ICS 11.040.55
CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.256-2023

Replacing YY 0785-2010

Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement

医用电气设备 第2-56部分：用于体温测量的临床体温计的基本安全和基本性能专用要求

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

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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 11.040.55, Chinese classification C39.

It replaces YY 0785-2010, which is superseded.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: This document is Part 2-56 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 0785-2010 "Performance Requirements for Electronic Thermometers for Continuous Measurement of Clinical Thermometers", and is consistent with YY 0785-2010 In comparison, except for structural adjustments and editorial changes, the main technical changes are as follows:

--- Added basic performance requirements (see:201:4:3);

--- Changed the measurement range (see:201:12:1:101, 6:2 of the:2010 edition);

--- Increased the relevant requirements in the general test (see:201:101:1);

---Changed the range of the maximum allowable error (see:201:101:2, 6:3 of the:2010 edition);

--- Added confirmation of clinical accuracy (see:201:102);

---Deleted the relevant requirements of "self-inspection device" (see 6:10:5 of the:2010 edition);

---Deleted the relevant requirements of "maximum energy dissipation" (see 6:11:1 of the:2010 edition);

--- Deleted the relevant requirements of "long-term stability" (see 6:11:2 of the:2010 edition);

--- Deleted the relevant requirements of "body fluid protection" (see 6:11:3 of the:2010 edition);

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

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

--- Added requirements for equipment used in emergency medical service environments (see Chapter 212): This document uses the redrafted method to revise and adopt ISO 80601-2-56:2017 "Medical Electrical Equipment Part 2-56: Used for body temperature measurement Special Requirements for Basic Safety and Essential Performance of Clinical Thermometers: This document incorporates the amendments to ISO 80601-2-56:2017/Amd1:2018, the clauses involved in these amendments have been adopted in It is indicated by a vertical double line (||) in the outer margin: The main differences between this document and ISO 80601-2-56:2017 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 60601-1-8:2006 AMD1:2012 with YY 9706:108-2021, which adopts international standards; * Replace IEC 60601-1-6:2010 AMD1:2013 with YY/T 9706:106-2021, which adopts international standards; * Replaced ISO 14937:2009 with GB/T:19974, which is equivalent to the international standard; * Replaced ISO 15223-1:2016 with YY/T 0466:1-2016, which is equivalent to the international standard; * Replaced ISO 17664:2004 with YY/T 0802, which is equivalent to the international standard; * 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; * Removed ISO 14155:2011:

--- The requirements for confirmation of clinical accuracy in the international text are revised to be carried out in accordance with the relevant regulations of clinical evaluation in my country (see:201:102): The following editorial changes have also been made to this document:

--- The title of Appendix CC is retained, and the specific content of Appendix CC is deleted;

--- Deleted "forehead skin" in the example of term:201:3:220: 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 0785-2010 in:2010;

--- 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 is mainly for electronic clinical thermometers that are currently on the market or will be on the market in the future: The purpose of a clinical thermometer is to provide an assessment of the true temperature of a reference body part: A patient's temperature is an important element in assessing their overall health: For vital signs, it is usually used in combination with blood pressure and pulse rate: One of the important purposes of a clinical thermometer is to determine whether a patient is febrile, afebrile, or Hypothermia, as fever indicates that the patient is ill: The temperature of each reference body part varies according to the thermal balance between heat generation, transfer, and loss [2]: Compare Clinical Thermometers The clinical body

temperature can be confirmed by comparing the output temperature of the reference thermometer (which has a specific true temperature measurement uncertainty) with the output temperature of the reference thermometer The clinical accuracy of the meter: For balanced clinical thermometers, it can be adequately determined under laboratory conditions in which the two thermometers form a state of equilibrium clinical accuracy: For clinical thermometers operating in conditioning mode, laboratory validation alone is not sufficient because the temperature used to derive the output temperature Patient and environment characteristics are also included in the adjustment algorithm [3]: Therefore, the clinical accuracy of clinical thermometers operating in adjustment mode Clinical confirmation must be performed using statistical methods: Its output temperature needs to be compared with a reference clinical thermometer (the thermometer is measured at a specific reference body The temperature of the site has a specific clinical accuracy) compared to the output temperature: For clinical thermometers operating in the adjusted mode, the laboratory accuracy is verified in the direct mode, and the clinical accuracy is verified in the adjusted mode: Validation is performed in the mode of operation (operating mode), during which a sufficiently large cohort of human subjects is used: The purpose of this document is to: Validate the laboratory accuracy of all types of electronic clinical thermometers and operate in adjustment mode The clinical accuracy validation of clinical thermometers specifies the corresponding requirements and test procedures: An asterisk (*) as the first character of a heading, paragraph heading, or table heading indicates that there is a reference to the entry in Appendix AA: Nam or reason description: Medical electrical equipment part 2-56: for body temperature Basic safety and basics of clinical thermometers for measuring Performance Specific Requirements 201:1 *Scope, purpose and related criteria Except for the following, Chapter 1 of GB 9706:1-2020 applies: 201:1:1 Scope replace: This document specifies the special requirements for basic safety and basic performance of clinical thermometers and their accessories (hereinafter referred to as ME equipment): This article This part is applicable to all electronic clinical thermometers used to measure the body temperature of patients, including medical electrical equipment for measuring and displaying body temperature: Example 1: ME EQUIPMENT for determining cardiac output by thermodilution using an accessory (for example, a pulmonary artery catheter) is included within the scope of this document if it indicates body temperature: Example 2: ME EQUIPMENT using accessories (for example, Foley catheters with temperature probes) is within the scope of this document: Clinical thermometers can be equipped with interfaces to contain secondary indicators, printing equipment and other auxiliary equipment, thus forming a medical electrical system System: This document does not apply to assistive devices: It is also not suitable for non-invasive fever temperature screening of the crowd under indoor environmental conditions: Screen thermal imager (see IEC 80601-2-59 [4]): The inherent hazards of the intended physiological functions of ME EQUIPMENT or ME SYSTEMS are not included in the specific requirements of this document, but GB 9706:1- Except for 7:2:13 and 8:4:1 of 2020: