements. And other basic safety and basic performance requirements may be supplemented. The requirements of a particular standard take precedence over the general standard. In this document, GB 9706.1-2020 is referred to as the general standard. Collateral standards are indicated by their respective standard numbers. The numbers of chapters and clauses in