

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 9706.235-2021

**Medical electrical equipment - Part 2-35: Particular requirements for the
basic safety and essential performance of heating devices using
blankets, pads or mattresses intended for heating in medical use**

医用电气设备 第2-35部分：医用毯、垫或床垫式加热设备的基本安全和基本性能
专用要求

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Foreword

This document was issued on 9 March 2021 by the National Medical Products Administration and takes effect on 1 May 2023.

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

It is classified under Chinese classification C42.

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

---Part 1: General and parallel requirements;

---Part 2: Special requirements. This part is part 2-35. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0834-2011 "Medical Electrical Equipment Part 2: Medical electric blankets, electric heating pads and

electric mattresses for safety Requirements", compared with YY 0834-2011, the main technical changes except for editorial changes are as follows.

- Modified the scope of application of the standard (see.201.1.1, 1.1 of YY 0834-2011);
- Added some terms and definitions
(see.201.3.204,.201.3.205,.201.3.206,.201.309,.201.3.210,.201.3.211,
201.3.214,.201.317);
- Added basic performance (see.201.4.
- Added the risk control measures or test methods for ME equipment or ME system substitution (see.201.4.5);
- The combination of equipment has been added (see.201.4.101);
- Added ME equipment identification, marking and documentation (see.201.7);
- Modified the protective measures for patients; (see.201.8.5.1.2, Chapter 17 of YY 0834-2011)
- Increased the mechanical hazards related to the support system (see.201.9.8);
- Modified the protection against over-temperature and other hazards (see Chapter.201.11, Chapter 42 of YY 0834-2011);
- Modified the power supply/power supply network interruption of ME equipment (see.201.11.8, Chapter 49 of YY 0834-2011);
- Modified the accuracy of the controller and the instrument and the protection of dangerous output (see.201.12, Chapter 50, Chapter YY 0834-2011 Chapter 51);
- Modified the hazard situation and failure conditions of ME equipment (see.201.13, Chapter 52 of YY 0834-2011);
- Modified the structure of ME equipment (see.201.15, Chapter 54 and Chapter 56 of YY 0834-2011);
- Modified the electromagnetic compatibility requirements (see 202, Chapter 36 of YY 0834-2011);
- Additional requirements for the termination of inactive alarm signal (see 208.6.8.4.101). This part uses the redrafting law to amend and adopt the international standard IEC 80601-2-35:2009 AMD1:2016 CSV "Medical Electrical Equipment" Part 2-35: Special requirements for the basic safety and basic performance of medical blanket, pad or mattress heating equipment. The technical differences between this part and IEC 80601-2-35:2009 AMD1:2016CSV and the reasons are as follows.
- Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments. The

situation is collectively reflected in.201.2 "Normative Reference Documents", and the specific adjustments are as follows. * Replace IEC 60601-1-2 with YY 9706.102 modified to adopt international standards; * Replace IEC 60601-1-8 with YY 9706.108 modified to adopt international standards; * Replace IEC 60601-1-10 with YY/T 9706.110 modified to adopt international standards; * Deleted ISO 14971.2007, because the standard is not cited in the main text; * ISO 2439.2008 was deleted because the standard was not cited in the main text.

--- Deleted the temperature control setting mark unit "degreeC", only keep " degrees C" [see.201.7.4.2.101,.201.12.1.101.2c)], Consistent with the International System of Units.

--- Deleted "through the transformer" (see.201.8.1), taking into account whether the heating equipment is isolated from the grid power supply through the transformer and.201.8. The risk of a single failure state described by the third dash is irrelevant.

---Modify IEC 60083 to GB/T 1002 (see.201.15.4.1.101), in line with my country's regulations on the types of power plugs and sockets for the grid To avoid incorrect connection to the network power supply. This section has made the following editorial changes.

--- Modify the translations of.201.1.3 and.201.1.4 to be consistent with domestic standards;

---Delete references, correspondingly delete the note in "normative references" (see.201.2);

--- Delete the index of terms and definitions, correspondingly delete the note in "Terms and Definitions" (see.201.3);

--- Modify the titles of.201.4.5 and.201.14.13 to be consistent with the general standard;

--- Modify the misuse of terms in the original text

[see.201.7.2.1.101.1e),.201.11.1.2.1.101.3,.201.13.1.2.101.5,.201.15.4.103];

---Fixed the error of international document reference numbers

(see.201.8.8.4.101,.201.12.4.105,.201.13.1.2.101.3, Appendix AA (In clause.201.7.2.1.101, clause.201.11.1.2.1.102.3, clause.201.15.4.2.1.101);

--- Amend the misused term "heating equipment" to "applied part"

[see.201.7.9.2.9.102,.201.13.1.2.101.5, Appendix CC

d)] to distinguish it from "heating equipment" including "controller";

---"See the explanation of principle" is amended to "See Appendix AA General Guidelines and Explanation of Principles" (see.201.11.2,.201.11.8.101,.201.14.13), To be consistent with the appendix title;

---In order to facilitate understanding, editorial changes are made during translation

(see.201.12.3.103,.201.12.3.104, Table.201.102);

--- Amend the 202.6 clause number to be consistent with domestic standards. Please note

that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This part was proposed by the State Drug Administration. This part is under the jurisdiction of the National Medical Electrical Appliance Standardization Technical Committee Physical Therapy Equipment Subcommittee (SAC/TC10/SC4). Drafting organizations of this section. Tianjin Medical Device Quality Supervision and Inspection Center, Beijing Medical Device Technology Evaluation Center, Beijing Hengbang Branch Technology Development Co., Ltd., Jiangmen Dacheng Medical Equipment Co., Ltd. The main drafters of this section. Zhang Yun, Zhang Haiming, Qian Xuebo, You Yijie, Chen Ran, Gong Yuxiang, Deng Hui, Chen Zhi. The previous releases of the standards replaced by this part are as follows.

---YY 0834-2011. Medical electrical equipment part 2-35.medical blankets, pads or Basic safety and basic performance of mattress heating equipment Dedicated requirements 201.1 Scope, purpose and related standards In addition to the following, Chapter 1 of the general standard applies. 201.1.1 *Scope replace. This Part specifies the basic safety and basic performance of medical blanket, pad or mattress heating equipment, which is medical electrical equipment (Hereinafter referred to as ME equipment). This section applies to medical blanket, mat or mattress heating equipment, including heating equipment intended to preheat the bed. If the chapter or article clearly states that it is only applicable to ME equipment or medical electrical systems (hereinafter referred to as ME system), the title and text of the chapter or article Will explain. If not stated, this chapter or article applies to both ME equipment and ME systems. If the chapter or article clearly states that it is applicable to a specific type of ME equipment, such as inflatable equipment, the title of the chapter or article will be indicated. Apply to this The chapters or articles of all types of ME equipment in some areas will not be specifically noted. In addition to 7.2.13 and 8.4.1 of the general standard, the expected physiological effects of the ME equipment or ME system within the scope of this part are caused by Hazards are not included in the specific requirements of this section.

Note 1: See 4.2 of the General Standard.

Note 2: Some clauses are annotated in the "General Guidelines and Principles" section, see Appendix AA. Clauses or sub-clauses corresponding to the notes in Appendix AA The models are marked with an asterisk (*). This section does not apply to.

--- Heating equipment intended for physical therapy;

---Infant radiant warmer, see YY 0455;

---Infant incubator, see GB 11243;

---Transport incubator, see YY 9706.220;

---Cooling equipment. 201.1.2 Purpose replace. The purpose of this section is to establish specific requirements for basic safety and basic performance, and to minimize the use of