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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.231-2023

Replacing YY 0945.2-2015

Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

医用电气设备 第2-31部分：带内部电源的体外心脏起搏器的基本安全和基本性能专用要求

Issued on: March 14, 2023 **Implemented on: May 1, 2026**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 14 March 2023 by the National Medical Products Administration and takes effect on 1 May 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 C39.

It replaces YY 0945.2-2015, which is superseded.

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 2-31: This document replaces YY 0945:2-2015 "Medical Electrical Equipment - Part 2: Safety Special Purposes for External Pacemakers with Internal Power Supply" Require": Compared with YY 0945:2-2015, except for structural adjustment and editorial changes, the main technical changes of this document are as follows:

--- Changed the defibrillation protection (see:201:8:5:5:1, 51:101 of the:2015 edition);

---Changed the measurement of patient auxiliary current (see:201:8:7:4:8, 19:4 of the:2015 edition);

--- Increased the protection of high-frequency surgery ME equipment (see:201:8:101);

--- Changed electrostatic discharge (see 202:6:2:2:1, 36:202:1 of the:2015 edition): This document is modified to adopt IEC 60601-2-31:2020 "Medical Electrical Equipment Part 2-31: External Cardiac Pacing with Internal Power Supply Basic Safety and Essential Performance Requirements for Devices": The technical differences between this document and IEC 60601-2-31:2020 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 60601-1:2005 AMD1:2012 with GB 9706:1-2020, which adopts the revised international standard; * Replace IEC 60601-1-2:2014 with YY 9706:102-2021, which adopts the international standard: 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 0945:2-2015 in:2015;

---This is the first revision, and the file number is changed to YY 9706:231-2023:

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 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: The minimum safety requirements specified in this document are considered to provide a degree of safe practicality in the operation of external cardiac pacemakers: This document modifies and supplements GB 9706:1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance beg": Specifications for relevant tests follow the requirements: 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 in Appendix AA is not only helpful for the correct use of this document, but also for practical use: After changes in practice or technological development, the process of standard revision can be accelerated in a timely manner: However, Appendix AA is not a requirement of this document: part:

1 Scope

YY 9706.231 is the mandatory Chinese standard for external cardiac pacemakers with an internal power source, the battery-powered units used temporarily after cardiac surgery or in the management of an unstable rhythm, connected to the heart through temporary leads. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the pacing output and its control, the sensing of the patient's own rhythm, protection against inappropriate pacing, the battery and the warnings that precede its exhaustion. The patient is pacemaker-dependent for as long as the device is connected, so a failure is immediate. Being a YY standard without the /T suffix, compliance is compulsory. It replaces YY 0945.2-2015 and takes effect in May 2026.